

HEALTH

HEALTH SYSTEMS BRANCH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE PROGRAM

Hospice Licensing Standards; General Provisions: Definitions

Patient Care Services: Acceptance and Disposal of Prescription Medication

Proposed New Rule: N.J.A.C. 8:42C-6.4

**Proposed Amendments: N.J.A.C. 8:42C-1.2, 2.1, 2.5, 2.7, 3.1, 3.2, 3.3, 3.5, 10.2,
10.3, 10.7, and 11.8**

Authorized By: Shereef Elnahal, M.D., M.B.A., Commissioner, Department of Health,
with the approval of the Health Care Administration Board.

Authority: N.J.S.A. 26:2H-5, 12, 81.1, and 81.2; 26:8A-12; and 37:1-35; and P.L. 2017,
c. 135.

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

Proposal Number: PRN 2019-126.

Submit written comments by October 18, 2019, electronically to
<http://www.nj.gov/health/legal/ecomments.shtml>, or by regular mail postmarked by
October 18, 2019, 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

On July 21, 2017, Governor Christie approved P.L. 2017, c. 135, which is codified in part at N.J.S.A. 26:2H-81.1 and 81.2 (Act) and took effect February 1, 2018. The Act authorizes hospices to choose to accept prescription medication for disposal from hospice care patients who cease to either use medication or receive services from a hospice. N.J.S.A. 26:2H-81.1.b. The Act requires hospices that elect to accept surrendered medication to establish a written policy for the acceptance and disposal thereof and submit a written request for the surrender of unused medication to a hospice care patient or a hospice care patient's health care representative. *Ibid.* The Act states that only a nurse can accept surrendered medication and that a hospice must dispose of surrendered medication at the site where the hospice provided services to the hospice care patient whose medication is surrendered. *Ibid.* The Act directs the Commissioner of the Department of Health (Department) to promulgate implementing rules. N.J.S.A. 26:2H-81.2. In accordance with this mandate, the Department proposes to amend existing N.J.A.C. 8:42C-1.2 and add new N.J.A.C. 8:42C-6.4 to implement the Act.

The Department proposes to amend existing N.J.A.C. 8:42C-1.2 to make technical changes to codify the existing text as subsection (a), to conform the text to New Jersey Administrative Code style conventions, and to correct grammar. The Department proposes to add new subsection (b), which would define, only with respect

to proposed new N.J.A.C. 8:42C-6.4, the terms, “family member,” “health care representative,” “hospice care patient,” and “third-party caregiver.” The proposed definitions would be consistent with the definitions of these terms that N.J.S.A. 26:2H-81.1 establishes; however, the proposed definitions would differ from the statutory definitions of these terms to correct punctuation and to conform the rule text and syntax to New Jersey Administrative Code style conventions.

In addition, in the proposed definition of the term “family member,” the Department proposes to supplement the statute’s definition of this term by adding references to civil union partners and domestic partners, to reflect the health care decision-making and other rights of these persons with respect to their partners under the Domestic Partnership Act, N.J.S.A. 26:8A-1 et seq., and the civil union statute, N.J.S.A. 37:1-28 et seq.

Proposed new N.J.A.C. 8:42C-6.4 would establish standards to which hospices that elect to accept and dispose of surrendered prescription medications must adhere. Subsection (a) would authorize hospices to elect to accept the unused prescription medication of its hospice care patients for disposal and the circumstances under which this can occur. Subsection (b) would require hospices that elect to accept unused prescription medications for disposal to establish written policies by which they will accept and dispose of surrendered prescription medication and would identify minimum topics that hospices’ policies are to address. Subsection (c) would establish the minimum content of a form of written request for surrender of unused prescription medication. Subsection (d) would prohibit a hospice from accepting unused prescription medication for disposal absent the issuance of surrender authorization by a hospice

care patient, a health care representative of a hospice care patient, or, if a hospice care patient is unable to issue authorization and does not have a health care representative, a third-party caregiver. Subsection (e) would prohibit hospices from accepting prescription medications except by a nurse who is in the hospice's employ and would establish the disposal procedure. Subsection (f) would establish minimum procedures for presentation of a request for surrender. Subsection (g) would establish the minimum procedure to which a designated hospice representative is to adhere upon the declination of a request to surrender. Subsection (h) would establish the minimum procedure to which a nurse is to adhere upon the approval of a request to surrender. Subsection (i) would identify the publication of the New Jersey Department of Environmental Protection, Division of Solid and Hazardous Waste, entitled, "Guidelines for Proper Disposal of Household Medication" (DEP guidelines), that designated hospice representatives are to present to persons declining to surrender the unused prescription medication of hospice care patients, and to which nurses are to adhere in disposing of surrendered prescription medication. The publication is a pamphlet that gives instructions for proper disposal of prescription and over-the-counter medication in trash, to ensure environmentally appropriate disposal.

The Department is proposing technical corrections throughout the chapter to reflect the accurate or updated names of government agencies and to correct grammar and a cross-reference.

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

Social Impact

The proposed substantive amendments at N.J.A.C. 8:42C-1.2 and proposed new N.J.A.C. 8:42C-6.4 would have a positive social impact on the State by facilitating the proper disposal of unused prescription medication, thereby preventing misappropriation thereof and negative environmental impacts associated with improper disposal methods. As the DEP guidelines state, “[over-the-counter] and prescription medications should not be disposed down the drain because wastewater treatment facilities are not designed to remove pharmaceutical compounds and they may end up in … local waterways, and … eventually be found in drinking water. Properly disposing of unwanted and expired prescriptions and over-the-counter medications in the trash promotes a healthy aquatic environment and prevents accidental poisoning and intentional abuse.”

Economic Impact

The proposed substantive amendments at N.J.A.C. 8:42C-1.2 and proposed new N.J.A.C. 8:42C-6.4 would not impose direct costs on the State, other than by the establishment of an added licensing standard that the licensed health care facility survey program of the Department would have to enforce. The Department would subsume the cost of enforcement of this standard within its existing survey budget and operations. Therefore, the taxpaying public would realize a negligible direct economic impact resulting from the proposed amendments and new rule.

It is possible that the supervised oversight of prescription medication disposal, which the proposed amendments and new rule would facilitate, would have an indirect beneficial economic impact on the people of New Jersey by helping to avoid costs

associated with remediation of contaminated natural resources such as waterways and wildlife, provision of therapeutic assistance to persons whose health is impaired by exposure to contaminated natural resources, and response to the health care needs of persons negatively affected by direct consumption of unsurrendered prescription medication by accidental ingestion or diversion associated with substance use disorder.

The proposed amendments and new rule would have no economic impact on hospice care patients or their health care representatives.

The proposed amendments and new rule would have no economic impact on hospices that do not elect to accept surrendered unused prescription medication for disposal. The proposed amendments and new rule would have an economic impact on hospices that elect to accept surrendered unused prescription medication for disposal, in that they would incur administrative, training, personnel, and recordkeeping costs to comply with the requirements that the Summary above describes, and may incur costs to comply with applicable local, State, or Federal requirements associated with medication disposal. The Department anticipates that hospices would subsume these costs within their existing administrative, training, personnel, recordkeeping, and waste disposal overhead costs. As described in the Summary above, hospices that elect to accept for disposal their patients' surrendered prescription medication would need to maintain the employment of a nurse to accept and dispose of the surrendered medication and to annotate required information. The Department anticipates that hospices would use their existing nursing staff to perform these tasks and would not need to employ additional nursing staff for this purpose.

Federal Standards Statement

The Department proposes the amendments and new rule under the authority of N.J.S.A. 26:2H-81.2, 26:8A-12, and 37:1-35, and not to implement, comply with, or participate in, any program established under Federal law or a State law that incorporates or refers to any Federal law, standard, or requirement. Therefore, a Federal standards analysis is not required.

Jobs Impact

The Department does not expect that the proposed amendments and new rule would result in the generation or loss of jobs in the State.

Agriculture Industry Impact

The proposed substantive amendments at N.J.A.C. 8:42C-1.2 and new N.J.A.C. 8:42C-6.4 might discourage or prevent improper disposal of medication that otherwise could reach and contaminate groundwater and other State water resources used for hydration of crops and farm animals, thereby avoiding adverse effects to consumers of those contaminated crops and animals, and to the animals themselves from the ingestion of contaminated water. Except as thus described, the Department does not anticipate that the proposed amendments and new rule would have an impact on the agriculture industry of the State.

Regulatory Flexibility Analysis

The proposed substantive amendments at N.J.A.C. 8:42C-1.2 and new N.J.A.C. 8:42C-6.4 would impose reporting, recordkeeping, and compliance requirements, which the Summary above describes, on hospices that elect to accept unused medication for disposal. Most, if not all, of the approximately 61 licensed hospices in the State are

small businesses, as the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., defines that term. The Economic Impact above describes these costs.

Consistent with the Act, the proposed amendments and new rule would not require hospices to participate in the acceptance of surrendered unused medication for disposal. The Act requires, and the proposed new rule would require, a hospice that elects to participate in the acceptance and disposal of its patients' unused medication to implement the acceptance and disposal thereof through a nurse who is in the hospice's employ. However, as the Economic Impact above describes, the proposed amendments and new rule would require hospices that elect to participate in acceptance and disposal of their patients' unused medication to neither employ especially an additional nurse for this purpose nor retain the services of professionals, such as direct care and administrative staff, in addition to those they already employ as part of routine hospice operations, to comply.

The Department does not propose lesser or differing standards based on business size, because the Act allows hospices to elect not to participate in the acceptance and disposal of their patients' unused medication. With respect to hospices that elect to participate, the Department has determined that the proposed amendments and new rule would establish the minimum standards necessary to implement the Act and maintain accountability for, protect the environment from improper disposal of, and avoid accidental ingestion and intentional diversion of, surrendered medications.

Housing Affordability Impact Analysis

The proposed substantive amendments at N.J.A.C. 8:42C-1.2 and new N.J.A.C. 8:42C-6.4 would have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that they would evoke a change in the average costs associated with housing because the proposed amendments and new rules would establish an elective process for hospices to accept and dispose of surrendered unused prescription medication and would have no bearing on housing costs.

Smart Growth Development Impact Analysis

The proposed substantive amendments at N.J.A.C. 8:42C-1.2 and new N.J.A.C. 8:42C-6.4 would have an insignificant impact on smart growth and there is an extreme unlikelihood that they would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the proposed amendments and new rule would establish an elective process for hospices to accept and dispose of surrendered unused prescription medication and would have no bearing on smart growth or housing production.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Full text of the proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. GENERAL PROVISIONS

8:42C-1.2 Definitions

(a) The following words and terms, as used in this chapter, **and subject to (b) below**, shall have the following meanings, unless the context clearly indicates otherwise:

“Advanced [Practice Nurse] **practice nurse**” or “APN” means an individual who is certified as an advanced practice nurse by the New Jersey Board of Nursing as established at N.J.S.A. 45:11-23.

...

“Certificate of Need and Healthcare Facility Licensure Program” means the health care facility licensing unit within the Division of Certificate of Need and Licensing of the Health Systems Branch of the Department, for which the contact information is Certificate of Need and Healthcare Facility Licensure Program, Division of Certificate of Need and Licensing, NJ Department of Health, PO Box 358, Trenton, NJ 08625-0358, telephone: (609) 292-5960.

...

[“Office of Certificate of Need and Healthcare Facility Licensure” means the health care facility licensing unit within the Division of Certificate of Need and Licensing of the Health Systems Branch of the Department for which the contact information is:

1.Mailing address: Office of Certificate of Need and Healthcare Facility Licensure, Division of Certificate of Need and Licensing, Health Systems Branch, Department of Health, PO Box 358, Trenton, NJ 08625-0358; and
2.Telephone number: (609) 292-5960.]

...

“Volunteer” means a person trained by a hospice who serves a hospice program without monetary compensation.

(b) The following words and terms, as used in N.J.A.C. 8:42C-6.4, shall have the following meanings:

“Family member” means a hospice care patient’s spouse, civil union partner, domestic partner, parent, adult sibling, adult child, or adult grandchild.

“Health care representative” means a person, including a patient’s family member, who is authorized to make health care decisions on behalf of a hospice care patient.

“Hospice care patient” means a person receiving hospice care services in a private home or an assisted living facility through a licensed hospice care program.

“Third-party caregiver” means a person who:

- 1. Is 18 years of age or older;**
- 2. Provides care or assistance to a hospice care patient;**
- 3. Is not the health care representative or family member of the hospice care patient; and**
- 4. Is not an employee of the hospice care program that is providing hospice care services to the hospice care patient.**

SUBCHAPTER 2. LICENSURE AND LICENSURE PROCEDURES

8:42C-2.1 Functional review applicability

(a) (No change.)

(b) Requests for a functional review shall be in writing, specifying the type of facility and/or service proposed, and shall be forwarded to the Director, [of the Office of] Certificate of Need and Healthcare Facility Licensure **Program**.

(c) (No change.)

8:42C-2.5 Licensure

- (a) (No change.)
- (b) At the request of the applicant, an office conference for review of the conditions for licensure and operation may take place between the [Office of] Certificate of Need and Healthcare Facility Licensure [within the Department] **Program** and the applicant, who shall be advised that the purpose of the license is to allow the Department to determine whether the applicant complies with N.J.S.A. 26:2H-1 et seq., 26:2H-79 through 80 specifically, and any relevant rules promulgated pursuant thereto, including this chapter.

- (c)-(n) (No change.)

8:42C-2.7 Waiver

- (a) (No change.)
- (b) A hospice seeking a waiver of these rules shall apply in writing to the Director, [of the Office of] Certificate of Need and Healthcare Facility Licensure **Program**.
- (c)-(d) (No change.)

SUBCHAPTER 3. GENERAL REQUIREMENTS

8:42C-3.1 Compliance with rules and laws

- (a)-(i) (No change.)
- (j) A hospice providing services at multiple locations shall operate in compliance with the [rules] **hospice provider certification standards** of the United States Department of Health and Human Services [hospice provider certification specified] at 42 CFR Part 418, Subpart D, incorporated herein by reference.

8:42C-3.2 Ownership

(a) (No change.)

(b) Any proposed change in ownership shall be reported to the Director, [of the Office of] Certificate of Need and Healthcare Facility Licensure **Program**, in writing, at least 30 days prior to the change and in conformance with the requirements for Certificate of Need applications at N.J.A.C. 8:33-3.3.

(c)-(d) (No change.)

8:42C-3.3 Submission of documents

The hospice shall, upon request, submit any documents which are required by these rules to the [Office of] Certificate of Need and Healthcare Facility Licensure **Program**.

8:42C-3.5 Policy and procedure manual

(a) The hospice shall establish, implement, and review at least annually, a policy and procedure manual(s) for the organization and operation of the hospice.

1. (No change.)

2. The manual(s) shall include at least the following:

i.-iv. (No change.)

v. Policies and procedures for complying with applicable statutes and protocols to report child abuse and/or neglect, sexual abuse and abuse of elderly or disabled adults, specified communicable disease, rabies, poisonings and unattended or suspicious deaths including, but not limited to, the following:

(1) (No change.)

(2) The designation of a staff member(s) to be responsible for coordinating the reporting of child abuse and/or neglect in compliance with N.J.S.A. 9:6-1[,] et seq., [recording notification of] **memorializing the issuance of such a report to** the Division of [Youth] **Child Protection** and [Family Services] **Permanency** of the Department of Children and Families [on] **in** the medical/health record, and serving as a liaison between the facility and the Division of [Youth] **Child Protection** and [Family Services] **Permanency**; and

(3) (No change.)

(b) (No change.)

SUBCHAPTER 6. PATIENT CARE SERVICES

8:42C-6.4 Acceptance and disposal of prescription medication

(a) A hospice may choose to accept for disposal a hospice care patient's unused prescription medication when the hospice care patient ceases to:

- 1. Use the prescription medication; or**
- 2. Receive services from the hospice.**

(b) A hospice that chooses to accept for disposal the unused prescription medication of its hospice care patients pursuant to (a) above shall establish a written policy setting forth procedures for requesting and accepting the surrender, and disposing, of unused prescription medication, which addresses:

- 1. The hospice's establishment of a written form of request for surrender of a hospice care patient's unused prescription medication consistent with (c) below;**
- 2. The hospice's designation of one or more hospice representatives (designated hospice representative);**
- 3. Upon the enrollment of a hospice care patient, a designated hospice representative's obligation to provide a copy of the written policy established pursuant to this section to the hospice care patient and the health care representative of the hospice care patient and to discuss with them the attendant procedures and requirements;**
- 4. The hospice's obligation to accept, and dispose of, in accordance with the publication at (i) below, prescription medication that the hospice dispenses to a hospice care patient pursuant to the hospice care patient's hospice care plan, and any other prescription medication that the hospice care patient or the health care representative of the hospice care patient chooses to surrender to the hospice;**
- 5. The hospice's obligation to condition its acceptance of surrendered prescription medication for disposal on:**

 - i. The hospice care patient ceasing to either use the prescription medication or receive services through the hospice;**
 - ii. The hospice obtaining all certifications, authorizations, or waivers that State or Federal law may require for the acceptance and disposal of surrendered prescription medication; and**

iii. The hospice exclusively accepting and disposing of surrendered prescription medication at the site of the hospice care patient's receipt of care, in accordance with the publication at (i) below, by a registered professional nurse or a licensed practical nurse (nurse) whom the hospice employs.

(c) A form of request for surrender shall:

1. Request, and offer to accept and dispose of, on behalf of the hospice:

i. Unused prescription medication that the hospice dispensed to a hospice care patient pursuant to the hospice care patient's hospice care plan; and

ii. Any other prescription medication that the hospice care patient, or the health care representative of the hospice care patient, chooses to surrender to the hospice;

2. Inform the person to whom the hospice submits a request for surrender that, if the person declines to surrender a hospice care patient's unused prescription medication for disposal, the hospice will provide the person a copy of the publication identified at (i) below, and the link to the webpage of Project Medicine Drop of the New Jersey Division of Consumer Affairs at

<http://www.njconsumeraffairs.gov/meddrop/Pages/default.aspx>;

3. Provide space at which a nurse accepting surrendered prescription medication is to record:

i. The name and quantity of each medication surrendered;

- ii. The name of the person authorizing the surrender and the relationship of the person to the hospice care patient;
 - iii. The date and method of disposal; and
 - iv. The quantity and type of any unused prescription medication that the hospice prescribed and dispensed to the hospice care patient pursuant to the patient's hospice care plan, of which the nurse is aware, which is not being surrendered to the hospice or otherwise disposed of by another person in the nurse's presence; and

4. Provide space at which:

- i. A person authorizing a surrender of, or declining to surrender, prescription medication is to verify and sign the form, after the nurse completes the part of the form described at (c)3 above;
 - ii. The nurse receiving a declination to surrender prescription medication is to verify and sign the form, to confirm the provision of the documents listed at (g) below to the person declining to surrender prescription medication pursuant to (f) below; and
 - iii. The nurse accepting a surrender of prescription medication is to verify and sign the form to confirm on behalf of the hospice the acceptance and disposal of the surrendered prescription medication listed on the form pursuant to (c)3 above.

(d) A hospice shall not accept unused prescription medication of a hospice care patient for disposal pursuant to this section unless:

1. The hospice care patient or the health care representative of the hospice care patient authorizes the surrender pursuant to (h) below; or
2. If the hospice care patient is unable to issue written authorization and does not have a health care representative, a third-party caregiver authorizes the surrender pursuant to (h) below.

(e) A hospice exclusively shall accept unused prescription medication pursuant to this section upon surrender to a registered professional nurse or a licensed practical nurse (nurse) whom the hospice employs, who shall dispose of the medication at the site where the hospice care patient receives care in accordance with the publication at (i) below.

(f) A designated program representative shall submit a request for surrender to a hospice care patient, or the health care representative of a hospice care patient, when the hospice care patient ceases to either use the prescription medication or receive hospice services.

(g) If a person to whom the designated program representative submits a request for surrender pursuant to (f) above declines to surrender unused prescription medication, the designated program representative shall give the person a copy of the publication identified at (i) below, and a page containing the link to the webpage of Project Medicine Drop of the New Jersey Division of Consumer Affairs at <http://www.njconsumeraffairs.gov/meddrop/Pages/default.aspx>.

(h) If a person to whom a designated program representative submits a request for surrender pursuant to (f) above agrees to surrender prescription medication, a

nurse who is accepting and disposing of the surrendered unused prescription medication on behalf of a hospice shall:

- 1. Record the information listed at (c)3 above on the request for surrender;**
- 2. Offer the person authorizing the surrender the opportunity to review, verify, and sign the request for surrender in the space on the form described at (c)4i above, to indicate the person's agreement with the information recorded therein pursuant to (h)1 above.**
 - i. If the person authorizing a surrender declines to verify and sign the request for surrender, the nurse shall verify and sign the request for surrender in the space on the form described at (c)4iii above, to indicate that the person declined to surrender and declined to sign and verify the form, and proceed pursuant to (g) above.**
 - ii. The nurse shall not accept a surrender unless the person to whom the request is submitted verifies and signs the request for surrender;**
- 3. Dispose of the surrendered prescription medication at the site where the hospice provided hospice care to the hospice care patient, consistent with the instructions in the publication identified at (i) below.**
 - i. The nurse shall not transport the surrendered prescription medications off-site for disposal or for any other purpose;**
- 4. Sign the request for surrender to verify the nurse's acceptance and disposal of the surrendered prescription medication on behalf of the hospice; and**
- 5. Retain the executed request for surrender in the hospice care patient's record.**

(i) The pamphlet issued by the New Jersey Department of Environmental Protection, Division of Solid and Hazardous Waste, entitled, “Guidelines for Proper Disposal of Household Medication,” available at <http://www.state.nj.us/dep/dshw/rrtp/disposal.pdf>, establishes instructions for proper disposal of prescription and over-the-counter medication in trash.

SUBCHAPTER 10. INFECTION PREVENTION AND CONTROL

8:42C-10.2 Infection control policies and procedures

- (a) (No change.)
- (b) The interdisciplinary [Committee] **committee** shall develop, implement and review, at least annually, written policies and procedures regarding infection prevention and control, including:
 - 1.-4. (No change.)
- (c) (No change.)

8:42C-10.3 Infection control measures

- (a) The hospice shall follow all recommendations in the following **publications of the Centers for Disease Control** [publications, and any amendments or supplements thereto] **and Prevention**, incorporated herein by reference, **as amended and supplemented**:

- 1.-9. (No change.)
- (b) **Publications of the Centers for Disease Control and Prevention (CDC)** [publications] are available [as follows]:

1. (No change.)
2. Through [verbal] **telephonic** request at (800) 553-6847 or (703) 605-6000; [or]

and

3. (No change.)

8:42C-10.7 Orientation, in-service, and education

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

(c) The [Interdisciplinary Committee] **interdisciplinary committee** shall coordinate educational programs to address specific problems at least annually for staff in all disciplines and patient care services [which] **that** includes blood borne pathogens and tuberculosis (TB) exposure control.

SUBCHAPTER 11. INPATIENT HOSPICE CARE UNIT

8:42C-11.8 Food service for inpatient hospice care units

(a) (No change.)

(b) The dietary service shall comply with N.J.A.C. 8:24, Sanitation in Retail Food Establishments and Food and **Beverage** Vending Machines.

(c)-(f) (No change.)