

**HEALTH**

**HEALTH SYSTEMS BRANCH**

**CERTIFICATE OF NEED AND LICENSING DIVISION**

**OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE**

**Licensing Standards for Home Health Agencies**

**Readoption with Amendments: N.J.A.C. 8:42**

**Adopted Repeal and New Rule: N.J.A.C. 8:42-6.3**

**Proposed New Rules: N.J.A.C. 8:42-6.5, 6.6, and 6.7 and 8:42 Appendix B**

Proposed: February 1, 2016, at 48 N.J.R. 157(a).

Adopted: June 3, 2016, by Cathleen D. Bennett, Commissioner, Department of Health  
(with the approval of the Health Care Administration Board).

Filed: June 14, 2016, as R.2016 d.082, **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-1 et seq., particularly 26:2H-5.

Effective Dates: June 14, 2016, Readoption;

July 18, 2016, Amendments, Repeal, and New Rules.

Expiration Date: June 14, 2023.

**Summary** of Public Comments and Agency Responses:

The Department of Health (Department) received timely comments from the  
following commenters during the 60-day public comment period, which ended on April  
1, 2016:

1. Chrissy Buteas, President & CEO, Home Care & Hospice Association of New

Jersey; and

2. Theresa Edelstein, Vice President Post-Acute Care Policy & Special Initiatives, New Jersey Hospital Association.

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

### **General Comments**

1. COMMENT: A commenter thanks the Department for the "opportunity to submit comments on Proposal Number: PRN 2016-018. The Home Care & Hospice Association of NJ represents Home Health Agencies (HHA) that care for nearly 100,000 Medicare beneficiaries. We appreciate the Department of Health's commitment to provide a reasonable, necessary, efficient, understandable and sound regulatory framework that allows home health agencies to service New Jersey's patients. New Jersey HHAs have consistently proven to provide quality, dependable, cost effective and coordinated health care while complying with state and federal regulations." (1)

2. COMMENT: A commenter states on "behalf of the New Jersey Hospital Association's home health agency members, we appreciate the opportunity to offer comments on the proposed readoption with amendments to the licensing standards for home health agencies at N.J.A.C 8:42. Overall, NJHA supports the amendments to the licensing standards." (2)

RESPONSE TO COMMENTS 1 AND 2: The Department acknowledges and thanks the commenters for their support for the rules proposed for readoption with amendments, new rules, and repeals.

3. COMMENT: The commenter states that we “agree with the technical amendments that have been instituted in an attempt to update terminology, properly identify other entities and recognize new resources. These include, but are not limited to, the revisions to some outdated definitions, replacing the term ‘facility’ with the term ‘agency,’ replacing the acronym DYFS with the current agency title of Department of Children and Families, Division of Child Protection and Permanency, and providing web/internet links to various resource sites in order to provide access to the most relevant information and data (i.e.: CDC, OSHA BBP, and Board of Nursing websites).”

(1)

RESPONSE: The Department acknowledges and thanks the commenter for their support of the technical amendments.

#### **N.J.A.C. 8:42-2.1**

4. COMMENT: The commenter states that “since the Department is removing reference to N.J.A.C. 8:33L, which expired in 1997, NJHA believes that the Department needs to clarify that a certificate of need will only be issued by the Commissioner pursuant to a CN call as required by statute.” (2)

RESPONSE: The Department agrees with the commenter and will make a technical change upon adoption at N.J.A.C. 8:42-2.1(a) to make a reference to the certificate of need call requirements at N.J.A.C. 8:33, which applies to home health agencies.

#### **N.J.A.C. 8:42-3.2**

5. COMMENT: The commenter states that the “regulations extend the change in ownership notification requirement from 30 days to 90 days and prohibit the closing of the transfer of ownership without prior Department approval. We suggest that the ownership notification requirement remain at 30 days.” (1)

RESPONSE: Due to the increased complexity and volume of licensing applications received by the Department in recent years, the average time that it takes for the Department to review each application has risen to an average of 90 days. As such, a 30-day review period is no longer feasible. Accordingly, the Department will make no change upon adoption in response to this comment.

#### **N.J.A.C. 8:42-3.4**

6. COMMENT: The commenter “is pleased to see the revised employee health requirements for detecting Mycobacterium tuberculosis Infection and rubella/rubella immunity screening. Implementing that agencies comply with the CDC’s guidelines for tracking immunity of these communicable diseases for health care providers will ensure that screening and immunization practices are medically compliant with Federal public health standards for safety and prevention. The CDC established the use of the QuantiFERON-TB Gold Test for detecting Mycobacterium tuberculosis Infection to be equally, if not more accurate, than a tuberculin skin test and recommends that QFT-G may be used in all circumstances in which the TST is currently used. We recommend that [N.J.A.C.] 8:43-3.4(h) read: Agency personnel, both directly employed and under contract, upon employment shall receive a tuberculosis screening test and any required retesting in accordance with the Centers for Disease Control (CDC) ‘Guidelines for

Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Settings.”

(1)

RESPONSE: The Department agrees with the commenter that the QuantiFERON-TB Gold Test, which is a blood test, is an appropriate tuberculosis test as it is contained in the CDC standard that the Department is requiring agencies to comply with in the proposed amendment. The standard for “skin” testing was inadvertently left in the proposed rule when the amendment was drafted as this requirement conflicts with the CDC standards in the referenced document. Therefore, based on this comment and the incorporation by reference of the CDC guidelines, the Department is deleting the word “skin” and will accept any testing approved by the CDC in the referenced document.

#### **N.J.A.C. 8:42-4.1**

7. COMMENT: The commenter supports “the governing authority’s new requirement to develop and implement a written conflict of interest policy that will establish a structure for identifying and disclosing conflicts of interest within the agency’s operations or leadership and improve transparency.” (1)

RESPONSE: The Department acknowledges and thanks the commenter for their support of the proposed amendments.

#### **N.J.A.C. 8:42-5.3**

8. COMMENT: The commenter supports “the expansion of the description of the roles and responsibilities of the agency Director of Nursing. The additional items provide edification for what has always been the Director of Nursing’s role. 1. Overall planning,

supervision, and administration of nursing services 2. Coordination and integration of nursing services with other home health services to provide a continuum of care for patients. 3. Development of protocols for regular communications, including case conferencing between the nursing service and other disciplines based on the needs of each patient. 4. Development of written job descriptions and performance criteria for nursing personnel, and assigning duties based upon education, training, competencies and job descriptions 5. Ensuring that nursing services are provided to patients as specified in each patient's nursing plan of care 6. Ensuring community health nursing supervision to nursing personnel. It is recommended that the term [community health nursing] supervision be changed to nursing supervision, as the term and definition for community health nurse was removed from 8:42-1.2." (1)

9. COMMENT: The commenter states that proposed N.J.A.C. 8:42-5.3(a)6 "under the director of nursing responsibilities uses the term community health nursing supervision; however, the definition of community health nursing has been removed from the proposed rule. NJHA recommends that paragraph (a)6 be reworded to say "Ensuring nursing supervision to nursing personnel." (2)

RESPONSE TO COMMENTS 8 AND 9: The Department agrees that a technical amendment to the regulation is needed because the term "community health nurse" along with its definition were deleted from the chapter. Additionally, the director of nursing is responsible for supervising all aspects of nursing care, not just community health. As such, the Department will change paragraph (a)6 by deleting the term "community health."

**N.J.A.C. 8:42-6.1**

10. COMMENT: The commenter supports “the change to clarify the inclusion of one representative from each discipline (PT, OT, ST, Social Work and Dietary Counseling) in the advisory group, if the agency offers these services, in order to foster interdisciplinary assessment and evaluation of policies and procedures.” (1)

RESPONSE: The Department acknowledges and thanks the commenter for their support of the proposed amendments.

**N.J.A.C. 8:42-6.3**

11. COMMENT: The commenter commends “the Department for its revision of the section at N.J.A.C. 8:42-6.3 Advance Directives.” (2)

RESPONSE: The Department acknowledges and thanks the commenter for their support of the proposed amendments.

**N.J.A.C. 8:42-6.5**

12. COMMENT: The commenter agrees “with the inclusion of the existing POLST Act and the outline of responsibilities that home health clinicians have in recognizing, honoring and complying with the orders.” (1)

RESPONSE: The Department acknowledges and thanks the commenter for their support of the proposed amendments.

**N.J.A.C. 8:42-6.6**

13. COMMENT: The commenter states that this “section outlines the only

acceptable reasons for transferring a patient to another agency: 1. A valid medical reason, including the agency's inability to care for the patient 2. Patient choice 3. Conformance with NJ Advance Directives for Health Care Act 4. Conformance with the POLST Act. There are other instances when a patient may need to be transferred from one agency's service to another. These reasons can be mutually shared by the patient and the agency or could be as a result of a significant conflict that impedes a home health agency from providing a service. 1. Conflicts between agency representatives and the patients and/or family 2. Patient's religious observances or beliefs 3. Patient relocates to a location outside of the agency service area 4. Security issues that may pose a risk to the agency staff 5. Patients who refuse to follow the prescribed plan of care. We request clarification as to the purpose for the transfer reasons listed and whether this section is designed to recognize patient rights of care based on self-determination only." (1)

RESPONSE: Pursuant to the current version of the home health agency patient's rights set forth at N.J.A.C. 8:42-13.1(b)19, which is recodified in this rulemaking as N.J.A.C. 8:42-13.2(a)19, a patient may be "transferred to another facility only for one of the reasons delineated at N.J.A.C. 8:42-6.3(e)." The current version of N.J.A.C. 8:42-6.3(e) sets forth the only reasons why a patient may be transferred to another home health agency; and these reasons are proposed for recodification as N.J.A.C. 8:42-6.6 with the addition of a new provision for the transfer of a patient in conformance with the POLST Act. Thus, the circumstances under which a home health agency may transfer a patient to another agency have not changed under this rulemaking, with the exception of the new provision for POLST Act transfers. Moreover, the Department believes that the

scenarios raised by the commenter are addressed at proposed new N.J.A.C. 8:42-6.6. Scenarios 1 and 3 through 5 would be encompassed in proposed new N.J.A.C. 8:42-6.6(a)1, as the situation would render the agency unable to care for the patient. And, Scenario 2 would be addressed by proposed new N.J.A.C. 8:42-6.6(a)2, as this would be the patient's choice, as well as under proposed new N.J.A.C. 8:42-6.6(a)1, because the agency would be unable to render care to the patient. Because the circumstances under which a patient may be transferred by a home health agency have not substantially changed with this rulemaking and the reasons for transfer are broad enough to encompass a variety of scenarios while at the same time protecting patients from improper transfers, the Department will make no change upon adoption in response to this comment.

#### **N.J.A.C. 8:42-6.7**

14. COMMENT: The commenter states that the "New Jersey Declaration of Death Act explained in N.J.A.C. 13:35-6A does not apply to the services provided by an HHA. This Act defines how a physician determines neurological brain death and the steps needed to come to that medical diagnosis/conclusion. Home Health Professional Registered Nurses are permitted by law and regulation to pronounce a person's death based on recognition of traditional cardio-respiratory criteria-irreversible cessation of all circulatory and respiratory functions, but cannot declare someone neurologically dead. The Association would request further clarification of the intent of [N.J.A.C.] 8:42-6.7 as the Declaration pertains to the non-physician health care professionals that work for the HHA." (1)

RESPONSE: As clarification, the standards cited at N.J.A.C. 8:42-6.7 are applicable only to a health care professional acting within the scope of his or her license. The New Jersey Declaration of Death Act, N.J.S.A. 26:6A-1 et seq, sets forth the standards for declaring an individual deceased. Specifically, the Act sets forth cardio-respiratory criteria and neurological criteria for declaring a person dead. The Department acknowledges that the standards at N.J.A.C. 13:35-6A for declaring an individual deceased based on neurological criteria apply only to physicians. However, the Department's intent for including this provision in the rule is to ensure that health care professionals, including physicians, have the full scope of their applicable license available to them in the event the health care professional is called upon to declare an individual who was under the care of a home health agency deceased.

**N.J.A.C. 8:42-7.5**

15. COMMENT: The commenter states that given "the recently finalized changes to the Board of Nursing regulations that permit the delegation of medication administration to certified home health aides, NJHA asks that the Department ensures that this subchapter is consistent with the new Board of Nursing rules." (2)

RESPONSE: After reviewing N.J.A.C. 8:42-7.5 in light of the recent amendments made by the Board of Nursing to the delegation standards at N.J.A.C. 13:37-6.4, the Department has determined that the subchapter continues to be consistent with the Board of Nursing standards. Based on this determination, the Department will be making no change to the rules upon adoption.

**N.J.A.C. 8:42-11.2**

16. COMMENT: The commenter states that N.J.A.C. 8:42-11.2 “refers to pieces of the medical record that must be included when transferring a patient to another facility, but does not address the Universal Transfer Form (UTF) which is found in [N.J.A.C.] 8:43E-13.5. It is our recommendation that the UTF be included in [N.J.A.C.] 8:42-11.2.” (1)

RESPONSE: The UTF is already required to be used in all transfers between licensed healthcare facilities or programs pursuant to N.J.A.C. 8:43E-13.4. To ensure consistency between the rules and eliminate any confusion regarding the use of the UTF for transfers, the Department will make a technical change upon adoption to include the UTF in the list of items required to be sent to the receiving facility when transferring a patient pursuant to N.J.A.C. 8:42-11.2(d).

**N.J.A.C. 8:42-13.1**

17. COMMENT: The commenter “understands that the Department is seeking to achieve consistency in its standards by proposing to require home health agencies to distribute the statement of patients’ rights to patients, as well as to staff and contracted personnel. There is a grammatical error at N.J.A.C. 8:42-13.1(a)1; patient’s should be patients.” (2)

RESPONSE: The Department thanks the commenter for pointing out the grammatical error, which was included in the rule proposal that was submitted to the Health Care Administration Board, and notes that the error was corrected prior to publication of the notice of proposal in the New Jersey Register.

## **Federal Standards Analysis**

The rules readopted with amendments, repeal, and new rules would continue to impose standards on home health agencies in New Jersey that do not exceed the Federal standards for home health agencies, with limited exceptions that are necessary for patient safety and well-being. The Federal home health agency standards are established by Medicare and are set forth at 42 CFR Part 484. Additionally, 42 CFR 440.70(d) provides that home health agencies must comply with the Medicare home health agency requirements as a condition of participation in the Medicaid program. Thus, the two programs maintain the same requirements for participation. Because the Medicaid requirements for home health agencies are the same as those for the Medicare program, this analysis applies equally to the Medicaid and the Medicare programs.

42 CFR 484.14 requires that, as a condition of Medicare participation, home health agencies provide part-time or intermittent skilled nursing services, and that at least one other therapeutic service (physical, speech, or occupational therapy; medical social services; or home health aide services) be made available on a visiting basis. N.J.A.C. 8:42-3.1 would continue to require home health agencies to provide preventive, rehabilitative, and therapeutic services, including, but not limited to, nursing, homemaker-home health aide, and physical therapy services. Although this requirement exceeds the Federal requirement because it requires both home-maker home health aide and physical therapy services, the Department believes that these are essential services that home health agencies should continue to provide.

Additionally, N.J.A.C. 8:42-7.3(d) would continue to require that a home health agency have a registered nurse (RN) available 24 hours a day to return a patient's call within one hour regarding clinical issues. Federal law does not require on-call coverage by an RN and does not require a patient's call to be returned within one hour. However, in order to ensure that a patient's needs are addressed appropriately and in a timely fashion, the Department believes that agencies must have 24 hour on-call RN coverage that includes having the RN return a patient's call within one hour.

N.J.A.C. 8:42-3.1(b) would also continue to impose a prohibition on full contracting of nursing services, and provides that the subcontracting of nursing services shall only be permitted under certain conditions. Federal law does not limit the subcontracting of nursing services by home health agencies. The Department believes that the subcontracting of nursing services by home health agencies should only be permitted under limited circumstances in order to ensure continuity of care for patients.

The Department is unable to estimate the cost of providing two therapeutic services in addition to nursing services and 24/7 coverage by an RN, or any increase in costs because of the limitation on subcontracting of services. However, the Department believes that patient safety is paramount, and that the costs of these requirements are justified because they serve to ensure patient health and safety through the provision of high quality care.

**Full text** of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 8:42.

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

#### 8:42-2.1 Certificate of Need

(a) According to N.J.S.A. 26:2H-1 et seq., and amendments thereto, a home health agency shall not be instituted, constructed, expanded, licensed to operate, or closed, except upon application for and receipt of a Certificate of Need issued by the Commissioner **\*pursuant to a Certificate of Need Call as required by N.J.A.C. 8:33\***.

(b) –(c) (No change from proposal.)

#### 8:42-3.2 Ownership

(a) (No change from proposal.)

(b) An agency shall submit an application for transfer of ownership on Form CN-7 to the Director of the Office of Certificate of Need and Healthcare Facility Licensure in writing at least 90 days prior to the proposed closing date and in conformance with the requirements for Certificate of Need applications at N.J.A.C.\* 8:33-3.3.

#### 8:42-3.4 Personnel

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

(h) Agency personnel, both directly employed and under contract, shall receive upon employment tuberculin **\*[skin]\*** testing and any required retesting in accordance with the

Centers for Disease Control (CDC) "Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Settings," 2005 Guidelines, MMWR, December 30, 2005; Vol. 54; RR-17, incorporated herein by reference, as amended and supplemented, which can be found on the CDC website at

[http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s\\_cid=rr5417a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s_cid=rr5417a1_e).

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

#### 8:42-5.3 Director of nursing's responsibilities

(a) The director of nursing shall be responsible for the direction, provision, and quality of patient care services provided to patients, including:

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

6. Ensuring \*[community health]\* nursing supervision to nursing personnel.

#### 8:42-11.2 Medical/health records policies and procedures

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

(d) If the patient is transferred to another non acute health care facility, the agency shall maintain a transfer record reflecting the patient's immediate needs and send a copy of this record to the receiving facility at the time of transfer. The transfer record shall contain at least the following information:

1.-5. (No change.)

6. Reason for transfer; \*[and]\*

7. A notice of the existence of an advance directive, POLST Form, and/or Do Not Resuscitate (DNR) order\*.[.]\*\*; **and**

**8. The Universal Transfer Form as required by N.J.A.C. 8:43E-13.\***

(e)-(h) (No change from proposal.)