

CHAPTER 43E**GENERAL LICENSURE PROCEDURES AND
ENFORCEMENT OF LICENSURE
REGULATIONS****Authority**

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

Source and Effective Date

R.2001, d.59, effective February 20, 2001
See: 32 N.J.R. 3041(a), 33 N.J.R. 653(b).

Executive Order No. 66(1978) Expiration Date

Chapter 43E, General Licensure Procedures and Enforcement of Licensure Regulations, expires on February 20, 2006.

Chapter Historical Note

Chapter 43E, Policy Manual for Planning and Certificate of Need Reviews of Psychiatric Health Care Facilities and Services within the State of New Jersey, was recodified as N.J.A.C. 8:33R by R.1993 d.29, effective January 4, 1993. See: 24 N.J.R. 3598(a), 25 N.J.R. 111(a).

Chapter 43E, General Licensure Procedures and Enforcement of Licensure Regulations, was adopted as R.1995 d.198, effective April 3, 1995. See: 26 N.J.R. 4527(a), 27 N.J.R. 1411(a).

Pursuant to Executive Order No. 66(1978), Chapter 43E, General Licensure Procedures and Enforcement of Licensure Regulations, expired on April 3, 2000.

Chapter 43E, General Licensure Procedures and Enforcement of Licensure Regulations, was adopted as new rules by R.2001 d.59, effective February 20, 2001. See: Source and Effective Date.

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**SUBCHAPTER 1. SCOPE AND GENERAL
PURPOSE****8:43E-1.1 Scope**

The rules in this chapter pertain and apply to all health care facilities licensed by the Department pursuant to the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq. The rules set forth the procedures for the conduct of surveys of health care facilities, the basis and procedures for imposition of penalties and other enforcement actions and remedies, and the rights and procedures available to facilities to request a hearing to contest survey findings and the imposition of penalties.

8:43E-1.2 Purpose

The rules in this chapter are intended to promote the health, safety, and welfare of patients or residents of health care facilities through establishing rules and regulations implementing the Department's legislative mandate to enforce violations of licensing regulations. The rules also are intended to afford health care facilities with appropriate and adequate due process rights and procedures upon the finding of a violation or assessment of a penalty or other enforcement action.

8:43E-1.3 Definitions

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

"Commissioner" means Commissioner of the New Jersey Department of Health and Senior Services.

"Curtailment" means an order by the Department which requires a licensed health care facility to cease and desist all admissions and readmissions of patients or residents to the facility or affected service.

“Deficiency” means a determination by the Department of one or more instances in which a State licensing regulation or Federal certification regulation has been violated.

“Department” means the New Jersey Department of Health and Senior Services.

“Division” means Division of Health Care Systems Analysis, New Jersey Department of Health and Senior Services.

“Facility” means the entity which has been issued a license to operate a health care facility pursuant to N.J.S.A. 26:2H-1 et seq. For the purposes of this chapter, “facility” includes ambulance and invalid coach services.

“Immediate and serious threat” means a deficiency or violation that has caused or will imminently cause at any time serious injury, harm, impairment, or even death to residents or patients of the facility and therefore requires immediate corrective action.

“Patient” means an individual under the medical and nursing care and supervision of a licensed health care facility. For purposes of this chapter, “patient” is synonymous with “resident.”

“Plan of correction” means a plan developed by the facility and reviewed and approved by the Department which describes the actions the facility will take to correct deficiencies and specifies the time frame in which those deficiencies will be corrected.

“Resident” means an individual residing in a licensed health care facility and under the supervision of that facility for the purpose of receiving medical, nursing, and/or personal care services. For purposes of this chapter, “resident” is synonymous with “patient.”

“Survey” means the evaluation of the quality of care and/or the fitness of the premises, staff, and services provided by a facility as conducted by the Department and/or its designees to determine compliance or non-compliance with applicable State licensing regulations, statutes, or Federal Medicare/Medicaid certification regulations or statutes.

SUBCHAPTER 2. SURVEY PROCEDURES

8:43E-2.1 Scope and types of surveys

(a) The Department, or another State agency to which the Department has delegated the authority for conduct of surveys either partially or fully, may conduct periodic or special inspections of licensed health care facilities to evaluate the fitness and adequacy of the premises, equipment, personnel, policies and procedures, and finances, and to ascertain whether the facility complies with all applicable State and Federal licensure regulations and statutes.

(b) The Department or its designee may also conduct periodic surveys of facilities on behalf of the U.S. Department of Health and Human Services or other Federal agency for purposes of evaluating compliance with all applicable Federal regulations or Medicare and Medicaid certification regulations.

(c) The Department may evaluate all aspects of patient care, and operations of a health care facility, including the inspection of medical records; observation of patient care where consented to by the patient; inspection of all areas of the physical plant under the control or ownership of the licensee; and interview of the patient or resident, his or her family or other individuals with knowledge of the patient or care rendered to him or her.

(d) All information pertaining to an individual patient shall be maintained as confidential by the Department and shall not be available to the public in a manner that identifies an individual patient, unless so consented to by the patient or pursuant to an order by a court of law.

(e) The Department may conduct a survey of a facility upon the receipt of complaint or allegation by any person or agency, including a patient, his or her family, or any person with knowledge of the services rendered to patients or operations of a facility.

(f) The Department may evaluate the quality of patient care rendered by a facility through analysis of statistical data reported by facilities to the Department or other agency, or by review of reportable event information or other notices filed with the Department pursuant to regulation. Upon receipt of information indicating a potential risk to patient safety or violations of licensing regulations, the Department may conduct a survey to investigate the causes of this finding, or request a written response from the facility to ascertain the validity of the data and to describe the facility's plan or current actions to address the identified findings.

(g) Following a reasonable opportunity for facilities to review and comment on the validity of the Department's statistical data related to the quality of patient care by facilities, the Department may make such information, as appropriately amended available to the public.

8:43E-2.2 Deficiency findings

(a) A deficiency may be cited by the Department upon any single or multiple determination that the facility does not comply with a licensure regulation. Such findings may be made as the result of either an on-site survey or inspection or as the result of the evaluation of written reports or documentation submitted to the Department, or the omission or failure to act in a manner required by regulation.

(b) At the conclusion of a survey or within 10 business days thereafter, the Department shall provide a facility with a written summary of any factual findings used as a basis to determine that a licensure violation has occurred, and a statement of each licensure regulation to which the finding of a deficiency relates.

8:43E-2.3 Informal dispute resolution

(a) A facility may request an opportunity to discuss the accuracy of survey findings with representatives of the Department in the following circumstances during a survey:

1. During the course of a survey to the extent such discussion does not interfere with the surveyor's ability to obtain full and objective information and to complete required survey tasks; or

2. During the exit interview or other summation of survey findings prior to the conclusion of the survey.

(b) Following completion of the survey, an acute care facility may contact the Inspections, Complaints and Compliance Program and a long term care facility may contact the Long Term Care Assessment Survey Program to request an informal review of deficiencies cited. The request must be made in writing within 10 business days of the receipt of the written survey findings. The written request must include:

1. A specific listing of the deficiencies for which informal review is requested; and

2. Documentation supporting any contention that a survey finding was in error.

(c) The review will be conducted within 10 business days of the request by supervisory staff of the Inspections, Complaints and Compliance Program or the Long Term Care Assessment Survey Program, as applicable, who did not directly participate in the survey. The review can be conducted in person at the offices of the Department or, by mutual agreement, solely by review of the documentation as submitted.

(d) A decision will be issued by the Department within seven business days of the conference or the review, and if the determination is to agree with the facility's contentions, the deficiencies will be removed from the record. If the decision is to disagree with the request to remove deficiencies, a plan of correction is required within five business days of receipt of the decision. The facility retains all other rights to appeal deficiencies and enforcement actions taken pursuant to these rules.

8:43E-2.4 Plan of correction

(a) The Department may require that the facility submit a written plan of correction specifying how each deficiency that has been cited will be corrected along with the time frames for completion of each corrective action. A single plan of correction may address all events associated with a given deficiency.

(b) The plan of correction shall be submitted within 10 business days of the facility's receipt of the notice of violations, unless the Department specifically authorizes an extension for cause. Where deficiencies are the subject of informal dispute resolution pursuant to N.J.A.C. 8:43E-2.3, the extension shall pertain only to the plans of correction for the deficiencies under review.

(c) The Department may require that the facility's representatives appear at an office conference to review findings

of serious or repeated licensure deficiencies and to review the causes for such violations and the facility's plan of correction.

(d) The plan of correction shall be reviewed by the Department and will be approved where the plan demonstrates that compliance will be achieved in a manner and time that assures the health and safety of patients or residents. If the plan is not approved, the Department may request that an amended plan of correction be submitted within five business days. In relation to violations of resident or patient rights, the Department may direct specific corrective measures that must be implemented by facilities.

SUBCHAPTER 3. ENFORCEMENT REMEDIES

8:43E-3.1 Enforcement remedies available

(a) Pursuant to N.J.S.A. 26:2H-13, 14, 15, 16 and 38, the Commissioner or his or her designee may impose the following enforcement remedies against a health care facility for violations of licensure regulations or other statutory requirements:

1. Civil monetary penalty;
2. Curtailment of admissions;
3. Appointment of a receiver or temporary manager;
4. Provisional license;
5. Suspension of a license;
6. Revocation of a license;
7. Order to Cease and Desist operation of an unlicensed health care facility; and
8. Other remedies for violations of statutes as provided by State or Federal law, or as authorized by Federal survey, certification, and enforcement regulations and agreements.

8:43E-3.2 Notice of violations and enforcement actions

The Commissioner shall serve notice to a facility of the proposed assessment of civil monetary penalties, suspension or revocation of a license, or placement on a provisional license, setting forth the specific violations, charges or reasons for the action. Such notice shall be served on a licensee or its registered agent in person or by certified mail.

8:43E-3.3 Effective date of enforcement actions

The assessment of civil monetary penalties, or revocation of a license, or the placement of a license on provisional status shall become effective 30 days after the date of mailing or the date personally served on a licensee, unless the licensee shall file with the Department a written answer to the charges and give written notice to the Department of

its desire for a hearing in which case the assessment, suspension, revocation or placement on provisional license status shall be held in abeyance until the administrative hearing has been concluded and a final decision is rendered by the Commissioner. Hearings shall be conducted in accordance with N.J.A.C. 8:43E-4.1.

8:43E-3.4 Civil monetary penalties

(a) Pursuant to N.J.S.A. 26:2H-13 and 14, the Commissioner may assess a penalty for violation of licensure regulations in accordance with the following standards:

1. For operation of a health care facility without a license, or continued operation of a facility after suspension or revocation of a license, \$1,000 per day from the date of initiation of services;

2. For violation of an order for curtailment of admissions, \$250.00 per patient, per day from the date of such admission to the date of discharge or lifting of the curtailment order;

3. For failure to obtain prior approval from the Licensing Program, Division of Health Facilities Evaluation and Licensing, for occupancy of an area or initiation of a service following construction or application for licensure, \$250.00 a day;

4. For construction or renovation of a facility without the Department's approval of construction plans, \$1,000 per room or area renovated and immediate suspension of use of the room or area;

5. For the transfer of ownership of a health care facility without prior approval of the Department, \$500.00 per day from the date of the transfer of interest to the date of discovery by the Department. Such fine may be assessed against each of the parties at interest;

6. For maintaining or admitting more patients or residents to a facility than the maximum capacity permitted under the license, except in an emergency as documented by the facility in a contemporaneous notice to the Department, \$25.00 per patient per day plus an amount equal to the average daily charge collected from such patient or patients;

7. For violations of licensure regulations related to patient care or physical plant standards that represent a risk to the health, safety, or welfare of patients or residents of a facility or the general public, \$500.00 per violation where such deficiencies are isolated or occasional and do not represent a pattern or widespread practice throughout the facility;

8. Where there are multiple deficiencies related to patient care or physical plant standards throughout a facility, and/or such violations represent a direct risk that a patient's physical or mental health will be compromised, or where an actual violation of a resident's or patient's rights is found, a penalty of \$1,000 per violation may be assessed for each day noncompliance is found;

9. For repeated violations of any licensing regulation within a 12-month period or on successive annual inspections, or failure to implement an approved plan of correction, where such violation was not the subject of a previous penalty assessment, \$500.00 per violation, which may be assessed for each day noncompliance is found. If the initial violation resulted in the assessment of a penalty, within a 12-month period or on successive annual inspections, the second violation shall result in a doubling of the original fine, and the third and successive violations shall result in a tripling of the original fine;

10. For violations resulting in either actual harm to a patient or resident, or in an immediate and serious risk of harm, \$2,500 per violation, which may be assessed for each day noncompliance is found;

11. For failure to report information to the Department as required by statute or licensing regulation, after reasonable notice and an opportunity to cure the violation, \$250.00 per day; or

12. For failure to implement a Certificate of Need condition of approval, \$1,000 per day, which shall be assessed either from the date specified in the Certificate of Need for implementation of the specific condition of approval, if identified, or from the date on which the Certificate of Need was considered to be implemented.

(b) Except for violations deemed to be immediate and serious threats, the Department may decrease the penalty assessed in accordance with (a) above, based on the compliance history of the facility; the number, frequency and/or severity of violations by the facility; the measures taken by the facility to mitigate the effects of the current violation, or to prevent future violations; the deterrent effect of the penalty; and/or other specific circumstances of the facility or the violation.

(c) The Department may increase the penalties in (a) above up to the statutory maximum per violation per day in consideration of the economic benefit realized by the facility for noncompliance.

8:43E-3.5 Failure to pay a penalty; remedies

(a) Within 30 days after the mailing date of a Notice of Proposed Assessment of a Penalty, a facility which intends to challenge the enforcement action shall notify the Department of its intent to request a hearing pursuant to the Administrative Procedure Act.

(b) The penalty becomes due and owing upon the 30th day from mailing of the Notice of Proposed Assessment of Penalties, if a notice requesting a hearing has not been received by the Department. If a hearing has been requested, the penalty is due 45 days after the issuance of a Final Agency Decision by the Commissioner, if the Department's assessment has not been withdrawn, rescinded, or reversed, and an appeal has not been timely filed with the New Jersey Superior Court, Appellate Division pursuant to New Jersey Court Rule 2:2-3.

Source and Effective Date

R.2004 d.38, effective January 20, 2004.
See: 35 N.J.R. 1828(a), 36 N.J.R. 426(a).

8:43E-6.1 Pain management standards; scope

The standards set forth in this subchapter apply to all health care facilities licensed in accordance with N.J.S.A. 26:2H-1 et seq.

8:43E-6.2 Purpose

The rules in this subchapter are intended to promote the health, safety, and welfare of patients or residents of health care facilities by establishing requirements for the assessment, monitoring and management of pain.

8:43E-6.3 Definitions

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

“Pain” means an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

“Pain management” means the assessment of pain and, if appropriate, treatment in order to assure the needs of patients or residents of health care facilities who experience problems with pain are met. Treatment of pain may include the use of medications or application of other modalities and medical devices such as, but not limited to, heat or cold, massage, transcutaneous electrical nerve stimulation (TENS), acupuncture, and neurolytic techniques such as radiofrequency coagulation and cryotherapy.

“Pain rating scale” means a tool that is age cognitive and culturally specific to the patient or resident population to which it is applied and which results in an assessment and measurement of the intensity of pain.

“Pain treatment plan” means a plan, based on information gathered during a patient/resident pain assessment, that identifies the patient’s/resident’s needs and specifies appropriate interventions to alleviate pain, to the extent feasible and medically appropriate.

8:43E-6.4 Pain assessment procedures

(a) A facility shall formulate a system for assessing and monitoring patients’/residents’ pain using a pain rating scale.

1. A facility serving different patient/resident populations shall utilize more than one pain scale, as appropriate.

(b) Assessment of a patient’s/resident’s pain shall occur, at a minimum, upon admission, on the day of a planned discharge, and when warranted by changes in a patient’s/resident’s condition, self-reporting of pain and/or evidence of behavioral cues indicative of the presence of pain. In the

case of individuals receiving home health care services, assessment shall coincide with a visit by staff of the home health service agency and assessment on the day of discharge is not required if the individual has been admitted to an inpatient or residential health care facility and discharge from the home health service agency takes place after the admission.

(c) If pain is identified, a pain treatment plan shall be developed and implemented within the health care facility or the patient/resident shall be referred for treatment or consultation.

(d) If the patient/resident is cognitively impaired or non-verbal, the facility shall utilize pain rating scales for the cognitively impaired and non-verbal patient/resident. Additionally, the facility shall seek information from the patient’s/resident’s family, caregiver or other representative, if available and known to the facility. The results of the pain rating scales and the response to the additional inquiry shall be documented in the patient’s/resident’s medical record.

(e) Pain assessment findings shall be documented in the patient’s/resident’s medical record. This shall include, but not be limited to, the date, pain rating, treatment plan and patient/resident response.

(f) The facility shall establish written policies and procedures governing the management of pain that are reviewed at least every three years and revised more frequently as needed. They shall include at least the following:

1. A written procedure for systematically conducting periodic assessment of a patient’s/resident’s pain, as specified in (b) above. At a minimum, the procedure must specify pain assessment upon admission, upon discharge, and when warranted by changes in a patient’s/resident’s condition and self-reporting of pain;

2. Criteria for the assessment of pain, including, but not limited to: pain intensity or severity, pain character, pain frequency or pattern, or both; pain location, pain duration, precipitating factors, responses to treatment and the personal, cultural, spiritual, and/or ethnic beliefs that may impact an individual’s perception of pain;

3. A written procedure for the monitoring of a patient’s/resident’s pain;

4. A written procedure to insure the consistency of pain rating scales across departments within the health care facility;

5. Requirements for documentation of a patient’s/resident’s pain status on the medical record;

6. A procedure for educating patients/residents and, if applicable, their families about pain management when identified as part of their treatment; and

7. A written procedure for systematically coordinating and updating the pain treatment plan of a patient/resident in response to documented pain status.

8:43E-6.5 Staff education and training programs

(a) Each facility shall develop, revise as necessary and implement a written plan for the purpose of training and educating staff on pain management. The plan shall include mandatory educational programs that address at least the following:

1. Orientation of new staff to the facility's policies and procedures on pain assessment and management;

2. Training of staff in pain assessment tools; behaviors potentially indicating pain; personal, cultural, spiritual and/or ethnic beliefs that may impact a patient's/resident's perception of pain; new equipment and new technologies to assess and monitor a patient's/resident's pain status;

3. Incorporation of pain assessment, monitoring and management into the initial orientation and ongoing education of all appropriate staff; and

4. Patient/resident rights.

(b) Implementation of the plan shall include records of attendance for each program.

8:43E-6.6 Pain management continuous quality improvement

The facility's continuous quality improvement program shall include a systematic review and evaluation of pain assessment, management and documentation practices. The facility shall develop a plan by which to collect and analyze data in order to evaluate outcomes or performance. Data analysis shall focus on recommendations for implementing corrective actions and improving performance.