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HEALTH

HEALTH SYSTEMS BRANCH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE

Hospice Licensing Standards

Adopted Amendments: N.J.A.C. 8:42C-1.2, 2.4, 2.5, 3.2, and 3.4

Adopted New Rules: N.J.A.C. 8:42C-11

Proposed: February 6, 2017, at 49 N.J.R. 232(a).

Adopted: December 19, 2017, by Christopher R. Rinn, Acting Commissioner, Department of Health, with the approval of the Health Care Administration Board.

Filed: December 19, 2017, as R.2018 d.050, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 26:2H-5, 12, 79, and 81.

Effective Date: January 16, 2018.

Expiration Date: April 20, 2024.

Summary of Public Comments and Agency Responses:

The Department received comments from the following:

1. Chrissy Buteas, President and CEO, Home Care & Hospice Association of NJ, Iselin, NJ;

2. Theresa Edelstein, Vice President, Post-Acute Care Policy and Special Initiatives, New Jersey Hospital Association, Princeton, NJ; and

3. Catherine Yaxley, Holy Name Medical Center, Vice President, Planning and Government Affairs, Teaneck, NJ.

Quoted, summarized, and/or paraphrased below, are the comments and the Department's responses. The numbers in parentheses following the comments below correspond to the commenter numbers above.

General Comments

1. COMMENT: A commenter states that "[o]ur Association has worked with the Department for many years on this proposal and appreciates the Department's collaboration." (1)

2. COMMENT: A commenter "[commends] the Department for the inclusion of stakeholders in the development of these licensing standards and looks forward to the rules' ultimate adoption." (2)

3. COMMENT: A commenter appreciates "the State's decision to incorporate the [Federal conditions of participation ('CoPs')] in" the proposed amendments and new rules, because the commenter believes that "they do indeed ensure quality of care within a safe, patient-centric environment. As [such, the commenter has] no recommendations for revisions to the proposed rules and … applaud[s] the work of Commissioner Bennett and her staff." (3)

RESPONSE TO COMMENTS 1 THROUGH 3: The Department acknowledges the commenters' support for the proposal and thanks the stakeholders for their collaboration in its development.

N.J.A.C. 8:42C-2.4

4. COMMENT: A commenter requests clarification as to the "inspection and biennial licensure fees after initial licensure. The inspection fee is $1,000 for the hospice and $1,500 for each inpatient facility. The annual licensing fee is $2,000 for the

hospice and an additional $1,500 plus [$15.00] per bed for licensure of an inpatient hospice. If a hospice has two inpatient units already licensed and operational, except for the first year when [the facility] would be converting from … licensure [as a comprehensive personal care home (CPCH)] to [licensure as an] inpatient hospice [care provider], would [the facility] be subject to the annual renewal licensing fee of $1,500 plus [$15.00] per bed? Every two years, would [it] also have the $1,500 inspection fee added for each of the inpatient hospice [care units]?" (2)

RESPONSE: With respect to the example that the commenter provides, the hospice and each separate inpatient hospice care unit would be subject annually to the applicable licensing renewal fee and biennially to the applicable inspection fee.

N.J.A.C. 8:42C-11.1(c)1

5. COMMENT: A commenter states its "understanding that an inpatient hospice that is already licensed by the [Department] as a [CPCH] would have to seek new licensure within 60 days of the effective date of [the proposed amendments and] new rules. Is there an option for the inpatient hospice unit to remain licensed as a [CPCH]?" (2)

RESPONSE: No. Proposed new N.J.A.C. 8:42C-11.1(c) would require the operator of each existing inpatient hospice unit that is licensed as a CPCH to apply for licensure of the CPCH as an inpatient hospice care unit within 60 days of the effective date of the proposed amendments and new rules.

N.J.A.C. 8:42C-11.2(a)2

6. COMMENT: A commenter notes that proposed new N.J.A.C. 8:42C-11.2(a)2 would require a unit administrator to "be in the building in which the unit is located at

least half-time each week." The commenter inquires whether "half-time" means "a 168-hour week or a 40-hour workweek." The commenter believes that "half of the 40-hour workweek would be sufficient, inasmuch as the unit itself must be staffed at all times by both a registered professional nurse and a second licensed healthcare worker." (1)

7. COMMENT: "Please clarify what half-time means. Is half-time based on the number of hours in a full-time work week based on the hospice's policy and procedure?" (2)

RESPONSE TO COMMENTS 6 AND 7: Existing N.J.A.C. 8:42C-1.2 defines the term "full-time" to mean "a time period established by the facility as a full working week, which is defined and specified within the facility's policies and procedures." Therefore, the term "half-time" would mean half of the "time period" that a facility establishes in its policies and procedures "as a full working week." As the existing definition of the term "full-time" is sufficient to identify the meaning of the term "half-time," the Department will make no change on adoption in response to the comments.

N.J.A.C. 8:42C-11.4(b)

8. COMMENT: A commenter notes that proposed new N.J.A.C. 8:42C-11.4(b) would state, "the maximum unit size is 30 beds," and advises that there "is at least one hospice inpatient unit … that exceeds that maximum (with 33 beds)." The commenter suggests that "the rule allow the 'grandfathering' of any unit larger than 30 beds as of the date the proposal becomes effective." (1)

RESPONSE: The maximum of 30 licensed beds per inpatient hospice care unit would apply prospectively to applicants for licensure of new inpatient hospice care units and applicants for authorization to expand existing units. The maximum of 30 licensed

beds per unit would not apply to existing inpatient hospices that are licensed and operating as CPCHs as of the effective date of the proposed amendments and new rules, provided their operators apply for licensure thereof as inpatient hospice care units within 60 days of the effective date of the proposed amendments and new rules pursuant to proposed new N.J.A.C. 8:42C-11.1(c). Thus, the Department will "grandfather," that is, authorize licensure as inpatient hospice care units, existing inpatient hospice units that are licensed and operating as CPCHs as of the effective date of the proposed amendments and new rules with their existing number of licensed beds, even if there are more than 30 existing licensed beds in a unit. Because the Department intends to apply the rule prospectively, as the commenter suggests, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:42C-11.4(c)

9. COMMENT: A commenter notes that proposed new N.J.A.C. 8:42C-11.4(c) would require "that 'All beds in a unit are in a contiguous area on the same floor.'" The commenter states that "the phrase 'contiguous' may be too restrictive. In a facility with wings, for example, each wing may touch a central nursing hub but the wings are not contiguous to each other." The commenter suggests the "use of wording like, 'All beds in a unit must be accessible without leaving the building or crossing into other areas of the facility.'" The commenter notes that "there are currently at least two hospice inpatient facilities in the [State] that have patients on two floors." The commenter suggests "that either the phrase 'on the same floor' be deleted or that any multi-story unit operating on the date the proposal becomes effective be 'grandfathered' to continue operation as then constructed." (1)

RESPONSE: With respect to the example the commenter provides, the Department would view wings joining at a central nursing hub to be contiguous; therefore, the commenter's concern is inapplicable to the provided example. Nonetheless, proposed new N.J.A.C. 8:42C-11.4(c) would apply prospectively to applicants for licensure of new inpatient hospice care units and applicants for authorization to expand existing units. The unit bed contiguity requirement at proposed new N.J.A.C. 8:42C-11.4(c) would not apply to existing inpatient hospices that are licensed and operating as CPCHs as of the effective date of the proposed amendments and new rules, provided their operators apply for licensure thereof as inpatient hospice care units within 60 days of the effective date of the proposed amendments and new rules, pursuant to proposed new N.J.A.C. 8:42C-11.1(c). Thus, the Department would "grandfather," that is, deem compliant with N.J.A.C. 8:42C-11.4(c) and authorize licensure as inpatient hospice care units, existing inpatient hospice units that are licensed and operating as CPCHs as of the effective date of the proposed amendments and new rules, including those that exist in multi-story configurations. Because the Department intends to apply the rule prospectively, as the commenter suggests, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:42C-11.4(e)

10. COMMENT: A commenter recommends that the Department reconsider proposed new N.J.A.C. 8:42C-11.4(e), which would require, "[at] least 50 percent of the unit rooms [to be] single occupancy." The commenter states that "hospitals [currently] are trending toward all private rooms due to the nature of the patients' health condition[s] and to protect privacy and confidentiality at all times. In an inpatient

hospice facility, just the very nature of a patient expiring in the same room as another patient with a terminal illness warrants reconsideration of the double occupancy. The privacy and confidentiality is difficult to protect in this environment even when meetings can be held in an outside conference room. These patients are terminally ill and the majority of patients admitted will expire in the facility. Therefore, it is unavoidable that they will have to share this very private moment with another patient and family who will inevitably have the same experience. Having to accommodate the privacy of a family, in a double room, after the death of their loved one means removing them from the double room environment and escorting them to another area in the facility, or worse, asking the other family to step out while this family grieves. Private rooms allow the family to grieve at the bedside for as long as needed. For all of these reasons [the commenter recommends] that any new inpatient hospice that was not previously licensed as a CPCH should have all private rooms." (2)

RESPONSE: The Department acknowledges the commenter's concern as to the appropriateness of hospices maintaining single-occupancy rooms as a preferred practice, given the likely conclusion of hospice stays and the attendant implications for privacy needs. Members of the regulated community raised and discussed these concerns during the Department's meeting with them to solicit recommendations in the development of the proposal. Proposed new N.J.A.C. 8:42C-11.4(e) would reflect the regulated community members' consensus recommendation at that meeting that fifty-percent of the rooms in a unit might accommodate double occupancy. The proposed amendments and new rules would not prohibit licensees from making all rooms in a unit accommodate only single occupancy. However, in deference to licensees' good faith

exercise of business and clinical judgment, to provide flexibility, and to reflect the regulated community's consensus recommendation, described above, the Department declines to mandate the maintenance of only single-occupancy rooms in inpatient hospice care units. Therefore, the Department will make no change on adoption in response to this comment.

N.J.A.C. 8:42C-11.4(k)

11. COMMENT: A commenter states that the use of the term "corridor area" at proposed new N.J.A.C. 8:42C-11.4(k) "may be inadequate" and suggests that the Department either provide "further definition of the phrase 'corridor area'" or change the sentence to state that each patient shall have access to a bathroom that is "directly accessible from the patient's room." (1)

RESPONSE: Proposed new N.J.A.C. 8:42C-11.4(aa) would require inpatient hospice care units to adhere to the Facility Guidelines Institute, Guidelines for Design and Construction of Residential Health, Care, and Support Facilities (2014), published by the American Society for Healthcare Engineering, Chicago, Illinois (Guidelines), as amended and supplemented. Section 3.1-2.2.2.6 of the Guidelines states, "[e]ach resident shall have access to a toilet room without entering a general corridor." Because the Guidelines use the term "corridor" rather than the term, "corridor area," and to address the commenter's suggestion of the inadequacy of the term "corridor area," the Department will make a change on adoption to delete the word "area" from the term "corridor area" to ensure that the rule terminology would be consistent with, and construed in accordance with, the Guidelines.

Except as described above, the Department will make no change on adoption in response to the comment.

12. COMMENT: A commenter states that the “final ‘s’ should be removed from ‘swings’” in N.J.A.C. 8:42C-11.4(k)1i.

RESPONSE: The commenter correctly notes that the term should be “swing” and the Department thanks the commenter for pointing out this grammatical error. Therefore, in response to the comment, the Department will make a non-substantial change on adoption at proposed new N.J.A.C. 8:42C-11.4(k)1i to correct the error. In addition, the Department will make non-substantial changes on adoption in the lead-in to this provision at proposed new N.J.A.C. 8:42C-11.4(k) to correct a redundant use of the term “access” and in the succeeding phrase of the provision at proposed new N.J.A.C. 8:42C-11.4(k)1ii to correct a verb conjugation error, by deleting the verb “is” and adding in its place the verb “be.”

N.J.A.C. 8:42C-11.4(n)

13. COMMENT: A commenter suggests that the Department delete “the phrase ‘stretcher-accessible,’ because hospice units do not use stretchers to bring patients to bathing areas. Patients who are not able to achieve access to bathing areas on foot or by wheelchair are cleaned in bed.” The commenter states that the “use of stretchers violates the homelike environment sought in the hospice units.” (1)

RESPONSE: The Department agrees that inpatient hospice care units are to “provide a homelike atmosphere,” pursuant to proposed new N.J.A.C. 8:42C-11.4(r), and acknowledges that using stretchers to transport a patient to the central bathing area might diminish the homelike atmosphere of an inpatient hospice care unit. However, a

consensus of the working group recommended that the Department require bathing areas to be “stretcher-accessible” because, on occasion, a patient, who is or becomes transferable only by stretcher, might be unable to bathe in bed and need to bathe in the bathing area. The working group agreed that a facility’s ability to accommodate a patient’s safe and appropriate transfer to the bathing area, by means of a stretcher, if necessary, outweighed the potential diminishment of a homelike environment that might result from the occasional presence of a stretcher on the unit. Proposed new N.J.A.C. 8:42C-11.4(n) would not preclude or prohibit licensees from bathing in bed those patients for whom use of the central bathing area would be difficult or otherwise contraindicated. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:42C-11.4(s)1vi

14. COMMENT: Commenters suggest that the Department delete the word, “room,” from the phrase, “double-locked narcotic storage room,” at proposed new N.J.A.C. 8:42C-11.4(s)1vi, stating, “Hospice units do not have a ‘stock supply’ of medications requiring a room per se. Rather, they lock up medications in the refrigerator or in med carts on each unit or wing.” (1)

RESPONSE: The Department agrees with the commenters’ assertion that requiring a double-locked narcotic storage “room” would be unnecessary. The Department intended to require only that narcotics be stored under a double-lock storage method. Therefore, for the reasons the commenters state, the Department will make a non-substantial change on adoption to delete the requirement that inpatient

hospice care units have double-locked narcotic storage “rooms,” and to require instead that units have a double-lock “method” of narcotics storage.

N.J.A.C. 8:42C-11.6(c)

15. COMMENT: A commenter states that proposed new N.J.A.C. 8:42C-11.6(c), would require licensees to maintain an emergency drug kit “for all possible patients” and “would create additional burden on waste and disposal of … medications [that are controlled substances on United States Department of Justice, Drug Enforcement Administration Drug Schedules II to IV]. Currently, inpatient hospices rely on having floor stock medications obtained through the participating pharmacy under the [controlled substance] license of the medical director. This enables the hospice to rely on just the emergently ordered medication that is needed to manage the symptom and not [have] to waste the unused drug when the patient expires.” (2)

RESPONSE: Proposed new N.J.A.C. 8:42C-11.6(c) would not require licensees to maintain an emergency drug kit to meet the needs of “all possible patients.” Proposed new N.J.A.C. 8:42C-11.6(c) would require licensees to maintain an emergency drug kit that is “appropriate to the needs of patients of the facility,” meaning the reasonably anticipated needs of a facility’s actual existing patient population, to be revised on an ongoing basis to reflect changes in that population and corresponding changes to the population’s emergency drug needs, “that is [assembled] in consultation with the licensed pharmacist,” with whom licensees establish a relationship pursuant to proposed new N.J.A.C. 8:42C-11.6(a). The comment is unclear in explaining how compliance with proposed new N.J.A.C. 8:42C-11.6(c) would be different from, or more burdensome than, the commenter’s existing practice, in which “inpatient hospices rely

on having floor stock medications obtained through the participating pharmacy under the [controlled substance] license of the medical director[, which] enables the hospice to rely on just the emergently ordered medication that is needed to manage the symptom and not [have] to waste the unused drug when the patient expires." The Department anticipates that the emergency drug kit, which N.J.A.C. 8:42C-11.6(c) would require inpatient hospice care units to maintain, would contain the "stock medications" that the commenter addresses, subject to modification or supplementation as the needs of a facility's patient population change.

Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:42C-11.8(c)

16. COMMENT: A commenter states that the requirement at proposed new N.J.A.C. 8:42C-11.8(c), that each unit "have a staff member" who is trained or experienced in food management, "may imply that the person experienced in food management must be a staff member of the unit. A unit may, however, secure such services from a hospice employee who does not work in the unit, from a contracted nutritionist employed by the hospital in which the unit is located, or elsewhere." The commenter suggests that the Department revise this phrase to require each unit to "have access to a professional" who is trained or experienced in food management. (1)

RESPONSE: The Department does not interpret the phrase, "have a staff member," at proposed new N.J.A.C. 8:42C-11.8(c), as prohibiting the required "staff member" from being a worker that an inpatient hospice care provider retains by contractual agreement. Proposed new N.J.A.C. 8:42C-11.8(a) would authorize inpatient

hospice care providers to “provide dietary services either directly or through a documented agreement with a food services provider that details the services provided.”

Even if one could construe the phrase “staff member” at proposed new N.J.A.C. 8:42C-11.8(c) as meaning an employee, the CoPs, at 42 CFR 418.3, define the term “employee” to mean “a person who: (1) Works for the hospice and for whom the hospice is required to issue a W–2 form on his or her behalf; (2) if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is assigned to the hospice; or (3) is a volunteer under the jurisdiction of the hospice.” This definition would include the example that the commenter suggests, that is, a hospice employee who does not work in the unit or is employed by the hospital in which the unit is located, as being acceptable pursuant to the applicable Federal standards.

For the foregoing reasons, the Department will make no change on adoption in response to the comment.

Summary of Agency-Initiated Changes:

1. The Department is making a change on adoption to the definition of the term “hospice” at existing N.J.A.C. 8:42C-1.2 to include inpatient hospice care units, with accompanying grammatical changes to improve sentence structure and readability.

2. The Department is making a change on adoption to grammar and punctuation at N.J.A.C. 8:42C-11.4(s)1 to avoid potential ambiguity of meaning.

Federal Standards Analysis

The adopted amendments and new rules at N.J.A.C. 8:42C are generally consistent with the Medicare Program regulations at 42 CFR Part 418—Hospice Care, with which inpatient hospice care providers must comply to obtain Medicare certification

and eligibility for Medicare reimbursement. However, the adopted amendments and new rules would continue to exceed these Federal standards with respect to the required employee health standards, especially for direct patient care workers, the patient rights policies and procedures, and the infection prevention and control program. The enhanced standards would be consistent with standards that the Department requires in other New Jersey licensed healthcare facilities. New Jersey consumers of healthcare facility services have come to expect these enhanced requirements as standard across all New Jersey licensed healthcare facilities. The Department has determined that it is appropriate to make these enhanced requirements applicable to inpatient hospice care units to ensure a consistent level of care and quality across all New Jersey licensed healthcare facilities.

The cost to comply with implementation of patient rights requirements in licensed healthcare facilities generally is not significant within the context of providing other healthcare services. Outbreaks of communicable disease among patients and staff can result in death and, at the very least, staff absenteeism. As the Summary and Economic Impact described in the Notice of Proposal, the cost to facilities to comply with enhanced employee health standards and to implement infection prevention and control programs is less than the cost to respond to outbreaks and their consequences. These enhanced requirements are particularly appropriate in the context of treating hospice patients, who might be (1) immunocompromised and/or (2) in hospice because they have communicable disease diagnoses.

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

8:42C-1.2 Definitions

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

…

"Hospice" means a program *[which is licensed by]* ***that*** the Department ***licenses*** to provide palliative services***, including medical, nursing, social work, volunteer, and counseling services,*** to terminally ill patients in *[the patient's]* ***their*** home***s,*** *[or]* ***at their*** place***s*** of residence, *[including medical, nursing, social work, volunteer, and counseling services]* ***or at inpatient hospice care units***.

…

SUBCHAPTER 11. INPATIENT HOSPICE CARE UNIT

8:42C-11.1 Scope

(a) – (b) (No change from proposal.)

(c) An inpatient hospice care provider operating a unit prior to *[(the effective date of this new rule)]* ***January 16, 2018,*** shall:

1. File a licensing application by *[(60 days after the effective date of this new rule)]* ***March 17, 2018***, for which the Department shall charge the applicant no fee;

2. (No change from proposal.)

N.J.A.C. 8:42C-11.4 Patient care area requirements for inpatient hospice care units

(a) – (j) (No change from proposal.)

(k) Each patient shall have *[access to]* ***the use of*** a bathroom, access to which does not require the patient to enter *[the]* ***a*** corridor *[area]*.

1. The bathroom door shall either:

i. Swing*[s]* outward; or

ii. *[Is]* ***Be*** an inward-swinging door that complies with the clearance requirements of the Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12101 et seq.

(l) – (r) (No change from proposal.)

(s) Each unit shall have the following:

1. A medication preparation area *[that]* ***, which*** is located either adjacent to *[the nurses' station]* ***,*** or *[under]* ***within*** the visual control of ***,*** the nursing station *[and shall have]* ***, that has***:

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

vi. A double-lock*[ed]* ***method of*** narcotic***s*** storage *[room]*;

2. – 9. No change from proposal.)

(t) – (aa) (No change from proposal.)