

**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).

**Chapter Expiration Date**

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 43E, General Licensure Procedures and Enforcement of Licensure Regulations, expires on August 19, 2006. See: 38 N.J.R. 1121(b).

**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.

**CHAPTER TABLE OF CONTENTS****SUBCHAPTER 1. SCOPE AND GENERAL PURPOSE**

- 8:43E-1.1 Scope
- 8:43E-1.2 Purpose
- 8:43E-1.3 Definitions

**SUBCHAPTER 2. SURVEY PROCEDURES**

- 8:43E-2.1 Scope and types of surveys
- 8:43E-2.2 Deficiency findings
- 8:43E-2.3 Informal dispute resolution
- 8:43E-2.4 Plan of correction

**SUBCHAPTER 3. ENFORCEMENT REMEDIES**

- 8:43E-3.1 Enforcement remedies available
- 8:43E-3.2 Notice of violations and enforcement actions
- 8:43E-3.3 Effective date of enforcement actions
- 8:43E-3.4 Civil monetary penalties
- 8:43E-3.5 Failure to pay a penalty; remedies
- 8:43E-3.6 Curtailment of admissions
- 8:43E-3.7 Appointment of a receiver
- 8:43E-3.8 Suspension of a license
- 8:43E-3.9 Revocation of a license
- 8:43E-3.10 Provisional license
- 8:43E-3.11 Cease and desist order

**SUBCHAPTER 4. HEARINGS**

- 8:43E-4.1 Hearings
- 8:43E-4.2 Settlement of enforcement actions

**SUBCHAPTER 5. LICENSURE PROCEDURES**

- 8:43E-5.1 Track record evaluation
- 8:43E-5.2 Facility surveys
- 8:43E-5.3 Facility licensure
- 8:43E-5.4 Conditional license
- 8:43E-5.5 Surrender of license
- 8:43E-5.6 Waiver

**SUBCHAPTER 6. PAIN MANAGEMENT PROCEDURES**

- 8:43E-6.1 Pain management standards; scope
- 8:43E-6.2 Purpose
- 8:43E-6.3 Definitions
- 8:43E-6.4 Pain assessment procedures
- 8:43E-6.5 Staff education and training programs
- 8:43E-6.6 Pain management continuous quality improvement

**SUBCHAPTER 7. REQUIREMENT TO USE NEEDLES AND SHARP INSTRUMENTS CONTAINING INTEGRATED SAFETY FEATURES OR NEEDLELESS DEVICES**

- 8:43E-7.1 Use of needles and sharp instruments containing integrated safety features
- 8:43E-7.2 Definitions
- 8:43E-7.3 Requirement and responsibilities of evaluation committees
- 8:43E-7.4 Waiver from the requirement to utilize available sharp devices with integrated safety features or needleless devices
- 8:43E-7.5 Recording requirements

**SUBCHAPTER 8. MANDATORY OVERTIME**

- 8:43E-8.1 Mandatory overtime; scope and general purpose
- 8:43E-8.2 Applicability
- 8:43E-8.3 Definitions
- 8:43E-8.4 Purpose
- 8:43E-8.5 Overtime procedures
- 8:43E-8.6 Records; dissemination of information
- 8:43E-8.7 Enforcement and administrative penalties
- 8:43E-8.8 Policies and procedures
- 8:43E-8.9 Discharge or discrimination against an employee making a complaint
- 8:43E-8.10 Complaint system
- 8:43E-8.11 Protection of the right to collective bargaining
- 8:43E-8.12 Data

**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.

"Curtailement" 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.

(b) The Commissioner may also impose other enforcement actions pursuant to these rules for operation of an unlicensed health care facility.

(c) The Department may maintain an action in the New Jersey Superior Court to enjoin any entity from operation of a health care facility without a license or after the suspension or revocation of a license pursuant to these rules.

#### SUBCHAPTER 4. HEARINGS

##### 8:43E-4.1 Hearings

(a) Notice of a proposed enforcement action shall be afforded to a facility pursuant to N.J.A.C. 8:43E-3.2.

(b) A facility shall notify the Department of its intent to request a hearing in a manner specified in the Notice within 30 days of its receipt.

(c) The Department shall transmit the hearing request to the Office of Administrative Law.

(d) Hearings shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1.1.

##### 8:43E-4.2 Settlement of enforcement actions

(a) The facility may request that the matter be settled in lieu of conducting an administrative hearing concerning an enforcement action.

(b) If the Department and the facility agree on the terms of a settlement, a written agreement specifying these terms shall be executed.

(c) Pursuant to N.J.S.A. 26:2H-16, civil penalties may be settled by the Department in cash or in-kind services to patients where circumstances warrant such agreement and the settlement does not compromise the health, safety, or welfare of patients. In no case shall such settlement reduce a penalty below \$250.00, or \$500.00 for second and subsequent offenses.

(d) The Department may agree to accept payment of penalties over a schedule not exceeding 18 months where a facility demonstrates financial hardship.

(e) All funds received in payment of penalties shall be deposited in the Health Care Facilities Improvement Fund. Such fund shall be designated for use by the Commissioner to make corrections in a health care facility which is in violation of a licensure standard and in which the owner or operator is unable or unwilling to make the necessary corrections. The owner of the facility shall repay the fund any monies plus interest at the prevailing rate that were

expended by the State to correct the violation at the facility. If the owner fails to promptly reimburse the fund, the Commissioner shall have a lien in the name of the State against the facility for the cost of the corrections plus interest and for any administrative cost incurred in filing the lien.

(f) If a facility fails to meet the conditions of the settlement, the Department may immediately impose the original enforcement action without any further right to an administrative hearing.

#### SUBCHAPTER 5. LICENSURE PROCEDURES

##### 8:43E-5.1 Track record evaluation

(a) In the case of an application for licensure of a long-term care facility, subacute care unit in an acute care general hospital, assisted living residence, comprehensive personal care home, assisted living program, alternate family care sponsor agency, or residential health care facility, for which a certificate of need is required, the applicant's track record shall be evaluated as part of the certificate of need application process, in accordance with N.J.A.C. 8:33-4.10.

(b) In the case of an application for which a certificate of need is not required, including an application for transfer of ownership of a long-term care facility, subacute care unit in an acute care general hospital, assisted living residence, comprehensive personal care home, assisted living program, alternate family care sponsor agency, adult day health care facility, or residential health care facility, an application to establish or expand an adult day health care facility or to expand a residential health care facility, and an application for any long-term care beds or services offered as part of a continuing care retirement community, the track record rules regarding certificate of need applications at N.J.A.C. 8:33-4.10 shall be applied. These rules include, but are not limited to, those addressing criteria for denial of applications, the scope of the track record review, the use of categories of health care service similarity or relatedness, the meaning of the term "applicant," and the duration of the waiting period following application denial.

(c) In the case of an application to add one or more beds in accordance with N.J.A.C. 8:39-2.12, for which a certificate of need is not required, the track record rules regarding certificate of need applications at N.J.A.C. 8:33-4.10 shall be applied only to the facility which is requesting the additional beds.

##### 8:43E-5.2 Facility surveys

(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 Department's Inspections, Complaints and Compliance Program or the Long

Term Care Assessment and Survey Program, as applicable, shall be conducted to determine if the facility complies with 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 Department's Inspections, Complaints and Compliance Program or Long Term Care Assessment and Survey Program, as applicable, when the deficiencies, if any, have been corrected, and the program so notified will schedule one or more resurveys of the facility prior to occupancy.

(b) No facility shall admit patients to the facility until the facility has the written approval and/or license issued by the Certificate of Need and Acute Care Licensure Program or the Long Term Care Licensure Program of the Department.

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

#### 8:43E-5.3 Facility licensure

(a) A license shall be issued only where the survey conducted pursuant to N.J.A.C. 8:43E-5.2 demonstrates that the facility meets the requirements as set forth in N.J.S.A. 26:2H-1 et seq. and the applicable rules duly promulgated pursuant thereto.

(b) A license shall be granted for a period of one year or less, as determined by the Department.

(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, if the facility's ownership changes, or if the facility is relocated to a different state.

(e) The license, unless suspended or revoked in accordance with these rules, shall be renewed annually on the anniversary date of the issuance of the original license, or within 30 days thereafter. In cases where the license issues after, but within 30 days of, the anniversary date, it shall be deemed to have issued on the anniversary date and dated accordingly. The facility shall receive from the Department a request for licensure renewal fee 30 days prior to the expiration of the license. A renewed license shall not issue unless and until the licensure renewal fee is received by the Department.

(f) The license may not be renewed if local rules, regulations and/or other applicable requirements are not met, or if the Department determines that the facility is in violation of applicable licensure standards.

#### 8:43E-5.4 Conditional license

A conditional license may be issued to a health care facility providing a type or category of health care service neither listed nor otherwise addressed in the applicable licensure chapter for that type of facility.

#### 8:43E-5.5 Surrender of license

The facility shall notify each patient/resident, each patient/resident's physician, and any guarantors of payment at least 30 days prior to the surrender of a license, or as directed under an order of revocation, refusal to renew, or suspension of a license. In such cases, the license shall be returned to the Certificate of Need and Acute Care Licensure Program or the Long Term Care Licensure Program, as applicable, within seven working days after the surrender, revocation, non-renewal, or suspension of the license.

#### 8:43E-5.6 Waiver

(a) The Commissioner or his or her designee may, in accordance with the general purposes and intent of N.J.S.A. 26:2H-1 et seq., and the licensure rules applicable to the type of facility in question, waive sections of applicable licensure 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 waiver pursuant to this rule shall apply in writing to the Director of the Certificate of Need and Acute Care Licensure Program or the Long Term Care Licensure Program, as applicable.

(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 sought;
2. Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the facility if the waiver does not issue;
3. An alternative proposal, ensuring patient safety and compliance with the general intent and purpose of the applicable licensure rules; and
4. Documentation to support the request for waiver.

(d) In cases where the Department requests additional information before or during the course of processing a waiver request, the facility shall comply with the request for additional information or the waiver shall be denied.

### SUBCHAPTER 6. PAIN MANAGEMENT PROCEDURES

#### Authority

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

## 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.

### SUBCHAPTER 7. REQUIREMENT TO USE NEEDLES AND SHARP INSTRUMENTS CONTAINING INTEGRATED SAFETY FEATURES OR NEEDLELESS DEVICES

#### Authority

N.J.S.A. 26:2H-1 et seq. and 26:2H-5.10 et seq.

#### Source and Effective Date

R.2004 d.301, effective August 2, 2004.  
See: 35 N.J.R. 3513(a), 36 N.J.R. 3536(a).

#### 8:43E-7.1 Use of needles and sharp instruments containing integrated safety features

(a) All facilities shall purchase, for use by health care workers only, available sharp devices containing integrated safety features or available needleless devices designed to prevent needle stick injuries, in accordance with N.J.S.A. 26:2H-5.10 through 5.16, as well as this subchapter.

(b) In cases where there is no available sharp device containing integrated safety features or needleless device, for a specific patient use, facilities shall utilize the appropriate sharp device that is available for that specific patient use, including any sharp device which employs non-integrated, add-on safety features, until such time as an appropriate sharp device containing integrated safety features becomes available.

(c) The provisions of this section shall apply to both empty and pre-filled syringes upon the effective date of these rules.

#### 8:43E-7.2 Definitions

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

"Available" means cleared or approved for marketing by the Federal Food and Drug Administration and commercially offered for distribution.

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

"Emergency" means an unforeseen circumstance involving a patient in need of immediate medical attention in order to save the patient's life and/or limb or prevent serious and/or permanent injury.

"Evaluation committee" means a group of individuals appointed within each facility or health care system which satisfies the requirements of N.J.S.A. 26:2H-5.13 and N.J.A.C. 8:43E-7.3.

"Facility" means a health care facility licensed by the Department, pursuant to the provisions set forth in the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq., as amended.

"Health care system" means a licensed health care provider/entity that either owns and operates more than one licensed facility within the State of New Jersey or can document operational control over more than one licensed facility within the State of New Jersey, but which is not a management company.

"Health care worker" or "health care professional" means a physician, physician assistant, advanced practice nurse, registered nurse, licensed practical nurse, or any other individual employed by the facility or having privileges at the facility whose job duties require the use of sharp devices, as that term is defined herein.

"Integrated safety features" means needles and all other sharp instruments with engineered injury prevention protections in the form of a built-in safety feature or mechanism designed to protect the user of the sharp device from needle stick injuries.

“Needleless device” means a device that does not use needles for the following procedures:

1. The collection or withdrawal of bodily fluids after initial venous or arterial access is established;
2. Administration of medication or other fluids; or
3. Any other procedure involving potential for exposure to blood or other potentially exposed infectious material.

“Needle stick injury” means the actual or potential parenteral introduction, into the body of a health care worker, of blood or other potentially exposed infectious material, by any type of sharp device, as that term is defined in this section.

“Sharp device(s)” means needles and all other sharp instruments used by health care workers to administer patient care, the use of which creates the potential for exposure to blood or other potentially exposed infectious material, regardless of whether the specific patient being treated has been diagnosed with a bloodborne disease or infection.

#### **8:43E-7.3 Requirement and responsibilities of evaluation committees**

(a) Every licensed health care facility or health care system shall appoint an evaluation committee which shall be responsible for evaluating and selecting sharp devices with integrated safety features or needleless devices for use by health care workers at the facility or facilities.

(b) At least one half of all members of the evaluation committee shall be direct-care health care workers employed by the facility or health care system, whose job duties include the use of sharp devices to treat patients of the facility and resulting potential exposure to blood and other potentially exposed infectious material through accidental needle stick injuries. In the case of a health care system, not only shall at least one half of the evaluation committee be comprised of direct-care health care workers, but the evaluation committee shall also include at least one direct-care health care worker from every facility within the health care system.

(c) In determining which needles and other sharp devices or needleless devices to purchase in compliance with these rules, every evaluation committee shall establish and follow guidelines for determining which devices are to be purchased for use by facility staff. An example of such guidelines may be found in the June 1999 edition of the “California Guide to Preventing Sharps Injuries.” That manual is available by contacting the California Healthcare Association by telephone at (800) 494-2001 or (916) 928-5123, via the internet at [www.calhealth.org](http://www.calhealth.org) or in writing at the following address:

California Healthcare Association  
 Publication Sales Center  
 1101 North Market Boulevard, #9  
 Sacramento, CA 95834

Guidelines may also be found at [www.tdict.org](http://www.tdict.org).

(d) All facilities shall develop and maintain policies and procedures for the continual review and evaluation of sharp devices or needleless devices as they are newly introduced and become available. Review of newly marketed devices shall occur at a minimum frequency of once annually. The policies and procedures shall include a requirement that all health care workers receive appropriate training in the use of all safety devices, whether sharp or needleless, purchased for use during the course of their duties. Training shall be provided to the extent necessary to ensure the proper and appropriate use of all devices with integrated safety features or needleless devices used within the facility. The policies and procedures shall be reviewed and reevaluated every three years.

#### **8:43E-7.4 Waiver from the requirement to utilize available sharp devices with integrated safety features or needleless devices**

(a) All facilities shall develop policies and procedures setting forth a mechanism for health care professionals to request non-emergency waivers from the requirements set forth in N.J.A.C. 8:43E-7.1. All waiver requests shall be submitted to the evaluation committee on forms prescribed by the Department.

(b) Non-emergency waiver requests shall be presented to the evaluation committee for approval and shall be considered only for a specific device to be used for a specific medical procedure that shall be performed on a specific class of patients. In cases where the evaluation committee determines that the use of a sharp device with integrated safety features may potentially have a negative impact on patient safety or the success of a specific medical procedure, the waiver request shall be granted by the evaluation committee.

(c) In the case of an emergency, a health care professional may utilize sharp devices which do not contain integrated safety features without a waiver, provided:

1. The professional determines that use of a sharp device with integrated safety features potentially may have a negative impact on patient safety or the success of a specific medical procedure; and
2. The professional making the determination required in (c)1 above, notifies the evaluation committee, in writing, on a form prescribed by the Department, within five days of the date the sharp device was used, of the reasons why it was necessary to use a sharp device without integrated safety features.

**8:43E-7.5 Recording requirements**

All facilities shall maintain a record of needle stick injuries, either in a Sharps Injury Log or an OSHA 300 Log. All entries made pursuant to this subchapter shall include a description of the injury and the type and brand name of the sharp device involved in the injury.

**SUBCHAPTER 8. MANDATORY OVERTIME****Authority**

N.J.S.A. 26:2H-1 et seq., specifically 26:2H-5 and 34:11-56(a)31 et seq.

**Source and Effective Date**

R.2004 d.71, effective February 17, 2004.  
See: 35 N.J.R. 4195(a), 36 N.J.R. 1017(a).

**8:43E-8.1 Mandatory overtime; scope and general purpose**

The procedures set forth in this subchapter apply to all health care facilities licensed in accordance with N.J.S.A. 26:2H-1 et seq., including a State or county psychiatric hospital, a State developmental center, or a health care service firm registered by the Division of Consumer Affairs in the Department of Law and Public Safety pursuant to N.J.S.A. 56:8-1.1 et seq. The rules set forth the standards and procedures governing the use by health care facilities of required overtime by hourly wage employees involved in direct patient care activities or clinical services in health care facilities.

**8:43E-8.2 Applicability**

(a) The rules in this subchapter do not apply to the following:

1. Physicians;

2. Volunteers;

3. Employees who volunteer to work overtime;

4. Employees of assisted living facilities that are licensed in accordance with N.J.A.C. 8:36 and who receive room and board as a benefit of employment and reside at the facility on a full-time basis;

5. Employees who assume on-call duty;

6. Employees participating in a surgical or therapeutic interventional procedure that is in progress, when it would be detrimental to the patient if the employee left. However, in the case of elective procedures, the rules do apply if the procedure was scheduled such that the length of time ordinarily required to complete the procedure would exceed the end of the employee's scheduled shift; and

7. Employees not involved in direct patient care activities or clinical services.

**8:43E-8.3 Definitions**

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

"Chronic short staffing" means a situation characterized by long standing vacancies in that portion of the facility's master staffing plan applicable to the work unit of an employee who files a complaint where such vacancies are the result of open positions that continually remain unfilled over a period of 90 days or more despite active recruitment efforts.

"Commissioner" means the Commissioner of Health and Senior Services.

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