

Labor Standards and Safety Enforcement  
 Directorate  
 Division of Wage and Hour Compliance of the  
 Department of Labor  
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 Trenton, New Jersey 08625-0389

1. If requested, records of such reports shall be made available upon request to the Department or to the Department of Law and Public Safety or to the Department of Human Services.

**8:43E-8.11 Protection of the right to collective bargaining**

Nothing in this subchapter shall be construed to impair or negate any employer-employee collective bargaining agreement or any other employer/employee contract in effect as of January 1, 2003 for licensed general hospitals and July 1, 2003 for all other facilities subject to these rules as set forth at N.J.A.C. 8:43E-8.1.

**8:43E-8.12 Data**

A facility shall submit data related to the effects of prohibiting mandatory overtime in accordance with this chapter as well as data required to determine whether chronic staffing shortages exist, as the State agency which licenses the facility shall request from time to time directly from each facility.

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SUBCHAPTER 9. (RESERVED)

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SUBCHAPTER 10. PATIENT OR RESIDENT SAFETY REQUIREMENTS AND REPORTABLE EVENTS

**8:43E-10.1 Purpose**

(a) The purpose of this subchapter is as follows:

1. To implement the Patient Safety Act, N.J.S.A. 26:2H-12.23 through 12.25, to increase the safety of patients and residents in health care facilities by reducing the frequency and severity of preventable adverse events; and
2. To assure the Department receives timely notification of various events in health care facilities that may significantly affect their ability to continue to deliver health care services and/or may pose a danger to the life or safety of patients or residents, employees, medical staff or the public.

**8:43E-10.2 Scope**

(a) This subchapter shall apply to all health care facilities licensed pursuant to N.J.S.A. 26:2H-1 et seq. and to State psychiatric hospitals operated by the Department of Human Services in accordance with the following:

1. For assisted living residences and comprehensive personal care homes licensed pursuant to N.J.A.C. 8:36, effective March 3, 2009;
2. For assisted living programs licensed pursuant to N.J.A.C. 8:36, effective March 3, 2009;
3. For long-term care facilities licensed pursuant to N.J.A.C. 8:39, effective March 3, 2009;
  - i. With respect to the mandatory reporting requirements found in N.J.A.C. 8:43E-10.6, Medicare and/or Medicaid nursing homes shall be deemed in compliance with N.J.A.C. 8:43E-10.6, provided they report in compliance with applicable Federal and State reporting statutes and regulations;
4. For home health care agencies licensed pursuant to N.J.A.C. 8:42, effective August 30, 2008;
5. For hospice care providers licensed pursuant to N.J.A.C. 8:42C, effective August 30, 2008;
6. For residential health care facilities licensed pursuant to N.J.A.C. 8:43, effective March 3, 2009;
7. For ambulatory care facilities licensed pursuant to N.J.A.C. 8:43A, effective August 30, 2008;
8. For adult and pediatric day health services facilities licensed pursuant to N.J.A.C. 8:43F, effective March 3, 2009;
9. For general, special, and psychiatric hospitals licensed pursuant to N.J.A.C. 8:43G, effective March 3, 2008;
10. For rehabilitation hospitals licensed pursuant to N.J.A.C. 8:43H, effective March 3, 2008; and
11. With respect to the following facilities operated or licensed by the Department of Human Services:
  - i. For State psychiatric hospitals, effective August 30, 2008; and
  - ii. For residential and outpatient substance abuse treatment facilities licensed pursuant to N.J.S.A. 26:2H-1 et seq., effective August 30, 2008.

**8:43E-10.3 Definitions**

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

“Adverse event” means an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.

“Allergic reaction” means an abnormal immune response to a substance or allergen that does not normally cause a reaction and that results in a broad range of inflammatory responses.

1. Allergies are caused by inherited sensitivity or sensitivity acquired over time to a foreign substance.

2. Immediate reactions may be local, such as urticaria, angioedema, or systemic, such as severe bronchial obstruction, vasodilation, pulmonary edema, and shock.

“Anonymous” means that information is presented in a form and manner that prevents the identification of the person filing the report.

“Biologics” means therapeutics and products, including blood and vaccines, derived from living sources (such as humans, animals, and microorganisms).

“Disability” means a physical or mental impairment that substantially limits one or more major life activities of an individual.

1. A physical impairment is any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, hemic, lymphatic, skin, and endocrine.

2. A mental impairment is any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

“Event” means a discrete, auditable, and clearly defined occurrence.

“Health care facility” or “facility” means a health care facility licensed pursuant to P.L. 1971, c. 136, N.J.S.A. 26:2H-1 et seq. or a State psychiatric hospital operated by the Department of Human Services and listed in N.J.S.A. 30:1-7.

“Health care professional” means an individual who, acting within the scope of her or his licensure or certification, provides health care services, and includes, but is not limited to, a physician, dentist, nurse, pharmacist or other health care professional whose professional practice is regulated pursuant to Title 45 of the Revised Statutes.

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

“Hyperbilirubinemia” means bilirubin levels greater than 30 milligrams per deciliter.

“Hypoglycemia” means a physiologic state in which the blood sugar falls below 60 milligrams per deciliter and physiological or neurological dysfunction begins.

“Informed consent” means a process of communication between a patient and physician that results in the patient’s

written authorization or agreement to undergo a specific medical intervention.

“Kernicterus” means the medical condition in which elevated levels of bilirubin cause brain damage.

“Low-risk pregnancy” means a pregnancy in a woman aged 18 through 39, with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.

“Medical device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease.

“Medicare and/or Medicaid nursing homes” means a long-term care facility participating in Title XVIII (Medicare) and/or Title XIX (Medicaid) programs of the Federal Social Security Act (42 U.S.C. §§1396-1396v, subchapters XVIII and XIX).

“Near-miss” means an occurrence that could have resulted in an adverse event, but the adverse event was prevented.

“Neonate” means an infant in its first 28 days of life.

“Patient or resident elopement” means a situation in which a registered or admitted patient or resident, excluding competent adults, leaves a health care facility without staff being aware that the patient or resident has done so.

1. In the case of a State-operated psychiatric hospital, patient or resident elopement shall be governed by the policies and procedures of the Department of Human Services with respect to elopement.

“Pressure ulcer” means a skin ulcer that develops as a result of pressure on the skin.

1. “Pressure ulcer” does not include a skin ulcer that develops as a result of an underlying vascular etiology, including arterial insufficiency, venous insufficiency, and/or venous hypertension; or that develops as a result of an underlying neuropathy, such as a diabetic neuropathy.

“Preventable event” means an event that could have been anticipated and prepared against, but occurs because of an error or other system failure.

“Root cause analysis” or “RCA” means an in-depth analysis of a preventable adverse event that is designed to identify both direct and underlying causes of the event, in order to develop corrective actions that could reduce the potential for similar preventable adverse events in the future.