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

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

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

Authorized By: _____, Heather Howard, Commissioner, Department of Health and Senior Services (with the approval of the Health Care Administration Board).

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

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

Proposal Number: PRN 2009- .

Written comments must be postmarked on or before _____ _____, 2010 and mailed to:

Ruth Charbonneau, Director

Office of Legal and Regulatory Affairs

Office of the Commissioner

New Jersey Department of Health and Senior Services

PO Box 360

Trenton, New Jersey 08625-0360

The agency proposal follows:

Summary

On April 24, 1997, P.L. 1997, c. 78, codified at N.J.S.A. 26:2H-79 through 81, was enacted. N.J.S.A. 26:2H-79 established standards for hospice care programs operating in New Jersey, specifying the care and services that must be provided to hospice patients and their families. N.J.S.A. 26:2H-80 set forth that hospice care programs must be certified to participate in the Medicare program, and licensed by the Department of Health and Senior Services (Department) in order to operate in this State. N.J.S.A. 26:2H-80e exempts hospice care programs from compliance with certificate of need requirements set forth at N.J.S.A. 26:2H-7 through 10. N.J.S.A. 26:2H-81 requires the Department to develop rules for licensure of hospice care programs as necessary to implement N.J.S.A. 26:2H-79 through 81. The rules at N.J.A.C. 8:42C fulfill this statutory mandate and the Department proposes to readopt the chapter with amendments and a repeal.

The Department is in the process of working with stakeholders to complete a comprehensive analysis of the full range of hospice care services, particularly with respect to inpatient hospice services. The Department anticipates that future rulemaking to amend N.J.A.C. 8:42C will be necessary as a result of this analysis. In the interim, the existing rules proposed for readoption along with the proposed amendments would continue to establish standards for the licensure of hospice care

programs.

Pursuant to N.J.S.A. 52:14B-5.1 and Executive Order No. 66 (1978), N.J.A.C. 8:42C is scheduled to expire on November 22, 2009. In accordance with N.J.S.A. 52:14B-5.1c, the filing of this notice of proposal for readoption with amendments and a repeal with the Office of Administrative Law prior to November 22, 2009, operates to extend the expiration date of N.J.A.C. 8:42C to May 21, 2010. The Department has reviewed N.J.A.C. 8:42C and has determined that the existing rules continue to be necessary, adequate, reasonable, efficient, understandable, and responsive to the purposes for which they were originally promulgated. Therefore, the Department has determined to readopt the chapter with amendments and a repeal. The rules proposed for readoption with amendments and a repeal would continue to provide the regulatory framework to fulfill the Department's obligation to assure access to hospice services of the highest quality.

The Department expects that the rules proposed for readoption and the proposed amendments would continue to bring uniformity and consistency to the delivery of hospice care Statewide. The readoption of these licensing rules with amendments would permit the Department to continue to ensure the quality of services provided by hospice care programs through effective inspections and appropriate enforcement. The chapter was initially established through a collaborative effort between the Department and the Hospice Licensing Standard Advisory Committee. The Committee included representatives of the New Jersey Hospice and Palliative Care Organization, as well as

hospice care providers.

This chapter is based on the standards for hospice participant certification established by Medicare. However, additional standards apply for hospice licensure, so that the hospice licensing standards are consistent with licensure requirements established for most health care facilities or services in New Jersey. This chapter would continue to establish standards that are in addition to, or exceed Medicare standards. The additional standards are discussed further in the Federal Standards Analysis.

Following is a summary of the rulemaking history of the chapter:

The Department first adopted N.J.A.C. 8:42C, Hospice Licensing Standards effective on June 21, 1999 (31 N.J.R. 321(a), 1620(a)). The Department readopted the chapter without change, effective November 22, 2004 (36 N.J.R. 2599(a), 5677(a)).

Following is a summary of the proposed amendments and repeal:

The Department proposes to make formatting and codification revisions throughout the chapter in order to bring the chapter in line with existing rulemaking practices and make the rules easier to use for the regulated community.

The Department proposes to amend N.J.A.C. 8:42C-1.2 to add definitions of the Department's licensing unit, "Office of Certificate of Need and Healthcare Facility Licensure," and health care facility inspection unit, "Office of Health Facilities Assessment and Survey." The definitions reflect a Department reorganization of the administrative assignment of these units and would provide the units' respective addresses and telephone numbers. The Department proposes corresponding

amendments throughout the chapter to delete references to the prior unit names and contact information, and to add references to the correct unit names. The Department proposes amendments to prior unit names and contact information in the following sections: N.J.A.C. 8:42C-2.1(b), 2.7(b), 3.2(a), 3.3, and 5.1(b)3.

The Department proposes to amend N.J.A.C. 8:42C-1.2 to add a definition of "advanced practice nurse" (APN) and to amend the definitions of "interdisciplinary plan of care" and "plan of care" to include reference to the APN. The Department proposes an amendment to the term "bereavement services" to indicate that the required counseling services are to be provided before and after a patient's death. The Department proposes to amend the definition of "Commissioner" to add his or her designee. The Department proposes to add a new definition for the term "core services." The Department proposes an amendment to delete the terms "dietician" and "dietary consultant" since these terms are not used in the chapter. The Department proposes an amendment to the term "restraint" to include a drug or medication when it is used to manage or restrict the patient's behavior rather than being used for treatment of the patient's condition.

The Department is also proposing amendments, set forth throughout N.J.A.C. 8:42C-2.1, 2.2, and 2.3, which replace the term "suitability review" with the term "functional review," which is the correct name for the voluntary pre-licensure process that is offered by the Department.

The Department proposes to amend N.J.A.C. 8:42C-2.3(c) to remove the existing

citation and instead add the correct citation, which is N.J.A.C. 8:42C-2.2(a)1 through 8.

The Department proposes to amend N.J.A.C. 8:42C-2.4(a) to delete obsolete language that required existing hospice providers that had existed prior to the effective date of the chapter to be licensed by September 30, 1999. The Department also proposes amendments at N.J.A.C. 8:42C-2.4(d)2 and (e)2 which would replace the name of the federal department that oversees the Medicare and Medicaid programs from the "Health Care Financing Administration" to "Centers for Medicare and Medicaid Services." The Department proposes an amendment at N.J.A.C. 8:42C-2.6(b) to include the term advanced practice nurse, which is proposed for definition.

The Department proposes to amend recodified N.J.A.C. 8:42C-3.1(e)2 to permit licensed hospice providers to employ contracted staff under extraordinary circumstances, such as staffing shortages, unanticipated high patient demand, or a patient's temporary travel outside the hospice provider's service area. The Department proposes an amendment at recodified N.J.A.C. 8:42C-3.1(e)3 to permit licensed hospice providers to enter into an agreement with another New Jersey Licensed and Medicare certified hospice program for the provision of core services. The Department proposes an amendment at recodified N.J.A.C. 8:42C-3.1(j) to provide the correct citation to the United States Department of Health and Human Service regulations for hospice provider certification.

The Department proposes an amendment to N.J.A.C. 8:42C-3.4(d), which would add criminal background checks to the list of required items to be maintained in each

hospice employee's confidential personnel records.

The Department proposes amendments at N.J.A.C. 8:42C-3.4(h) that would provide an option for how to test employees and contract personnel for tuberculosis by adding interferon gamma release assay (IGRA) as an acceptable test and to establish the meaning of a positive, negative, or intermediate test result. The Department proposes amendments throughout recodified N.J.A.C. 8:42C-3.4(h)2 to add IGRA as an optional test for tuberculosis. The Department proposes an amendment at recodified N.J.A.C. 8:42C-3.4(h)2ii that would establish that, after an "initial" Mantoux, when a second test is necessary to determine latent or active tuberculosis disease. The Department proposes an amendment at recodified N.J.A.C. 8:42C-3.4(h)2iii to establish when medical evaluation is required. The Department proposes an amendment to remove existing N.J.A.C. 8:42C-3.4(h)3, which would remove the requirement for submitting Mantoux tuberculin testing results for employees to the Department and instead add recodified N.J.A.C. 8:42C-3.4(h)3, which would require maintenance of those records at the facility.

The Department proposes amendments at N.J.A.C. 8:42C-3.4(k) to update the incorporated by reference guidelines to protect health care workers that may have been exposed to blood-borne diseases.

The Department proposes and amendment at N.J.A.C. 8:42C-3.4(l) to establish that the Department cannot issue or continue a license for a hospice program unless the owner, any current or prospective employees in a position that involves direct

contact with patients, any current or prospective administrator or any current or prospective volunteer that has direct contact with patients has obtained clearance from the Department's Criminal Background Investigation Unit. The proposed amendments would also establish that the Department will not issue a clearance for any person that has been convicted of a crime or offense that would relate adversely to his or her ability to provide care or convicted of the specified list if crimes, unless rehabilitation has been demonstrated pursuant to the Rehabilitated Convicted Offenders Act, N.J.S.A. 2A:168A-1 et seq. The proposed amendments would also establish that a disqualified person may challenge the accuracy of the disqualifying criminal history record.

At recodified N.J.A.C. 8:42C-3.5(a)2v(2) the Department proposes an amendment that would replace the Department of Human Services with the Department of Children and Families as the department of State government that contains the Division of Youth and Family Services.

At N.J.A.C. 8:42C-3.8(c) the Department proposes an amendment that would require hospice programs to report every serious preventable adverse event to the Department in accordance with Department rules at N.J.A.C. 8:43E-10 and the Patient Safety Act at N.J.S.A. 26:2H-12.23–12.25.

The Department proposes to repeal N.J.A.C. 8:42C-3.10 and recodify existing section 3.11 as the new 3.10. The existing N.J.A.C. 8:42C-3.10 references N.J.S.A. 26:2H-12.2, which related to written notice to the Medical Practitioner Review Panel. However, N.J.S.A. 26:2H-12.2 was repealed effective October 30, 2005, therefore

N.J.A.C. 8:42C-3.10 is no longer applicable.

At N.J.A.C. 8:42C-3.11 (proposed for recodification as section 3.10) the Department proposes an amendment that would add a reference to N.J.S.A. 45:1-33 that requires the reporting of actions taken against health professionals to the appropriate licensing or certification boards.

The Department proposes an amendment at N.J.A.C. 8:42C-4.1 to remove an incorrect citation and provide the correct citation.

The Department proposes amendments to the patient's rights subchapter, set forth at N.J.A.C. 8:42C-5, which would add both rights and additional language that is consistent with Centers for Medicare and Medicaid Services (CMS) patient rights requirements. The Department proposes amendments at N.J.A.C. 8:42C-5.1(b)2, which would require verbal, as well as written, notice to patients of their rights and that the notice must be given in a language and manner that the patient understands. The Department proposes amendments at new N.J.A.C. 8:42C-5.1(b)2i-iii that would require the hospice to obtain a signature from the patient or patient representative that a copy of the notice of rights and responsibilities has been provided and establishes who can exercise the rights of the patient in specific circumstances. The proposed amendment at new N.J.A.C. 8:42C-5.1(b)3 would require that the patient receive information concerning the services covered under the hospice benefit as well as the scope of services that the hospice will provide and specific limitations on those services. The Department proposes an amendment at recodified N.J.A.C. 8:42C-5.1(b)6i, which would

require a hospice to make all reasonable efforts to secure a professional and objective interpreter for hospice-patient communication, including those involving patient rights.

The Department proposes an amendment at recodified N.J.A.C. 8:42C-5.1(b)8 that would add the patient right to receive effective pain management and symptom control from the hospice for conditions related to the terminal illness in accordance with N.J.A.C. 8:43E-6.1 et seq.

The Department proposes an amendment at recodified N.J.A.C. 8:42C-5.1(b)9 that would add the patient right to choose his or her attending physician.

The Department proposes an amendment at recodified N.J.A.C. 8:42C-5.1(b)14 that would extend a patient's right to express grievances regarding care and services "by anyone who is furnishing services on behalf of the hospice."

The Department proposes an amendment at recodified N.J.A.C. 8:42C-5.1(b)15 that would add to a patient's freedom from mental and physical abuse and exploitation, the freedom from mistreatment, neglect, verbal and sexual abuse, including corporal punishment, injuries of unknown source, and misappropriation of patient property.

The Department proposes an amendment at recodified N.J.A.C. 8:42C-5.1(b)17, which would add the patient right "to be free from seclusion, of any form, imposed as a means of coercion, discipline, convenience or retaliation by staff."

The Department proposes an amendment to add new N.J.A.C. 8:42C-5.1(b)22, which would add the patient right to be informed and receive written information concerning the hospice's policies on advanced directives, including a description of

applicable State law.

The Department proposes an amendment at N.J.A.C. 8:42C-5.1(c) that would require a hospice to ensure that all verified violations involving anyone providing services on behalf of the hospice are reported to State and local authorities having jurisdiction within five working days of becoming aware of the violation.

The Department proposes an amendment at N.J.A.C. 8:42C-6.2(c) that would require a hospice to ensure that each patient and the primary caregiver(s) receive education and training appropriate to their responsibilities for the care and services identified in the plan of care.

The Department is proposing amendments at N.J.A.C. 8:42C-10.2 that would update infection control policies and procedures to include updated Centers for Disease Control and Prevention (CDC), Occupational Safety and Health Administration (OSHA), Association for the Advancement of Medical Instrumentation (AAMI), and Association for Professionals in Infection Control and Epidemiology, Inc. - Healthcare Infection Control Practices Advisory Committee (APIC-HICPAC) policies as set forth at N.J.A.C. 8:42C-10.2(b) and (c).

The Department is proposing amendments at N.J.A.C. 8:42C-10.3 that would update and add appropriate CDC “best practices” guidance documents regarding infection control practices to be followed by all hospice providers as set forth at N.J.A.C. 8:42C-10.3(a)1-9 and would correct contact information for the National Technical Information Service (NTIS) and the CDC as set forth at N.J.A.C. 8:42C-10.3(b).

The Department is proposing an amendment at N.J.A.C. 8:42C-10.7(b) that, consistent with CMS requirements, extends infection control education to employees, contracted providers, patients, family members and other caregivers.

Following is a summary of the rules proposed for readoption:

N.J.A.C. 8:42C-1 would continue to set forth the purpose and scope of the rules, and the definitions used throughout the chapter. N.J.A.C. 8:42C-2 would continue to establish the process for making application for and obtaining a license and license renewal to be a hospice service provider. Among other things, subchapter 2 establishes a functional review procedure for those entities seeking guidance from the Department as to whether they are likely to meet the licensing requirements, and a determination of those areas in which they are weak. Subchapter 2 would also continue to establish the fees for licensure and licensure renewal; the process for surrender of license; the process for applying for a waiver; reference the procedure for implementation of penalties; and reference the opportunity for a hearing.

N.J.A.C. 8:42C-3 would continue to set forth the general requirements with which a hospice must comply in order to be licensed. Subchapter 3 would continue to include health requirements for employees, specify that hospices must have policy and procedure manuals for the organization and operation of the hospice that must be reviewed annually and updated as necessary, specify those events which are reportable to the Department, and those reports that must be made to the State Board of Medical Examiners and other professional licensing boards. Subchapter 3 would continue to

establish personnel and staffing requirements.

N.J.A.C. 8:42C-4 would continue to set forth standards for the administration of the hospice, including the qualifications and responsibilities of the administrator. N.J.A.C. 8:42C-5 would continue to sets forth minimum patient rights. N.J.A.C. 8:42C-6 would continue to provide standards for patient care services, including the role of the interdisciplinary team, the establishment of an advisory group, and the required policies and procedures. N.J.A.C. 8:42C-7 would continue to establish standards for nursing services and homemaker-home health aide services. N.J.A.C. 8:42C-8 would continue to set forth standards for pharmacy services and pharmaceutical supplies. N.J.A.C. 8:42C-9 would continue to specify the manner in which a hospice is to maintain medical records, including in the event that the hospice ceases operation. N.J.A.C. 8:42C-10 would continue to require that all hospices have an infection prevention and control program, and sets forth the minimum standards for such a program.

Because a 60-day comment period has been provided on this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

N.J.S.A. 26:2H-79 through 81 mandates the Department to develop “standards and procedures” relating to the licensing of hospice care programs to ensure high-quality hospice services to the residents of New Jersey in a coordinated and cost-effective manner. This proposed readoption maintains appropriate minimum

requirements for the provision of hospice services in New Jersey and promotes the delivery of these services at a high quality level.

The proposed readoption of these rules will benefit hospice patients, their families and caregivers, as well as hospice care programs. The Department recognizes the positive social impact of the hospice care movement upon patient quality of life in this State. For chronically ill patients who meet the criteria for hospice care, this care is used as an alternative to institutionalization as well as a means of maintaining as much of an independent living status as possible for terminally ill individuals in the community. Hospice care has had a significant positive impact upon the quality of life for terminally ill individuals and their families because this type of care allows an individual to receive the diverse services needed during the final stage of his or her life, while residing at home with his or her family or in another place that has become home to the individual.

The proposed readoption with amendments of licensing rules for hospice care programs, together with the Medicare certification standards, would serve to promote high-quality palliative care for terminally ill patients. The readoption of these rules would continue to ensure the employment of qualified staff and a well trained group of volunteers, adequate record-keeping, and policies and procedure to govern patient care services, assuring that the needs of the patients and their families are met. Patients who remain in their homes (their own or another facility which has become their home) to receive palliative care would continue to retain their dignity and independence during the final stage of their life. The hospice care program minimizes further disruption to the

patient's life, as well as that of his or her family, and provides him or her with a degree of control over the circumstances.

The Department's proposed amendments to include criminal background checks and clearance from the Department's Criminal Background Investigation Unit would have the beneficial impact of better ensuring that those persons having direct contact with patients do not possess a background that would adversely impact their ability to provide appropriate care. The Department's amendments to update and add guidance documents for hospice care providers would have the beneficial impact of ensuring that they obtain the best patient outcomes by following best practices. The Department's amendment to add an additional means of testing staff for Tuberculosis would provide further assurance in preventing the spread of this communicable disease. The Department's amendment to add to the existing patient rights would have the beneficial social impact of allowing patients more autonomy in decision-making; providing a better explanation to patients and their caregivers of the components of their plan of care; and providing a better understanding of advanced directives. The Department's amendment to update the infection prevention and control practices would have the beneficial social impact of minimizing potential medical complications due to infections during provision of care.

The proposed readoption with amendments of licensing rules for hospice care programs would continue to play an important role in maintaining satisfactory levels of patient care for existing Medicare certified providers and in monitoring the quality of

care provided by new programs. The Department's proposed readoption with amendments of hospice licensure rules is essential for ensuring high-quality care that is accessible and acceptable to the terminally ill consumer.

Economic Impact

The Department foresees minimal financial consequences of the proposed readoption with amendments of licensure rules for hospice care programs, because the State licensing rules and proposed amendments build upon Medicare Certification Standards that the hospice care programs must already satisfy. It is anticipated that the industry would continue to incur the same cost as it has been incurring in order to operate a hospice care program and that costs would continue to be readily absorbed as the majority of the compliance requirements are the same as those required by Medicare. The Department will continue to charge a nonrefundable fee for a license and any renewal thereof, as permitted by N.J.S.A. 26:2H-80b, which shall not exceed $2,000. In addition, hospices will continue to incur a biennial inspection fee of $1,000, as authorized by N.J.S.A. 26:2H-12.

The proposed amendment to add an additional test for tuberculosis may lead to additional costs for those hospice care providers that voluntarily choose to use the new test. The proposed amendment to add criminal background checks to the rules would lead to additional costs for the hospice care providers, however, Medicare already requires that criminal background checks be provided for employees that have direct contact with patients. The proposed amendments to include advanced practice nurses

(APNs) may result in a cost saving because APNs would now be permitted to complete some of the activities that were previously only completed by physicians. The proposed amendments to allow hospice providers to utilize contracted staff under the specified circumstance may result in cost savings because in those circumstances hospice providers can hire contractors on an as needed basis.

No significant additional cost to the State is expected to result from the licensing and inspections of these facilities. The Department will have sufficient resources to conduct surveys, respond to complaints and develop and maintain appropriate licensure rules and has the authority to increase inspection fees if necessary within specific limits in accordance with N.J.S.A. 26:2H-12. The delivery of services by licensed hospice care programs is expected to result in considerable economic savings as opposed to institutional alternatives. Additionally, many health care authorities maintain that hospice reduces the drain on personal finances for terminally ill patients and their families when compared with the other more costly alternatives, such as an inpatient setting.

Federal Standards Analysis

The licensure rules at N.J.A.C. 8:42C, proposed for readoption with amendments, are similar to the Medicare Certification Standards for Hospice, established pursuant to 42 C.F.R. Part 418, with which hospice care providers must comply in order to be Medicare certified. However, the rules proposed for readoption 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 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.

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 proposed readoption with amendments and a repeal.

_____
Heather Howard, Commissioner
Department of Health and Senior Services

_____
Date

Jobs Impact

The Department does not expect that any jobs will be generated or lost as a result of the proposed readoption with amendments and a repeal of the hospice licensing rules.

Agriculture Industry Impact

The rules proposed for readoption with amendments and a repeal have not had and would not have an impact on the agriculture industry of the State.

Regulatory Flexibility Analysis

The majority of New Jersey's hospice care programs may be considered small businesses, as that term is defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et. seq. The rules proposed for readoption with amendments would continue to impose some reporting, recordkeeping and compliance requirements as described in the Summary above, which would affect the approximately 61 licensed hospice care programs and 10 licensed hospice branches in New Jersey. N.J.A.C. 8:42C would continue to require costs, as set forth in the Economic Impact above, which will be the same for hospice programs that are small businesses. The rules at N.J.A.C. 8:42C do

not require the hiring of professional services beyond those professional services that are required by N.J.S.A. 26:2H-79 and Medicare.

The Department is not proposing to lower or offer different standards for compliance by hospice care programs that may be small businesses. The Department believes that the need to assure the health and welfare of a hospice patient and his or her family is the same regardless of whether the patient is receiving care from a large or small hospice care program. The rules at N.J.A.C. 8:42C do permit a hospice care program to seek waiver of certain licensing requirements but in doing so, the application must provide an alternative proposal to ensure patient safety.

Smart Growth Impact

The rules proposed for readoption with amendments and a repeal have not had and would not have an impact on the achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

Housing Affordability Impact

The rules proposed for readoption with amendments and a repeal would have an insignificant impact on affordable housing in New Jersey and there is an extreme unlikelihood that the rules would evoke a change in the average costs associated with housing because the rules have and would continue to concern licensure standards for hospice services.

Smart Growth Development Impact

The rules proposed for readoption with amendments and a repeal would have an

insignificant impact on smart growth and there is an extreme unlikelihood that the rules 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 rules have and would continue to concern licensure standards for hospice services.

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

Full text of the proposed amendments and repeal follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. GENERAL PROVISIONS

8:42C-1.2 Definitions

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

"Advanced 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.

"Available" means[, pertaining] :

1. Pertaining to equipment, ready for immediate use; [pertaining] **and**

2. Pertaining to personnel, ["available" means] capable of being reached.

"Bereavement services" means counseling services provided [to a family of a hospice care patient after the hospice care] **before and after the** patient's death.

…

"Commissioner" means the New Jersey State Commissioner of **the Department of** Health and Senior Services**, or his or her designee**.

…

"Core services" means nursing services, medical social services and counseling services routinely provided directly by hospice employees.

…

["Dietitian" or "dietary consultant" means a person who:

1. Is registered or eligible for registration by the Commission on Dietetic Registration of the American Dietetic Association;

2. Has a bachelor's degree from a college or university with a major in foods, nutrition, food service or institution management, or the equivalent course work for a major in the subject area; and has completed a dietetic internship accredited by the American Dietetic Association or a dietetic traineeship approved by the American Dietetic Association or has one year of full-time, or full-time equivalent, experience in nutrition and/or food service management in a health care setting; or

3. Has a master's degree plus six months of full-time, or full-time equivalent, experience in nutrition and/or food service management in a health care setting.]

…

"Interdisciplinary plan of care" means a written plan of care established for each individual admitted to a hospice program by the attending physician, the medical

director or physician designee**, or APN** and interdisciplinary team prior to providing care, including reviews and updates, at intervals specified in the plan.

…

"**Office of Certificate of Need and Healthcare Facility Licensure" means the health care facility licensing unit within the Division of Health Facilities Evaluation and Licensing of the Senior Services and Health Systems Branch of the Department.**

1. The contact information is as follows:

i. Mailing Address: Office of Certificate of Need and Healthcare Facility Licensure, Division of Health Facilities Evaluation and Licensing, Department of Health and Senior Services, PO Box 358, Trenton, NJ 08625-0358; and

ii. Telephone number: (609) 292-5960.

"Office of Health Facilities Assessment and Survey" means the survey and inspections unit for acute care services within the Division of Health Facilities Evaluation and Licensing of the Senior Services and Health Systems Branch of the Department.

1. The contact information is as follows:

i. Mailing address: Office of Health Facilities Assessment and Survey, Division of Health Facilities Evaluation and Licensing, Department of Health and Senior Services, PO Box 367, Trenton, NJ 08625-0367; and

ii. Telephone number: (609) 292-9900.

…

"Plan of care" means a written plan established and authorized in writing by the physician **or advanced practice nurse** based on an evaluation of the patient's immediate and long-term needs.

…

"Restraint" means [devices,] :

1. Devices, materials, or equipment that are attached or adjacent to a person and that prevent free bodily movement to a position of choice[.] ; and/or

2. A drug or medication when it is used as a restriction to manage a patient's behavior or restrict a patient's freedom of movement and when it is not a standard treatment or dosage for the patient's condition.

…

SUBCHAPTER 2. LICENSURE AND LICENSURE PROCEDURE

8:42C-2.1 [Suitability] **Functional** review applicability

(a) (No change.)

(b) Requests for a [suitability] **functional** review shall be in writing, specifying the type of facility and/or service proposed, and shall be forwarded to:

Director

[Certificate of Need and Acute Care Licensure]

Office of Certificate of Need and Healthcare Facility Licensure

NJ Department of Health and Senior Services

PO Box [360, Room 604] **358**

Trenton, New Jersey [08625-0360] **08611-0358**

(c) There shall be no fee charged for [suitability] **functional** review

8:42C-2.2 [Suitability] **Functional** review procedure

(a) Applications for [suitability] **functional** review shall include the following, as applicable:

1.–8. (No change.)

(b) The Department shall complete the [suitability] **functional** review within 60 days of the request following receipt of a complete application.

1. If an application is incomplete, the Department shall provide notice to the applicant of any deficiencies in the application.

i. The applicant may resubmit the application or corrections to the application at any time.

2. Following review of a complete application, the Department shall provide to the applicant a written determination either approving or denying the [suitability] **functionality** of the proposed project, together with the reasons therefore and any limitations or conditions of future licensure approval, where applicable.

i. In cases where the applicant has so requested, the determination shall also contain the Department's determination of waiverability of any otherwise applicable licensure standard.

8:42C-2.3 Effect of [suitability] **functional** review approval

(a) [Suitability] **Functional** review approval shall remain in effect for a period of two years from the date of approval.

(b) Notwithstanding any of the provisions as set forth in this chapter, [suitability] **functional** review approval is advisory only and shall not be construed as a guarantee of eventual licensure approval in any case.

(c) Notwithstanding any of the provisions as set forth in this chapter, in order to obtain a license, every facility and/or service must comply with applicable licensure standards in effect at the time of the licensure application evaluation, including N.J.A.C. 8:42C-[2.4(c)2 through 8] **2.2(a)1 through 8**, and at all times thereafter.

8:42C-2.4 Licensure application

(a) The applicant shall submit to the Department a nonrefundable fee of $2,000 for the filing of an application for licensure of a hospice and $2,000 for the annual renewal of the license.

1. An additional $150.00 shall be submitted for the filing of an application for each branch office of the facility, and $150.00 for its annual renewal. [Existing hospices shall apply for a license no later than September 30, 1999.]

(b) All applicants must demonstrate character and competence, the ability to provide quality of care commensurate with applicable licensure standards, and an acceptable track record of past and current compliance with in- and out-of-State licensure requirements for new licenses, as applicable, and Federal requirements, as

applicable, including, but not limited to, the following:

1. The performance of the applicant in meeting its obligations under any previously approved New Jersey certificate of need, where applicable, including full compliance with all conditions of approval, if applicable; and

2. The capacity to provide quality of care which meets or surpasses the requirements contained in applicable licensure standards pertinent to the proposed facility and/or service, as set forth below:

i. Applicants shall demonstrate a satisfactory record of compliance in accordance with this section with licensure standards in existing health care facilities which are owned, operated, or managed, in whole or in part, by the applicant, according to the provisions in [(h)] **(i)** below. In addition to demonstrating compliance with in-State licensure provisions, applicants shall also include reports issued by licensing agencies in other states, where applicable;

ii.-iii. (No change.).

(c) (No change.)

(d) An applicant for a new license which operates or manages licensed or Federally certified health care facilities in other states shall have performed an evaluation of each facility's compliance with State and Federal licensing and certification requirements during the 12 months preceding application submission, and extending to the date on which a determination is made to either approve or deny the license.

1. This information shall be submitted on the letterhead of the state agency

responsible for health facility inspection, monitoring, and enforcement of State and Federal requirements.

2. The following information shall be included:

[1] **i**. Written notice that the subject facilities have been in substantial compliance with licensing and/or certification requirements during the 12 months immediately preceding application submission; and

[2] **ii**. In instances in which substantial compliance has not been achieved, a description of the deficiency or deficiencies and a description of penalties and other enforcement action impose by the state agency and/or imposed by, or recommended to the [Health Care Financing Administration] **Centers for Medicare and Medicaid Services**.

(e) An applicant for a license who was cited for any State licensure or Federal certification deficiency during the period identified in (c) and (d) above, which presented a serious risk to the life, safety, or quality of care of the facility's patients or residents, shall be denied, except in cases where the applicant has owned/operated the facility for less than 12 months and the deficiencies occurred during the tenure of the previous owner/operator.

1. A serious risk to life, safety, or quality of care of patients or residents includes, but is not limited to, any deficiency in State licensure or Federal conditions of participation requirements (42 C.F.R. 488.400) resulting in:

i. An action by a State or Federal agency to ban, curtail or temporarily

suspend admissions to a facility or to suspend or revoke a facility's license; or

ii. A termination, or exclusion from Medicaid or Medicare participation, including denial of payment for new admissions, imposed by the Department or by the Centers for Medicare and Medicaid Services, as a result of noncompliance with Medicaid or Medicare conditions of participation.

(f) In any facility, the existence of a track record violation during the period identified in (c) and (d) above shall create a rebuttable presumption, which may be overcome as set forth below, that the applicant is unable to meet or surpass licensure standards of the State of New Jersey.

1. Those applicants with track record violations which would result in denial of the application shall submit with their application any evidence tending to show that the track record violations do not presage operational difficulties and quality of care violations at the facility which is the subject of the application or in any other licensed facility in New Jersey, which is operated or managed by the applicant.

2. If after review of the application and the evidence submitted to rebut a negative track record, the Commissioner denies the application, the applicant may request a hearing which will be held in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1.1.

i. At the Commissioner's discretion, the hearing shall be conducted by the Commissioner or transferred to the Office of Administrative Law.

ii. The purpose of the hearing is to provide the applicant with the opportunity to present additional evidence in conjunction with evidence already included with the initial application, for the purpose of demonstrating the applicant's operational history and capacity to deliver quality of care to patients or residents which meets or surpasses licensure standards of the State of New Jersey to the satisfaction of the Commissioner [or his or her designee].

iii. The conclusion of that process with either a decision by the Commissioner or the Commissioner's acceptance or denial of an initial decision by an administrative law judge shall constitute a final agency decision. [A serious risk to life, safety, or quality of care of patients or residents includes, but is not limited to, any deficiency in State licensure or Federal conditions of participation requirements (42 C.F.R. 488.400) resulting in:

1. An action by a State or Federal agency to ban, curtail or temporarily suspend admissions to a facility or to suspend or revoke a facility's license; or

2. A termination, or exclusion from Medicaid or Medicare participation, including denial of payment for new admissions, imposed by the Department or by the Health Care Financing Administration, as a result of noncompliance with Medicaid or Medicare conditions of participation.]

Recodify existing N.J.A.C. 8:42C-2.4(f)-(i) as (g)-(j) with no change in text.

8:42C-2.6 Surrender of license

(a) (No change.)

(b) The hospice shall notify each patient, resident, or client, their physicians **or advanced practice nurses**, and any guarantors of payment at least 30 days prior to the voluntary surrender of a license, or as directed under an order of revocation, refusal to renew, or suspension of license.

1. In such cases, the license shall be returned to the Department within seven working days after the voluntary surrender, non-renewal, or suspension of license.

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 [Certificate of Need and Acute Care Licensure Program of the Department] **Department's Office of Certificate of Need and Healthcare Facility Licensure**.

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

SUBCHAPTER 3. GENERAL REQUIREMENTS

8:42C-3.1 Compliance with rules and laws

(a)–(d) (No change.)

(e) The hospice shall routinely provide nursing services through its own staff.

1. Nursing services provided under contract shall be rendered only if:

[1] **i**. All available full and part-time employees have achieved maximum caseloads, or specialized care which is unavailable through existing staff can be provided under contract;

[2] **ii**. Contracted nursing personnel are oriented to the policies and procedures

of the facility and receive supervision from supervisor staff employed by the facility; and

[3] **iii**. Provisions are made for continuity of patient care by the same contracted nursing personnel whenever possible.

2. Notwithstanding paragraph (e)1i through iii above, the hospice may use contracted staff, if necessary, to supplement hospice employees in order to meet the needs of patients under extraordinary or other non-routine circumstances, such as, but not limited to:

i. Unanticipated periods of high patient loads;

ii. Staffing shortages due to illness, or other short term temporary events; or,

iii. Temporary travel of a patient outside the hospice's service area.

3. Notwithstanding paragraphs (e)1i through iii above, the hospice may enter into a written arrangement with another New Jersey Licensed and Medicare certified hospice program for the provision of core services to supplement hospice employee or staff to meet the needs of patients in circumstances, such as, but not limited to:

i. Unanticipated periods of high patient loads;

ii. Staffing shortages due to illness or other short-term temporary situations that threaten to interrupt patient care; and

iii. Temporary travel of a patient outside of the hospice's service area.

(f)–(i) (No change.)

(j) A hospice providing services at multiple locations shall operate in compliance with the rules of the United States Department of Health and Human Service hospice provider certification specified at [Section 2081 of] 42 CFR Part 418, Subpart [C] **D**, incorporated herein by reference.

8:42C-3.2 Ownership

(a) The hospice shall disclose the ownership of the hospice and the property on which it is located to the Department.

1. Proof of this ownership shall be available in the facility.

2. Any proposed change in ownership shall be reported to the Director of [Certificate of Need and Acute Care Licensure Program of the Department] **the Department's Office of Certificate of Need and Healthcare Facility Licensure** 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.

(b) (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 [Certificate of Need and Acute Care Licensure Program of the Department] **Department's Office of Certificate of Need and Healthcare Facility Licensure**.

8:42C-3.4 Personnel

(a)–(c) (No change.).

(d) The hospice shall have policies and procedures for the maintenance of confidential personnel records for each employee, including at least his or her name, previous employment, educational background, license number with effective date and date of expiration (if applicable), certification (if applicable), verification of credentials and references, **criminal background check,** health evaluation records, job description, and evaluations of job performance.

(e)–(g) (No change.)

(h) All personnel, both directly employed and under contract to provide direct care to patients, as well as volunteers, shall receive a Mantoux tuberculin skin test with five tuberculin units of purified protein derivative **or have blood drawn for an interferon gamma release assay (IGRA)**.

1. The only exceptions are personnel with documented negative Mantoux skin test results (zero to nine millimeters of induration) within the last year, personnel with documented positive Mantoux skin test results (10 or more millimeters of induration), personnel who received appropriate medical treatment for tuberculosis, or when medically contraindicated.

[1] **2**. Results of the **IGRA or** Mantoux tuberculin skin tests shall be acted upon as follows:

i. Employees with an IGRA result of "positive" have latent TB infection, a "negative" result indicates no latent TB infection and employees with an "indeterminate" result shall repeat the IGRA.

[i.] **ii.** If the **initial** Mantoux tuberculin skin test result is between zero and nine millimeters of induration, the test shall be repeated one to three weeks later.

[ii.] **iii.** If the **IGRA result is "positive" or the** Mantoux test result is 10 millimeters or more of induration, a chest x-ray shall be performed and, if necessary, followed by chemoprophylaxis or therapy.

[2] **3.** The **IGRA or** Mantoux tuberculin skin test shall be administered to all agency personnel, both directly employed and under contract, and thereafter to all new personnel at the time of employment, as well as volunteers.

i. The **IGRA or Mantoux** tuberculin skin test shall be repeated on an annual basis for all persons who provide direct patient care and every two years for all other employees. [All employees shall be tested no later than September 30, 1999.]

[3. The hospice shall report annually on forms provided by the Department the results of tuberculin testing for all agency personnel and volunteers.]

4. The facility shall maintain records of the results of employee Mantoux and IGRA tuberculin testing.

(i)–(j) (No change.)

(k) The hospice shall have available and shall comply with the guidelines listed below, incorporated herein by reference**, as amended and supplemented** to protect health care workers who may be exposed to infectious blood-borne diseases, such as AIDS and hepatitis-B:

[1. "Enforcement Procedures for Occupational Exposure to Hepatitis B Virus

(HBV) and Human Immunodeficiency Virus (HIV)," OSHA Instruction CPL-2-2.44B, August 15, 1990, as amended and supplemented;

2. "Recommendations for prevention of HIV Transmission in Health-Care Settings," CDC, Morbidity and Mortality Weekly Report (MMWR) 1987; Volume 36 (supplement 2S), as amended and supplemented; and

3. "Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings," CDC Morbidity and Mortality Weekly Report (MMWR) 1988; Volume 37, as amended and supplemented.]

1. The following CDC Guidelines published in the CDC Morbidity and Mortality Weekly Report (MMWR), which are available electronically at the CDC website, www.cdc.gov:

i. Guidelines for the Management of Occupational Exposures to Hepatitis B, Hepatitis C, and HIV and Recommendations for Postexposure Prophylaxis, CDC Morbidity and Mortality Weekly Report (MMWR), June 29, 2001, Volume 50 (RR11), 1-17;

ii. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis, CDC Morbidity and Mortality Weekly Report (MMWR), September 30, 2005, Volume 54 (RR09), 1-54;

iii. Immunization of Health-Care Workers, Recommendations of the

Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC), CDC Morbidity and Mortality Weekly Report (MMWR), December 26, 1997, Volume 46 (RR-18), 1-42; and

iv. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Settings, CDC Morbidity and Mortality Weekly Report (MMWR); December 30, 2005, Volume 54 (RR-17).

2. The Guideline for Infection Control in Health Care Personnel, American Journal of Infection Control, 1998, Volume 26, 289-354;

(l) The Department shall be prohibited from issuing or continuing a license for the operation of a hospice unless, the owners, any current or prospective employee in a position which involves direct patient contact, any current or prospective administrator, or any current or prospective volunteer staff who would have direct patient contact, have obtained clearance from the Department's Criminal Background Investigation Unit, prior to owning, operating, administering, volunteering in a position that requires direct patient contact or being employed in a position that requires direct patient contact in a hospice.

1. The Department shall be prohibited from issuing clearance to any current or prospective owner, employee in a position which involves direct patient contact, administrator, contracted or volunteer staff who would have direct patient contact, who has been convicted of a crime or offense relating

adversely to the person's ability to provide care, including, but not limited to, homicide, assault, kidnapping, sexual offenses, robbery, crimes against the family, children or incompetents, and financial crimes, except when the current or prospective owner, employee, administrator or volunteer with a criminal history has demonstrated his or her rehabilitation in order to qualify as an owner or administrator in accordance with the standards set forth in the Rehabilitated Convicted Offenders Act, N.J.S.A. 2A:168A-1 et seq.

2. In accordance with the provisions of the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1, any individual disqualified from owning, operating, being employed in a position that requires direct patient contact, administering, contracting or volunteering for a position that would involve direct patient contact in a hospice shall be given an opportunity to challenge the accuracy of the disqualifying criminal history record prior to being permanently disqualified from participation.

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. Each review of the manual(s) shall be documented, and the manual(s) shall be available in the hospice at all times.

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

Recodify existing N.J.A.C. 8:42C-3.5(a)1 through 4 as (a)2i through iv with no change in text.

[5] **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[. These policies and procedures shall include,] **including** but not [be] limited to, the following:

[i] **(1)**. (No change.)

[ii] **(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 the Division of Youth and Family Services of the Department of [Human Services] **Children and Families** on the medical/health record, and serving as a liaison between the facility and the Division of Youth and Family Services; and

[iii] **(3)**. (No change.)

(b) (No change.)

8:42C-3.8 Reportable events

(a)–(b) (No change.)

(c) The facility shall report to the Department every serious preventable adverse event that occurs in the facility, pursuant to N.J.A.C. 8:43E-10.

[8:42C-3.10 Reporting Information to the State Board of Medical Examiners

(a) A hospice shall make reports to the Medical Practitioner Review Panel for all

events specified at N.J.S.A. 26:2H-12.2 with respect to any practitioner employed by, or under contract to, the hospice.

(b) For purposes of (a) above, "practitioner" means physician, medical resident or intern, or podiatrist.

(c) The hospice shall provide the required notification within seven days of the date of the action, settlement, judgment or award and shall be reported to the New Jersey State Board of Medical Examiners, 140 East Front Street, Trenton, New Jersey 08608. (Questions may be directed to the Board office at (609) 292-4843.)]

8:42C-[3.11] **3.10** Reporting to professional licensing boards

The hospice shall comply with all requirements of the professional licensing boards for reporting termination, suspension, revocation, or reduction of privileges of any health professional licensed in the State of New Jersey**, pursuant to N.J.S.A. 45:1-33.**

SUBCHAPTER 4. ADMINISTRATION

8:42C-4.1 Administration

The governing authority shall comply with Federal rules at 42 CFR [418.52] **418.100**, Conditions of Participation—[Governing Body] **Organization and administration of services**, incorporated herein by reference.

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. To be given a **verbal and** written notice **in a language and manner that the patient understands**, prior to the initiation of care, of these patient rights and any additional policies and procedures established by the agency involving patient rights and responsibilities. If the patient is unable to respond, the notice shall be given to a family member or an individual who is a legal representative of the patient;

i. The hospice shall obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

ii. If a patient has been adjudged incompetent under State law by a court with jurisdiction, the rights of the patient are exercised by the person appointed pursuant to State law to act on the patient's behalf.

iii. If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.

3. To receive information about the services covered under the hospice benefit and to receive information about the scope of services that the hospice will provide and specific limitations on those services.

[3.] **4.** To be informed in writing of the following:

i.–iv. (No change.)

v. Notification regarding the filing of complaints with the New Jersey Department of Health and Senior Services' 24-hour Complaint Hotline at 1-800-792-9770, or in writing to:

New Jersey State Department of Health and Senior Services

[Inspection, Processing and Regulatory Development Program]

Office of Health Facilities Assessment and Survey

PO Box [360] **367**

Trenton, New Jersey 08625-[0360] **0367**

[4.] **5.** (No change.)

[5.] **6.** To receive, as soon as possible, the services of a translator or interpreter to facilitate communication between the patient and health care personnel.

i. Hospices shall make all reasonable efforts to secure a professional, objective interpreter for hospice-patient communications, including those involving the notice of patient rights;

[6.] **7.** (No change.)

8. To receive effective pain management and symptom control from the hospice for conditions related to the terminal illness, in accordance with N.J.A.C. 8:43E-6.1 et seq.;

9. To choose his or her attending physician;

[7.] **10.** To [participate] **be involved** in the planning of his or her hospice care

and treatment;

Recodify existing N.J.A.C. 8:42C-5.1(b)8 through 10 as 11 through 13 with no change in text.

[11.] **14.** To express grievances regarding care and services **by anyone who is furnishing services on behalf of the hospice** to the hospice's staff and governing authority without fear of reprisal, and to receive an answer to those grievances within a reasonable period of time;

[12.] **15.** To be free from **mistreatment, neglect, and** mental**, verbal, sexual** and physical abuse and from exploitation**, including corporal punishment, injuries of unknown source, and misappropriation of patient property**;

[13.] **16.** (No change.)

17. To be free from seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff;

Recodify existing N.J.A.C. 8:42C-5.1(b)14 through 17 as 18 through 21 with no change in text.

22. To be informed by the hospice and receive written information concerning the hospice's policies on advance directives, including a description of applicable State law.

Recodify existing N.J.A.C. 8:42C-5.1(b)18 and 19 as 23 and 24 with no change in text.

(c) The hospice shall ensure that all verified violations involving anyone

furnishing services on behalf of the hospice are reported to State and local authorities having jurisdiction within five working days of becoming aware of the violation.

SUBCHAPTER 6. PATIENT CARE SERVICES

8:42C-6.2 Role of interdisciplinary team

(a)–(b) (No change.)

(c) The hospice shall ensure that each patient and the primary care giver(s) receive education and training provided by the hospice as appropriate to their responsibilities for the care and services identified in the plan of care.

SUBCHAPTER 10. INFECTION PREVENTION AND CONTROL

8:42C-10.2 Infection control policies and procedures

(a) (No change.)

(b) The interdisciplinary Committee shall develop, implement, and review, at least annually, written policies and procedures regarding infection prevention and control, including:

[1. Compliance with "Enforcement Procedures for Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)," OSHA Instruction CPL-2-2.44B, August 15, 1990, as amended and supplemented, incorporated herein by reference;

2. Compliance with "Recommendations for Prevention of HIV Transmission in Health-Care Settings," CDC, Morbidity and Mortality Weekly Report (MMWR) 1987;

Volume 36 (supplement 2S), as amended and supplemented, incorporated herein by reference;

3. Compliance with "Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings," CDC Morbidity and Mortality Weekly Report (MMWR) 1988; Volume 37, as amended and supplemented, incorporated herein by reference;]

[4.] **1.** A method of complying with the Department's rules on reportable communicable diseases at N.J.A.C. 8:57;

[5.] **2.** (No change.)

[6.] **3.** Surveillance techniques to identify infections and develop systems to reduce risk **using "APIC – HICPAC Surveillance Definitions for Home Health Care and Home Hospice Infections," February 2008, incorporated herein by reference, as amended and supplemented, available electronically at www.apic.org or at www.cdc.gov**; and

[7.] **4.** Sterilization and high level of disinfection of reusable medical devices, following guidelines recommended by the Association for the Advancement of Medical Instrumentation (AAMI, Suite [602] **220**, [1901 North Fort Myer Drive] **1110 North Glebe Road**, Arlington, VA [22209] **22201-4795 or available at the AAMI website at www.aami.org**), and any amendments thereto, which are incorporated herein by reference, including, at a minimum:

i. [Steam sterilization and sterility assurance in office based, ambulatory care, medical and dental facilities] **"Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," ANSI/AAMI ST 79 (2006) incorporated herein by reference, as amended and supplemented, available electronically at www.aami.org or by telephone at (877) 249-8226**;

ii. [Safe use and handling of glutaraldehyde-based products in health care facilities] **"Chemical Sterilization and High-level Disinfection in Health Care Facilities," ANSI/AAMI ST 58 (2005) incorporated herein by reference, as amended and supplemented, available electronically at www.aami.org or by telephone at (877) 249-8226**;

iii. Aseptic transfer of sterile supplies; and

iv. Chemicals used for cleaning general environmental surfaces.

(c) Any hospice which out-sources the reprocessing of reusable medical devices to another health care facility or a commercial reprocessing firm shall conduct an annual audit to ensure conformance with the AAMI standards set forth at (b)[7] **4** above.

1. Documentation of such audits shall be maintained for a period of three years.

8:42C-10.3 Infection control measures

(a) The hospice shall follow all recommendations in the following Centers for Disease Control publications, and any amendments or supplements thereto, incorporated herein by reference:

1. Guideline for Prevention of Catheter-Associated Urinary Tract Infections,

PB84-923402, **1981**;

2. Guideline for Prevention of Intravascular **Catheter-Related** Infections, [PB97-130074] **CDC Morbidity and Mortality Weekly Report (MMWR) 2002, Volume 51(RR-10)**;

3. Guideline for Prevention of Surgical [Wound Infections, PB85-923403] **Site Infection, 1999**;

4. [Guideline for Handwashing and Hospital Environmental Control, [PB85-923404] **Guideline for Hand Hygiene in Health Care Settings, CDC Morbidity and Mortality Weekly Report (MMWR) 2002, Volume 51 (RR16)**; [and]

5. Guideline for Infection[s] Control for Health Care Personnel, [PB99-105454] **1998**[.] ;

6. Guidelines for Environmental Infection Control in Health-Care Facilities, CDC Morbidity and Mortality Weekly Report (MMWR), 2003, Volume 52 (RR10);

7. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, 2007;

8. Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006; and

9. Guidelines for Preventing Health-Care-Associated Pneumonia, CDC Morbidity and Mortality Weekly Report (MMWR), 2004, Volume 53 (RR03).

(b) Centers for Disease Control **(CDC)** publications are available **as follows:**

[from]

1. From the National Technical Information Service **(NTIS),** U.S. Department of Commerce, [5285 Port Royal Road, Springfield, VA 22101] **5301 Shawnee Road, Alexandria, VA 22312**[,] **;**

2. Through verbal request at (800) 553-6847[,] **or** (703) 605-6000**; or**

3. Electronically at the NTIS website at www.ntis.gov or the CDC website at www.cdc.gov.

8:42C-10.7 Orientation**,** [and] in-service **and** education.

(a) (No change.)

(b) The hospice shall provide infection control education to employees, contracted providers, patients, and family members and other caregivers.

[(b)] **(c)** (No change.)