

HEALTH

HEALTH SYSTEMS BRANCH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE PROGRAM

Drug Donation Programs

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

Proposed: August 7, 2023, at 55 N.J.R. 1608(a).

Adopted: August 5, 2024, by Kaitlan Baston, MD, MSc, DFASAM, Commissioner, Department of Health, in cooperation with the New Jersey State Board of Pharmacy and the Director of the Division of Taxation in the Department of the Treasury.

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

Filed: August 5, 2024, as R.2024 d.082, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Effective Date: September 3, 2024.

Expiration Date: September 3, 2031.

Summary of Public Comments and Agency Responses:

The Department of Health (Department) received comments from the following:

1. John W. Indyk, Vice President of the Health Care Association of New Jersey, Hamilton NJ; and
2. George Wang, Ph.D., Co-Founder and Director, SIRUM Supporting Initiatives to Redistribute Unused Medicine, Palo Alto, CA.

In accordance with N.J.S.A. 24:6M-7 (the Act), the Department reviewed the comments in cooperation with the State Board of Pharmacy (Board) in the Department

of Law and Public Safety, and the Director of the Division of Taxation (Director) in the Department of the Treasury.

Quoted, summarized, and/or paraphrased below, are the comments and the Department's responses thereto, following consultation with the Board and the Director. The numbers in parentheses following each comment below correspond to the commenters listed above.

1. COMMENT: A commenter provides a copy of the proposed rule text showing commenter-provided changes, among which is the deletion of proposed new N.J.A.C. 8:32-2.1(c)6, which, as proposed, would require an entity proposing a drug donation program to include, within its proposal, standards and procedures for calculating donor tax credits. The commenter provides no accompanying comment explaining the proposed deletion. (2)

RESPONSE: As the commenter provides no explanation for the proposed deletion, the Department is unsure whether the revision was submitted in error. As the Department perceives no rationale for the deletion, the Department will make no change upon adoption in response thereto.

2. COMMENT: A commenter notes that proposed new N.J.A.C. 8:32-2.1(c)9 would require an application for approval of a drug donation program to include a detailed list of individuals who would come into contact with donated drugs and the oversight that would apply to them. The commenter suggests that the Department remove this requirement so that changes in volunteers and staffing following approval of a drug donation program would not require an applicant to update the list accompanying the

application. The commenter states that drug donation programs are often run by volunteers and that normal staffing changes and hiring would require amendments and approval by the Department. The commenter recommends that proposed N.J.A.C. 8:32-2.1(c)9 be deleted for these reasons. In the alternative, the commenter suggests that the Department revise the rule to require an application to list only the position titles of personnel who “may,” not “will” as proposed in the rule, come into contact with donated drugs, rather than list by name each individual would come into contact with donated drugs. (2)

RESPONSE: The Board recommends against the commenter’s suggestion that the Department not adopt proposed new N.J.A.C. 8:32-2.1(c)9, because it believes that the rule should require drug donation programs to identify the individuals who would come into contact with donated drugs and the oversight that would apply to them, to protect the integrity of the donated drugs. In consideration of the Board’s concern and the commenter’s suggestion for an alternative solution, the Department finds that it would be appropriate to revise the rule upon adoption to require an applicant to identify in its application the position titles of personnel who will come into contact with donated drugs as sufficient to address the concerns of both the Board and the commenter. For these reasons, the Department will make a change upon adoption at proposed new N.J.A.C. 8:32-2.1(c)9 to require an applicant to identify by position title, rather than by name, the individuals who may come into contact with donated drugs.

3. COMMENT: A commenter suggests that the Department change proposed new N.J.A.C. 8:32-2.1(d) upon adoption to provide that the Department, in consultation with

the Board, “shall” (instead of “will”) review, and determine whether to approve, a program proposal, “within 30 days of submission.” (2)

RESPONSE: Consistent with the Act, at N.J.S.A. 24:6M-3.c, proposed new N.J.A.C. 8:32-2.1(d) would require the Department to review applications in consultation with the Board. The Board convenes only once a month to review applications. Given the need for interagency consultation and the Board’s public meeting schedule, the Department would not be able to accommodate a deadline of 30 days, as the commenter suggests, for review of applications. Therefore, the Department will make no change upon adoption in response to the comment.

4. COMMENT: A commenter recommends that the Department revise proposed new N.J.A.C. 8:32-2.1 to add a provision requiring the Department, in rejecting an applicant’s proposed drug donation proposal, to provide the applicant a justification for the rejection and an opportunity to cure deficiencies within 30 days, because this “will give interested entities the opportunity to correct any proposal deficiencies based on the Department’s insight.” (2)

RESPONSE: The Department, in consultation with the Board, acknowledges the commenter’s concern. If the Department believes that an applicant’s drug donation program proposal can be cured and made acceptable for authorization, the Department would simply request revisions to the proposal, in accordance with proposed new N.J.A.C. 8:32-2.1(d)1. Further, the Department and the Board have the flexibility to permit reapplications pursuant to the existing rulemaking.

5. COMMENT: A commenter states that proposed new N.J.A.C. 8:32-3.1(d) “could be misinterpreted to limit the types of drugs eligible for donation.” The commenter states that the Act indicates that three item types, OTC drugs, prescription drugs, and administration supplies, which otherwise would be destroyed, may be donated, and that by enumerating eligible drugs into a list, rather than mirroring statutory language, proposed new N.J.A.C. 8:32-3.1(d) inadvertently might exclude from donation items that should be eligible for donation. The commenter suggests that the Department change proposed new N.J.A.C. 8:32-3.1(d) upon adoption to mirror the language of the Act at N.J.S.A. 24:6M-3.e, which states that “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.” (2)

RESPONSE: The Department declines to use the Act’s language verbatim because separately listing the types of items that are eligible for donation brings attention to each type. The Department agrees that the Act’s use of the word “any” applies to each of the three categories of items that the Act identifies as eligible for donation and that the Act uses the phrase, “including, but not limited to,” items “that are discontinued in a health care facility, and that would otherwise be destroyed,” to apply to all the items listed at proposed new N.J.A.C. 8:32-3.1(d)1, 2, and 3, and as not modifying only the phrase, “prescription drugs” and “administration supplies.” The Department disagrees with the commenter’s assertion that proposed new N.J.A.C. 8:32-3.1(d)4 might be construed as excluding over-the-counter drugs from eligibility because the phrase, “administration

supplies,” at proposed new N.J.A.C. 8:32-3.1(d)3, expressly includes over-the-counter drugs. However, upon reconsideration, the Department finds that it is inappropriate to include “over-the-counter drugs” within the meaning of the term “administration supplies,” at paragraph (d)3, because the Act establishes separate meanings for each of these terms. For these reasons, the Department will make changes upon adoption to reflect these findings. The Department will change proposed new N.J.A.C. 8:32-3.1(d) upon adoption to indicate that “any” of the three types of items listed at paragraphs (d)1, 2, or 3 are eligible for donation, and to conform the subsection to the Act, which provides that eligibility for donation applies to these items, “including, but not limited to,” when the use thereof is discontinued and the items otherwise would be destroyed. To correspond to the addition of the text at proposed new N.J.A.C. 8:32-3.1(d) and to ensure that the rule is understood to provide that items of discontinued use that would be destroyed are eligible for donation among any of the types of items listed at proposed new N.J.A.C. 8:32-3.1(d)1, 2, and 3, the Department will change proposed new N.J.A.C. 8:32-3.1(d)3 upon adoption to delete the phrase, “including, but not limited to, over-the-counter drugs” and will delete proposed new N.J.A.C. 8:32-3.1(d)4. Except as discussed above, the Department will make no change upon adoption in response to the comment.

6. COMMENT: A commenter states that proposed new N.J.A.C. 8:32-4.1(i) “has the potential to force an insurmountable burden upon [long-term] care facilities, which can be expected to donate a substantial amount of unused [over-the-counter] and prescription drugs. This would create a deterrent to [long-term] care facility participation

in the drug donation program. Keeping track of which drugs were donated to which [yet-to-be-determined] number of authorized redistributors would be a herculean task, detracting from these facilities' primary focus on providing resident and patient care." The commenter states "that the system for drug recalls now allows for electronic notification of recalls by drug manufacturers or the Food and Drug Administration to pharmacy providers, physicians, facilities, and more. Rather than allowing a redistributor to provide donors with a written statement attesting that they receive recall notice for all transferred and dispensed drugs through other means, redistributors should be *required* to utilize those other means." The commenter suggests that the Department add the following text at proposed new N.J.A.C. 8:32-4.1(i): "Upon request by a licensed health care facility, a redistributor shall be required to provide the licensed health care facility with a written statement attesting that the redistributor will receive recall notice of all transferred and dispensed drugs through other means." (1)

RESPONSE: The comment does not disclose why a long-term care facility, when initially establishing a relationship with a redistributor with which it will share donated drugs, could not condition the relationship and the sharing of donated drugs upon the redistributor's execution of the described attestation before any relationship begins or sharing occurs. If the redistributor declines to execute and provide the attestation, the long-term care facility has the option of declining to engage in, or severing, any drug-sharing relationship with that redistributor. Long-term care facilities have this ability to impose conditions on their relationships with redistributors regardless of whether the Department was to change the rule as the commenter suggests. Proposed new N.J.A.C. 8:32-4.1(i) tracks the text of the Act, at N.J.S.A. 24:6M-4(f), and, therefore, is

consistent with the legislative intent. For the foregoing reasons, the Department will make no change upon adoption in response to the comment.

7. COMMENT: A commenter states, with respect to proposed new N.J.A.C. 8:32-4.1(i)8, that patients or residents of long-term care facilities “are either Medicare or Medicaid beneficiaries whose medications are funded through these programs, or ... residents [paying from private funds, who pay for] medications ... through Medicare Part D, private health insurance, or out of pocket”; that the facility does not *own*, but only administers, medications to residents and patients under the facility’s care; and that it “would be impossible for long-term care facilities to certify that they own unused drugs that they are otherwise unable to donate.”

The commenter states that long-term care facilities do not return unused drugs to a resident who no longer needs them, cannot turn them over them to a patient’s responsible party, even upon a patient’s death, and currently destroy unused medication. The commenter suggests that the Department change proposed new N.J.A.C. 8:32-4.1(i)8 to permit a long-term care facility or other licensed healthcare facility to certify its “control,” rather than ownership, of medications that they do not own, to thereby make the medications eligible for donation. The commenter states that because a long-term care facility “is not able to certify that [it owns] unused drugs, [the facility] would be unable to donate [the drugs,] leaving only the option that these unused drugs be destroyed.” (1)

RESPONSE: The Board indicated its disapproval of the suggestion that “control” over medications should qualify those medications for donation because the term is

imprecise and insufficient to permit the safe transfer of the drug to a redistributor, noting that the Act, at N.J.S.A. 24:6M-3.e, requires a donor to “legally possess” drugs that are proposed for donation. The Board states that to protect patient safety, the chain of custody of a drug must be documented due to the proliferation of counterfeit drugs and drug storage requirements (such as temperature control), citing the Federal Drug Supply Chain Security Act, 21 U.S.C. §§ 301 et seq. The Board agrees with the commenter’s statement that a long-term care facility patient, rather than the facility, owns the medications that the patient receives at the facility, and a patient must authorize the facility to donate the patient’s medications or transfer ownership to the facility.

The Department concurs with the Board’s statement that the Act, at N.J.S.A. 24:6M-3.e(1), requires a donor to “legally possess” medications proposed for donation. In consideration of the Board’s concerns, the Department declines to modify the rule as the commenter suggests, that is, to include “control” over medications as sufficient to render those medications eligible for donation. A facility that establishes a drug donation program may determine to establish a procedure to allow a patient (or the patient’s legal representative) to transfer to the facility ownership of the patient’s unused medications upon the patient’s discharge or demise. In addition, while a facility cannot turn over a patient’s unused drugs to the patient’s “responsible party” or legal representative upon a patient’s discharge or demise, the representative nonetheless may be the legal owner thereof as the representative and custodian of the patient’s estate, and have authority to execute the documentation necessary to donate unused medications or transfer ownership thereof to the facility, depending on the nature of the

legal relationship and/or delegation of authority that exists between the patient and the representative, be it as holder of a power of attorney or court-appointed guardian (while the patient is alive), or as the patient's estate executor or administrator, or heir (upon the patient's demise). For the foregoing reasons, the Department will make no change upon adoption in response to the comment.

8. COMMENT: A commenter recommends that the Department delete proposed new N.J.A.C. 8:32-4.1(l)4, which would require a redistributor, prior to the first donation from a new donor, to verify and record 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." The commenter states that this "requirement does not heighten safety precautions and is not required by statute, but rather adds an additional administrative burden on donors" and that "removing this requirement will reduce the paperwork burden while maintaining the same level of accountability and transparency." The commenter recommends that, if the Department were to decline to delete proposed new N.J.A.C. 8:32-4.1(l)4, that it revise the provision "to require a more general donor certification, and ... to require [a] donor to certify [that it] will only make donations in accordance with program rules" because this would "clarify donor eligibility while maintaining the same level of accountability and safety precautions." (2)

RESPONSE: The Board disagreed with the comment, stating that proposed new N.J.A.C. 8:32-4.1(l)4 does heighten safety precautions due to the risks of adulterated drugs and the need to document chains of custody, and that given this concern, it would be insufficient to require a donor to certify that the donor will make donations "in

accordance with program rules,” instead of requiring a certification of ownership.

The Department agrees with the Board’s reasoning. Moreover, proposed new N.J.A.C. 8:32-4.1(l)4 would be consistent with the Act, which, at N.J.S.A. 24:6M-4, requires a redistributor, “[p]rior to the first donation from a new donor,” to “verify and confirm that the donor meets the definition of a donor.” The Act, at N.J.S.A. 24:6M-2, defines a “donor” as an “entity that is ... authorized to possess prescription drugs, and which elects to donate [them],” and, at N.J.S.A. 24:6M-3.e(1), states that drugs eligible for donation are those that a “donor legally possesses.” An entity that does not own drugs proposed for donation or is under a legal or contractual obligation to return the drugs to another entity is not a “donor” because the entity does not have the legal authority to “elect” to donate that which the entity does not own or has an obligation to return to another. For the foregoing reasons, the Department will make no change upon adoption in response to the comment.

9. COMMENT: A commenter states, with respect to proposed new N.J.A.C. 8:32-4.1(l)6, that it would be burdensome to require a long-term care facility to redact a donating patient’s information from medication packaging given the volume of unused medication that such facilities currently destroy. The commenter states that if the medication needs of a resident or patient change or the resident or patient dies, “facilities destroy the entire packaging of the drug, including labels.” The commenter states that due to the “volume of unused drugs in these facilities, requiring [facilities] to redact information would be a [time-consuming] and costly burden, deterring donations of unused drugs by long-term care facilities. More importantly, long-term care facilities are prohibited from

altering, redacting, or tampering with drug labels.” The commenter requests that the Department revise proposed new N.J.A.C. 8:32-4.1(l)6 to require a redistributor to enter into a confidentiality agreement with a donor. (1)

RESPONSE: Proposed new N.J.A.C. 8:32-4.1(l)6 would require a redistributor, “[p]rior to the first donation from a new donor,” to verify and record “[c]ertification 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.” The comment does not disclose why a long-term care facility, when initially establishing a relationship with a redistributor with which it will share donated drugs, could not condition the relationship and the sharing of donated drugs upon the redistributor’s execution of the described confidentiality agreement before any relationship begins or sharing occurs. If the redistributor declines to execute and provide a confidentiality agreement, the long-term care facility has the option of declining to engage in, or severing, any drug-sharing relationship with that redistributor. Long-term care facilities have this ability to impose conditions on their relationships with redistributors regardless of whether the Department was to change the rule as the commenter suggests. Proposed new N.J.A.C. 8:32-4.1(l)6 tracks the Act, at N.J.S.A. 24:6M-4.g(4), and, therefore, is consistent with the legislative intent. For the foregoing reasons, the Department will make no change upon adoption in response to the comment.

10. COMMENT: A commenter states that proposed new N.J.A.C. 8:32-4.1(o), by requiring a redistributor, “[p]rior to or upon accepting a donation or transfer into

inventory, [to] maintain a written or electronic inventory of the donation, consisting of ... proof of a donor's cost of donated drugs, and the ... Social Security or Federal tax identification number ... of the donor," is inconsistent with the Act, at N.J.S.A. 24:6M-4.j, which states, "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." The commenter states that "the tax deduction benefit for donating drugs is optional, and not all donors will choose to exercise this option or qualify for the benefit as out-of-[State] entities are eligible to donate. Therefore, requiring proof of the donor's cost of the donated drugs [and] Social Security or Federal tax ID number, is not relevant for all donors and will add an additional administrative burden for potential donors." The commenter suggests that the Department revise proposed new N.J.A.C. 8:32-4.1(o) to remove the requirement that redistributors collect and retain a donor's drug cost and Social Security or Federal tax identification number, "to be consistent with statute and reduce unnecessary and duplicative recordkeeping burdens." (2)

RESPONSE: Upon further review of the Act, the Department agrees that the proposed language exceeds what is set forth within the statute. For this reason, and in response to the comment, the Department will make a change upon adoption at proposed new N.J.A.C. 8:32-4.1(o) to delete the requirement that redistributors collect and retain a donor's drug cost and Social Security or Federal tax identification number.

11. COMMENT: A commenter states that proposed new N.J.A.C. 8:32-4.1(p) would require “a redistributor, following accepting a donation, to provide a receipt detailing the transaction to the donor” and that “this transaction receipt [requirement] would be better suited in [S]ubchapter 6, Tax Credit for Donors, which sets forth the policies and procedures for receiving tax credits as part of the drug donation program. [T]he opportunity for a tax credit will only be available to certain donors, therefore ... including the transaction receipt in [S]ubchapter 6 would be more relevant and helpful for those donors exercising the option for a tax benefit. Additionally, pursuant to N.J.S.A. 24:6M-4(j) a redistributor is not required to maintain a record of donation other than (1) the transaction date, (2) the name, strength, and quantity of each accepted drug and the name and quantity of any accepted administration supplies, and (3) the name, address, and phone number of the donor. As the donor is requesting and potentially receiving the tax deduction benefit, the responsibility should be on the donor to request and maintain the transaction receipt. This would mirror the [F]ederal tax deduction process in which the donor is responsible for the record IRS Form 8283, with the redistributor acknowledging but not responsible for the costs and/or value.” The commenter suggests that the Department relocate proposed new N.J.A.C. 8:32-4.1(p) as a new section at N.J.A.C. 8:32-6.1. The commenter’s suggested additions are shown below in boldface and suggested deletions shown in brackets. (2)

“8:32-6.1 Transaction receipt

[8:32-4.1(p) Once] **(a) If a donor chooses to apply for a tax credit under sections 8:32-6.2 or 8:32-6.3, once** the redistributor examines the drugs and formally accepts

them, the drug donation program will provide a receipt **shall be maintained** (*sic*) **consisting of the record created pursuant to section 8:32-4.1(o)** 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.-2. (No change from proposal.)

3. The name, strength, quantity, and cost to the taxpayer of each accepted drug, **as determined by the donor;**

4. The name, quantity, and cost to the taxpayer of any accepted administration supplies, **as determined by the donor;**

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 **donor'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; **and**

7. The record created pursuant to N.J.A.C. 8:32-4.1(o)."

RESPONSE: The Department notes that the commenter's representation of proposed new N.J.A.C. 8:32-4.1(p) is imprecise, in that while it would require a redistributor to examine and formally accept the drugs into the program, it would require the drug donation program, which may be, but is not necessarily, the redistributor, to provide a receipt of the transaction.

The Board states that the recordkeeping requirements are essential to documenting the chain of custody of the drugs. Moving these requirements from proposed N.J.A.C. 8:32-4.1 to Subchapter 6 would remove them from the six-year recordkeeping requirement at proposed new N.J.A.C. 8:32-4.1(r). The Board does not recommend relocating them or making them contingent on whether a donor seeks a tax credit. The Department concurs with the Board's recommendation. Therefore, the Department will make no change upon adoption in response to the comment.

12. COMMENT: A commenter states that the requirement at proposed new N.J.A.C. 8:32-7.1(a)1, which would require a prospective new owner of a drug distribution program to submit a cover letter stating, among other items of information, the county wherein the drug donation program is located, could "inadvertently restrict the ownership of a drug donation program to entities located within a county in New Jersey." To address this concern, the commenter recommends deletion of the requirement to provide the county in which a drug donation program proposed for transfer to a new owner is located. (2)

RESPONSE: The Board states that adding the phrase, "if applicable," after the word, "county," at proposed new N.J.A.C. 8:32-7.1(a)1, would address the commenter's concern. The Department notes that the Act, at N.J.S.A. 24:6M-3.d, states: "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." Thus, the request of the identification of

the county in which a drug donation program is located would not undermine the Act's express authorization allowing interstate transfers. However, the Department is amenable to a change to address the commenter's concern but does not find that adding the phrase, "if applicable," would clarify the rule. Instead, in response to the comment, the Department will make a change upon adoption at proposed new N.J.A.C. 8:32-7.1(a), to add the phrase, "if located in New Jersey," before the word, "county," to indicate that a drug donation program that is proposed for transfer need not be located in the State.

13. COMMENT: With respect to proposed new N.J.A.C. 8:32-7.1(a)2iii, which requires disclosure of the ownership of a prospective transferee of a drug donation program by submission of an organizational chart, a commenter suggests that the Department insert the word "relevant" before the phrase "parent corporations and wholly owned subsidiaries," which are to be included in the organizational chart because "there may be subsidiaries that are not associated with or relevant to the operation of the drug donation program." (2)

RESPONSE: Neither the Board nor the Department supports the proposed suggestion because it is important that the ownership of redistributors is known to the Department. The word "relevant" as used in this context would be vague and would not provide sufficient guidance to regulated entities as to which subsidiaries and parents they are to disclose. For the foregoing reasons, the Department will make no change upon adoption in response to the comment.

Federal Standards Statement

The new rules are not adopted pursuant to the authority of, or in order to implement, comply with, or participate in, any program established pursuant to Federal law or any State statute that incorporates or refers to any Federal law, standard, or requirement. Therefore, a Federal standards analysis is not required.

Full text of the adopted new rules follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

CHAPTER 32

DRUG DONATION PROGRAMS

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

8:32-2.1 Applying for authorization

(a)-(b) (No change from proposal.)

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

1.-8. (No change from proposal.)

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

(d)-(i) (No change from proposal.)

8:32-3.1 Maintenance

(a)-(c) (No change from proposal.)

(d) *[The] ***Any of the*** following are eligible for donation*, **including, but not limited to, any of the following if their use is discontinued and they otherwise would be destroyed***:

1. *[Any over-the-counter]* **Over-the-counter*** drugs;
2. Prescription drugs; ***and***
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)-(g) (No change from proposal.)

8:32-4.1 Conditions

(a)-(n) (No change from proposal.)

(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)-(s) (No change from proposal.)

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*, **if located in New Jersey,*** county.

- 2.-4. (No change from proposal.)

(b) (No change from proposal.)