

CHAPTER 42

LICENSING STANDARDS FOR HOME HEALTH AGENCIES

Authority

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

Source and Effective Date

R.1992 d.322, effective August 17, 1992.
See: 24 N.J.R. 2031(a), 24 N.J.R. 2941(a).

Executive Order No. 66(1978) Expiration Date

Pursuant to the requirements and criteria of Executive Order No. 66(1978), Chapter 42 expires on August 17, 1997.

Historical Note

All provisions of this chapter "Home Health Agencies" became effective May 26, 1976 as R.1976 d.164. See: 8 N.J.R. 182(c), 8 N.J.R. 282(a).

1976 Revisions: Amendments to Subchapter 2 "Standards for Licensure of Residential and Inpatient Drug Treatment Facilities" became effective December 9, 1976 as R.1976 d.356. See: 8 N.J.R. 462(a), 8 N.J.R. 550(b).

1978 Revisions: Amendments to Subchapter 2 became effective November 9, 1978 as R.1978 d.373. See: 10 N.J.R. 330(c), 10 N.J.R. 484(b).

1979 Revisions: Subchapter 3 "Alcohol Abuse Treatment Facilities" was adopted effective July 5, 1979 as R.1979 d.240. See: 11 N.J.R. 233(c), 11 N.J.R. 331(c). An amendment that extended the expiration of this Subchapter 3 was filed on December 14, 1979 as R.1979 d.486 to become effective December 31, 1979. See: 11 N.J.R. 546(a), 12 N.J.R. 15(d). Further amendments to extend the expiration date of Subchapter 3 became effective June 19, 1980. See: 12 N.J.R. 407(b).

1980 Revisions: Amendments became effective February 1, 1980 as R.1979 d.485. See: 11 N.J.R. 545(d), 12 N.J.R. 15(c). Further amendments became effective October 9, 1980 as R.1980 d.399. See: 12 N.J.R. 463(b), 12 N.J.R. 578(c).

1981 Revisions: Amendments became effective June 4, 1981 as R.1981 d.157. See: 13 N.J.R. 12(a), 13 N.J.R. 342(b). Subchapter 3 expired pursuant to Executive Order 66(1978) on June 30, 1981. (For current rules concerning "Alcoholism Treatment Facilities," see Chapter 42A.)

1982 Revisions: Subchapter 2 was readopted and became effective on November 1, 1982 (operative November 9, 1982) as R.1982 d.391. See: 14 N.J.R. 812(a), 14 N.J.R. 1214(a).

1983 Revisions: Amendments became effective March 7, 1983 as R.1983 d.66. See: 14 N.J.R. 1273(a), 15 N.J.R. 336(a). Subchapter 2 was repealed effective August 1, 1983, by R.1983 d.309. See: 15 N.J.R. 397(a), 15 N.J.R. 1248(a). (For the current "Standards for Licensure of Drug Treatment Facilities," see Chapter 42B.)

1985 Revisions: Amendments became effective February 4, 1985 as R.1985 d.26. See: 16 N.J.R. 3125(a), 17 N.J.R. 285(a). This chapter was readopted pursuant to Executive Order 66(1978) effective March 18, 1985 as R.1985 d.117. See: 16 N.J.R. 3250(a), 17 N.J.R. 704(b).

1987 Revisions: There was an administrative recodification to N.J.A.C. 8:42-1.4(b) from N.J.A.C. 8:31-26.5(b). See: 19 N.J.R. 662(c). There was an administrative recodification repealing old subsection (p) of N.J.A.C. 8:42-1.8 and recodifying to N.J.A.C. 8:31-26.4(p)-(s). See: 19 N.J.R. 662(c).

1989 Revisions: Petition for rulemaking, effective February 21, 1989. See: 21 N.J.R. 578(a). Petition concerns the testing and certification of homemaker/home health aides.

Pursuant to Executive Order No. 66(1978), Chapter 42 was readopted as R.1987 d.333, effective August 17, 1987 (operative October 17, 1987). See: 19 N.J.R. 2287(a), 19 N.J.R. 1547(a).

Chapter 42, Home Health Agencies, was repealed, and a new Chapter 42, Standards for Licensure of Home Health Agencies, was adopted by R.1992 d.322, effective August 17, 1992. See: Source and Effective Date.

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SUBCHAPTER 1. DEFINITIONS

8:42-1.1 Scope: purpose

(a) The rules in this chapter pertain to all home health agencies in the State of New Jersey.

(b) The purpose of this chapter is to assure the provision of high quality home health care services to the residents of New Jersey in a coordinated and cost-effective manner.

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:

“Activities of daily living (ADL)” means the functions or tasks for self-care which are performed either independently or with supervision or assistance. Activities of daily living include at least mobility, transferring, walking, grooming, bathing, dressing and undressing, eating, and toileting.

“Administrator” means a person who is administratively responsible and available for all aspects of facility operations, and:

1. Has a master's degree in administration or a health related field, and at least two years of supervisory or administrative experience in home health care or in a health care setting; or
2. Has a baccalaureate degree in administration or a health related field and four years of supervisory or administrative experience in home health care or in a health care setting.

“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.

“Audiologist” means a person who is so licensed by the Audiology and Speech-Language Pathology Advisory Committee of the Division of Consumer Affairs of the New Jersey State Department of Law and Public Safety.

“Available” means ready for immediate use (pertaining to equipment); capable of being reached (pertaining to personnel).

“Branch office” means a facility 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 a nursing supervisor or alternate coverage by a registered professional nurse on the premises during its hours of operation.

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

"Cleaning" means the removal by scrubbing and washing, as with hot water, soap or detergent, and vacuuming, of infectious agents and/or organic matter from surfaces on which and in which infectious agents may find conditions for surviving or multiplying.

"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 policies and procedures.

"Commissioner" means the New Jersey State Commissioner of Health.

"Communicable disease" means an illness due to a specific infectious agent or its toxic products, which occurs through transmission of that agent or its products from a reservoir to a susceptible host.

"Conspicuously posted" means placed at a location within the facility 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.

"Current" means up-to-date, extending to the present time.

"Department" means the New Jersey State Department of Health.

"Dietitian or dietary consultant" means a person who:

1. Is registered or eligible for registration by the Commission on Dietetic Registration of the American Dietetic Association; 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 or a dietetic traineeship approved by the American Dietetic Association or has one year of full-time, or full-time equivalent, experience in nutrition and/or food service management in a health care setting; or

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

"Director of Nursing" means a registered professional nurse who has at least one of the following qualifications:

1. A master's degree in nursing or a health related field and two years combined public health nursing and progressive management experience in public health nursing; or
2. A bachelor of science degree in nursing or a health related field and three years combined public health nursing and progressive management experience in public health nursing.

"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.)

"Documented" means written, signed and dated.

"Drug administration" means a procedure in which a prescribed drug or biological is given to a patient by an authorized person in accordance with all laws and rules governing such procedures. The complete procedure of administration includes removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container), verifying it with the prescriber's orders, giving the individual dose to the patient, seeing that the patient takes it (if oral), and recording the required information, including the method of administration.

"Full-time" means a time period established by the facility as a full working week, as defined and specified in the facility'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.

"Home health agency" means a facility which is licensed by the New Jersey State Department of Health to provide preventive, rehabilitative, and therapeutic services to patients in the patient's home or place of residence. All home health agencies shall provide nursing, homemaker-home health aide, and physical therapy services.

"Homemaker-home health aide" means a person who has completed a training program approved by the New Jersey Board of Nursing and who is so certified by that Board.

"Hours of operation" means normal business hours, during which the agency is open for business.

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

"Licensed nursing personnel" (licensed nurse) means registered professional nurses and practical (vocational) nurses licensed by the New Jersey State Board of Nursing.

"Licensed practical nurse" means a person who is so licensed by the New Jersey State Board of Nursing.

"Medication" means a drug or medicine as defined by the New Jersey State Board of Pharmacy.

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

"Nursing supervisor" means a registered professional nurse who has at least one of the following qualifications:

1. A bachelor of science degree in nursing and two years combined public health nursing and progressive professional responsibilities in public health nursing; or
2. Three years combined public health nursing and progressive professional responsibilities in public health nursing.

"Occupational therapist" means a person who is certified or eligible for certification as an occupational therapist, registered (OTR) by the American Occupational Therapy Association, and has at least one year of experience as an occupational therapist.

"Physical therapist" means a person who is so licensed by the New Jersey State Board of Physical Therapy.

"Physician" means a person who is licensed or authorized by the New Jersey State Board of Medical Examiners to practice medicine in the State of New Jersey.

"Plan of care" (nursing, rehabilitation, social work, dietary counseling) means a written plan based on an assessment of the patient and the care and treatment to be provided by each discipline. Each discipline that provides service shall initiate the development and implementation of its own service plan, including measurable goals with timeframes, at the time of the patient's admission to that service. If the patient does not need a specific service, a plan is not needed for that service.

"Plan of treatment" means a written plan established and authorized in writing by the physician based on an evaluation of the patient's immediate and long-term needs. This plan shall be:

1. Initiated and implemented when the patient is admitted;
2. Coordinated and maintained by the nursing service or the physical therapy service, if physical therapy is the sole service;
3. Inclusive of, but not limited to, the patient's diagnosis, patient goals, means of achieving goals, and care and treatment to be provided;
4. Current and available to all personnel providing patient care; and
5. Included in the patient's medical/health record.

"Progress note" means a written, signed, and dated notation by the practitioner providing care, periodically summarizing information about the care provided and the patient's response to it.

"Public health nursing" means a branch of nursing practice which has as its goals health promotion, health maintenance, primary prevention, health education and management, coordination of health care services, and continuity of care through the provision of health care to individuals, families, and groups in the community. These goals may be accomplished through activities which include, but are not limited to, making home visits to assess, plan for, and provide nursing services; providing instruction and direct nursing services in community health agencies; teaching subjects related to individual and community welfare; and coordinating services with other community agencies.

"Registered professional nurse" means a person who is so licensed by the New Jersey State Board of Nursing.

"Restraint" means devices, materials, or equipment that are attached or adjacent to a person and that prevent free bodily movement to a position of choice.

"Signature" means at least the first initial and full surname and title (for example, R.N., L.P.N., D.D.S., M.D.) of a person, legibly written either with his or her own hand, generated by computer with authorization safeguards, or communicated by a facsimile communications system (FAX) followed by the original.

"Social worker" means a person who has a master's degree in social work from a graduate school of social work accredited by the Council on Social Work Education, and at least one year of post-master's social work experience in a health care setting.

“Speech-language pathologist” means a person who is so licensed by the Audiology and Speech-Language Pathology Advisory Committee of the Division of Consumer Affairs of the New Jersey State Department of Law and Public Safety.

“Staff education plan” means a written plan developed at least annually and implemented throughout the year which describes a coordinated program for staff education for each service, including in-service programs and on-the-job training.

“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.

“Sterilization” means a process of destroying all microorganisms, including those bearing spores, in, on, and around an object.

“Supervision” means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity within his or her sphere of competence, with initial direction and periodic on-site inspection of the actual act of accomplishing the function or activity.

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 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 N.J.A.C. 8:33L. Application forms for a Certificate of Need and instructions for completion may be obtained from:

Certificate of Need Program
Division of Health Planning and Resources Development
New Jersey State Department of Health
CN 360
Trenton, NJ 08625

(c) The facility shall implement all conditions imposed by the Commissioner as specified in the Certificate of Need approval letter. 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 shall make application to the Commissioner for a license on forms prescribed by the Department in accordance with the requirements of this chapter. Such forms may be obtained from:

Director
Licensing, Certification and Standards
Division of Health Facilities Evaluation
New Jersey State Department of Health
CN 367
Trenton, NJ 08625

(b) The Department shall charge a nonrefundable fee of \$2,000 for the filing of an application for licensure and each annual renewal of a home health agency.

(c) The Department shall charge a nonrefundable fee of \$1,000 for the filing of an application for the transfer of ownership of a home health agency.

(d) The Department shall charge a nonrefundable fee of \$250.00 for the filing of an application for the relocation of a home health agency.

(e) Any person, organization, or corporation considering application for license to operate a facility shall make an appointment for a preliminary conference at the Department with the Licensing, Certification and Standards Program.

Amended by R.1996 d.339, effective July 15, 1996.
See: 28 N.J.R. 2365(a), 28 N.J.R. 3556(a).

8:42-2.3 Surveys and temporary license

(a) When the written application for licensure is approved and the building is ready for occupancy, a survey of the facility by representatives of the Health Facilities Inspection Program of the Department shall be conducted to determine if the facility adheres to the rules in this Chapter.

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

2. The facility shall notify the Health Facilities Inspection Program of the Department when the deficiencies, if any, have been corrected, and the Health Facilities Inspection Program will schedule one or more resurveys of the facility prior to issue of license.

(b) A temporary license may be issued to a facility when the following conditions are met:

1. An office conference for review of the conditions for licensure and operation has taken place between the Licensing, Certification and Standards Program and representatives of the facility, who will be advised that the purpose of the temporary license is to allow the Depart-

ment to determine the facility's compliance with N.J.S.A. 26:2H-1 et seq., and amendments thereto, and the rules pursuant thereto;

2. Written approvals are on file with the Department from the local zoning, fire, health, and building authorities;

3. Survey(s) by representatives of the Department indicate that the facility adheres to these rules; and

4. Professional personnel are employed in accordance with the staffing requirements in these rules.

(c) No health care facility shall accept patients until the facility has the written approval and/or license issued by the Licensing, Certification and Standards Program of the Department.

(d) Survey visits may be made to a facility at any time, or to a patient's home, by authorized staff of the Department. Such visits may include, but not be limited to, a review of all facility documents and patient records, and conferences with patients and/or their families.

(e) A temporary license may be issued to a facility for a period of six months and may be renewed as determined by the Department.

(f) The temporary license shall be conspicuously posted in the facility.

(g) The temporary license is not assignable or transferable and shall be immediately void if the facility ceases to operate or if its ownership changes.

8:42-2.4 Full license

(a) A full license shall be issued on expiration of the temporary license, 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., and amendments thereto, and by the rules in this chapter.

(b) A license shall be granted for a period of one year or less as determined by the Department. (See N.J.S.A. 26:2H-12.)

(c) The license shall be conspicuously posted in the facility.

(d) The license is not assignable or transferable and it shall be immediately void if the facility 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. The facility will receive a request for renewal fee 30 days prior to the expiration of the license. A renewal license shall not be issued unless the licensure fee is received by the Department.

(f) The license may not be renewed if local rules, regulations, and/or requirements are not met.

8:42-2.5 Surrender of license

The facility shall directly notify each patient, the patient's physician, and any guarantors of payment concerned at least 30 days prior to the voluntary surrender of a license, or as directed under an order of revocation, refusal to renew, or suspension of license. In such cases, the license shall be returned to the Licensing, Certification and Standards Program of the Department within seven working days after the revocation, non-renewal, or suspension of license.

8:42-2.6 Waiver

(a) The Commissioner or his or her designee may, in accordance with the general purposes and intent of this chapter, waive sections of the rules if, in his or her opinion, such waiver would not endanger the life, safety, or health of patients or the public.

(b) A facility seeking a waiver of these rules shall apply in writing to the Director of the Licensing, Certification and Standards Program of the Department.

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

1. The specific rule(s) or part(s) of the rule(s) for which waiver is requested;
2. Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the facility upon full compliance;
3. An alternative proposal which would ensure patient safety; and
4. Documentation to support the application for waiver.

(d) The Department reserves the right to request additional information before processing a request for waiver.

8:42-2.7 Action against a license

(a) If the Department determines that operational or safety deficiencies exist, it may require that all new admissions to the facility cease. This may be done simultaneously with, or in lieu of, action to revoke licensure and/or impose a fine. The Commissioner or his or her designee shall notify the facility in writing of such determination.

(b) The Commissioner may order the immediate cessation of services by a facility whenever he or she determines imminent danger to any person's health or safety.

(c) The provisions of (a) and (b) above shall apply to facilities with a temporary license and facilities with a full license.

8:42-2.8 Hearings

(a) If the Department proposes to suspend, revoke, deny or refuse to renew a license, the licensee or applicant may request a hearing which shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq. and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

(b) Prior to transmittal of any hearing request to the Office of Administrative Law, the Department may schedule a conference to attempt to settle the matter.

SUBCHAPTER 3. GENERAL REQUIREMENTS
8:42-3.1 Compliance with rules and laws

(a) The facility shall provide preventive, rehabilitative, and therapeutic services to patients. This shall include, but not be limited to, nursing, homemaker-home health aide, and physical therapy services. 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 case-loads, or in order to provide specialized care which is unavailable through existing staff;
2. Contracted nursing personnel are oriented to the policies and procedures of the facility and receive supervision from supervisory staff employed by the facility; and
3. Provisions are made for continuity of patient care by the same contracted nursing personnel whenever possible.

(c) Other services such as physical therapy, occupational therapy, speech-language pathology, audiology, dietary counseling, and social work services shall be available directly or through written agreement.

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

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

8:42-3.2 Ownership

(a) The ownership of the facility and the property on which it is located shall be disclosed to the Department. Proof of this ownership shall be available in the facility. Any proposed change in ownership shall be reported to the Director of the Licensing, Certification and Standards Pro-

gram of the Department in writing at least 30 days prior to the change and in conformance with the requirements for Certificate of Need applications.

(b) No health care facility shall be owned or operated by any person convicted of a crime relating adversely to the person's capability of owning or operating the facility.

8:42-3.3 Submission of documents

The facility shall, upon request, submit any documents which are required by these rules to the Director of the Licensing, Certification and Standards Program of the Department.

8:42-3.4 Personnel

(a) The facility 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) All personnel who require licensure, certification, or authorization to provide patients care shall be licensed, certified, or authorized under the appropriate laws or rules of the State of New Jersey.

(c) All personnel, both directly employed and under contract to provide direct care to patients, shall at all times wear or produce upon request employee identification.

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

(e) All new personnel, both directly employed and under contract to provide direct patient care, shall receive an initial health evaluation which includes at least a documented history.

(f) Employee health records shall be maintained for each employee. Employee health records shall be confidential, and kept separate from personnel records.

(g) The employee health record shall include documentation of all medical screening tests performed and the results.

(h) All personnel, both directly employed and under contract to provide direct care to patients, shall receive a Mantoux 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 by December 1, 1992 to all agency personnel, both directly employed and under contract, and thereafter to all new personnel at the time of employment. 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) The agency shall report annually on forms provided by the Department of Health the results of tuberculin testing for all agency personnel.

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

(l) The facility shall inform each person in writing of the results of his or her rubella screening test.

(m) The facility shall maintain a list identifying the name of each person who is seronegative and unvaccinated.

(n) 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.

(o) 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 shall be established, implemented, and reviewed at least annually. Each review of the manual(s) shall be documented, and the manual(s) shall be available in the facility 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;

2. An organizational chart delineating the lines of authority, responsibility, and accountability, so as to ensure continuity of care to patients;

3. A description of the quality assurance program for patient care and staff performance;

4. Definition and specification of full-time employment;

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. The development of written protocols for the identification and reporting of children and elderly or disabled adults who are abused and/or neglected;

ii. The designation of a staff member(s) to be responsible for coordinating the reporting 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 on the medical/health record, and serving as a liaison between the facility and the Division of Youth and Family Services; and

iii. The provision at least annually of education and/or training programs for all staff and subcontracted personnel who provide direct patient care regarding the identification and reporting of child abuse and/or neglect; sexual abuse; domestic violence; and abuse of the elderly or disabled adult.

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 Program Support, Division of Youth and Family Services, New Jersey State Department of Human Services, CN 717, Trenton, NJ 08625.

(b) The policy and procedure manual(s) shall be available and accessible to all patients, staff, and the public.

8:42-3.6 Staffing

(a) Provision shall be made for staff with equivalent qualifications to provide services for absent staff members. Staffing schedules shall be implemented to facilitate continuity of care to patients. The facility shall maintain staff attendance records.

(b) The facility 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 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 and by the person or agency providing the service;
2. Specify each party's responsibilities, functions, and objectives, the time during which services are to be provided, the financial arrangements and charges, and the duration of the written agreement or its equivalent;
3. Specify that the facility retain administrative responsibility for services rendered, including subcontracted services;
4. Require that services are provided in accordance with these rules and that personnel providing services meet training and experience requirements and are supervised in accordance with these rules; and
5. Require the provision of written documentation to the facility, including, but not limited to, documentation of services rendered by the person or agency providing the service.

8:42-3.8 Reportable events

(a) The facility shall notify the Department immediately by telephone (609-588-7725), followed within 72 hours by written confirmation, of the following:

1. Termination of employment of the administrator and/or the Director of Nursing, and the name and qualifications of his or her replacement;
2. Expected or actual interruption or cessation of operations and services listed in these rules; and
3. Any deaths resulting from accidents or incidents related to the facility's services.

(b) The facility shall provide statistical data as required by the Department.

8:42-3.9 Notices

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

1. All waivers granted by the Department;
2. All documents required by these rules;
3. A list of deficiencies from the last annual licensure inspection and certification survey report (if applicable), and the list of deficiencies from any valid complaint investigation during the past 12 months;
4. A list of the facility's committees, or their equivalents, and the membership and reports of each;

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

6. Any changes of membership of the governing authority, within 30 days after the change; and

7. Policies and procedures regarding patient rights.

8:42-3.10 Reporting information to the State Board of Medical Examiners

(a) In accordance with the Professional Medical Conduct Reform Act, P.L. 1989, c.300, the facility shall notify the Medical Practitioner Review Panel established by the New Jersey State Board of Medical Practitioners if a practitioner who is employed by or who is under contract to render professional services of all actions which result in reduction or restriction of staff privileges. The information to be reported shall include, but not be limited to, the following:

1. A disciplinary proceeding or action taken by the governing body against any practitioner licensed by the Board when the proceeding or action results in a practitioner's reduction or suspension of privileges or removal or resignation from the medical staff; and
2. A medical malpractice liability insurance claim settlement, judgment or arbitration award in which the facility is involved.

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

(c) Notifications shall be provided within seven days of the date of the action, settlement, judgment or award and shall be submitted on forms provided for that purpose. Forms shall be submitted to the New Jersey State Board of Medical Examiners, 28 West State Street, Trenton, New Jersey 08608. (Questions may be directed to the Board office at (609) 292-4843.)

8:42-3.11 Reporting to professional licensing boards

The facility 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. The governing authority shall be responsible for, but not limited to, the following:

1. Services provided and the quality of care rendered to patients;

2. Adoption and documented review of written bylaws or their equivalent at least every two years;
3. Development and documented review of all policies and procedures;
4. Establishment and implementation of a system to identify and resolve patient and staff grievances and/or recommendations, including those relating to patient rights. This system shall include a feedback mechanism through management to the governing authority, indicating what action was taken;
5. Determination of the frequency of meetings, which shall be at least annually, of the governing authority, holding such meetings, and documenting them through minutes, including a record of attendance;
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.

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 operations. If the facility has only one office, and if the qualifications for both positions are met, the director of nursing may function as the administrator.

(b) An alternate or alternates shall be designed in writing to act in the absence of the administrator.

8:42-5.2 Administrator's responsibilities

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

1. Ensuring the development, implementation, and enforcement of all policies and procedures, including patient rights;
2. Planning for and administering the managerial, operational, fiscal, and reporting components of the facility;
3. Participating in the quality assurance program for patient care;
4. Ensuring that all personnel are assigned duties based upon their education, training, competencies, and job descriptions;

5. Ensuring the provision of staff orientation and staff education; and

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

8:42-5.3 Director of Nursing's responsibilities

The director of nursing shall be responsible for the direction of patient care services provided to patients.

SUBCHAPTER 6. PATIENT CARE SERVICES

8:42-6.1 Advisory group

(a) The governing authority shall appoint an advisory group which ensures participation by at least one physician, the director of nursing and/or nursing supervisor, a consumer, and a representative of physical therapy services, and, if offered by the agency, occupational therapy, speech-language therapy, audiology, social work, and dietary counseling.

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

(c) The full advisory group shall meet at least annually.

Law Review and Journal Commentaries

Disputing Care Advance Care Directives. Robert J. Romano, Jr., 132 N.J.L.J. No. 15, S16 (1992).

8:42-6.2 Policies and procedures

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

1. Criteria for admission, discharge, and readmission of patients. Admissions criteria shall be based solely upon the patient's needs and the ability of the facility to meet safely the medical, nursing, and social needs of the patient. Discharge policies shall preclude punitive discharge.

2. Criteria for physicians orders for home health services, including timeframes and other requirements for written, verbal, and renewal orders. Physician orders for physical therapy, occupational therapy, and speech therapy shall include the modality, frequency, and duration of treatment.

3. Protocols for initiation, implementation, review, and revision of plans of care and of the service plan;

4. Protocols for reassessment of patients, in accordance with timeframes documented by each health care practitioner in the service plan;
5. Protocols for providing continuity of care by the same health care practitioner whenever possible;
6. Provision of care in accordance with the plan of care;
7. Provision of emergency care;
8. Policies and procedures for the use of restraints, including at least:
 - i. The need for written physicians orders;
 - ii. Indications and contraindications for use, including emergency use or use during medical procedures;
 - iii. Alternatives to physical restraints, such as environmental interventions or behavior management;
 - iv. The designation of staff who are authorized to use restraints according to scope of practice; and
 - v. Teaching the patient's family or primary caregiver the use of a progressive range of restraining procedures from the least restrictive to the most restrictive, the appropriate application and release of restraints, and observation of the patient;
9. Requirements for a discharge plan for each patient developed prior to the patient's discharge, and methods for including the patient and/or the patient's family in planning and implementing the discharge plan; and
10. A system for referral of patients to other sources of care.

8:42-6.3 Advance directives

(a) In accordance with the New Jersey Advance Directives for Health Care Act, P.L. 1991, c.201, the agency shall establish procedures for the resolution of conflict concerning the patient's decision-making capacity or the appropriate interpretation and application of the terms of an advance directive to the patient's course of treatment. The procedures may include consultation with an institutional ethics committee, a regional ethics committee, or another type of affiliated ethics committee, or with any individual or individuals who are qualified by training or experience to make clinical and ethical judgments.

(b) The agency shall establish a process for patients, families, and staff to address concerns relating to advance directives.

(c) The agency shall provide community education programs at least annually, individually or in coordination with other area agencies or organizations. These programs shall be provided within the agency's service area as recognized by the Certificate of Need process and shall provide infor-

mation to consumers regarding advance directives and their rights under New Jersey law to executive advance directives.

(d) The agency shall establish written policies and procedures governing the services provided to implement the New Jersey Advance Directives for Health Care Act, P.L. 1991, c.201. These policies and procedures shall be reviewed annually, revised as needed, and shall include at least:

1. Providing to each patient prior to the provision of care, or to family member or other representative if the patient is unable to respond, a written statement of the patient's rights under New Jersey law to make decisions including the right to refuse medical care and to formulate an advance directive, as well as the agency's written policies and procedures regarding implementation of such rights. This statement shall be issued by the Commissioner and shall be made available in any language which is spoken as the primary language by more than 10 percent of the population in the agency's service area;

2. Routinely inquiring of each adult patient, in advance of coming under the care of the agency and at other appropriate times, about the existence and location of an advance directive. If the patient is incapable of responding to this inquiry, the agency shall request the information from the patient's family or other representative. The response to this inquiry shall be documented in the patient's medical record;

3. Requesting and taking reasonable steps to obtain for all patients copies of currently executed advance directives, which shall be entered into the medical record;

4. Evaluating the validity of the advance directive, where a question of validity is indicated, and establishing procedures for assisting in the execution of a currently valid advance directive;

5. Providing appropriate written informational materials concerning advance directives to all interested patients, families, and health care representatives, and assistance or referral to staff or community resource persons for patients interested in discussing and executing an advance directive.

6. Delineation of the responsibilities of attending physicians, administration, nursing, social service, and other staff in regards to (d)1 through 5 above; and

7. Policies for transfer of the responsibility for care of patients with advance directives when a health care professional declines as a matter of professional conscience to participate in withholding or withdrawing life-sustaining treatment. Such transfer shall assure that the advance directive is implemented by the agency in accordance with the patient's wishes.

(e) A patient shall be transferred in 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 regulations; or

3. In conformance with the New Jersey Advance Directives for Health Care Act in the instance of a private, religiously affiliated home health agency which 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 which will implement the advance directive.

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

(g) The agency shall provide staff training and education programs regarding the New Jersey Advance Directives for Health Care Act, P.L. 1991, c.201, and the Federal Patient Self Determination Act, Pub.L. 101-508. This education and training shall address at least the following:

1. The rights and responsibilities of staff; and

2. Internal policies and procedures to implement these laws.

(h) The agency shall establish policies and procedure for the declaration of death of patients in accordance with N.J.S.A. 26:6 and the New Jersey Declaration of Death Act, P.L. 1991, c.90. Such policies shall also be in conformance with regulations and policies promulgated by the New Jersey Board of Medical Examiners which address declaration of death based on neurological criteria and the acceptable medical criteria, tests, and procedures that may be used. The policies and procedures must accommodate the patient's religious beliefs with respect to declaration of death.

8:42-6.4 Pharmacy and supplies

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

1. Provision for emergency supplies, including the contents, locations, and frequency of checking (including checking of expiration dates) of emergency supplies;

2. Requirements for the purchase, storage, handling, safeguarding, accountability, use, and disposition of medications in accordance with the New Jersey State Board of Pharmacy Rules (N.J.A.C. 13:39), the Controlled Dangerous Substances Act of 1970 (Title II, Pub.L. 91-153), and the New Jersey Controlled Dangerous Substances Act of 1970 (N.J.S.A. 24:21-1 et seq.) and amendments thereto;

3. Procedures for documenting all drug administration; and

4. Reporting and documenting medication errors and adverse drug reactions.

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

SUBCHAPTER 7. NURSING SERVICES

8:42-7.1 Provision of nursing services

The facility shall provide nursing services to patients who need these services.

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

(a) 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.

(b) The agency shall have written policies and procedures for the provision of nursing services that guide nursing practices in the agency. These policies shall be reviewed annually, revised as needed, and implemented. These policies and procedures shall conform with 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.

(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 shall appoint a full-time director of nursing who shall be available in the facility. An alternate or alternates shall be designated in writing to act in the absence of the director.

(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 verbal 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 public health nursing supervision to nursing personnel.

(c) A full-time nursing supervisor or alternate coverage by a registered professional nurse shall be available on the premises of each facility 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. 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; and

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.

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

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

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

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

2. Clinical notes and progress notes; and

3. A record of medications administered. After each administration of medication, the following shall be documented by the nurse who administered the drug: name and strength of the drug, data and time of administration, dosage administered, method of administration, and signatures of the licensed nurse who administered the drug.

8:42-7.5 Homemaker-home health aide services

(a) The facility shall provide homemaker-home health aide services in accordance with the following:

1. The homemaker-home health aide shall have completed a training program approved by the New Jersey Board of Nursing, shall be certified by the Board of Nursing, and shall provide verification of current certification for inclusion in the agency personnel record;

2. The homemaker-home health aide shall provide personal care and/or homemaking services under the direction and supervision of a registered professional nurse;

i. The registered professional nurse shall assign the homemaker-home health aide to a patient and shall give written instructions to the homemaker-home health aide regarding the home health services to be provided. The homemaker-home health aide shall document the 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;

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 meets the requirements specified in (a)1 above and 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, and assisting with prescribed exercises and the use of special equipment.

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

8:42-8.1 Services

(a) The facility shall provide physical therapy and may provide occupational therapy, speech-language pathology,

and audiology services, directly or through written agreement, to patients who need these services.

(b) The facility shall develop and implement written objectives, policies, a procedural manual, and a quality assurance program for rehabilitation services.

8:42-8.2 Responsibilities of rehabilitation personnel

(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 speech-language pathology and audiology personnel, in accordance also with the State of New Jersey Audiology and Speech-Language Pathology Practice Act, N.J.S.A. 45:3B-1 et seq.), each physical therapist, occupational therapist, speech-language pathologist, and audiologist shall be responsible for, but not limited to, the following:

1. Assessing the physical therapy, occupational therapy, speech-language pathology, or audiology needs of the patient, preparing the rehabilitation plan of care based on the assessment, providing rehabilitation services to the patient as specified in the rehabilitation plan of care, reassessing the patient's response to services provided, and revising the rehabilitation plan of care as needed. Each of these activities shall be documented in the patient's medical/health record;
2. Participating in the quality assurance program for rehabilitation services and patient care;
3. Participating in staff education activities and providing consultation to facility personnel; and
4. Communicating and documenting the communication with other disciplines and services to provide continuity and coordination of patient care.

8:42-8.3 Rehabilitation entries in the medical/health record

(a) Each physical therapist, occupational therapist, speech-language pathologist, or audiologist shall document in the patient's medical/health record:

1. The rehabilitation plan of care, which may be the rehabilitation portion of the patient's plan of care. The plan of care shall be reviewed and revised by the therapist, speech-language pathologist, or audiologist; and
2. Clinical notes and progress notes.

SUBCHAPTER 9. SOCIAL WORK SERVICES

8:42-9.1 Services

(a) Social work services may be provided directly or through written agreement to patients who need these services.

(b) Written objectives, policies, a procedure manual, an organizational plan, and a quality assurance program for social work services shall be developed and implemented.

8:42-9.2 Social worker's responsibilities

(a) Each social worker shall be responsible for, but not limited to, the following:

1. Performing a psychosocial assessment of the patient; preparing the social work plan of care based on the assessment; providing social work services to the patient as specified in the social work plan of care; reassessing the patient's response to services provided; and revising the social work plan of care as needed. Each of these activities shall be documented in the patient's medical/health record;
2. Contacting social service and other community resources for information, referrals, and services;
3. Providing social work counseling to the patient and his or her family;
4. Participating in the quality assurance program for social work services and patient care; and
5. Participating in staff education activities and providing consultation to facility personnel.

8:42-9.3 Social work entries in the medical/health record

(a) The social worker shall document in the patient's medical/health record:

1. The social work plan of care, which may be the social work portion of the patient treatment plan. The plan of care shall be reviewed and revised by the social worker; and
2. Clinical notes and progress notes.

SUBCHAPTER 10. DIETARY COUNSELING SERVICES

8:42-10.1 Services

(a) Dietary counseling services may be provided directly or through written agreement to patients who need these services.

(b) The facility shall develop and implement written objectives, policies, a procedure manual, and a quality assurance program for dietary counseling services.

8:42-10.2 Responsibilities of dietitian or dietary consultant

(a) Each dietitian or dietary consultant 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, providing dietary counseling services to the patient as specified in the dietary plan of care, reassessing the patient's response to services provided, and revising the dietary plan of care as needed. Each of these activities shall be documented in the patient's medical/health record;
2. Communicating and documenting the communication with other disciplines and services to provide continuity and coordination of patient care;
3. Participating in the quality assurance program for dietary counseling services and patient care; and
4. Participating in staff education activities and providing consultation to facility personnel.

8:42-10.3 Dietary entries in the medical/health record

- (a) The dietitian or dietary consultant shall document in the patient's medical/health record:
1. The dietary plan of care, which may be the dietary counseling portion of the patient's plan of care. The plan of care shall be reviewed and revised by the dietitian or dietary consultant; and
 2. Clinical notes and progress notes.

SUBCHAPTER 11. MEDICAL/HEALTH RECORDS

8:42-11.1 Medical/health records organization

- (a) The facility shall develop written objectives, policies and procedures, an organizational plan, and a quality assurance program for medical/health records services. The quality assurance program shall include monitoring medical/health records for accuracy, completeness, legibility, and accessibility.
- (b) At least 14 days before a facility plans to cease operations, it shall notify the New Jersey Department of Health in writing of the location and method for retrieval of medical/health records.
- (c) There shall be a system for identifying medical/health records to facilitate their retrieval by patient identifier.
- (d) Medical/health records shall be organized with a uniform format for all records.
- (e) The patient's medical/health record shall be available to the health care practitioners involved in the patient's care.

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

- (a) The facility 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. Entries for clinical treatment, which shall be included in the medical/health record within 14 days;
 2. Procedures for record completion, including review for accuracy and completion, which shall occur within 45 days;
 3. Procedures for the protection of medical record information against loss, tampering, alteration, destruction, or unauthorized removal or use;
 4. Conditions, procedures, and fees for releasing medical information; and
 5. Release and/or provision of copies of the patient's medical/health record to the patient and/or the patient's authorized representative, including, but not be limited to, the following:
 - i. Establishment of a fee schedule for obtaining copies of the patient's medical/health record;
 - ii. Availability of the patient's medical/health record to the patient's authorized representative if it is medically contraindicated (as documented by a physician in the patient's medical/health record) for the patient to have access to or obtain copies of the record; and
 - iii. Procedures to ensure that a copy of the patient's medical/health record is provided within 30 calendar days of a written request.
- (b) All entries in the patient's medical/health record shall be typewritten or written legibly in ink, and shall include date, signature, title, or authentication if an electronic system is used.
- (c) A medical/health record shall be initiated for each patient upon admission and shall include at least the following:
1. Patient identification data, including name, date of admission, address, date of birth, sex, race and religion (optional), next of kin, and person to notify in an emergency;
 2. Name, address, and telephone number of the patient's physician, an alternate physician, and other primary health care providers if any;
 3. A plan of treatment as defined at N.J.A.C. 8:42-1.1. This plan shall be:
 - i. Initiated and implemented when the patient is admitted;

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

iii. Inclusive of, but not limited to, the patient's diagnosis, patient goals, means of achieving goals, and care and treatment to be provided;

iv. Current and available to all personnel providing patient care; and

v. Included in the patient's medical/health record.

4. A plan of care as defined at N.J.A.C. 8:42-1.1, including an assessment and plan by each discipline involved in the patient's care;

5. All physician orders;

6. All telephone orders, which must be countersigned by a physician within 14 days;

7. Clinical notes;

8. Progress notes;

9. A record of medications if administered, including the name and strength of the drug, date and time of administration, dosage administered, method of administration, and signature of the person who administered the drug. This record shall include action, side effects and contraindications of medications where clinically indicated;

10. Documentation of allergies in the medical/health record and on its outside front cover;

11. An immunization record, in accordance with the facility's policies and procedures;

12. Written informed consents if indicated;

13. A copy of the patient's advance directive, if available, or documentation of the existence or nonexistence of an advance directive; and documentation of the agency's inquiry to the patient, family, or health care representative regarding this;

14. Copies of written instructions given to the patient and/or the patient's family;

15. A record of any treatment, medication, or service in the service plan that is not provided and the reason, including patient refusal; and

16. A comprehensive discharge summary with narrative information from each service within 30 days of discharge unless the patient is readmitted during that 30 day period.

(d) If the patient is transferred to another 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 agency at the time of transfer. The transfer record shall contain at least the following information:

1. Diagnosis, including history of any serious condition unrelated to the proposed treatment which might require special attention to keep the patient safe;

2. Physician orders in effect at the time of transfer and the last time each medication was administered;

3. The patient's nursing needs;

4. Hazardous behavioral problems;

5. Drug and other allergies;

6. Reason for transfer; and

7. A copy of the patient's advance directive if available or notice of the existence of an advance directive.

(e) All consent forms for treatment shall be printed in an understandable format and the text written in clear, legible, nontechnical language. If a family member or other patient representative signs the form, the reason for the patient's not signing it and the signer's relationship to the patient shall be indicated on the form.

(f) Medical records shall be completed within 45 days of discharge.

(g) The agency shall develop policies and procedures for the removal of the medical/health record, which shall occur only under the following conditions:

1. No medical/health record or parts thereof shall be removed from the agency except for purposes of providing clinical patient care and treatment;

i. Any such record or part thereof which is removed from the agency shall be returned to the agency during the next business day;

2. If there is a court order or subpoena for its release; or

3. To safeguard the record in case of a physical plant emergency or natural disaster; and

4. There shall be a system to protect the security and confidentiality of all components of the medical/health record at all times.

(h) Medical records shall be retained and preserved in accordance with N.J.S.A. 26:8-5 et seq.

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.

(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. The designated person shall be responsible for, but not limited to, developing and maintaining written objectives, a policy and procedure manual, a system for data collection, and a quality assurance program for the infection prevention and control service.

8:42-12.2 Infection control policies and procedures

(a) The facility shall have a multidisciplinary committee which establishes and implements an infection prevention and control program.

(b) The designated committee 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 Occupational Exposure to Hepatitis B Virus (HVB) and Human Immunodeficiency Virus (HIV)," OSHA Instruction CPL 2-2.44A, August 15, 1988 or revised or later editions, if in effect incorporated herein by reference;
2. In accordance with N.J.A.C. 8:57, a system for investigating, reporting, and evaluating the occurrence of all infections or diseases which are reportable or conditions which may be related to activities and procedures of the facility, and maintaining records for all patients or personnel having these infections, diseases, or conditions;
3. Aseptic technique, employee health, and staff training, the prevention of infection, and general improvement of patient care as it relates to infection control and prevention;
4. Exclusion from work, and authorization to return to work, for personnel with communicable diseases;
5. Surveillance techniques to minimize sources and transmission of infection;
6. The prevention of decubitus ulcers;
7. Sterilization, disinfection, and cleaning practices and techniques including, but not limited to, the following:
 - i. Care of utensils, instruments, solutions, dressings, articles, and surfaces;
 - ii. Selection, storage, use, and disposition of single use and nondisposable patient care items;
 - iii. Methods to ensure that sterilized materials are packaged, labeled, processed, transported, and stored

to maintain sterility and to permit identification of expiration dates; and

iv. Care of urinary catheters, intravenous catheters, respiratory therapy equipment, and other devices and equipment that provide a portal of entry for pathogenic microorganisms; and

8. Collection, handling, storage, decontamination, disinfection, sterilization, and disposal of regulated medical waste and all other solid or liquid waste.

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, D.C. 20402

8:42-12.3 Infection control measures

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

1. Guideline for Prevention of Catheter-Associated Urinary Tract Infections;
2. Guideline for Prevention of Intravascular Infections;
3. Guideline for Prevention of Surgical Wound Infections; and
4. Guideline for Handwashing and Hospital Environmental Control.

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

(a) The facility 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. Other patient care items which are reused shall be reprocessed and reused in accordance with manufacturers' recommendations;
2. Sterilized materials shall be marked with an expiration date and shall not be used subsequent to the expiration date;
3. Sterilized materials shall be packaged and labeled so as to maintain sterility and so as to permit identification of expiration dates; and

4. Expiration dates shall be assigned to sterilized materials in accordance with the following:

- i. Double-wrapped muslin/paper wrappers shall be marked with an expiration date not to exceed one month following sterilization;
- ii. Heat-sealed paper/plastic wrappers shall be marked with an expiration date not to exceed one year following sterilization; and
- iii. Self-sealed packaging shall be marked with an expiration date not to exceed the manufacturer's recommendation.

8:42-12.5 Care and use of sterilizers

- (a) Sterilizers shall be kept clean.
- (b) Sterilizer drains shall be flushed at least weekly, unless otherwise specified by the manufacturer, and a record shall be maintained.
- (c) At the completion of each sterilization load, the time, temperature, and pressure readings shall be checked and recorded.
- (d) A record of each sterilization load, including the date, the load number, the contents of the load, and the expiration dates of the contents, shall be maintained for at least one year.

8:42-12.6 Regulated medical waste

- (a) Regulated medical waste shall be collected, stored, handled, and disposed of in accordance with applicable Federal and State laws and regulations.
- (b) The facility 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, and all rules and regulations promulgated pursuant to the aforementioned Acts.

8:42-12.7 Communicable diseases alert

The facility shall develop protocols for identifying and handling high-risk bodies, in accordance with centers for Disease Control guidelines and in compliance with N.J.S.A. 26:6-8. In accordance with the provisions of P.L. 1988, c.125 (Assembly bill 1457), the facility shall complete the New Jersey State Department of Health form HFE-4, "Communicable Diseases Alert," in applicable cases.

8:42-12.8 Orientation and in-service education

- (a) Orientation for all new employees and staff under contract to provide direct patient care shall include infection control practices for the employee's specific discipline and the rationale for the practices.

- (b) The designated committee shall coordinate educational programs to address specific problems at least annually for staff in all disciplines and patient care services.

SUBCHAPTER 13. PATIENT RIGHTS

8:42-13.1 Policies and procedures

(a) The facility shall establish and implement written policies and procedures regarding the rights of patients and the implementation of these rights. A complete statement of these rights, including the right to file a complaint with the New Jersey Department of Health, shall be conspicuously posted in the facility and shall be distributed to all staff and contracted personnel. These patient rights shall be made available in any language which is spoken as the primary language by more than 10 percent of the population in the agency's service area.

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

1. To treatment and services without discrimination based on race, age, religion, national origin, sex, sexual preferences, 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. If the patient is unable to respond, the notice shall be given to family member or other responsible individual;
3. To be informed in writing of the following:
 - i. Services available from the facility;
 - ii. The names and professional status of personnel providing and/or responsible for care;
 - iii. The frequency of home visits to be provided;
 - iv. The agency's daytime and emergency telephone numbers; and
 - v. Notification regarding the filing of complaints with the New Jersey Department of Health 24-hour Complaint Hotline at 1-800-792-9770, or in writing to:

Division of Health Facilities Evaluation and Licensing

New Jersey State Department of Health

CN 367

Trenton, New Jersey 08625

4. To receive, in terms that the patient understands, an explanation of his or her plan of care, expected results, and reasonable alternatives. If this information would be detrimental to the patient's health, or if the patient is not able to understand the information, the explanation shall be provided to a family member or guardian and documented in the patient's medical record;

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

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

7. To participate in the planning of his or her home health care and treatment;

8. To refuse services, including medication and treatment, provided by the facility 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. If he or she chooses to participate, his or her written informed consent shall be obtained;

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

i. Fees and charges, including any fees and charges for services not covered by sources of third-party payment;

ii. Copies of written records of financial arrangements;

iii. Notification of any additional charges, expenses, or other financial liabilities in excess of the predetermined fee; and

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

11. To express grievances 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 Complaint Hotline at 1-800-792-9770;

12. To freedom from mental and physical abuse and from exploitation;

13. To freedom 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 medical/health record, and to approve or refuse in

writing its release to any individual outside the facility, except as required by law or third-party payment contract;

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

16. To be assured of respect for the patient's personal property;

17. To join with other patients or individuals to work for improvements in patient care;

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 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;

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

20. To discharge himself or herself from treatment by the facility.

SUBCHAPTER 14. QUALITY ASSURANCE

8:42-14.1 Quality assurance organization

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

(b) The facility shall establish and implement a written plan for a quality assurance program for patient care. 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. Responsibility for reviewing and revising the plan shall be designated in the plan itself.

(b) The quality assurance program shall include regularly collecting and analyzing data to help identify health-service problems and their extent, and recommending, implementing and monitoring corrective actions on the basis of these data.

(c) The quality assurance plan shall designate the frequency of data collection to ensure regular monitoring of patient care activities.

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

1. Incident review;
2. Evaluation of patient care services and statistics;
3. Monitoring of infection prevention and control;
4. Evaluation of staffing patterns and staff qualifications and credentials;
5. Evaluation of clinical competence of all clinical practitioners;
6. Evaluation of staff orientation and staff education;
7. Evaluation by patients and their families of care and services provided by the facility; and

8. Audit, at least quarterly, of patient medical/health records (including those of both active and discharged patients) to determine if care has conformed to criteria established by each patient care service for the maintenance of quality of care.

(e) Reports of the activities of all facility 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. The administrator shall, with the approval of the governing authority, implement measures to ensure that corrections or improvements are made.