

HEALTH AND SENIOR SERVICES

SENIOR SERVICES AND HEALTH SYSTEMS BRANCH

HEALTH FACILITIES EVALUATION AND LICENSING DIVISION

OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY

LICENSURE

Hospice Licensing Standards

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

Adopted Repeal: N.J.A.C. 8:42C-3.10

Proposed: January 4, 2010 at 42 N.J.R. 25(a).

Adopted: _____, 2010 by _____,

Poonam Alaigh, MD, MSHCPM, FACP, Commissioner, Department of Health
and Senior Services (with the approval of the Health Care Administration Board).

Filed: _____, 2010 as R.2010 d. _____, **with a substantive change** not requiring
additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 26:2H-79, 80 and 81 and 26:2H-12.

Effective Date: _____, 2010, Readoption; and
_____, 2010, Amendments and Repeal.

Expiration Date: _____, 2015.

Summary of Public Comments and Agency Responses:

The 60-day public comment period ended on March 5, 2010. Three comment
letters were received. The comments were received from:

1. Theresa Edelstein, MPH, LNHA, Vice President, Continuing Care Services,
New Jersey Hospital Association, Princeton, NJ;

The official version of any departmental rulemaking activity (notices of proposal or adoption) are published in the *New Jersey Register* or *New Jersey Administrative Code*. Should there be any discrepancies between this document and the official version of the proposal or adoption, the official version will govern.

2. Donald L. Pendley, M.A., CAE, APR, President, New Jersey Hospice and Palliative Care Organization, Scotch Plains, NJ; and

3. Carolyn Torre, RN, MA, APN, Director, Regulatory Affairs, New Jersey State Nurses Association, Trenton, NJ.

A summary of the comments and the Department's responses follows. The number(s) in parentheses after each comment identifies the respective commenter(s) listed above.

N.J.A.C. 8:42C-1.2

1. COMMENT: The commenter recommends that the Department amend the definition of "social worker" to "recognize that some hospice social workers are LSWs, and according to the Board of Social Work Examiners' regulations, are not required to have at least one year of post-master's experience." The commenter's suggested remedy is to add the phrase "if an LCSW" prior to the language requiring the one year of post-master's experience. (1)

RESPONSE: The Department anticipates further amendments to this chapter shortly in order to promulgate new rules governing inpatient hospice services. The amended language proposed by the commenter would serve to lower the existing standard and is therefore too substantive of a change to make on adoption because it would require additional notice and opportunity to comment. The Department is not including this proposed change in the notice of adoption at this time. The definition of social worker at N.J.A.C. 8:42C-1.2 establishes the meaning of the term specific to the hospice licensing standards. Each hospice that hires social workers must ensure that the social workers have "at least one year of post-mater's social work experience in a

health care setting. . . .” The Department intends to discuss the commenter’s proposed change with stakeholders and will consider it as part of the inpatient hospice proposal that will be forthcoming in the near future.

N.J.A.C. 8:42C-3.4(I)

2. COMMENT: The commenter applauded the Department’s efforts to address the concerns and suggestions discussed with stakeholders in the preparation of the proposed readoption with amendments and expressed overall support for the Department’s proposal. The commenter recommends that the Department add a definition of “direct patient contact” to the chapter and that the definition include anyone with access to patient records, which would be consistent with the Centers for Medicare and Medicaid Services’ (CMS) conditions of participation for hospice. (1)

RESPONSE: The Department appreciates the commenter’s general support. The Department does not agree with the commenter that there is a need to define the term “direct patient contact” because, for the purposes of the rules at N.J.A.C. 8:42C, it is the Department’s intention to exclusively capture those individuals that have direct contact with the patient. The Department’s authority to access Federal Bureau of Investigation (FBI) criminal background information is limited by the National Child Protection Act of 1993 (P.L. 103-209), as amended by the Violent Crime Control and Law Enforcement Act of 1994 (P.L. 103-322), hereinafter the “Act.” As applicable to chapter 42C, the Act permits a criminal background check for an individual that has responsibility for the safety and well being of children, the elderly or disabled. Individuals that have direct patient contact would also be responsible for the safety and well being of children, the elderly and disabled. It is the Department’s belief that

conducting national criminal background checks for individuals that solely have access to patient records, would be beyond the scope of the Department's authority. The Department is aware that the CMS conditions of participation at 42 CFR 418.114(d) require criminal background checks for hospice employees who have direct patient contact or access to patient records. However, the Department reminds the commenter that the rules at N.J.A.C. 8:42C are State administrative rules applicable to hospice providers in New Jersey. Aside from State administrative rules, hospice providers are responsible for complying with applicable Federal statutes and regulations. The Department has already incorporated the regulations at 42 CFR Part 418 into the administrative rules at N.J.A.C. 8:43C-3.1(a) by reference. The Department makes no change on adoption. However, the Department will continue working with the hospice industry to review the impact of the two differing standards.

3. COMMENT: The commenter states that the Federal conditions of participation require the hospice to obtain the criminal background information clearance for all of its staff that is subject to the criminal background information requirement. The commenter expressed concern with the language in the proposal that "states that the individual is responsible for obtaining clearance from" the Department's criminal background investigation (CBI) unit because the language could cause difficulty for hospices in terms of complying with the Federal conditions of participation. The commenter suggests that the Department "consider discussing this with CMS to ensure that the State's language and process will not cause compliance concerns." (1)

RESPONSE: The Department understands the commenter's concerns but does not believe that the difference in the language at N.J.A.C. 8:42C-3.4(l) and the Federal

conditions of participation would create a compliance problem. Practically, as a condition of licensure, the hospice has to require that every individual that has direct patient contact must complete a criminal background check and be cleared. The Department's CBI unit cannot complete a criminal background check on an individual without the individual's consent, so the individual is in fact the applicant for the criminal background check and the person that will or will not be cleared. In addition to providing the results to the individual, the Department's CBI unit provides a notice to the hospice stating whether or not there is clearance so the hospice also obtains the results of the criminal background check. The Department is considering the addition of future explanatory language at N.J.A.C. 8:42C stating the current CBI practice, which may alleviate some of the compliance concerns.

4. COMMENT: The commenter suggests alternate wording for the criminal background investigation requirement set forth at N.J.A.C. 8:42C-3.4(l) and N.J.A.C. 8:42C-3.4(l)1 "so that the regulation is directed toward the hospice, not the Department." The commenter suggested alternate language, namely "The applicant for licensure shall be prohibited from receiving a license. . . ." in place of the proposed language at N.J.S.A. 8:42C-3.4(l)). Similarly, the commenter suggested alternate language in place of the proposed language at N.J.A.C. 8:42C-3.4(l)1 that would read "The applicant shall not receive clearance for any current" The commenter also states that "the conditions of participation require a criminal background check within 3 months of the date of employment for all states the individual has lived or worked in the past 3 years." The commenter suggests that the Department either include this requirement at N.J.A.C. 8:42C or "refer to the fact that licensees have to comply with

additional federal CBI requirements.” (1)

RESPONSE: The Department disagrees with the commenter’s suggestions and declines to make any changes on adoption. With regard to the suggested revisions at N.J.A.C. 8:42C-3.4(l) and 3.4(l)1, the commenter does not provide a reason for making the revision except to direct the requirement toward the hospice instead of the Department. The Department believes that the language as written is appropriate because it is the entity that is responsible for the actions of issuing or continuing a license for the operation of a hospice (N.J.A.C. 8:42C-3.4(l)) and issuing clearance (N.J.A.C. 8:42C-3.4(l)1). The language as written is not confusing or incorrect. As the Department stated in its response to comment 3, above, the proposed amendments are consistent with previous criminal background check requirements that the Department placed on adult day health facilities at N.J.A.C. 8:43F-2.1(a)9 (see 36 N.J.R. 5240(a), 37 N.J.R. 4931(a)). Similar language appears in chapter 43F and has not presented any problems.

With regard to the comment on the timing of the criminal background check, the Federal conditions of participation specific to obtaining criminal background checks at 42 CFR 418.114(d)(2) only apply in the absence of State requirements. The proposed rule at N.J.A.C. 8:42C-3.4(l) requires every employee at a hospice that has direct patient contact to obtain clearance from the Department’s Criminal Background Investigation Unit (CBI) prior to being employed. Also, the Department’s criminal background check is nationwide and is not limited to the three prior years or location. The Department does not believe any change to the rule is necessary and declines to make any change on adoption. The Department is considering the addition of future

explanatory language to the rules stating the current CBI practice, which may alleviate confusion about this requirement. The Department would also furnish the hospice facility with the required fingerprinting forms to comply with this rule.

8:42C-5.1(b)9

5. COMMENT: The commenter expressed her organization's full support of the proposed readoption with amendments, but suggested the addition of "advanced practice nurse" at N.J.A.C. 8:42C-5.1(b)9. The commenter noted that since the Department has added "advanced practice nurse" in the definition section and elsewhere in the chapter, there is already tacit acknowledgement that "the APN may be directing the hospice patient's care." The commenter also states that the addition of this language would confirm that consumers continue to have a choice of provider in hospice, just as they would in the community. (3)

RESPONSE: The Department agrees with the commenter that the Department's proposal, added the term "advanced practice nurse" (APN) to the definition section and included APNs in the writing of a hospice patient's "plan of care" and "interdisciplinary plan of care." The Department inadvertently neglected to add the choice of an APN in the list of hospice patient rights set forth at N.J.A.C. 8:42C-5.1(b)9. CMS conditions of participation for hospice services (42 CFR Part 418) has recognized the use of nurse practitioners to function as attending physicians if the patient identifies the nurse practitioner as such. The commenter's recommendation is consistent with both CMS policy and the Department's intent in proposing the inclusion of advanced practice nurse in the proposed amendments to the chapter. This substantive change is appropriate on adoption because it will not increase a burden on the regulated community or decrease

a protection to the public. On adoption, the Department will amend N.J.A.C. 8:42C-5.1(b)9 to include a hospice patient's right to select either an attending physician or an "APN."

8:42C-1.1 et seq.

6. COMMENT: The commenter, representing hospice service providers, expressed the organization's endorsement of the readoption and their appreciation of the Department's "willingness to collaborate with the hospice community." The commenter also stated that "the Department has taken good care to bring the rules into compliance with other legal and regulatory changes since the last readoption." (2)

RESPONSE: The Department appreciates the commenter's support.

Federal Standards Analysis

The licensure rules at N.J.A.C. 8:42C, readopted with amendments, are similar to the Medicare Certification Standards for Hospice, established pursuant to 42 CFR Part 418, with which hospice care providers must comply in order to be Medicare certified. However, the readopted rules would continue to exceed the federal certification standards in the following areas: employee health requirements, especially for direct patient care; policies and procedures regarding patient rights; and, the establishment of an infection prevention and control program. The additional standards for hospice care programs were previously adopted in order to maintain consistency with companion licensure regulations for similar institutions in New Jersey. Incorporating each of these areas into the rules served to promote and protect the public health and welfare of terminally ill patients and their families and/or caregivers during the final stage of the patient's life.

The Department believes it is appropriate to exceed the Federal standards because the health and welfare of hospice patients and their families is no less important than the health and welfare of other patients under the care of State-licensed health care facilities or services. The costs of compliance have not been and would not be significant, in that they require health screening tests, such as TB tests, and implementation of patient rights requirements within the context of provision of services generally. The infection prevention and control program required is appropriate in New Jersey, since a large number of hospice patients have communicable diseases. The cost of prevention has been and would continue to be minimal, and is far less than the cost of treatment.

In this rulemaking, the rules adopted at N.J.A.C. 8:42C-3.4(l) would exceed the criminal background check requirements in the Medicare Certification Standards for Hospice because the Department's Criminal Background Investigation Unit conducts a nationwide criminal background check. The authority for conducting a nationwide criminal background check comes from the National Child Protection Act of 1993 (P.L. 103-209), as amended by the Violent Crime Control and Law Enforcement Act of 1994 (P.L. 103-322) ("Act"), which authorizes states to require organizations serving the elderly or disabled to conduct a nationwide criminal background check on those providing services to the covered population. As discussed in the Economic Impact in the Notice of Proposal published on January 4, 2010 at 42 N.J.R. 25(a), the adopted amendment to add criminal background checks to the rules would lead to additional costs for the hospice care providers or prospective employees, depending on whether each hospice care provider pays for the cost or requires the prospective employee to

pay for the cost. Nevertheless, a criminal background check is also required by the Medicare Certification Standards for Hospice. Since hospice care could be provided to the covered population, which is a vulnerable population, in their home or residence, the Department believes it is appropriate to invoke the nationwide criminal background check of the Act. The benefit of better ensuring the safety of the elderly and disabled outweighs the costs of conducting the nationwide criminal background check.

Certification Pursuant to N.J.A.C. 1:30-5.1(c)4iii(4)

I certify that the above analysis permits the public to accurately and plainly understand the purposes and expected consequences of the readoption with amendments and adopted repeal.

Poonam Alaigh, MD, MSHCPM, FACP
Commissioner,
Department of Health and Senior Services

Date

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

Full text of the adopted amendments follows (additions indicated in boldface with asterisks ***thus***; deletions from the proposal indicated in brackets with asterisks

[thus]):

SUBCHAPTER 5. PATIENT RIGHTS

8:42C-5.1 Policies and procedures

(a) (No change.)

(b) Each patient shall be entitled to the following rights, none of which shall be abridged or violated by the hospice or any of its staff:

1. (No change.)

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

4. To be informed in writing of the following:

i. – iv. (No change.)

v. (No change from proposal.)

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

9. To choose his or her attending physician ***or APN***;

10.-24. (No change from proposal.)

(c) (No change from proposal.)