significant adverse drug reactions, drug-to-drug and drug-food interactions, allergies, contraindications, rationality of therapy, drug use evaluation, and laboratory test results.

"Epidemic" means the occurrence or outbreak in a facility of one or more cases of an illness in excess of normal expectancy for that illness, derived from a common or propagated source.

"Facility" means a facility or distinct part of a facility licensed by the New Jersey State Department of Health and Senior Services as a long-term care facility.

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

"Guardian" means a person appointed by a court of competent jurisdiction to handle the affairs and protect the rights of any resident of the facility.

"Health care facility" means a facility so defined in N.J.S.A. 26:2H-1 et seq., and amendments thereto.

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

"Medication error" means a discrepancy between what the prescriber ordered and what the resident receives. The error may or may not be seen by the (pharmacist) surveyor during an observation of a resident receiving medication. If a medication error is seen by the surveyor during a medication observation pass, it shall be included in determining the medication error rate.

"Medication error rate" is calculated by the following equation: (number of errors observed divided by the opportunities for errors) x 100.

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

"Pharmacist" means an individual so licensed by the New Jersey State Board of Pharmacy, pursuant to N.J.A.C. 13:39-3.

"Physician" means a person licensed to practice medicine by the New Jersey State Board of Medical Examiners, pursuant to N.J.S.A. 45:9-1 et seq.

"Reasonable hour" means any time between the hours of 8:00 A.M. and 8:00 P.M. daily.

"Resident" means a person who resides in the facility and is in need of 24-hour continuous nursing supervision.

"Self administration" means a procedure in which any medication is taken orally, injected, inserted, or topically or otherwise administered by a resident to himself or herself. The complete procedure of self-administration includes:

1. Removing an individual dose from a previously dispensed (in accordance with the New Jersey State Board of Pharmacy Rules, N.J.A.C. 13:39), labeled container (including a unit dose container);

2. Verifying it with the directions on the label; and

3. Taking orally, injecting, inserting, or topically or otherwise administering the medication.

"Shift" means a time period defined as a full working day by the facility in its policy manual.

"Signature" means at least the first initial and full surname and title (for example, R.N., L.P.N., D.D.S., M.D., D.O.) of a person, legibly written with his or her own hand. A controlled electronic signature system may be used.

"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. "Direct supervision" means supervision on the premises within view of the supervisor.

"Unit-of-use" means a system in which drugs are delivered to the resident areas either in single unit packaging, bingo or punch cards, blister or strip packs, or other system where each drug is physically separate.

Amended by R.2005 d.400, effective November 21, 2005.
See: 37 N.J.R. 1932(a), 37 N.J.R. 4437(a).
Added definition "Defibrillator".

SUBCHAPTER 2. LICENSURE PROCEDURE

8:39-2.1 Certificate of need

(a) According to the Health Care Facilities Planning Act, P.L. 1971, c.136 and c.138, N.J.S.A. 26:2H-1 et seq., and amendments thereto, a health care facility shall not be instituted, constructed, expanded, or licensed to operate except upon application for and receipt of a certificate of need issued by the Commissioner, in accordance with N.J.A.C. 8:33. Facilities exempt from certificate of need pursuant to law shall follow licensing procedures identified in N.J.A.C. 8:39-2.2.

(b) Application forms for a certificate of need and instructions for completion may be obtained from:

Office of Certificate of Need and Healthcare Facility Licensure
Division of Healthcare Facilities Evaluation and Licensing
New Jersey State Department of Health and Senior Services
PO Box 358
Trenton, NJ 08625-0358

(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 the

Health Care Facilities Planning Act, P.L. 1971, c.136 and c.138, N.J.S.A. 26:2H-1 et seq., and amendments thereto.

Amended by R.2007 d.83, effective March 19, 2007.
See: 38 N.J.R. 4141(a), 39 N.J.R. 924(a).
In (b), updated address.

8:39-2.2 Application for licensure

(a) Following acquisition of a certificate of need, or a determination that a certificate of need is not required, any person, organization, or corporation desiring to operate a facility shall make application to the Commissioner for a license on Appendix E, incorporated herein by reference which includes information regarding facility ownership, corporate officers and stockholders, and approval forms from local building, fire, health and zoning departments. A license application may be obtained from:

Office of Certificate of Need and Healthcare Facility Licensure
Division of Healthcare Facilities Evaluation and Licensing
New Jersey State Department of Health and Senior Services
PO Box 358
Trenton, NJ 08625-0358

(b) The Department shall charge the following nonrefundable fees:

Annual licensure fee (new and renewal)	$1,500 plus $15.00 per bed
Add-a-bed	$1,500 plus $15.00 per additional bed
Hemodialysis provided by the LTC facility	$1,125
Hemodialysis provided by a separate provider	$750.00
Relocation of a facility (within the same county)	$375.00
Transfer of ownership (includes initial licensure fee)	$2,500 plus $15.00 per bed
Reduction in services or beds	$250.00

Neither the maximum annual licensure fee nor the fee for transfer of ownership for any single facility shall exceed $4,000.

(c) 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 Long-Term Care Licensing and Certification Program.

(d) For all projects that are exempt from the certificate of need requirement, the Department shall evaluate the track record of the applicant in accordance with N.J.A.C. 8:33-4.10(e).

(e) Any applicant denied a license to operate a facility shall have the right to a hearing in accordance with N.J.A.C. 8:33-4.10(e)4.

Amended by R.2004 d.160, effective April 19, 2004.
See: 35 N.J.R. 4838(a), 36 N.J.R. 1962(a).
In (b), increased fees throughout the table.
Amended by R.2007 d.83, effective March 19, 2007.
See: 38 N.J.R. 4141(a), 39 N.J.R. 924(a).
In (a), substituted "Appendix E, incorporated herein by reference" for "forms prescribed by the Department", "includes" for "include" and "A license application" for "Such forms", and updated address; and in (b), inserted table entry for "Reduction in services or beds".

8:39-2.3 Newly constructed, expanded, or renovated facilities

Any construction, expansion, or renovation of a facility shall be completed in accordance with N.J.A.C. 8:39-31, Mandatory Physical Environment.

8:39-2.4 Surveys and license

(a) A license shall be issued to the operator of a facility when all of the following conditions are met:

1. A completed licensure application and the appropriate fee have been submitted;

2. An office conference for review of the conditions for licensure and operation has taken place between the Long-Term Care Licensing and Certification Program and representatives of the facility;

3. The applicant has submitted the following documents to the Long-Term Care Licensing and Certification Program: a copy of the certificate of occupancy, and written approvals from the Health Care Plan Review Unit of the New Jersey Department of Community Affairs and the local health authority;

4. Written approvals of the water supply and sewage disposal system from local officials are on file with the Department for any water supply or sewage disposal system not connected to an approved municipal system; and

5. Survey(s) by representatives of the Department indicate that the facility meets the mandatory standards set forth in this chapter.

(b) No facility shall begin to operate without prior approval from the Long-Term Care Licensing and Certification Program of the Department.

(c) The facility shall accept no more than that number of residents for which it is approved and/or licensed.

(d) Survey visits shall be made to a facility at any time by authorized staff of the Department. Such visits shall include, but shall not be limited to, the review of all facility documents and resident records and conferences with residents.

(e) The license shall be granted for a period of one year, unless suspended or revoked, and shall be renewable annually on the original licensure date, or within 30 days thereafter, in accordance with the following:

1. The facility shall receive a request for renewal fee as provided in N.J.A.C. 8:39-2.2(b), along with an application

(b) Each resident, resident's next of kin, and resident's guardian shall be informed of the resident rights enumerated in this subchapter, and each shall be explained to him or her. None of these rights shall be abridged or violated by the facility or any of its staff.

SUBCHAPTER 5. MANDATORY ACCESS TO CARE

8:39–5.1 Mandatory policies and procedures for access to care

(a) The facility shall comply with applicable Federal, State, and local laws, rules, and regulations.

(b) There shall be no discrimination against any resident or group of residents based on method of payment.

(c) The facility shall meet all currently applicable conditions attached to any certificate of need that has been granted to it.

(d) If a facility has reason to believe, based on a resident's behavior, that the resident poses a danger to himself or herself or others, and that the facility is not capable of providing proper care to the resident, then an evaluation should be performed and documented in accordance with the Guidelines for Inappropriate Behavior and Resident to Resident Abuse in Appendix B, incorporated herein by reference.

(e) The facility shall make available to indigent individuals at least five percent of its beds or, if the facility is licensed for 100 or more beds, at least 10 percent of its beds. For purposes of this section, an individual is "indigent" if he or she is an applicant for admission or a current resident of the facility, and if he or she would otherwise meet the eligibility requirements of Medicaid reimbursement or county or municipal financial assistance for nursing home care.

8:39–5.2 Admissions

(a) The facility shall establish a single waiting list in chronological order. The order of names shall be predicated upon the order in which a completed written application is received. Hospitalized individuals ready for readmission to the facility are to be added to the top of the list as soon as the hospital notifies the facility of the contemplated discharge. As soon as a bed becomes available, it shall be filled from this waiting list. Provisions can be made for emergency, life-threatening situations or life-care community admissions.

1. The facility shall meet the following requirements:

i. The facility shall maintain only one waiting list; this list shall reflect a roster updated on a regular basis, of all individuals who have applied for admission to the facility;

ii. The waiting list shall reflect in chronological order the full name and address of the individual applying by the date the written application for admission is made;

iii. Facilities that participate in the Medicaid program shall utilize the waiting list to admit individuals on a first-come, first-serve basis in the order in which they apply until the provider's Medicaid occupancy level equals the Statewide occupancy level, or the Medicaid occupancy level set forth in the provider's Certificate of Need, whichever is higher; and

iv. A file shall be maintained containing full documentation to support any valid reason why the individual whose name appears first on the waiting list is not admitted to the facility.

2. Any Medicaid participating facility whose Medicaid occupancy level is less than the Statewide occupancy level shall not deny admission to a Medicaid eligible individual who has been authorized for nursing facility services by the Long-Term Care Field Office when a bed becomes available in accord with the waiting list.

i. Under the provisions of N.J.S.A 10:5–12.2, a facility with a residential unit or a life-care community may give its own residents priority when a bed becomes available.

(b) The facility shall not deny admission to any applicant for admission ("applicant for admission" means an individual who has made a formal application) based on diagnosis or health care needs if the applicant's health care needs can be reasonably accommodated without reducing the quality of care provided to other residents, and are commensurate with the services provided by the facility.

(c) Whenever the facility denies admission to an applicant for admission, the facility, within 14 days of the denial, shall provide written notice of the denial and the reasons therefore, to the applicant or person applying on the applicant's behalf. A record of each completed application, including the disposition and stated reason if admission is denied, shall be kept for one year.

8:39–5.3 Transfers

(a) Policies for transfer shall include method of transportation, procedures for security of the resident and all personal belongings or other items that accompany or immediately follow a transferred resident, a transfer form that is consistent with "Patient Information Transfer Form" in Appendix C, incorporated herein by reference, copies of relevant medical records, including assessments (MDS; PASRR) and advance directives if applicable.

(b) The facility shall arrange for transfer of residents to other health care facilities, and to health care services

provided outside the nursing home, and in accordance with the physician's or advanced practice nurse's orders.

(c) All transfers shall be in accordance with N.J.A.C. 8:39–4.1.

8:39–5.4 Discharges

(a) No resident shall be discharged between 5:00 P.M. and 8:00 A.M., except in an emergency or with the consent of the resident and family or responsible person.

(b) Discharge plans, for those residents considered to be likely candidates for discharge into the community or a less intensive care setting, shall be developed by the interdisciplinary team prior to discharge and shall reflect communication with the resident and/or the resident's family.

(c) All discharges shall be in accordance with N.J.A.C. 8:39–4.1 and 39.

SUBCHAPTER 6. ADVISORY ACCESS TO CARE

8:39–6.1 Advisory admission policies and procedures

(a) The waiting list of the facility incorporates a system to contact applicants or families at least quarterly, or according to an alternate schedule approved by the Department, to advise them concerning the status of the application and to inquire of the applicant's interest in remaining on the waiting list.

(b) Before admission, the resident's physician, the facility's social worker, the facility's admissions officer (if different from the social worker), and a registered professional nurse discuss the appropriateness of the placement.

(c) The facility makes available to indigent individuals at least 10 percent of its beds or, if the facility is licensed for 100 or more beds, at least 15 percent of its beds. For purposes of this subsection, an individual is "indigent" if he or she is an applicant for admission or a current resident of the facility, and if he or she would otherwise meet the eligibility requirements of Medicaid reimbursement or county or municipal financial assistance for nursing home care.

(d) The facility provides a copy of admissions policies and criteria to all applicants for admission.

SUBCHAPTER 7. MANDATORY RESIDENT ACTIVITIES

8:39–7.1 Mandatory administrative organization for resident activities

(a) The director of resident activities shall supervise all resident activity staff and coordinate all resident activity programs.

(b) The director of resident activities shall hold at least one of the following four qualifications:

1. A baccalaureate degree from an accredited college or university with a major area of concentration in recreation, creative arts therapy, therapeutic recreation, art, art education, psychology, sociology, or occupational therapy;

2. A high school diploma and three years of experience in resident activities in a health care facility and satisfactory completion of an activities education program approved by the Department, after a review of the specific curriculum, consisting of 90 hours of training, and incorporating the following elements:

i. Overview of the activity profession;

ii. Human development: the late adult years;

iii. Standards of practice: practitioner behavior;

iv. Activity care planning for quality of life; and

v. Methods of service delivery in the activity profession;

3. Served as director of resident activities on June 20, 1988, and has continuously served as activities director since that time; or

4. Holds current certification from the National Certification Council for Activity Professionals (National Certification Council for Activity Professionals, P.O. Box 62589, Virginia Beach, Virginia 23466–2589) or the National Council for Therapeutic Recreation Certification (National Council for Therapeutic Recreation, Inc., P.O. Box 479, Thiells, NY 10984–0479).

(c) Activities directors who are employed in that capacity as of August 20, 2001, and who have completed an activities education course which was previously approved by the Department, shall not be required to complete the course described at (b)2 above.

8:39–7.2 Mandatory staffing amounts and availability for activities

An average of 45 minutes of resident activities staff time per resident per week shall be devoted to resident activities, which requires at least one full-time equivalent staff member for every 53 residents.

8:39–7.3 Mandatory resident activity services

(a) Resident activities staff shall arrange a diversity of programs to maintain residents' sense of usefulness and self-respect. Included shall be activities in each of the following categories:

1. Social (for example, parties, club meetings, picnics, and other special events);

2. Physical (for example, exercise, sports, dancing, and swimming);

4. Methods for documentation in the medical record, based on resident assessment;

5. Training of residents in self-administration by the nursing staff or the consultant pharmacist; and

6. Policies for individual assessment of residents' ability to self-administer medications.

(d) Medications shall be accurately administered and documented by properly authorized individuals, as per prescribed orders and stop order policies.

8:39-29.3 Mandatory pharmacy reporting policies and procedures

(a) The consultant pharmacist shall conduct a drug regimen review and enter appropriate comments into the medical record of every resident receiving medication, at least monthly, on a pharmacist consultation sheet or another portion of the medical record in accordance with N.J.A.C. 13:39. The drug regimen review shall be performed in accordance with Federal and State statutes, rules and regulations, and currently accepted standards of practice for rational drug therapy.

1. The consultant pharmacist shall report any irregularities promptly to the attending physician or advanced practice nurse and to the director of nurses and these reports shall be acted upon. These reports shall include, but are not limited to, problems and recommendations about drug therapy which may be affected by biologicals, laboratory tests, special dietary requirements and foods used or administered concomitantly with other medication to the same recipient. Also, these reports are required to include monitoring for potential adverse effects, allergies, drug interactions, contraindications, rationale, and drug evaluation.

2. Drug product defects and adverse drug reactions shall be reported in accordance with the ASHSP-USP-FDA (American Society of Health System Pharmacists, United States Pharmacopoeia, Food and Drug Administration) Drug Product Defect Reporting System and the USP Adverse Drug Reaction Reporting System.

3. All known drug allergies shall be documented in the resident's medical record including the medication administration records and physician or advanced practice nurse order sheets and on the outside front cover and communicated to the provider or dispensing pharmacy.

4. Drugs that are not specifically limited as to duration of use or number of doses shall be controlled by automatic stop orders. The resident's attending physician or advanced practice nurse shall be notified of the automatic stop order prior to the last dose so that he or she may decide whether to continue use of the drug.

5. If medication is withheld, the reason for withholding the medication shall be documented in the resident's medical record.

6. Medication errors and adverse drug reactions shall be reported immediately to the director of nursing or the alternate to the director of nursing, and a description of the error or adverse drug reaction shall be entered into the medical record before the end of the employee shift. If the resident has erroneously received medication, the resident's physician or advanced practice nurse shall be notified immediately. If a medication error originated in the pharmacy, the pharmacy shall be notified immediately. The Department shall be notified of an adverse drug reaction that results in death.

8:39-29.4 Mandatory pharmacy control policies and procedures

(a) The label of each resident's individual medication container or package shall be labeled in accordance with the New Jersey State Board of Pharmacy regulations at N.J.A.C. 13:39-5.9, permanently affixed, and contain the following information:

1. The resident's full name;

2. The prescriber's name;

3. The prescription number;

4. The name and strength of drug;

5. The quantity dispensed;

6. The lot number;

7. The date of issue;

8. The expiration date;

9. The manufacturer's name if generic;

10. Cautionary and/or accessory labels.

i. If a generic substitute is used, the drug shall be labeled according to the Drug Utilization Review Council Formulary, N.J.S.A. 24:6E-1 et seq. and N.J.A.C. 8:71.

ii. Required information appearing on individually packaged drugs or within an alternate medication delivery system need not be repeated on the label; and

11. The name, address, and telephone number of the pharmacy.

(b) If a unit dose distribution system is used ("unit dose drug distribution" means a system in which drugs are delivered to the resident areas in single unit packaging), the following requirements shall be met:

1. Each resident shall have his or her own medication tray labeled with the resident's name and location in the facility;

2. Each medication shall be individually wrapped and labeled with the generic or trade (brand) name and strength of the drug, lot number or reference code,

expiration date, dose, and manufacturer's name, and shall be ready for administration to the resident;

3. Cautionary instructions shall appear on the resident's record of medication, and the system shall include provisions for noting additional information, including, but not limited to, special times or routes of administration and storage conditions; and

4. Delivery and exchange of resident medication trays shall occur promptly, and, if a 24–hour unit-dose system is used, then at least one exchange of resident medication trays shall occur every 24 hours, including weekends and holidays.

(c) Both over-the-counter and prescription medications may be kept as stock. A limited amount of prescription medications may be kept as stock for the administration of stat (emergency) doses, lost doses, or doses not sent by the provider pharmacy. These medications shall be approved by the pharmacy and therapeutics committee, monitored for accountability, and labeled to include drug name, drug strength, manufacturers' name, lot number, expiration date, recommended dosage for over-the-counter medications, and applicable cautionary and/or accessory labels.

(d) The consultant pharmacist shall:

1. Make monthly inspection of all areas in the facility where medications are dispensed, administered, or stored;

2. Periodically, as determined by the quality assurance program, observe a medication pass and review the crediting system; and

3. Document any problems and propose solutions to these problems.

(e) The contents of emergency kits shall have been approved by the pharmacy and therapeutics committee. Emergency kits shall be stored securely at each nursing unit, but not kept under lock and key, checked after each use, and checked at least monthly by the consultant pharmacist. Emergency kits shall not be accessible to residents but shall be accessible to staff in a timely manner.

(f) All medications repackaged by the pharmacy shall be labeled with an expiration date, name and strength of drug, lot number, date of issue, manufacturer's name if generic, and cautionary and/or accessory labels, in accordance with N.J.A.C. 13:39–5.9, United States Pharmacopoeia (U.S.P.) requirements and applicable FDA regulations.

(g) The pharmacy and therapeutics committee shall establish and enforce procedures for removal of discontinued, unused, expired, recalled, deteriorated, and unlabeled drugs and intravenous solutions and for removal of containers of medications with worn, illegible, damaged, incomplete, or missing labels.

(h) All medications shall be stored in accordance with manufacturers' and United States Pharmacopoeia (U.S.P.) requirements and all medications shall be kept in locked storage areas.

(i) All medication destruction in the facility shall be witnessed by at least two persons, each of whom shall be either the pharmacist consultant, a registered professional nurse or a licensed practical nurse. A record of each instance of drug destruction shall be maintained.

(j) Where allowable by law, the facility shall generate a crediting mechanism for medications dispensed in a unit-of-use drug distribution system, or other system that allows for the re-use of medications. The crediting system shall be monitored by the provider pharmacist and a facility representative.

(k) The pharmacy and therapeutics committee shall establish and enforce procedures for the inventory of controlled substances in accordance with law.

(*l*) Based on prescriber's orders for medications, drug tests, diet and treatments, the facility shall implement written methods and procedures for obtaining prescribed prescription medications and biologicals from a pharmacy that has a permit from the New Jersey State Board of Pharmacy, in accordance with N.J.A.C. 13:39–4. The telephone number of the pharmacy and procedures for obtaining drugs shall be posted at each nursing unit.

(m) If the facility utilizes drugs marked "sample", the pharmacy and therapeutics committee shall develop a mechanism for the control and limitation of these drugs, in accordance with N.J.A.C. 13:35–6.6.

(n) The facility shall develop and implement a system whereby instructions for use are provided whenever medications are released to residents. Instructions shall be written in a manner intended to promote proper storage, secure handling, and safe administration of medications released to residents. Documentation of released medications shall be entered into the resident's medical record.

8:39–29.5 Mandatory pharmacy staff qualifications

If the facility maintains a pharmacy in-house, the pharmacy shall be licensed by the New Jersey State Board of Pharmacy, and shall possess a current Drug Enforcement Administration registration and a Controlled Dangerous Substance registration from the New Jersey State Department of Law and Public Safety.

8:39–29.6 Mandatory resident pharmacy services

(a) The facility shall provide pharmaceutical services, either directly or by contract with a provider pharmacy, 24 hours a day, seven days a week.