

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

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

Proposed 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

Authorized By: Cathleen D. Bennett, Acting Commissioner, Department of Health (with the approval of the Health Care Administration Board).

Authority: N.J.S.A. 26:2H-1 et seq., specifically N.J.S.A. 26:2H-5.

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

Proposal Number: PRN 2016-018.

Submit written comments by April 1, 2016, electronically to <http://www.nj.gov/health/legal/ecomments.shtml>, or by regular mail postmarked by that date to:

Joy L. Lindo, Director
Office of Legal and Regulatory Compliance
Office of the Commissioner
New Jersey Department of Health
PO Box 360
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The agency proposal follows:

Summary

The Health Care Facilities Planning Act (Act), N.J.S.A. 26:2H-1 et seq., requires the Department of Health (Department) to develop standards and procedures relating to the licensing of health care facilities and the institution of additional health care services to ensure the efficient and effective delivery of health care services. N.J.A.C. 8:42 implements the Act by establishing the standards for licensure of and the provision of services by home health agencies in New Jersey.

The Department has reviewed N.J.A.C. 8:42 and has determined that the existing rules, with the proposed amendments and new rules, continue to be necessary, adequate, reasonable, efficient, understandable, and responsive to the purposes for which they were originally promulgated. Additionally, the rules proposed for readoption with amendments and new rules would continue to provide the regulatory framework to fulfill the Department's obligation to assure home health agencies provide services of the highest quality. Therefore, the Department proposes to readopt N.J.A.C. 8:42 with amendments and new rules, as described below.

N.J.A.C. 8:42 was to expire on December 19, 2015, in accordance with N.J.S.A. 52:14B-5.1 and Executive Order No. 66 (1978). In accordance with N.J.S.A. 52:14B-5.1.c(2), the filing of this notice of proposal with the Office of Administrative Law prior to December 19, 2015, operated to extend the chapter expiration date by 180 days to June 16, 2016.

Home health care remains a growing segment of the health care industry nationwide and, in many cases, has proven to be a viable and desirable alternative to

institutional care. Home health care is desirable because it can shorten lengths of stay in acute care facilities and prevent long-term institutionalization. Thus, it is in the public interest to maintain standards that ensure quality, identify minimum care requirements, and define service offerings for home health agencies.

The Department licenses home health agencies to provide preventive, rehabilitative, and therapeutic services to patients in their own homes or places of residence. N.J.A.C. 8:42 requires home health agencies to provide, at a minimum, nursing, homemaker-home health aide, and physical therapy services, and authorizes them to provide additional services, such as occupational therapy, speech-language and audiology services, social work services, and dietary counseling. This diversity benefits the affected patient population.

New Jersey home health agencies differ in the number and variety of services they offer. While some agencies provide only basic required services, others provide more comprehensive home care programs, offering a broad range of services that they administer centrally.

Following is a summary of the regulatory history of N.J.A.C. 8:42:

Chapter 42, Home Health Agencies, became effective on May 26, 1976. 8 N.J.R. 182(c); 282(a). Subchapter 2, Standards for Licensure and Inpatient Drug Treatment Facilities, became effective on December 9, 1976. 8 N.J.R. 462(a); 550(b). Subchapter 3, Alcohol Abuse Treatment Facilities, became effective on July 5, 1979. 11 N.J.R. 233(c); 331(c). The expiration date of Subchapter 3 was extended on December 31, 1979 and June 19, 1980. 11 N.J.R. 546(a); 12 N.J.R. 15(d) and 407(b).

Chapter 42 was amended on February 1, 1980. 11 N.J.R. 545(d); 12 N.J.R. 15(c). (12 N.J.R. 463(b); 578(c); 13 N.J.R. 12(a); 342(b)).

Pursuant to Executive Order No. 66 (1978) Subchapter 3, Alcohol Abuse Treatment Facilities, expired on June 30, 1981. Pursuant to Executive Order No. 66 (1978), Subchapter 2, Standards for Licensure of Residential and Inpatient Drug Treatment Facilities, was readopted effective November 1, 1982. 14 N.J.R. 812(a); 1214(a).

Chapter 42, Home Health Agencies, was amended on March 7, 1983. 14 N.J.R. 1273(a); 15 N.J.R. 336(a). Subchapter 2, Standards for Licensure of Residential and Inpatient Drug Treatment Facilities, was repealed on August 1, 1983. 15 N.J.R. 397(a); 1248(a). Pursuant to Executive Order No. 66 (1978), Chapter 42, Home Health Agencies, was readopted on March 18, 1985. 16 N.J.R. 3250(a); 17 N.J.R. 704(b). Pursuant to Executive Order No. 66 (1978), Chapter 42, Home Health Agencies, was readopted on August 17, 1987, with an operative date of October 17, 1987. 19 N.J.R. 2287(a); 1547(a). Chapter 42, Home Health Agencies, was repealed and a new Chapter 42, Standards for Licensure of Home Health Agencies, was adopted effective August 17, 1992. 24 N.J.R. 2031(a); 2941(a).

On July 15, 1996, N.J.A.C. 8:42-2.2(b) was amended to increase the initial application and annual renewal fees for home health agencies from \$500.00 to \$2,000. 28 N.J.R. 2365(a); 3556(a). At this time, N.J.A.C. 8:42-2.2(c) was also amended to add an application fee of \$1,000 for transfer of ownership of a home health agency, and N.J.A.C. 8:42-2.2(d) was amended to add an application fee of \$250.00 for the relocation of an agency. *Ibid.* Pursuant to Executive Order No. 66 (1978), Chapter 42,

Standards for Licensure of Home Health Agencies, expired on August 17, 1997. On December 7, 1998, N.J.A.C. 8:42-2.2 was amended to impose a \$500.00 biennial inspection fee on home health agencies. 30 N.J.R. 3633(a); 4221(b). Chapter 42, Licensing Standards for Home Health Agencies, was adopted as new rules without revisions on January 20, 1998. 29 N.J.R. 3802(a); 30 N.J.R. 345(a).

On August 21, 2000, various amendments were made to the chapter to reflect technical changes in the titles of certain agencies and boards, and to reflect certain changes in the practice of home health care. 32 N.J.R. 627(a); 3064(a).

Chapter 42 was readopted effective July 1, 2003. 35 N.J.R. 65(a); 3556(a).

On February 22, 2005, N.J.A.C. 8:42-3.1 and 11.2 were amended to require identification badges for homemaker-home health aides, consumer guides for patients regarding homemaker-home health aides, and to provide for the use of electronic signature consent forms for medical records. 36 N.J.R. 3239(a); 37 N.J.R. 591(a).

Chapter 42 was readopted effective December 19, 2008, with amendments and a new rule effective January 20, 2009. 40 N.J.R. 4273(a); 41 N.J.R. 602(a).

Specifically, N.J.A.C. 8:42-1.2 was amended to include a definition for “Medicare-certified” and to clarify the definition of “home health agency.” Additionally, N.J.A.C. 8:42-2.1(b) and 2.2 were amended to specify the manner in which certificate of need and licensure application forms could be obtained from the Department. N.J.A.C. 8:42-7.3(d) was also amended to require home health agencies to provide a registered professional nurse 24 hours a day, seven days a week and to require the registered nurse to make contact with a patient regarding clinical issues within one hour of the patient’s call to the agency. Technical amendments were also made to reflect the name

changes of programs and offices within the Department. Lastly, license form CN-7 was added as an appendix to the chapter.

A summary of the rules proposed for readoption and the proposed amendments follows.

The Department proposes to amend references to the Department throughout the chapter to reflect the change in the name of the Department from the "New Jersey State Department of Health and Senior Services" to the "New Jersey Department of Health" pursuant to N.J.S.A. 26:1A-2.1 (effective June 29, 2012).

The Department proposes technical amendments throughout the chapter to update the name of the licensure program from "Certificate of Need and Acute Care Licensure Program" to "Office of Certificate of Need and Healthcare Facility Licensure," update the name of the survey program from "Office of Health Facilities Assessment and Survey" to "Office of Health Facility Survey and Field Operations," update contact information for these and other entities to which the chapter refers, replace public law citations with their corresponding codified citations, delete references to the type of entity for which the chapter establishes licensure standards by the term, "facility," and to add in their stead references to these entities by the more apt term, "agency." The Department proposes technical amendments throughout the chapter to improve grammar and readability, update titles of and citations to publications to which the chapter refers to the most recent titles and editions thereof, and simplify complex provisions through reorganization and additional subcodification.

N.J.A.C. 8:42-1.1 would continue to establish the scope and purpose of the chapter.

N.J.A.C. 8:42-1.2 would continue to define words and terms that the chapter uses. The Department proposes to amend this section to delete the existing definitions of “community health nurse,” “contamination,” “monitor,” and “staff orientation plan,” to reflect proposed amendments elsewhere in the chapter that would delete provisions containing those terms. The Department proposes to amend the existing definition of “disinfection” to delete references to the terms, “concurrent disinfection” and “terminal disinfection,” which terms the chapter does not use. The Department proposes to add a definition for “Physician Orders for Life Sustaining Treatment form” and for the “Academy of Nutrition and Dietetics,” which is the organization formerly known as the “American Dietetic Association,” and to provide contact information for this entity. The Department proposes to amend the definition of “advance directive” for consistency with the definition of that term in the New Jersey Advance Directives for Health Care Act.

The term “advance directive” is currently defined in a general manner and the proposed amendment would capture the specific requirements associated with a valid advance directive, as set forth in the New Jersey Advance Directives for Health Care Act. The Department also proposes to amend the definition of the term “branch office” to require only a registered professional nurse to be present in the branch office when the branch office is open to the public without requiring the agency to designate the registered professional nurse as the supervisory nurse or alternate, which is currently provided for in the definition.

N.J.A.C. 8:42-2.1 would continue to establish Certificate of Need requirements for home health agencies. The Department proposes to amend existing N.J.A.C. 8:42-

2.1(b) to delete a reference to N.J.A.C. 8:33L, Certificate of Need: Home Health Agency Policy Manual, because this chapter expired on December 31, 1997.

N.J.A.C. 8:42-2.2 would continue to establish application submission procedures and associated fees. The Department proposes to amend existing N.J.A.C. 8:42-2.2(e) to delete the term “shall,” and to add in its stead the term “may” to indicate that the Department authorizes but does not require applicants for licensure and certificates of need to have a preliminary conference with the Department. The Department proposes to delete the option of receiving a licensure application from the Department via the mail as prospective applicants are directed to either the Department’s website or the chapter Appendix A for a copy.

N.J.A.C. 8:42-2.3 would continue to establish survey requirements.

N.J.A.C. 8:42-2.4 would continue to establish licensure requirements. The Department proposes to delete and replace existing N.J.A.C. 8:42-2.4(a) to make it clear that applicants for licensure as home health agencies are not permitted to provide services prior to license issuance. Existing subsection (a) suggests that the Department conducts a survey of a license applicant’s operating home health agency before issuing the applicant a license. The amendment eliminates this incorrect suggestion.

N.J.A.C. 8:42-2.5 would continue to establish standards for license surrender. The Department proposes to amend existing N.J.A.C. 8:42-2.5 to require an agency to surrender its home health agency license to the Office of Certificate of Need and Healthcare Facility Licensure when it voluntarily surrenders its license.

N.J.A.C. 8:42-2.6 would continue to establish procedures by which applicants for licensure and licensees can apply for a waiver of the standards in this chapter. The

Department proposes to amend existing N.J.A.C. 8:42-2.6(b) to require waiver requests to be submitted using the Application for Waiver, which would be incorporated into the rule by reference as proposed new chapter Appendix B and which would be available for download from the Department's forms page. The Department proposes to amend N.J.A.C. 8:42-2.6(c) to include two additional waiver request criteria.

N.J.A.C. 8:42-2.7 would continue to establish standards by which the Department would take action against a licensee.

N.J.A.C. 8:42-2.8 would continue to be reserved.

N.J.A.C. 8:42-3.1 would continue to require agencies to comply with all applicable rules and laws. The Department proposes to amend N.J.A.C. 8:42-3.1(f)3 to provide a website link to the Consumer's Guide to Homemaker-Home Health Aides on the Division of Consumer Affairs, Department of Law and Public Safety's website.

N.J.A.C. 8:42-3.2 would continue to address ownership requirements. The Department proposes to amend recodified N.J.A.C. 8:42-3.2(b) to provide that any proposed changes in ownership must be submitted to the Department at least 90 days prior to the expected closing date, in place of the 30-day requirement in the existing rule, and that the closing may not occur without prior Departmental approval. The Department proposes to amend recodified N.J.A.C. 8:42-3.2(c) to identify the types of crimes and offenses that disqualify an individual from owning or operating an agency, set forth the standards for rehabilitation in order to qualify for ownership, and provide an individual who is denied rehabilitation with an opportunity to request a hearing to challenge the denial.

N.J.A.C. 8:42-3.3 would continue to require an agency to submit documents requested of the Department.

N.J.A.C. 8:42-3.4 would continue to address personnel requirements. The Department is proposing to amend N.J.A.C. 8:42-3.4(c) by requiring agency personnel who provide direct care to patients to wear their employee identification tag required by N.J.A.C. 8:42-3.1(f)1i. The Department proposes to delete N.J.A.C. 8:42-3.4(h) and (i), which address tuberculin testing, and proposes new subsection (h) to cover tuberculin testing. The proposed amendment would require that agencies comply with the Centers for Disease Control and Prevention (CDC) “Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Settings,” 2005 Guidelines, MMWR, December 30, 2005; Vol. 54; RR-17, as amended and supplemented for tuberculin testing and retesting. Additionally, the Department proposes to delete subsections (j) , (m), and (n), which address rubella and measles testing, and proposes new subsection (i), which would require agencies to comply with the CDC guidelines for measles and rubella testing that are contained in the CDC document “Immunization of Health-Care Personnel, Recommendations of the Advisory Committee on Immunization Practices (ACIP),” MMWR, November 25, 2011; Vol. 60; No. 7, which is incorporated into the rule, as amended and supplemented.

N.J.A.C. 8:42-3.5 would continue to address an agency’s policy and procedure manual. The proposed amendment to N.J.A.C. 8:43-3.5 would update references by changing the name of the Division of Youth and Family Services to the Department of Children and Families, Division of Child Protection and Permanency, as well as delete a note that states copies of the law are available from this Division.

N.J.A.C. 8:42-3.6 would continue to address staffing, staffing schedules, and staff orientation and education plans.

N.J.A.C. 8:42-3.7 would continue to require written agreements for contracted and subcontracted services.

N.J.A.C. 8:42-3.8 would continue to address reportable events.

N.J.A.C. 8:42-3.9 would continue to contain the notices agencies are required to post. The proposed amendment to N.J.A.C. 8:42-3.9(a)5 would delete the requirement that the addresses of the governing authority members be posted.

N.J.A.C. 8:42-3.10 would continue to address reporting to professional boards.

N.J.A.C. 8:42-3.11 would continue to be reserved.

N.J.A.C. 8:42-4.1 would continue to address the responsibilities of an agency's governing authority. The Department is proposing to amend N.J.A.C. 8:42-4.1(a) by adding paragraph (a)8, which would require the development and implementation of a written conflict of interest policy.

Subchapter 5 would continue to address an agency's administration. N.J.A.C. 8:42-5.1 would continue to address the appointment of an administrator. N.J.A.C. 8:42-5.2 would continue to address an administrator's responsibilities.

N.J.A.C. 8:42-5.3 would continue to address the responsibilities of the director of nursing. The Department proposes to amend this rule by moving the responsibilities of the director of nursing that are currently contained at N.J.A.C. 8:42-7.3(b) to this section with no substantive change.

Subchapter 6 would continue to address patient care services. N.J.A.C. 8:42-6.1 would continue to provide for the appointment of an advisory group and the Department

proposes to amend the rule by replacing “leadership” with “governing authority” as a way of clarifying that the governing authority is the entity that is to receive recommendations from the advisory group. N.J.A.C. 8:42-6.2 would continue to require that the advisory group review patient care policies and procedures at least annually, as well as set requirements for those policies and procedures.

N.J.A.C. 8:42-6.3 would continue to address advance directives. The Department proposes to repeal the rule in its entirety and replace it to reorganize and restate the duties and responsibilities of home health agencies with regard to advance directives to make the rule easier to read. Existing subsection (h), addressing declaration of death, is relocated to proposed new N.J.A.C. 8:42-6.7. Proposed new N.J.A.C. 8:42-6.3(a) would ensure that agencies comply with the requirements set forth in the New Jersey Advanced Directives for Health Care Act, N.J.S.A. 26:2H-53 et seq. Proposed new N.J.A.C. 8:42-6.3(b) would require agencies to establish, implement, and annually review policies and procedures that effectuate the New Jersey Advanced Directives for Health Care Act. Proposed new N.J.A.C. 8:42-6.3(c) would address the community outreach requirement. Proposed new N.J.A.C. 8:42-6.3(d) would address the inquiry an agency is to make of a patient regarding the existence of an advance directive. Proposed new N.J.A.C. 8:42-6.3(e) would require staff training and education on the New Jersey Advance Directives for Health Care Act and the Federal Patient Self Determination Act.

N.J.A.C. 8:42-6.4 would continue to provide standards for the provision of pharmaceutical services. The proposed amendment to N.J.A.C. 8:42-6.4(c) would ensure that agencies comply with the requirements of N.J.S.A. 45:11-49.1 and the rules

promulgated pursuant thereto by the State Board of Nursing for the purchasing, storing, and transporting of non-controlled drugs by registered nurses for the purpose of administering the drugs to their home health patients by specifically citing to the statute and rules in this section. N.J.A.C. 8:42-6.4(c) currently lists the non-controlled drugs that registered nurses may purchase, store, and transport for the purpose of administration to home health patients and the criteria for the drugs to be administered without reference to these statutory and regulatory cites in the rule text.

Proposed new N.J.A.C. 8:42-6.5 would address Physician Orders for Life-Sustaining Treatment (POLST). The proposed new rule would require an agency to comply with the requirements of the Physician Orders for Life-Sustaining Treatment Act, N.J.S.A. 26:2H-129 et seq.

Proposed new N.J.A.C. 8:42-6.6 would address the transfer of a patient. The proposed new rule relocates the transfer requirements that were contained at N.J.A.C. 8:42-6.3(e) (which are proposed for repeal) and continues to provide the circumstances under which a patient may be transferred to another agency, as well as provides a new provision for the transfer of a patient in conformance with the POLST Act.

Proposed new N.J.A.C. 8:42-6.7 addresses the declaration of death. The proposed new rule relocates the declaration of death standards that were contained at N.J.A.C. 8:42-6.3(h) (which is proposed for repeal) and would require an agency to establish policies and procedures for the declaration of death of patients in accordance with the New Jersey Declaration of Death Act, N.J.S.A. 26:6A-1 et seq., and the regulations promulgated pursuant thereto at N.J.A.C. 13:35-6A.

Subchapter 7 would continue to address the provision of nursing services. N.J.A.C. 8:42-7.1 would continue to require a facility to provide nursing services to patients who need these services and N.J.A.C. 8:42-7.2 would continue to require an agency to have a written organizational chart and policies and procedures regarding the provision of nursing services. N.J.A.C. 8:42-7.3 would continue to specify nursing staff qualifications and responsibilities. The Department proposes to N.J.A.C. 8:42-7.3(b) to 5.3. The Department proposes to amend recodified N.J.A.C. 8:42-7.3(b) by eliminating the requirement that a full-time nursing supervisor or alternate be available at each agency branch office and instead require a registered professional nurse to be available, which is consistent with the proposed amended definition of “branch office” set forth at N.J.A.C. 8:42-1.2. N.J.A.C. 8:42-7.4 would continue to require nursing personnel to appropriately document a patient’s health record. N.J.A.C. 8:42-7.5 would continue to specify standards for the provision of homemaker-home health aide services. The Department proposes to repeal the rule and replace it with a new rule that reorganizes and restates the standards for homemaker-home health aide services to make the rule easier to read. Proposed new N.J.A.C. 8:42-7.5(a)1 would continue to address the employment criteria of homemaker-home health aides by home health agencies. Proposed new N.J.A.C. 8:42-7.5(a)2 would continue to address the scope of practice of homemaker-home health aides and the responsibilities of supervising registered professional nurses with specific citation to the rules promulgated by the New Jersey Board of Nursing that pertain to the practice scope of homemaker-home health aides and the responsibilities of supervising registered nurses, which are not included in the current rule text. Proposed new N.J.A.C. 8:42-7.5(a)3 would continue to address

medical record documentation of homemaker-home health services provided to patients. Subchapter 8 would continue to address the provision of rehabilitation services. N.J.A.C. 8:42-8.1 would continue to require an agency to provide physical therapy services, and would allow an agency to also provide occupational therapy and speech-language pathology services at the agency's discretion. Proposed N.J.A.C. 8:42-8.2 would continue to specify the responsibilities of rehabilitation personnel. The Department proposes to amend N.J.A.C. 8:42-8.2(a) by including a reference to the statutory authority that outlines the scope of practice of occupational therapy personnel, which would ensure that the job responsibilities crafted by home health agencies are consistent with the practice scope of these therapists. N.J.A.C. 8:42-8.3 would continue to require physical therapists, occupational therapists, and speech-language pathologists to appropriately document the plan of care and clinical, and progress notes in a patient's medical record.

Subchapter 9 would continue to address the provision of social work services. N.J.A.C. 8:42-9.1 would continue to provide that social work services may be provided directly or through written agreement, N.J.A.C. 8:42-9.2 would continue to specify the social worker's responsibilities, and N.J.A.C. 8:42-9.3 would continue to require a social worker to appropriately document the plan of care and clinical and progress notes in a patient's medical record.

Subchapter 10 would continue to provide the standards for dietary counseling services. N.J.A.C. 8:42-10.1 would continue to provide that dietary counseling services may be provided directly or through written agreement, N.J.A.C. 8:42-10.2 would continue to specify the dietitian's responsibilities, and N.J.A.C. 8:42-10.3 would continue

to require a dietitian to appropriately document the plan of care and clinical and progress notes in a patient's medical record.

Subchapter 11 would continue to provide the standards for medical/health records. N.J.A.C. 8:42-11.1 and 11.2 would continue to specify the policies and procedures that an agency must establish regarding medical records. The Department is proposing to amend N.J.A.C. 8:42-11.2(b)2 to update the "authentication" standard to the most current Centers for Medicare & Medicaid Services requirements. The Department is proposing to amend N.J.A.C. 8:42-11.2(c)3iii to add speech therapy services as an entity that can coordinate and maintain a plan of care if speech therapy is the sole service. The Department is also proposing to amend N.J.A.C. 8:42-11.2(d)7 to include that a notice of the existence of POLST form shall be included in the transfer record of patient that is transferred to another health care facility.

Subchapter 12 would continue to address infection prevention and control. N.J.A.C. 8:42-12.1 would continue to address the requirement that an agency have an infection prevention and control program. The Department is proposing to amend N.J.A.C. 8:42-12.1(a) to add that the purpose of the infection and control program is to reduce the risk of the acquisition and transmission of health care associated infections. The Department is also proposing to add a cross reference to N.J.A.C. 8:42-12.2(a) to clarify that the individual designated by the administrator to direct infection control services is to work in collaboration with the committee established in that rule.

N.J.A.C. 8:42-12.2 would continue to specify the policies and procedures for the infection control program and N.J.A.C. 8:42-12.2(b) is proposed for amendment to clarify that the multidisciplinary committee shall work in collaboration with the individual

designated by the administrator to direct infection control services. The Department is proposing to amend N.J.A.C. 8:42-12.2(b) by updating the citation to the most current “Enforcement Procedures for Occupational Exposure to Bloodborne Pathogens,” as well as providing a link to the document. The note at the end of this section is proposed for deletion as it is not necessary. N.J.A.C. 8:42-12.3 would continue to specify the guidelines for the infection control measures. The Department is proposing to amend N.J.A.C. 8:42-12.3 to include website links for the CDC publications referenced therein.

N.J.A.C. 8:42-12.4 would continue to require agencies to establish decontamination and sterilization protocols and provide guidelines for their establishment. The proposed amendment to N.J.A.C. 8:42-12.4 would clarify that sterilized materials need to be marked with a manufacturer’s expiration date, to explain where the expiration date comes from.

N.J.A.C. 8:42-12.5 would continue to establish guidelines for the care and use of sterilizers, and N.J.A.C. 8:42-12.6 would continue to establish guidelines for the collection, storage, handling, and disposal of medical waste. The Department is proposing to amend N.J.A.C. 8:42-12.6 to remove the reference to the Medical Waste Tracking Act of 1988, as this Federal statute is no longer relevant because this act only established a two-year medical waste program project.

Proposed N.J.A.C. 8:42-12.7 would continue to require agencies to develop protocols for the identification and handling of deceased bodies infected with communicable diseases and complete a Department “Communicable Disease Alert” in applicable cases. The proposed amendment to N.J.A.C. 8:42-12.7 would eliminate the term “high-risk bodies” and replace it with the more descriptive and apt phrase

“deceased bodies infected with a contagious, infectious or communicable disease.”

The proposed amendment to N.J.A.C. 8:42-12.7 would also correct the citation for the “Communicable Diseases Alert” form, as well as provide a link to the Department’s website where the form may be found.

N.J.A.C. 8:42-12.8 would continue to require agencies to provide staff orientation and education regarding infection control practices.

Subchapter 13 would continue to address patient rights. N.J.A.C. 8:42-13.1(a) would continue to require agencies to establish and implement written policies and procedures regarding the rights of patients and the implementation of these rights. The Department is proposing to amend N.J.A.C. 8:42-13.1(a) by stating that patients are to receive a copy of a statement of these rights.

N.J.A.C. 8:42-13.1(b) is proposed for recodification as N.J.A.C. 8:42-13.2. The recodified rule is proposed for amendment to provide additional methods in which a complaint may be filed with the Department and include the right of a patient to provide instructions and directions for health care in the event of future decision making incapacity in accordance with the Physician Orders for Life-Sustaining Treatment Act, N.J.S.A. 26:2H-129 et seq.

Subchapter 14 would continue to address quality assurance. N.J.A.C. 8:42-14.1 would continue to provide that the governing authority of the facility shall be responsible for the quality assurance program and that the facility shall establish and implement a written plan for a quality assurance program for patient care. N.J.A.C. 8:42-14.2 would continue to establish standards for the quality assurance program.

N.J.A.C. 8:42 Appendix, Application for a New or Amended Acute Care Facility License, form CN-7, remains unchanged (other than to codify it as chapter Appendix A) and the Department proposes to add form CN-28, Application for Waiver, as N.J.A.C. 8:42 Appendix B.

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

Social Impact

The rules proposed for readoption with amendments, repeal, and new rules would specify the licensing requirements for all home health agencies, and would therefore impact these agencies and the senior citizens and other individuals they serve. There are 46 existing Medicare-certified home health agencies in New Jersey.

As the number of senior citizens increases, and as the Department encourages alternatives to nursing homes and decreases in the length of hospital stays, the need for licensing rules for home health agency services is important. The rules proposed for readoption with amendments would continue to benefit home health care patients, their families and caregivers, the provider agencies, and health care professionals. The Department recognizes the social impact of the home health movement upon patient care in this State. For many patients, including those with both acute and chronic illnesses, home health care has been used as an alternative to institutionalization, including both long-term placement and hospitalization, and as a means of maintaining independent living status in the community. This method of service delivery has had a

significant positive impact upon the quality of life of patients by allowing patients to receive necessary care while residing at home.

As the home health industry continues to expand, the continued regulation of standards of care employed by home health agencies is necessary to protect the health, safety, and welfare of patients. It is essential that agencies employ qualified staff to provide services at the level of skill required; that agencies provide adequate continuity and coordination of services; and that adequate recordkeeping, administration, and direction are provided to support patient care services.

Under the current licensing standards proposed for re Adoption with amendments, repeal, and new rules, the benefits to patients and their families from receiving home health care are manifold. Patients who remain in their homes to receive care often respond better to treatment and recover more quickly. The psychological benefits associated with receiving care within a familiar home environment have been demonstrated to contribute significantly to convalescence. There is also a preventive aspect to home health care, in that the services provided, in some instances, help prevent disease, avert disability, and postpone or reduce the likelihood of institutionalization. For many patients, home care is less stressful than inpatient institutional care because feelings of isolation and dependence are reduced. Disruption of the patient's personal and family life is also minimized due to the patient's ability to remain and receive care in the home. Additionally, the patient and family retain a sense of control over their situation. Given the potential benefits to patients accruing from home health care, it is important that the agencies providing these services maintain high quality patient care.

The Department anticipates that the proposed amendments and new rules would have a beneficial social impact because they would continue to ensure the provision of high quality home health agency services. Therefore, the Department expects that the general public would react favorably to the rules proposed for readoption with amendments, repeal, and new rules.

Economic Impact

The Department foresees minimal to no financial consequences as a result of the readoption of the rules with amendments and new rules for home health agencies. Because the current rules are in effect and the Department has a survey process in place to ensure that home health agencies are in compliance with the rules, the Department expects no additional costs to the State as a result of the rules proposed for readoption with amendments, repeal, and new rules.

Additionally, because the proposed readoption of the rules with amendments, repeal, and new rules seeks to maintain the current status of home health care licensing standards, the Department does not anticipate the industry incurring any additional expenses in order for it to continue to comply with the rules. Specifically, the readoption with amendments, repeal, and new rules of N.J.A.C. 8:42 would continue to allow sufficient flexibility in agency management and administration by permitting the development of policies and procedures best suited to an agency's circumstances, by allowing agencies to hire and allocate staff to best meet patient care needs and by allowing agencies to decide whether and in what way to provide certain services. This would allow the agencies to conserve resources by determining the most efficient deployment of services and personnel. Thus, it is beneficial to maintain flexibility in the

qualifications of supervisory nursing personnel and the use of contracted nursing personnel under certain circumstances. Further, the use of professional staff members in patient assessment, treatment planning, and delivery of care promotes continuity and coordination of care to reduce duplication, overlap, and fragmentation of services while ensuring that patients receive all necessary services. Moreover, the rules proposed for readoption would not increase the current licensure fees (N.J.A.C. 8:42-2.2). Thus, it is not anticipated that the industry would incur additional costs as a result of the rules proposed for readoption with amendments, repeal, and new rules.

Furthermore, many patients receiving home health care from a licensed home health care agency realize a reduction in the incidence of disease and disability, thereby resulting in a medical cost-savings to patients, as well as private and public insurance companies.

Even more, home health care delivered by licensed home health care agencies can result in considerable savings over institutional alternatives because home health care can be a less expensive method than institutionalization for the delivery of long-term care services and acute post-hospital care. With the ability to provide patients living at home with many of the service modalities that were once only available in the long-term or acute care settings coupled with the rising costs for both acute and long-term care services throughout the nation, home health services are seen as a viable way to maintain patients in their homes and either forestall the need for costly institutional care or reduce the length of a patient's institutional stay by postponing the need for institutional care or by allowing earlier discharge. Indeed, the use of home health care reduces the drain on personal finances for many patients and their families.

Based upon the foregoing, the Department believes that the readoption of these rules with amendments and new rules would continue the positive economic impact that home health care has had upon patients and the health care sector in this State.

Federal Standards Analysis

The rules proposed for readoption 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.

Jobs Impact

The Department does not expect that any jobs will be generated or lost as a result of the rules proposed for readoption with amendments, repeal, and new rules. Rather, the rule requirements may have a positive impact on the generation of jobs as home health agencies must employ professional and other staff necessary to comply with the rules.

Agriculture Industry Impact

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

Regulatory Flexibility Analysis

The rules proposed for readoption with amendments, repeal, and new rules would impose requirements on the licensed home health agencies in New Jersey. The State's 46 existing Medicare-certified home health agencies are all considered "small businesses" within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., as would most new applicants for licensure under the rules proposed for readoption.

The readoption of N.J.A.C. 8:42 would maintain the current recordkeeping, reporting, and other compliance requirements. Home health agencies are required to obtain both a certificate of need (CN) and a license, and to incur administrative application costs for both. The CN application cost is a one-time only fee of \$7,500. The initial license application fee is \$2,000; each subsequent annual renewal fee is \$2,000; and the biennial inspection fee is \$500.00. Agencies would have the option of, but would not be required to, employ outside professionals, at varying fees, to assist them in the licensure process. Home health agencies would be required to report

certain events, such as service interruptions, and they must follow reporting requirements of professional licensing boards. The agencies would be required to have policies relating to various aspects of patient care, advance directives, and pharmacy and supplies. Minimal requirements for nursing care and for nursing entries in the medical/health records of patients would be imposed. Nursing, homemaker-home health aide, and physical therapy services would have to be provided. Requirements pertaining to medical/health records, infection prevention and control, patient rights, and quality assurance would be imposed. The cost of these requirements to the agencies would vary depending upon a number of factors, such as their size, location, and staff resources. As the requirements imposed are necessary to provide safe, efficient, and appropriate care, the costs are not considered inappropriately burdensome. The agencies must employ various professional staff, such as nurses and social workers, at such cost as agreed to between the employer and employee. No lesser requirements or exceptions can be provided based upon business size in the interest of public health, quality of care, and safety.

Housing Affordability Impact Analysis

The rules proposed for readoption with amendments, repeal, and new rules would have an insignificant impact on the affordability of housing in New Jersey, and it is extremely unlikely that they would evoke a change in the average costs associated with housing because the rules proposed for readoption with amendments, repeal, and new rules would only continue to establish licensure standards for home health agencies.

Smart Growth Development Impact Analysis

The rules proposed for readoption with amendments, repeal, and new rules would have an insignificant impact on smart growth, and it is extremely unlikely that they would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the rules proposed for readoption with amendments, repeal, and new rules would only continue to establish licensure standards for home health agencies.

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

Full text of the rule proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:42-6.3.

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

SUBCHAPTER 1. General provisions

8:42-1.2 Definitions

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

“Academy of Nutrition and Dietetics” means the organization formerly known as the “American Dietetic Association” which provides the Registered Dietitian credential and can be contacted at 120 South Riverside Plaza, Suite 2000, Chicago, Illinois 60606-6995, www.eatright.org, 800-877-1600 or 312-899-0040.

...

"Administrator" means a person who is administratively responsible and available for all aspects of [facility] **agency** operations, and:

1.-2. (No change.)

["Advance directive" means a written statement of the patient's instructions and directions for health care in the event of future decisionmaking incapacity in accordance with the New Jersey Advance Directives for Health Care Act, P.L. 1991, c.201. It may include a proxy directive, an instruction directive, or both.]

“Advance directive” means as defined in the New Jersey Advance Directives for Health Care Act, N.J.S.A. 26:2H-53 et seq.

...

"Branch office" means [a facility] **an agency** site from which services are provided to patients in their homes or place of residence; which is physically separate from the home health agency but shares administrative oversight and services; which meets all requirements for licensure; and which has available a [nursing supervisor or alternate coverage by a] registered professional nurse [. When the nursing supervisor or alternate is not] on the premises[, then there must be a licensed nurse on the premises] when the [facility] **branch office** is open to the public.

"Bylaws" means a set of rules adopted by the [facility] **agency** for governing its operation. (A charter, articles of incorporation, and/or a statement of policies and objectives is an acceptable equivalent.)

...

"Clinical note" means a signed and dated notation made at each patient visit by each health care professional who renders a service to the patient. The clinical note

shall include a written description of signs and symptoms, treatment, and/or medication(s) administered, the patient's response, and any changes in physical or emotional condition, and may be documented in a flow sheet format. The flow sheet shall be supplemented by a narrative clinical note at least once a week and whenever there is a change in the patient's condition or care, which cannot be clearly documented on a flow sheet. The clinical note shall be written or dictated on the day service is rendered and shall be incorporated into the patient's medical/health record according to the [facility's] **agency's** policies and procedures.

"Commissioner" means the [New Jersey State] Commissioner of Health [and Senior Services].

...

["Community health nurse" means a registered professional nurse whose practice emphasizes health promotion, health maintenance, primary prevention, health education and management, coordination of health care services, and continuity of care for individuals, families, and groups in the community. The community health nurse's practice includes, but is not limited to, home visits to assess, plan for, and provide nursing services; health guidance and direct care; and coordination of services with community resources, families and other health professionals and paraprofessionals.]

"Conspicuously posted" means placed at a location within the [facility] **agency** accessible to and seen by patients and the public.

["Contamination" means the presence of an infectious or toxic agent in the air, on a body surface, or on or in clothes, bedding, instruments, dressings, or other inanimate articles or substances, including water, milk, and food.]

...

"Department" means the New Jersey State Department of Health [and Senior Services].

"Dietitian" means a person who:

1. Is registered or eligible for registration by the [Commission on Dietetic Registration of the American Dietetic Association] **Academy of Nutrition and Dietetics**; or

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] **Academy of Nutrition and Dietetics** or a dietetic traineeship approved by the [American Dietetic Association] **Academy of Nutrition and Dietetics** 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. (No change.)

...

"Disinfection" means the killing of infectious agents outside the body, or organisms transmitting such agents, by chemical and physical means, directly applied.

[1. "Concurrent disinfection" means the application of measures of disinfection as soon as possible after the discharge of infectious material from the body of an infected person, or after the soiling of articles with such infectious discharges, all personal contact with such discharges or articles being minimized prior to such disinfection.

2. "Terminal disinfection" means the application of measures of disinfection after the patient has ceased to be a source of infection, or after the facility's isolation practices have been discontinued. (Terminal disinfection is rarely practiced; terminal cleaning generally suffices (see definition of "cleaning"), along with airing and sunning of rooms, furniture, and bedding. Terminal disinfection is necessary only for diseases spread by indirect contact.)]

...

"Full-time" means a time period established by the [facility] **agency** as a full working week, as defined and specified in the [facility's] **agency's** policies and procedures.

"Governing authority" means the organization, person, or persons designated to assume legal responsibility for the determination and implementation of policy and for the management, operation, and financial viability of the [facility] **agency**.

"Home health agency" or "agency" means [a facility, which is] **an entity** licensed by the Department to provide preventive, rehabilitative, and therapeutic services to patients on a visiting basis in a place of residence used as a patient's home. All home health agencies shall provide at a minimum nursing, homemaker-home health aide, and physical therapy services and are eligible for Medicare-certification.

...

"Job description" means written specifications developed for each position in the [facility] **agency**, containing the qualifications, duties, competencies, responsibilities, and accountability required of employees in that position.

...

["Monitor" means to observe, watch, or check.]

...

“Physician Orders for Life-Sustaining Treatment form” or “POLST form” means as defined in the Physician Orders for Life-Sustaining Treatment Act, N.J.S.A. 26:2H-129 et seq., particularly at 26:2H-131.

...

["Staff orientation plan" means a written plan for the orientation of each new employee to the duties and responsibilities of the service to which he or she has been assigned, as well as to the personnel policies of the facility.]

...

SUBCHAPTER 2: Licensure Procedure

8:42-2.1 Certificate of Need

(a) According to N.J.S.A. 26:2H-1 et seq., and amendments thereto, a [health care facility] **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.

(b) Applications shall provide the information required by N.J.A.C. 8:33[and 8:33L].

1. Application forms for a Certificate of Need (Form CN-3) and instructions for completion are available from the Office of Certificate of Need and Healthcare Facility Licensure through the methods specified in N.J.A.C. 8:33-4.2.

(c) The [facility] **agency** shall implement all conditions imposed by the Commissioner as specified in the Certificate of Need approval letter.

1. Failure to implement the conditions may result in the imposition of sanctions in accordance with N.J.S.A. 26:2H-1 et seq., and amendments thereto.

8:42-2.2 Application for licensure

(a) Following acquisition of a Certificate of Need, any person, organization, or corporation desiring to operate [a facility] **an agency** shall make application to the Commissioner for a license on form[s] **CN-7, Application for New or Amended Acute Care Facility License**, prescribed by the Department in accordance with the requirements of this chapter.

1. The application and instructions are available through the following methods:

[1.] i. Electronically at the Department's "Forms" webpage at

<http://nj.gov/health/forms>; **or**

[2.] ii. Attached as chapter Appendix **A**, which is incorporated herein by reference[;].

[3. Upon written request to:

Director

Office of Certificate of Need and Healthcare Facility Licensure

New Jersey Department of Health and Senior Services

PO Box 358

Trenton, NJ 08625-0358]

(b) – (d) (No change.)

(e) Any person, organization, or corporation considering application for [license] **licensure** to operate [a facility shall] **an agency may** make an appointment for a

preliminary conference at the Department with the **Office of Certificate of Need and [Acute Care Licensure Program] Healthcare Facility Licensure.**

(f) Each home health agency shall be assessed a biennial inspection fee of \$500.00.

1. This fee shall be assessed in the year the [facility] **agency** will be inspected, along with the annual licensure fee for that year.

2. The fee shall be added to the initial licensure for new [facilities] **agencies.**

3. Failure to pay the inspection fee shall result in non-renewal of the license for existing [facilities] **agencies** and the refusal to issue an initial license for new [facilities] **agencies.**

4. This fee shall be imposed only every other year even if inspections occur more frequently and only for the inspection required to either issue an initial license or to renew an existing license.

5. This fee shall not be imposed for any other type of inspection.

8:42-2.3 Surveys

(a) When the written application for licensure is approved and the building is ready for occupancy, a survey of the [facility] **agency** by representatives of the [Office] **Division of Health [Facilities] Facility [Assessment and] Survey and Field Operations** of the Department shall be conducted to determine if the [facility] **agency** adheres to the rules in this chapter.

1. The [facility] **agency** shall be notified in writing of the findings of the survey, including any deficiencies found.

2. The [facility] **agency** shall notify the Office of Certificate of Need and Healthcare Facility Licensure of the Department when the deficiencies, if any, have been corrected, and the [Office] **Division** of Health [Facilities] **Facility** [Assessment and] Survey **and Field Operations** shall schedule one or more resurveys of the [facility] **agency** prior to issue of license.

(b) No [health care facility] **agency** shall accept patients until the [facility] **agency** has the written approval and/or license issued by the Office of Certificate of Need and Healthcare Facility Licensure of the Department.

(c) Survey visits may be made to [a facility] **an agency** at any time, or to a patient's home, by authorized staff of the Department.

1. Such visits may include, but not be limited to, a review of all [facility] **agency** documents and patient records, and conferences with patients and/or their families.

8:42-2.4 Licensure

[(a) A license shall be issued if surveys by the Department have determined that the health care facility is being operated as required by N.J.S.A. 26:2H-1 et seq., the Health Care Facilities Planning Act and amendments thereto, and by the rules in this chapter.]

(a) A license shall be issued only when the survey conducted pursuant to N.J.A.C. 8:42-2.2(a) demonstrates that the agency meets the requirements set forth in N.J.S.A. 26:2H-1 et seq. and the rules in this chapter.

(b) (No change.)

(c) The license shall be conspicuously posted in the [facility] **agency**.

(d) The license is not assignable or transferable and it shall be immediately void if the [facility] **agency** ceases to operate or if its ownership changes.

(e) The license, unless sooner suspended or revoked, shall be renewed annually on the original licensure date, or within 30 days thereafter but dated as of the original licensure date.

1. The [facility] **agency** will receive a request for renewal fee 30 days prior to the expiration of the license.

2. A renewal license shall not be issued unless the licensure fee is received by the Department.

(f) (No change.)

8:42-2.5 Surrender of license

[The facility] **An agency** shall [directly] notify **directly** each patient, [the] **each** patient's physician, and any guarantors of payment [concerned] at least 30 days prior to the **agency's** voluntary surrender of [a] **its** license, or as [directed under] **the Department directs in** an order of revocation, refusal to renew, or suspension of license[. In such cases,] **and shall surrender** the license [shall be returned] to the Office of Certificate of Need and Healthcare Facility Licensure [of the Department] within seven working days after [the] **a** revocation, non-renewal, **voluntary surrender**, or suspension of license.

8:42-2.6 Waiver

(a) (No change.)

(b) [A facility] **An agency** seeking a waiver of [these rules] **a rule in this chapter** shall apply in writing to the Director of the Office of Certificate of Need and Healthcare Facility Licensure of the Department **on Form CN-28, Application for Waiver, which is incorporated herein by reference as chapter Appendix B and is also available on the Department's website at**

<http://web.doh.state.nj.us/apps2/forms/subforms.aspx?pro=healthfacilities#need-care>.

(c) A written request for waiver shall include the following:

1. (No change.)
2. Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the [facility] **agency** upon full compliance;
3. An alternative proposal, which would ensure patient safety; [and]
4. Documentation to support the application for waiver[.];
- 5. Whether the project is currently under review by the Department of Community Affairs, Health Care Plan Review; and**
- 6. Whether the waiver request is based on plan review comments by the Department of Community Affairs.**

(d) (No change.)

SUBCHAPTER 3. GENERAL REQUIREMENTS

8:42-3.1 Compliance with rules and laws

(a) The [facility] **agency** shall provide preventive, rehabilitative, and therapeutic services to patients.

1. This shall include[, but not be limited to,] nursing, homemaker-home health aide, and physical therapy services.

2. Nursing services shall be available 24 hours a day, seven days a week.

[(b) The facility shall routinely provide nursing services through its own staff. Nursing services provided under contract shall be rendered only if the following conditions pertain:

1. During temporary periods when all available full and part-time employees have achieved maximum caseloads, or;

2. To provide specialized care which is not available through existing staff;

3. Contracted nursing personnel are oriented to the policies and procedures of the facility and receive supervision from supervisory staff employed by the facility; and

4. Provisions are made for continuity of patient care by the same contracted nursing personnel whenever possible.]

(b) The agency shall routinely provide nursing services through its own staff. An agency may contract to retain personnel to provide nursing services subject to the following conditions:

1. The agency needs to retain nursing services by contract:

i. Temporarily because all available full and part-time employees have achieved maximum caseloads; or

ii. To provide specialized care that is not within either the expertise or the scope of practice of existing staff;

2. The agency ensures that contracted nursing personnel receive orientation to the policies and procedures of the agency and receive supervision from supervisory staff employed by the agency; and

3. The agency preserves continuity of patient care by retaining the same contracted nursing personnel for the same patients whenever possible.

(c) (No change.)

(d) The [facility] **agency** shall adhere to applicable Federal, State, and local rules, regulations, and requirements.

(e) The [facility] **agency** shall adhere to all applicable provisions of N.J.S.A. 26:2H-1 et seq., and amendments thereto.

(f) Each home health agency licensed pursuant to N.J.S.A. 26:2H-1 et seq. shall provide the following information to each patient receiving home-based services from that agency, or to a person designated by the patient:

1. The name and certification or licensure title, as applicable, of the homemaker-home health aide or other health care professional whose practice is regulated pursuant to Title 45 of the Revised Statutes.

i. Agencies shall issue an identification tag **that includes a photograph of the homemaker-home health aide or other health care professional** to each homemaker-home health aide[, and] **or** other health care professional in their employ.

[ii.] **2.** Agencies shall develop policies and procedures that require homemaker-home health aides[, and] other health care professionals[, and] in their employ to wear identification tags in an easily visible place upon their person at all times while examining, observing, or caring for the patient; **and**

[2. A photograph of the homemaker-home health aide or other health care professional that shall be included on the identification tag required pursuant to (f)1 above; and]

3. A copy of the most current edition of the consumer guide to homemaker-home health aides published by the New Jersey Board of Nursing, **which can be found on the Division of Consumer Affairs's website at <http://www.njconsumeraffairs.gov/News/PressAttachments/hhhaguide.pdf>.**

(g) (No change.)

8:42-3.2 Ownership

(a) The [ownership of the facility shall be disclosed] **agency shall disclose its owners** to the Department[. Proof of this] **and make available proof of the** ownership [shall be available in the facility. Any proposed change in] **at the agency.**

(b) An agency shall submit an application for transfer of ownership [shall be reported] **on Form CN-7** to the Director of the Office of Certificate of Need and Healthcare Facility Licensure [of the Department] in writing at least [30] **90** days prior to [the change] **the proposed closing date** and in conformance with the requirements for Certificate of Need applications **at N.J.A.C 8:33-3.3.**

1. An applicant for a transfer of ownership shall not finalize the transaction with the proposed transferee without prior approval of the Department.

[(b)] **(c) [No health care facility] An agency shall not** be owned or operated by any person convicted of a crime **or offense** relating adversely to the person's [capability of owning or operating] **ability to own or operate** the [facility.] **agency, including, but**

not limited to, homicide, assault, kidnapping, sexual offenses, robbery, crimes against the family, children, or incapacitated individuals, and financial crimes or offenses, except when the person has demonstrated his or her rehabilitation in order to qualify as an owner in accordance with the standards set forth in the Rehabilitated Convicted Offender Act, N.J.S.A. 2A:168A-1 et seq.

(d) In accordance with the provisions of the Administrative Procedures 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 or operating an agency pursuant to (c) above shall be given an opportunity for a hearing to challenge the denial of a determination of rehabilitation.

8:42-3.3 Submission of documents

The [facility] **agency** shall, upon request, submit any documents[, which] **that** are required by [these rules] **this chapter**, to the Director of the Office of Certificate of Need and Healthcare Facility Licensure of the Department.

8:42-3.4 Personnel

(a) The [facility] **agency** shall ensure that the duties and responsibilities of all personnel are described in job descriptions and in the policy and procedure manual for each service.

(b) (No change.)

(c) All personnel, both directly employed and under contract to provide direct care to patients, shall at all times wear [or produce upon request] **the** employee identification **tag required under N.J.A.C. 8:42-3.1(f)1i.**

(d) The [facility] **agency** shall have policies and procedures for the maintenance of confidential personnel records for each employee, including at least [his]:

1. **His** or her name[, previous];
2. **Previous** employment[, educational];
3. **Educational** background[, license];
4. **License** number with [effective]:
 - i. **Effective** date and date of expiration, [(]if applicable[)], certification];
5. **Certification**, [(]if applicable[)], verification];
6. **Verification** of credentials and references[, health];
7. **Health** evaluation records[, job];
8. **Job** description[,]; and [evaluations]
9. **Evaluations** of job performance.

(e) (No change.)

(f) Employee health records shall be maintained for each employee.

1. Employee health records shall be confidential and kept separate from personnel records.

(g) (No change.)

(h) [All] **Agency** personnel, both directly employed and under contract [to provide direct care to patients], shall receive [a Mantoux] **upon employment** tuberculin skin [test with five tuberculin units of purified protein derivative. 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. Results of the Mantoux tuberculin skin tests shall be acted upon as follows:

1. If the Mantoux tuberculin skin test result is between zero and nine millimeters of induration, the test shall be repeated one to three weeks later.

2. If 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.

(i) The Mantoux tuberculin skin test shall be administered to all agency personnel, both directly employed and under contract at the time of employment. To the extent, if any, that currently employed personnel have not been tested, they shall be tested immediately. The 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.

(j) All personnel, both directly employed and under contract to provide direct care to patients, shall be given a rubella screening test using the rubella hemagglutination inhibition test or other rubella screening test.] **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

(i) Agency personnel, both directly employed and under contract to provide direct care to patients, shall receive upon employment the appropriate testing and offered vaccinations, if necessary, for measles and rubella in accordance with the recommendations for these diseases contained in the CDC document “Immunization of Health-Care Personnel, Recommendations of the Advisory Committee on Immunization Practices (ACIP),” MMWR, November 25, 2011; Vol. 60; No. 7, incorporated herein by reference, as amended and supplemented, which can be found on the CDC website at <http://www.cdc.gov/mmwr/pdf/rr/rr6007.pdf>.

1. The only exceptions are personnel who can document seropositivity from a previous rubella **or measles** screening test or who can document inoculation with rubella **or measles** vaccine, or when medically contraindicated.

Recodify existing (k) and (l) as **(j) and (k)** (No change in text.)

[(m) All personnel, both directly employed and under contract to provide direct care to patients, who were born in 1957 or later shall be given a (measles) rubeola screening test using the hemagglutination inhibition test or other rubeola screening test. The only exceptions are personnel who can document receipt of live measles vaccine on or after their first birthday, physician-diagnosed measles, or serologic evidence of immunity.

(n) The facility shall ensure that all personnel, both directly employed and under contract to provide direct care to patients, who cannot provide serologic evidence of immunity are offered rubella and rubeola vaccination.]

8:42-3.5 Policy and procedure manual

(a) A policy and procedure manual(s) for the organization and operation of the [facility] **agency** shall be established, implemented, and reviewed at least annually.

(b) Each review of the manual(s) shall be documented, and the manual(s) shall be available in the [facility] **agency** at all times. The manual(s) shall include at least the following:

1. A written narrative of the program describing its philosophy and objectives, and the services provided by the [facility] **agency**;

2. – 4. (No change.)

5. 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, but not be limited to, the following:

i. (No change.)

ii. 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] **Department of Children and Families, Division of Child Protection and Permanency** on the medical/health record, and serving as a liaison between the [facility] **agency** and the [Division of Youth and Family Services] **Division of Child Protection and Permanency**; and

iii. (No change.)

[NOTE: Copies of the law may be obtained from the local district office of the Division of Youth and Family Services (DYFS) or from the Office of Community Education, Division of Youth and Family Services, New Jersey State Department of Human Services, PO Box 717, Trenton, NJ 08625.]

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

8:42-3.6 Staffing

(a) Provision shall be made for staff with equivalent qualifications to provide services for absent staff members.

(b) [Staffing] **The agency shall implement staffing** schedules [shall be implemented to] **that** facilitate continuity of care to patients.

(c) The [facility] **agency** shall maintain staff attendance records.

[(b)] **(d)** The [facility] **agency** shall develop and implement a staff orientation and a staff education plan, including plans for each service and designation of the person(s) responsible for training.

8:42-3.7 Written agreements

(a) The [facility] **agency** shall have a written agreement, or its equivalent, for services provided by contract or subcontract. The written agreement or its equivalent shall:

1. Be dated and signed by a representative of the [facility] **agency** and by the person or [agency] **entity** providing the service;

2. (No change.)

3. Specify that the [facility] **agency** retains administrative responsibility for services rendered, including subcontracted services;

4. (No change.)

5. Require the provision of written documentation to the [facility] **agency**, including, but not limited to, documentation of services rendered by the person or [agency] **entity** providing the service.

8:42-3.8 Reportable events

(a) The [facility] **agency** shall notify the Department immediately by telephone at (609) 292-5960, followed within 72 hours by written confirmation of the termination of employment of the administrator and/or the director of nursing, and the name and qualifications of his or her replacement.

(b) The [facility] **agency** shall provide statistical data as required by the Department.

8:42-3.9 Notices

(a) The [facility] **agency** shall conspicuously post a notice that **states that** the following information is available in the [facility] **agency** to patients and the public:

1. - 3. (No change.)

4. A list of the [facility's] **agency's** committees, or their equivalents, and the membership and reports of each;

5. The names [and addresses] of members of the governing authority;

6 - 7. (No change.)

8:42-3.10 Reporting to professional licensing boards

The [facility] **agency** 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.

SUBCHAPTER 4. GOVERNING AUTHORITY

8:42-4.1 Responsibility

(a) The governing authority shall assume legal responsibility for the management, operation, and financial viability of the [facility] **agency**. The governing authority shall be responsible for, but not limited to, the following:

1. – 5. (No change.)

6. Delineation of the powers and duties of the officers and committees, or their equivalent, of the governing authority; [and]

7. Establishment of the qualifications of members and officers of the governing authority, the procedures for electing, appointing, or employing officers, and the terms of service for members, officers, and committee chairpersons or their equivalents[.]; **and**

8. Development and implementation of a written conflict of interest policy, which shall include guidelines for the disclosure of existing or potential conflicts of interest and procedures for recusal when a conflict exists.

SUBCHAPTER 5. ADMINISTRATION

8:42-5.1 Administrator

(a) The governing authority shall appoint an administrator who is administratively responsible and available for all aspects of [facility] **agency** operations.

1. If the [facility] **agency** has only one office, [and if the qualifications for both positions are met,] the director of nursing may function as the administrator, **provided the director of nursing meets the qualifications of an administrator.**

(b) (No change.)

8:42-5.2 Administrator's responsibilities

(a) The administrator shall be responsible for, but not limited to, the following:

1. (No change.)

2. Planning for and administering the managerial, operational, fiscal, and reporting components of the [facility] **agency**;

3. – 5. (No change.)

6. Establishing and maintaining liaison relationships, communication, and integration with [facility] **agency** staff and services and with patients and their families, in accordance with the philosophy and objectives of the [facility] **agency**.

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. Overall planning, supervision, and administration of nursing services;

2. The 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 communication, 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; and

6. Ensuring community health nursing supervision to nursing personnel.

SUBCHAPTER 6. PATIENT CARE SERVICES

8:42-6.1 Advisory group

(a) The governing authority shall appoint an advisory group to review policy, evaluate programs, and make recommendations to the [leadership] **governing authority** for change or further study.

(b) Membership shall include: [at]

1. **At** least one physician[, the];

2. **The** director of nursing and/or nursing supervisor[, a];

3. **A** consumer[.]; and [a]

4. **A** representative of physical therapy services[,] and[, if offered by the agency,]

a representative of each of the following services, if the agency offers the service:

occupational therapy, speech-language therapy, social work, and dietary counseling.

[(b)] **(c)** At least one member of the advisory group shall be neither an owner nor an employee of the [facility] **agency**.

[(c)] **(d)** (No change in text.)

8:42-6.2 Policies and procedures

(a) The [facility] **agency** shall establish written policies and procedures governing patient care that are reviewed at least annually by the advisory group, revised as needed, and implemented. They shall include at least the following:

1. Criteria for admission and discharge of patients.

i. Admission criteria shall be based solely upon the patient's needs and the ability of the [facility] **agency** to meet safely the medical, nursing, and social needs of the patient.

ii. Discharge policies shall preclude punitive discharge;

2. Criteria for [physicians] **physician's** orders for home health services, including time frames and other requirements for written, verbal, and renewal orders.

i. [Physician] **Physician's** orders for physical therapy, occupational therapy, and speech therapy shall include the modality, frequency, and duration of treatment;

3. – 10. (No change.)

8:42-6.3 Advance directives

(a) An agency shall comply with the requirements of the New Jersey Advance Directives for Health Care Act, N.J.S.A. 26:2H-53 et seq.

(b) An agency shall establish and review, at least annually, and more often as needed, revise as needed, and implement, written advance directive policies and procedures to effectuate the New Jersey Advance Directives for Health Care Act, that include, but are not limited to:

1. The requirements imposed upon health care agencies at N.J.S.A. 26:2H-65;

2. Evaluation criteria for validating an advance directive when a question of validity is indicated, and procedures for assisting in the execution of a valid advance directive;

3. A delineation of the responsibilities of attending physicians, administration, nursing, social service, and other staff in regard to advance directives; and

4. In the event the agency is a private, religiously-affiliated health care institution, policies for a transfer of a patient in compliance with N.J.A.C. 8:42-6.6(a)3.

(c) Either independently or in collaboration with other area agencies or organizations, an agency shall annually provide one or more community education programs within the agency's service area identified during the Certificate of Need process that inform consumers regarding advance directives and their rights under New Jersey law to execute advance directives.

(d) Before providing care to an adult patient, and routinely thereafter at other appropriate times, an agency shall:

1. Inquire of the patient, the patient's family member, or other patient representative, if the patient is unable to respond, about the existence and location of an advance directive for the patient;

2. Document each response to this inquiry in the patient's medical record;

3. If this inquiry indicates that an advance directive for the patient exists and is in effect, request and take reasonable steps to obtain the original or a copy thereof; and

4. Enter the advance directive into the patient's medical record, if it is obtained.

(e) An agency shall provide staff training regarding the New Jersey Advance Directives for Health Care Act and the Federal Patient Self Determination Act, 42 U.S.C. §§ 1395cc and 1396a, that address at least the following:

1. The rights and responsibilities of staff; and

2. Internal policies and procedures to implement these laws.

8:42-6.4 Pharmacy and supplies

(a) [The facility] **An agency** shall establish written policies and procedures governing pharmacy and supplies that are reviewed annually, revised as needed, and implemented[. They shall], **which** include at least the following:

1. – 4. (No change.)

(b) The [facility] **agency** shall provide current pharmaceutical reference materials and sources of information to staff.

(c) [Pursuant to P.L. 1997, c.66, registered professional nurses may purchase, store or transport for the purpose of administering to their home health patients the following non-controlled drugs: sterile saline solution, sterile water, adrenalin/epinephrine, diphenhydramine, hydrochloride, heparin flush solution and any other noncontrolled drug approved] **An agency shall comply with N.J.S.A. 45:11-49.1 entitled, “Provision, administration of certain non-controlled drugs to home health patients,” and the rules promulgated pursuant thereto** by the New Jersey Board of Nursing in consultation with the State Board of Medical Examiners and the New Jersey Board of Pharmacy. [Such drugs shall only be administered pursuant to protocols utilized by a health care professional licensed to prescribe drugs in New Jersey.]

8:42-6.5 Physician Orders for Life-Sustaining Treatment (POLST)

(a) An agency shall comply with the requirements of the Physician Orders for Life-Sustaining Treatment Act, N.J.S.A. 26:2H-129 et seq.

(b) An agency shall establish and review, at least annually, and more often as needed, revise as needed, and implement, written policies and procedures to effectuate the POLST Act, that include, but are not limited to:

- 1. The requirements imposed upon agencies at N.J.S.A. 26:2H-134;**
- 2. Procedures in the event of a disagreement regarding the POLST Form that are consistent with N.J.S.A. 26:2H-136;**
- 3. A delineation of the responsibilities of attending physicians, administration, nursing, social service, and other staff in regard to the POLST Forms; and**

4. In the event the agency is a private, religiously-affiliated health care institution, policies for a transfer of a patient in compliance with N.J.A.C. 8:42-6.6(a)4.

(c) Before providing care to an adult patient, and routinely thereafter at other appropriate times, an agency shall:

1. Inquire of the patient, the patient's family member, or other patient representative if the patient is unable to respond, about the existence and location of the POLST Form for the patient;

2. Document each response to this inquiry in the patient's medical record;

3. If this inquiry indicates that the POLST Form for the patient exists and is in effect, request and take reasonable steps to obtain the POLST Form; and

4. Enter the POLST Form into the patient's medical record, if one is obtained.

(d) An agency shall provide staff training regarding the Physician Orders for Life-Sustaining Treatment Act that address at least the following:

1. The rights and responsibilities of staff; and

2. Internal policies and procedures to implement this law.

8:42-6.6 Transfer of a patient

(a) A patient shall be transferred to another agency only for the following reasons:

1. A valid medical reason, including the agency's inability to care for the patient.

2. In order to comply with clearly expressed and documented patient choice in accordance with applicable laws or rules.

3. In conformance with the New Jersey Advance Directives for Health Care Act in the instance of a private, religiously affiliated home health agency that establishes written policies defining circumstances in which it will decline to participate in the withholding or withdrawal of life-sustaining treatment. Such agencies shall:

i. Provide written notice of the policy to patients, families, or health care representatives prior to or at the time of admission to services; and

ii. Implement a timely and respectful transfer of the patient to an agency that will implement the advance directive.

4. In conformance with the POLST Act in the instance of a private, religiously affiliated home health agency that establishes written policies defining circumstances in which it will decline to participate in the withholding or withdrawal of life-sustaining treatment. Such agencies shall:

i. Provide written notice of the policy to patients, families, or health care representatives prior to or at the time of admission to services; and

ii. Implement a timely and respectful transfer of the patient to an agency that will implement the POLST Form.

(b) The sending agency shall receive approval from the receiving agency before transferring the patient.

8:42-6.7 Declaration of death

An agency shall establish policies and procedures for the declaration of death of patients in accordance with the New Jersey Declaration of Death Act, N.J.S.A. 26:6A-1 et seq., and the rules promulgated pursuant thereto at N.J.A.C. 13:35-6A.

SUBCHAPTER 7. NURSING SERVICES

8:42-7.1 Provision of nursing services

The [facility] **agency** shall provide nursing services to patients who need these services.

8:42-7.2 Nursing organization, policies, and procedures

(a) An agency shall establish and make available at all times to all nursing personnel of the agency:

[(a)] **1.** A written organizational chart and written plan that delineates lines of authority, accountability, and communication [shall be available to all nursing personnel in the agency at all times.]; **and**

2. The agency's current clinical and administrative nursing policies and procedures.

(b) [The] **An** agency shall have written policies and procedures for the provision of nursing services that [guide]:

1. Govern nursing practices in the agency[. These policies shall be reviewed];

2. The agency reviews annually, [revised] **revises** as needed, and

[implemented. These policies and procedures shall conform with] **implements; and**

3. Conform to the Nurse Practice Act, [at] N.J.S.A. 45:11-23 [and N.J.A.C. 13:37-1.4, 6.1, 6.2, 13.1, and 13.2] **et seq., and the rules promulgated thereunder.**

[(c) The agency's current clinical and administrative nursing policies and procedures shall be available to all nursing personnel at all times.]

8:42-7.3 Nursing staff qualifications and responsibilities

(a) The governing authority **of an agency** shall [appoint]:

1. Appoint a full-time director of nursing who shall be available at all times[. An alternate or]; **and**

2. Designate in writing, to act in the absence of the director of nursing, one or more alternates [shall be designated in writing to act in the absence of the director. The alternate or alternates shall be] **who are** registered professional nurses.

[(b) The director of nursing shall be responsible for the direction, provision, and quality of nursing services. He or she shall be responsible for, but not limited to, the following:

1. Overall planning, supervision, and administration of nursing services;
2. The coordination and integration of nursing services with other home health services to provide a continuum of care for the patient;
3. Development of protocols for regular communication, 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 the patient as specified in the nursing plan of care; and

6. Ensuring community health nursing supervision to nursing personnel.]

[(c)] **(b)** [A full-time nursing supervisor or alternate coverage by a] **A** registered professional nurse shall be available at each [facility] **agency** branch office during its hours of operation to provide clinical supervision.

[(d)] Registered professional nurses and licensed practical nurses shall provide nursing care to patients commensurate with their scope of practice, as delineated in the Nurse Practice Act. Nursing care shall include, but not be limited to, the following:

1. The promotion, maintenance, and restoration of health;

2. Ensuring the prevention of infection, accident, and injury;

3. Performing an initial assessment and identifying problems for each patient upon admission to the nursing service. For those clients requiring nursing services, the initial assessment shall be performed by a registered professional nurse;

4. Reassessing the patient's nursing care needs on an ongoing, patient-specific basis and providing care which is consistent with the medical plan of treatment;

5. Monitoring the patient's response to nursing care;

6. Teaching, supervising and counseling the patient, family members and staff regarding nursing care and the patient's needs, including other related problems of the patient at home. Only a registered professional nurse shall initiate these functions, which may be reinforced by licensed nursing personnel; and

7. A registered professional nurse who shall be available 24 hours a day, seven days a week, and who shall be required to contact a patient regarding clinical issues within one hour of the patient's call to the agency.

(e) Nursing staff shall administer medications in accordance with all Federal and State laws and rules.]

(c) An agency shall ensure that the registered professional nurses and licensed practical nurses it retains to provide nursing services to patients:

1. Hold the applicable credentials issued by the Board of Nursing pursuant to N.J.S.A. 45:11-23 et seq., and provide verification of those credentials to the agency, which the agency maintains in the agency personnel record for that nursing professional;

2. Provide nursing services within their respective scopes of practice pursuant to N.J.S.A. 45:11-23 et seq., and the rules promulgated thereunder;

3. Promote, maintain, and restore health;

4. Prevent infection, accident, and injury;

5. Perform initial patient assessments and identify each patient's service needs upon admission to the nursing service.

i. Only registered professional nurses are to perform patient assessments;

6. Reassess each patient's nursing care needs on an ongoing, patient-specific basis;

7. Provide care that is consistent with each patient's medical plan of treatment;

8. Monitor each patient's response to nursing care;

9. Teach, supervise, and counsel each patient, patients' family members, and staff regarding nursing care and each patient's needs, including other related problems of each patient.

i. Only registered professional nurses are to initiate these functions and, thereafter, delegate selected tasks to nursing personnel; and

10. Administer medications in accordance with applicable Federal and State law.

(d) An agency shall ensure that a registered professional nurse:

1. Is available 24 hours a day, seven days a week; and

2. Contacts a patient regarding clinical issues within one hour of the patient's call to the agency.

8:42-7.4 Nursing entries in the medical/health record

(a) In accordance with written job descriptions and with [these rules] **this chapter**, nursing personnel shall document in the patient's medical/health record:

1. The nursing plan of care in accordance with the [facility's] **agency's** policies and procedures;

2. (No change.)

3. A record of medications administered. After each administration of medication, the following shall be documented by the nurse who administered the drug:

[name]

i. Name and strength of the drug[, data];

- ii. **Date** and time of administration[, dosage];
- iii. **Dosage** administered[, method];
- iv. **Method** of administration[.]; and [signatures]
- v. **Signature** of the licensed nurse who administered the drug.

8:42-7.5 Homemaker-home health aide services

(a) [The facility shall provide] **An agency, in providing** homemaker-home health aide services, [in accordance with the following] **shall ensure that:**

1. The homemaker-home health aide [shall have completed a training program approved] **that the agency retains to provide these services holds certification as a homemaker-home health aide issued** by the New Jersey Board of Nursing[, shall be certified by the Board of Nursing,] and [shall] provides verification of [current] **that** certification [for inclusion in the], **to the agency, which the agency maintains in the** agency personnel record **for that homemaker-home health aide;**

2. [The] **A** homemaker-home health aide [shall] provides personal care and/or homemaking services **that are within the scope of practice of a homemaker-home health aide, in accordance with N.J.A.C. 13:37-14.3, and** under the supervision of a registered professional nurse[.], **in accordance with N.J.A.C. 13:37-6.2.**

i. [The] **Prior to a homemaker-home health aide rendering services to a patient, a** registered professional nurse shall orient the homemaker-home health aide to [a] **that** patient and shall give written instructions to the homemaker-home health aide regarding the home health services to be provided. **Copies of the written instructions**

shall be kept in the patient's home and documentation of services shall be kept in the patient's medical/health record;

ii. The delegation of tasks to a homemaker-home health aide by a registered professional nurse shall be consistent with N.J.A.C. 13:37-6.2 and 14.3; and

iii. A registered professional nurse makes supervisory visits to the patient's home and documents these visits in the patient's medical record, in accordance with the agency's policies and procedures; and

3. The homemaker-home health aide shall document the [home] homemaker-home health services provided[. Copies of the written instructions shall be kept in the patient's home and documentation of services provided shall be kept in the patient's medical/health record;] to a patient in the patient's medical record.

[ii. If the registered professional nurse delegates selected tasks to the homemaker-home health aide, the registered professional nurse shall determine the degree of supervision to provide, based upon an evaluation of the patient's condition, the education, skill, and training of the homemaker-home health aide to whom the tasks are delegated, and the nature of the tasks and activities being delegated. The registered professional nurse shall delegate a task only to a homemaker-home health aide who has demonstrated the knowledge, skill, and competency to perform the delegated tasks; and

iii. The registered professional nurse shall make supervisory visits to the patient's home and document these visits in the patient's medical record, in accordance with the facility's policies and procedures; and

3. The homemaker-home health aide shall be responsible for, but not limited to, providing personal care and homemaking services essential to the patient's health care and comfort at home, including shopping, errands, laundry, meal planning and preparation (including therapeutic diets), serving of meals, child care, assisting the patient with activities of daily living, assisting with prescribed exercises and the use of special equipment, and assisting with patient self-administration of medications.]

SUBCHAPTER 8. REHABILITATION SERVICES (PHYSICAL THERAPY, OCCUPATIONAL THERAPY, SPEECH-LANGUAGE PATHOLOGY, AND AUDIOLOGY)

8:42-8.1 Services

The [facility] **agency** shall provide physical therapy and may provide occupational therapy and speech-language pathology services, directly or through written agreement, to patients who need these services.

8:42-8.2 [Responsibilities of rehabilitation personnel] **Rehabilitation services**

(a) In accordance with written job descriptions (and for physical therapy personnel, in accordance also with the State of New Jersey Physical Therapy Practice Act, N.J.S.A. 45:9-37.11 et seq.; **and for occupational therapy personnel, in accordance also with N.J.S.A. 45:9-37.51 et seq.**, and for speech-language pathology in accordance also with the State of New Jersey Audiology and Speech Language Pathology Practice Act, N.J.S.A. 45:3B-1), each physical therapist, occupational therapist, and speech-language pathologist shall be responsible for, but not limited to, the following:

1. (No change.)

2. Participating in staff education activities and providing consultation to [facility]

agency personnel; and

3. (No change.)

SUBCHAPTER 9. SOCIAL WORK SERVICES

8:42-9.2 Social worker's responsibilities

(a) For those patients requiring social work services, each social worker shall be responsible for, but not limited to, the following:

1. Performing a psychosocial assessment of the patient; [preparing]

2. Preparing the social work plan of care based on the assessment; [and providing]

3. Providing social work services to the patient as specified in the social work plan of care.

4. Each of [these] **the activities specified in (a)1, 2, and 3 above** shall be documented in the patient's medical/health record;

Recodify existing 2.-4. as **5.-7.** (No change in text.)

[5.] **8.** Participating in staff education activities and providing consultation to [facility] **agency** personnel.

SUBCHAPTER 10. DIETARY COUNSELING SERVICES

8:42-10.2 Responsibilities of dietitian

(a) For those patients requiring dietary counseling services, each dietitian shall be responsible for, but not limited to, the following:

1. Assessing the dietary needs of the patient, preparing the dietary plan of care based on the assessment and providing dietary counseling services to the patient as specified in the dietary plan of care.

i. These activities shall be documented in the patient's medical/health record;

2. (No change.)

3. Participating in staff education activities and providing consultation to [facility] **agency** personnel.

SUBCHAPTER 11. MEDICAL/HEALTH RECORDS

8:42-11.1 Medical/health records organization

(a) The [facility] **agency** shall develop written objectives, policies and procedures, an organizational plan, and a quality assurance program for medical/health records services.

1. The quality assurance program shall include monitoring **of** medical/health records for accuracy, completeness, legibility, and accessibility.

(b) At least 14 days before [a facility] **an agency** plans to cease operations, it shall notify the New Jersey Department of Health [and Senior Services] in writing of the location and method for retrieval of medical/health records.

(c) – (e) (No change.)

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

(a) The [facility] **agency** shall have written policies and procedures for medical/health records that are reviewed annually, revised as needed, and implemented. They shall include at least:

1. - 5. (No change.)

(b) All entries in the patient's medical/health record shall be typewritten or written legibly in ink, and shall include date, signature, and title, or computer generated with authentication, if an electronic system is used.

1. (No change.)

2. "Authentication" **means as that term is** defined by the Centers for Medicare and Medicaid Services' [(Health Insurance Manual Publication 11),] **Risk Management Handbook, Volume III, Standard 3.1, CMS Authentication Standards, incorporated herein by reference, as amended and supplemented, available on the CMS website at https://www.cms.gov/research-statistics-data-and-systems/cms-information-technology/informationsecurity/downloads/rmh_viii_3-1_authentication.pdf, and** must include signatures, written initials, or computer secure entry by a unique identifier of a primary author who has reviewed and approved the entry. [Furthermore, the]

i. The home health agency must have safeguards to prevent unauthorized access to the records and a process for reconstruction of the records in the event of a system breakdown.

3. (No change.)

(c) A medical/health record shall be initiated for each patient upon admission and shall include at least the following:

1. – 2. (No change.)

3. A plan of treatment as defined at N.J.A.C. 8:42-1.2. This plan shall be:

i. (No change.)

ii. Coordinated and maintained by the nursing service, [or] the physical therapy service, **or the speech therapy service**, if physical therapy **or speech therapy** is the sole service;

iii. – v. (No change.)

4. – 17. (No change.)

(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.-6. (No change.)

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

(e) All consent forms for treatment shall be printed in an understandable format and the text written in clear, legible, nontechnical language.

1. If a family member or other patient representative signs the form, the reason [for] **why** the [patient's] **patient did** not [signing] **sign** it, and the signer's relationship to the patient shall be indicated on the form.

(f) – (h) (No change.)

SUBCHAPTER 12. INFECTION PREVENTION AND CONTROL

8:42-12.1 Infection prevention and control program

(a) The administrator shall ensure the development and implementation of an infection prevention and control program **to reduce the risk of the acquisition and transmission of health care associated infections.**

(b) The administrator shall designate a person who shall have education, training, completed course work, or experience in infection control or epidemiology, and who shall be responsible for the direction, provision, and quality of infection prevention and control services.

1. The designated person shall be responsible for, but not limited to developing and maintaining [written] **in collaboration with the committee established pursuant to N.J.A.C. 8:42-12.2(a):**

i. **Written** objectives[, a];

ii. **A** policy and procedure manual[, a];

iii. **A** system for data collection[,]; and [a]

iv. **A** quality assurance program for the infection prevention and control

service.

8:42-12.2 Infection control policies and procedures

(a) The [facility] **agency** shall have a multidisciplinary committee, which establishes and implements an infection prevention and control program.

(b) The designated committee, **along with the person designated by the administrator pursuant to N.J.A.C. 8:42-12.1(b)**, shall develop, implement, and review, at least annually, written policies and procedures regarding infection prevention and control, including, but not limited to, policies and procedures regarding the following:

1. Infection control and isolation, including Universal Precautions, in accordance with the Centers for Disease Control and Occupational Safety and Health Administration publication, "Enforcement Procedures for **the Occupational Exposure to [Hepatitis B Virus (HVB) and Human Immunodeficiency Virus (HIV),] Bloodborne Pathogens,**" OSHA Instruction CPL [2-2.44A, August 15, 1988 or revised or later editions, if in effect] **02-02-069, November 27, 2011**, incorporated herein by reference, **as amended and supplemented, which can be found on the OSHA website at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=2570;**

2. [In accordance with N.J.A.C. 8:57, a] **A** system for investigating, reporting, and evaluating the occurrence of all infections or diseases [which] **that** are reportable [or] **under N.J.A.C. 8:57, as well as** conditions [which] **that** may be related to activities and procedures of the [facility, and maintaining records] **agency**.

i. Records shall be maintained for all patients or personnel having these infections, diseases, or conditions;

3. – 7. (No change.)

[NOTE: Centers for Disease Control publications can be obtained from:

National Technical Information Service

U.S. Department of Commerce

5285 Port Royal Road

Springfield, VA 22161

or

Superintendent of Documents

U.S. Government Printing Office

Washington, DC 20402]

8:42-12.3 Infection control measures

(a) The [facility] **agency** shall follow all Category I recommendations in the current editions of the following [Centers for Disease Control] **CDC** publications, [and any amendments or supplements thereto,] **which are** incorporated herein by reference, **as amended and supplemented:**

1. Guideline for Prevention of Catheter-Associated Urinary Tract Infections, **2009**, **which can be found on the CDC website at**

<http://www.cdc.gov/hicpac/pdf/CAUTI/CAUTIguideline2009final.pdf>;

2. Guideline for Prevention of Intravascular **Catheter Related** Infections, **2011**, **which can be found on the CDC website at**

<http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf>;

3. Guideline for Prevention of Surgical [Wound] **Site** Infection[s], **1999**, **which can be found on the CDC website at**

http://www.cdc.gov/hicpac/pdf/guidelines/SSI_1999.pdf; and

4. Guideline for [Handwashing and Hospital Environmental Control] **Hand Hygiene in Health-Care Settings, MMWR/51 (RR-16), October 25, 2002, which can be found on the CDC website at <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>.**

8:42-12.4 Use and sterilization of patient care items

(a) The [facility] **agency** shall develop protocols for decontamination and sterile activities, including receiving, decontamination, storage, cleaning, packaging, labeling, disinfection, sterilization, transporting, and distribution of reusable items. These protocols shall ensure that:

1. Single use patient care items shall not be reused[.];

2. Other patient care items [which] **that** are reused shall be reprocessed and reused in accordance with manufacturers' recommendations;

[2.] 3. Sterilized materials shall be marked with [an] **a manufacturer's** expiration date and shall not be used subsequent to the expiration date;

Recodify existing 3. and 4. as **4. and 5.** (No change in text.)

8:42-12.6 Regulated medical waste

(a) [Regulated] **An agency shall ensure that** medical waste [shall be] **is** collected, stored, handled, and disposed of in accordance with applicable Federal and State law[s] and regulations].

(b) [The facility] **An agency** shall comply with the [provisions of the Medical Waste Tracking Act of 1988, and N.J.S.A. 13:1E-48.1 et seq., the] Comprehensive Regulated

Medical Waste Management Act, **N.J.S.A. 13:1E-48.1 et seq.**, and all rules [and regulations] promulgated pursuant [to the aforementioned Acts] **thereto**.

8:42-12.7 Communicable disease alert

(a) [The facility] **An agency** shall develop protocols for identifying and handling [high-risk] **dead bodies infected with a contagious, infectious, or communicable disease**, in accordance with [the Centers for Disease Control] **CDC** guidelines and in compliance with N.J.S.A. 26:6-8.2.

(b) In accordance with [the provisions of P.L. 1988, c.125 (Assembly bill 1457), the facility] **N.J.S.A. 26:6-8.2, an agency** shall complete the New Jersey State Department of Health [and Senior Services] form [HFE-4] **LCS-4**, “Communicable Diseases Alert,” [in] **available on the Department’s website at <http://www.state.nj.us/health/forms/lcs-4.pdf>**, when applicable [cases], and transmit **the form in the manner prescribed therein.**

SUBCHAPTER 13. PATIENT RIGHTS

8:42-13.1 Policies and procedures

(a) The [facility] **agency** shall establish and implement written policies and procedures regarding the rights of patients and the implementation of these rights.

1. A complete statement of these rights, including the right to file a complaint with the New Jersey Department of Health [and Senior Services], shall be distributed to all **patients**, staff, and contracted personnel.

2. These patient rights shall be made available in any language [which] **that** is spoken as the primary language by more than 10 percent of the population in the agency's service area.

8:42-13.2 Rights of each patient

[(b)] **(a)** Each patient shall be entitled to the following rights, none of which **an agency or its staff** shall [be] abridge[d] or violate[d by the facility or any of its staff]:

1. To treatment and services without discrimination based on race, age, religion, national origin, sex, sexual preference[s], handicap, diagnosis, ability to pay, or source of payment;

2. To be given a written notice, 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.

i. If [the] **a** patient is unable to respond, the **agency shall give the** notice [shall be given] to a family member or other responsible individual;

3. To be informed in writing of the following:

i. Services available from the [facility] **agency**;

ii. (No change.)

iii. The frequency of home visits to be provided; **and**

iv. The agency's daytime and emergency telephone numbers; [and]

[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:

Office of Certificate of Need and Healthcare Facility Licensure

New Jersey Department of Health and Senior Services

PO Box 358

Trenton, New Jersey 08625-0358]

4. To receive, in terms that the patient understands, an explanation of his or her plan of care, expected results, and reasonable alternatives.

i. If **receiving** this information would be detrimental to the patient's health, or if the patient is not able to understand the information, the **agency shall provide the** explanation [shall be provided] to a family member or guardian and document[ed] **the provision of the explanation** in the patient's medical record;

5. (No change.)

6. To receive [the] **ordered** care and health services [that have been ordered];

7. To participate in the planning of [his or her] **the patient's** home health care and treatment;

8. To refuse services, including medication and treatment, [provided by the facility] **that an agency provides** and to be informed of available home health treatment options, including the option of no treatment[,], and of the possible benefits and risks of each option;

9. To refuse to participate in experimental research.

i. If [he or she] **a patient** chooses to participate **in experimental research**, [his or her] **an agency shall obtain the patient's** written informed consent [shall be obtained];

10. To receive full information about financial arrangements, including, but not limited to:

i.-iii. (No change.)

iv. Description of agreements with third-party [payors] **payors** and/or other [payors] **payors** and referral systems for patients' financial assistance[.];

11. To express grievances **to an agency's staff and governing authority** regarding care and services [to the facility's staff and governing authority] without fear of reprisal, and to receive an answer to those grievances within a reasonable [period of] time[. The facility is required to provide each patient or guardian with the names, addresses, and telephone numbers of the government agencies to which the patient can complain and ask questions, including the New Jersey Department of Health and Senior Services Complaint Hotline at 1-800-792-9770];

12. To [freedom] **be free** from mental and physical abuse and from exploitation;

13. To [freedom] **be free** from restraints, unless they are authorized by a physician for a limited period of time to protect the patient or others from injury;

14. To be assured of confidential treatment of [his or her] **the patient's** medical/health record, and to approve or refuse in writing its release to any individual outside the [facility] **agency**, except as required by law or third-party payment contract;

15. To be treated with courtesy, consideration, respect, and recognition of [his or her] **the patient's** dignity, individuality, and right to privacy, including, but not limited to, auditory and visual privacy and confidentiality concerning patient treatment and disclosures;

16.-17. (No change.)

18. To retain and exercise to the fullest extent possible, all the constitutional, civil, and legal rights to which the patient is entitled by law, including religious liberties, the right to independent personal decisions, and the right to provide instructions and directions for health care in the event of future [decisionmaking] **decision making** incapacity in accordance with the New Jersey Advance Directives for Health Care Act, [P.L. 1991, c.201, and with N.J.A.C. 8:42-6.3] **N.J.S.A. 26:2H-53 et seq., the Physician Orders for Life-Sustaining Treatment Act, N.J.S.A. 26:2H-129 et seq., and with N.J.A.C. 8:42-6.5;**

19. To be transferred to another [facility] **agency** only for one of the reasons delineated at N.J.A.C. 8:42-[6.3(e); and] **6.6;**

20. To discharge himself or herself from treatment by the [facility.] **agency; and**

21. To file a complaint with the New Jersey Department of Health by:

i. Twenty-four-hour Complaint Hotline at 1 (800) 792-9770;

ii. In writing to:

Division of Health Facility Survey and Field Operations

New Jersey Department of Health

PO Box 367

Trenton, NJ 08625-0367;

iii. By fax to (609) 943-3013; or

iv. Online at: <http://web.doh.state.nj.us/fc/search.aspx>.

SUBCHAPTER 14. QUALITY ASSURANCE

8:42-14.1 Quality assurance organization

(a) The governing authority of the [facility] **agency** shall have ultimate responsibility for the quality assurance program.

(b) The [facility] **agency** shall establish and implement a written plan for a quality assurance program for patient care.

1. The plan shall include a mechanism to ensure participation of all disciplines in quality assurance activities and monitoring, and shall specify staff responsibilities for the quality assurance program.

8:42-14.2 Quality assurance policies and procedures

(a) The quality assurance plan shall be reviewed at least annually and revised as necessary.

1. Responsibility for reviewing and revising the plan shall be designated in the plan itself.

(b) – (c) (No change.)

(d) The ongoing quality assurance activities shall include, but not be limited to:

1. – 6. (No change.)

7. Evaluation by patients and their families of care and services provided by the [facility] **agency**; and

8. (No change.)

(e) Reports of the activities of all [facility] **agency** committees or their equivalents shall be made available to the advisory group specified in N.J.A.C. 8:42-6.1(a).

(f) The results of the quality assurance program shall be submitted to the governing authority at least annually, and shall include at least deficiencies found and recommendations for corrections or improvements.

1. The administrator shall, with the approval of the governing authority, implement measures to ensure that corrections or improvements are made.

**New Jersey Department of Health
Office of Certificate of Need and Healthcare Facility Licensure
P.O. Box 358
Trenton, NJ 08625-0358**

PROCEDURE FOR SUBMISSION OF A WAIVER REQUEST

- A request for waiver from the requirements of the Department of Health licensing standards or AIA Guidelines for Design and Construction of Hospital and Health Care Facilities shall be submitted to the Department of Health, Office of Certificate of Need and Healthcare Facility Licensure on the attached form.
- Application for Waiver shall be completed for EACH waiver requested and completed in its entirety.
- Application for Waiver shall be submitted by the owner, chief executive officer, chief operating officer or administrator of the existing or proposed facility.
- Application for Waiver shall be submitted to John A. Calabria, Director, at:

Mailing Address:

New Jersey Department of Health
Office of Certificate of Need and Healthcare Facility Licensure
P. O. Box 358
Trenton, NJ 08625-0358

Overnight Services (DHL, FedEx, UPS):

New Jersey Department of Health
Office of Certificate of Need and Healthcare Facility Licensure
171 Jersey Street, Building 5, 1st Floor
Trenton, NJ 08611-2425

- To obtain additional information regarding the waiver process, please call:

609-292-6552 Team A: for facilities located in Bergen, Hudson, Mercer, Morris, Passaic, Somerset, Sussex and Warren Counties

609-633-9042 Team B: for facilities located in Burlington, Gloucester, Hunterdon, Middlesex, Monmouth and Ocean Counties

609-292-7228 Team C: for facilities located in Atlantic, Camden, Cape May, Cumberland, Essex, Salem and Union Counties

**New Jersey Department of Health
Office of Certificate of Need and Healthcare Facility Licensure
P.O. Box 358
Trenton, NJ 08625-0358**

APPLICATION FOR WAIVER

(Requests for more than one waiver may not be combined. An Application for Waiver form must be completed for each waiver requested).

CN Ref. #	DCA Ref. #	Facility ID # (if currently licensed)
Name and Address of Facility:		
Name, Address and Telephone Number of Owner, Chief Executive Officer (CEO), Chief Operating Officer (COO), or Administrator of the Existing or Proposed Facility:		
Name, Address and Telephone Number of Architect:		
The owner, CEO, COO or Administrator of the existing or proposed health care facility hereby applies for a waiver to the following regulation (identify regulation by name, code citation (if applicable) and date (if applicable):		

APPLICATION FOR WAIVER (continued)

A. Provide the following information for each rule or part of rule for which a waiver is being requested. Attach additional sheets as necessary.

1. Restate rule or part of rule for which a waiver is being requested and identify the specific rule citation.

2. Describe the reasons for requesting a waiver, including a statement of the type and degree of hardship that would result upon compliance.

3. Describe an alternative proposal to ensure patient safety.

4. Is documentation attached to support the waiver request?

No Yes (Identify):

B. Is the project currently under review by the Department of Community Affairs, Health Care Plan Review?

No Yes (Identify DCA Reviewer)

C. Is the request for a waiver based on plan review comments by the Department of Community Affairs.

No Yes (Attach Comments)

Name of Owner, CEO, COO or Administrator	Title	
Signature of Owner, CEO, COO or Administrator		Date