

“Drug regimen review” means an individual resident record review conducted by the consultant pharmacist, including, but not limited to, laboratory tests, dietary requirements, physician’s or advanced practice nurse’s and nurse’s clinical notes, physician’s or advanced practice nurse’s orders and progress notes, in order to monitor for potentially 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.

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:

Certificate of Need Review Services
 Division of Health Care Systems Analysis
 New Jersey State Department of Health and Senior Services
 PO Box 360
 Trenton, NJ 08625-0360

(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.

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 forms prescribed by the Department which include information regarding facility ownership, corporate officers and stockholders, and approval forms from local building, fire, health and zoning departments. Such forms may be obtained from:

Long-Term Care Licensing and Certification
 Division of Long-Term Care Systems
 New Jersey State Department of Health and Senior Services
 PO Box 367
 Trenton, NJ 08625-0367

(b) The Department shall charge the following non-refundable fees:

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| Annual licensure fee (new and renewal) | \$1,000 plus \$10.00 per bed |
| Add-a-bed | \$1,000 plus \$10.00 per additional bed |
| Hemodialysis provided by the LTC facility | \$750.00 |
| Hemodialysis provided by a separate provider | \$500.00 |
| Relocation of a facility (within the same county) | \$250.00 |
| Transfer of ownership (includes initial licensure fee) | \$2,000 plus \$10.00 per bed |

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.

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:

4. Peritoneal dialysis shall be listed as a "service" on the facility's license.

(b) Separately licensed dialysis providers may offer peritoneal dialysis services in a long-term care facility under the following circumstances:

1. All requirements in (a) above shall be met;
2. The dialysis provider shall be licensed as specified at N.J.A.C. 8:39-2.9(c);
3. A copy of the contract agreement for service provision between the dialysis provider and the long-term care facility shall be reviewed and approved by the Long-Term Care Licensing and Certification Program of the Department prior to the authorization of the long-term care facility to provide the service through a separately licensed agency. The agreement shall clearly state the roles and responsibilities of both parties; and
4. Both the long-term care facility and the dialysis agency shall notify the Department in writing 30 days prior to any planned service interruption and shall include a plan for the continuing care of any dialysis patients.

8:39-2.11 Add-a-bed

(a) Pursuant to N.J.S.A. 26:2H-7.2, a facility may request approval from the Department to increase total licensed beds by no more than 10 beds or 10 percent of its licensed bed capacity, whichever is less, without certificate of need approval. No more than one such request for approval shall be submitted every five years.

(b) The Department shall charge a nonrefundable fee of \$1,000 plus \$10.00 per additional bed for the filing of an application to add beds to increase a facility's total licensed capacity. Applicants shall contact the Long-Term Care Licensing and Certification Program at (609) 633-9042 to obtain add-a-bed application forms. The completed forms, along with scaled floor plans and the appropriate fee, must be forwarded to the Department at the following address:

Director
 Long-Term Care Licensing and Certification Program
 New Jersey Department of Health and Senior Services
 PO Box 367
 Trenton, New Jersey 08625-0367

(c) The Department shall deny an add-a-bed application if any of the following conditions exist:

1. The facility's track record is unsatisfactory, in accordance with N.J.A.C. 8:33-4.10 and 8:43E-5.1;
2. The applicant fails to demonstrate that the facility has sufficient space to implement the new licensed bed capacity in a manner meeting Federal construction standards contained in the 1996-97 edition of "Guidelines For

Design and Construction of Hospital and Health Care Facilities" (American Institute of Architects Academy of Architecture for Health, with assistance from the U.S. Department of Health and Human Services. The American Institute of Architects Press: Washington, DC), incorporated herein by reference as amended and supplemented;

3. The applicant fails to demonstrate that the facility has provided sufficient nurse staffing hours, in accordance with this chapter, to meet the needs of the current resident census;

4. The addition of beds will result in a unit size in excess of 64 beds;

5. The addition of beds will result in a violation of State licensure or Federal certification requirements; or

6. The proposed additional beds will result in a room occupancy that exceeds two residents per room.

8:39-2.12 Transfer of ownership

(a) In accordance with N.J.A.C. 8:33-3.3(a)4, the transfer of ownership of a long-term care facility shall not require a certificate of need except when the proposed owner does not satisfy the Department's track record review.

(b) Prior to transferring ownership of a facility, the prospective new owner shall submit an application to the Long-Term Care Licensing and Certification Program. The application shall include the following items:

1. The transfer of ownership fee of \$2,000 plus \$10.00 per bed, in accordance with N.J.A.C. 8:39-2.2(b);

2. A cover letter stating the applicant's intent to purchase the facility, and identification of the facility by name, address, county, and number and type of licensed beds;

3. A description of the proposed transaction, including:

i. Identification of the current owners of the facility;

ii. Identification of 100 percent of the proposed new owners, including the names and addresses of all principals (that is, individuals and/or entities with a 10 percent or more interest); and

iii. If applicable, a copy of an organizational chart, including parent corporations and wholly owned subsidiaries;

4. A copy of the agreement of sale and, if applicable, a copy of any lease and/or management agreements; and

5. Disclosure of any licensed health care facilities owned, operated, or managed by the proposed owner or any of the principals, in New Jersey or any other state. If facilities are owned, operated, or managed in other states, letters from the regulatory agencies in each respective state, verifying that the facilities have operated in substan-

tial compliance during the last 12 month period and have had no enforcement actions imposed during that period of time, shall be included in the application.

(c) Approval of a transfer of ownership is contingent upon a review of the applicant's track record, in accordance with N.J.A.C. 8:33-4.10 and 8:43E-5.1.

(d) Approval of a transfer of ownership is contingent upon payment of all outstanding Medicaid audit claims and State penalties issued by the Department against the current owner, or written verification by the applicant that the applicant will assume responsibility for payment of such audit findings and State penalties.

(e) When a transfer of ownership application has been reviewed and deemed acceptable, an approval letter from the Long-Term Care Licensing and Certification Program shall be sent to the applicant along with licensure application forms.

(f) Within five days after the transaction has been completed, the applicant shall submit the following documents to the Long-Term Care Licensing and Certification Program:

1. Completed licensure application forms;
2. A notarized letter stating the date on which the transaction occurred; and
3. A copy of a certificate of continuing occupancy from the local township, or a letter from the township verifying a policy of not issuing any such document for changes of ownership.

(g) For Medicaid certification, the new owner shall contact the Long-Term Care Licensing and Certification Program at (609) 633-9042.

(h) For Medicare certification, the new owner shall contact the Assistant Director of Long-Term Care Assessment and Survey at (609) 633-8981.

SUBCHAPTER 3. COMPLIANCE WITH MANDATORY RULES AND ADVISORY STANDARDS

8:39-3.1 Mandatory rules

(a) Mandatory rules contain minimum and essential requirements of care provided by a facility.

(b) Failure to comply with any mandatory rules contained in this chapter shall constitute a deficiency for which the Department may take any or all of the enforcement actions set forth in N.J.A.C. 8:43E.

8:39-3.2 Advisory standards

(a) Advisory standards contain benchmarks of excellence or superior attainment in providing care of high quality.

(b) Facilities are strongly encouraged to use advisory standards in striving to provide the highest quality of care possible.

(c) Failure to comply with any or all advisory standards shall not constitute a deficiency or result directly or indirectly in any enforcement action by the Department.

(d) Compliance with advisory standards shall not be used as an indication of whether the facility is in compliance with mandatory rules or whether a facility should be made subject to a penalty or other action to protect residents.

8:39-3.3 Reporting compliance with advisory standards

(a) Compliance with advisory standards shall be calculated in accordance with the following:

1. The Department shall verify that at least 90 percent of no more than 30 advisory standards randomly selected from the total number of advisory standards which the facility claims to have met are in fact met; and
2. If the compliance rate determined at (a)1 above is 90 percent or greater, then, for any advisory subchapter in which the facility has claimed to meet 65 percent or more of the standards in the subchapter, recognition for meeting the entire subchapter shall be given.

(b) If a facility applies for a certificate of need, compliance with six or more of the following advisory subchapters at the time of the most recent survey of the facility shall be taken into consideration: access to care (N.J.A.C. 8:39-6), resident assessment and care plans (N.J.A.C. 8:39-12), pharmacy (N.J.A.C. 8:39-30), infection control and sanitation (N.J.A.C. 8:39-20), resident activities (N.J.A.C. 8:39-8), dietary services (N.J.A.C. 8:39-18), medical services (N.J.A.C. 8:39-24), nurse staffing (N.J.A.C. 8:39-26), physical environment (N.J.A.C. 8:39-32), and quality assessment and/or quality improvement (N.J.A.C. 8:39-34).

(c) If a facility can demonstrate that it has a system in place to meet the requirement, even though it is not applicable at the time of the survey, the surveyors may deem that, in their judgment, the standard is met.

SUBCHAPTER 4. MANDATORY RESIDENT RIGHTS

8:39-4.1 Resident rights

(a) Each resident shall be entitled to the following rights: