

CHAPTER 9

AN ACT concerning patient safety and supplementing Title 26 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

C.26:2H-12.23 Short title.

1. This act shall be known and may be cited as the "Patient Safety Act."

C.26:2H-12.24 Findings, declarations relative to patient safety.

2. The Legislature finds and declares that:
 - a. Adverse events, some of which are the result of preventable errors, are inherent in all systems, and the health care literature demonstrates that the great majority of medical errors result from systems problems, not individual incompetence;
 - b. Well-designed systems have processes built in to minimize the occurrence of errors, as well as to detect those that do occur; they incorporate mechanisms to continually improve their performance;
 - c. To enhance patient safety, the goal is to craft a health care delivery system that minimizes, to the greatest extent feasible, the harm to patients that results from the delivery system itself;
 - d. An important component of a successful patient safety strategy is a feedback mechanism that allows detection and analysis not only of adverse events, but also of "near-misses";
 - e. To encourage disclosure of these events so that they can be analyzed and used for improvement, it is critical to create a non-punitive culture that focuses on improving processes rather than assigning blame. Health care facilities and professionals must be held accountable for serious preventable adverse events; however, punitive environments are not particularly effective in promoting accountability and increasing patient safety, and may be a deterrent to the exchange of information required to reduce the opportunity for errors to occur in the complex systems of care delivery. Fear of sanctions induces health care professionals and organizations to be silent about adverse events, resulting in serious under-reporting; and
 - f. By establishing an environment that both mandates the confidential disclosure of the most serious, preventable adverse events, and also encourages the voluntary, anonymous and confidential disclosure of less serious adverse events, as well as preventable events and near misses, the State seeks to increase the amount of information on systems failures, analyze the sources of these failures and disseminate information on effective practices for reducing systems failures and improving the safety of patients.

C.26:2H-12.25 Definitions relative to patient safety; plans; reports; documentation, notification of adverse events, etc.

3. a. As used in this act:

"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.

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

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

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

"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 (C.26:2H-1 et seq.) and a State psychiatric hospital operated by the Department of Human Services and listed in R.S.30:1-7.

"Health care professional" means an individual who, acting within the scope of 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.

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

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

"Serious preventable adverse event" means an adverse event that is a preventable event and

results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility.

b. In accordance with the requirements established by the commissioner by regulation, pursuant to this act, a health care facility shall develop and implement a patient safety plan for the purpose of improving the health and safety of patients at the facility.

The patient safety plan shall, at a minimum, include:

(1) a patient safety committee, as prescribed by regulation;

(2) a process for teams of facility staff, which teams are comprised of personnel who are representative of the facility's various disciplines and have appropriate competencies, to conduct ongoing analysis and application of evidence-based patient safety practices in order to reduce the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures;

(3) a process for teams of facility staff, which teams are comprised of personnel who are representative of the facility's various disciplines and have appropriate competencies, to conduct analyses of near-misses, with particular attention to serious preventable adverse events and adverse events; and

(4) a process for the provision of ongoing patient safety training for facility personnel.

The provisions of this subsection shall not be construed to eliminate or lessen a hospital's obligation under current law or regulation to have a continuous quality improvement program.

c. A health care facility shall report to the department or, in the case of a State psychiatric hospital, to the Department of Human Services, in a form and manner established by the commissioner, every serious preventable adverse event that occurs in that facility.

d. A health care facility shall assure that the patient affected by a serious preventable adverse event or an adverse event specifically related to an allergic reaction, or, in the case of a minor or a patient who is incapacitated, the patient's parent or guardian or other family member, as appropriate, is informed of the serious preventable adverse event or adverse event specifically related to an allergic reaction, no later than the end of the episode of care, or, if discovery occurs after the end of the episode of care, in a timely fashion as established by the commissioner by regulation. The time, date, participants and content of the notification shall be documented in the patient's medical record in accordance with rules and regulations adopted by the commissioner. The content of the documentation shall be determined in accordance with the rules and regulations of the commissioner. If the patient's physician determines that the disclosure would seriously and adversely affect the patient's health, then the facility shall assure that the family member, if available, is notified in accordance with rules and regulations adopted by the commissioner. In the event that an adult patient is not informed of the serious preventable adverse event or adverse event specifically related to an allergic reaction, the facility shall assure that the physician includes a statement in the patient's medical record that provides the reason for not informing the patient pursuant to this section.

e. (1) A health care professional or other employee of a health care facility is encouraged to make anonymous reports to the department or, in the case of a State psychiatric hospital, to the Department of Human Services, in a form and manner established by the commissioner, regarding near-misses, preventable events and adverse events that are otherwise not subject to mandatory reporting pursuant to subsection c. of this section.

(2) The commissioner shall establish procedures for and a system to collect, store and analyze information voluntarily reported to the department pursuant to this subsection. The repository shall function as a clearinghouse for trend analysis of the information collected pursuant to this subsection.

f. Any documents, materials or information received by the department, or the Department of Human Services, as applicable, pursuant to the provisions of subsections c. and e. of this section concerning serious preventable adverse events, near-misses, preventable events and adverse events that are otherwise not subject to mandatory reporting pursuant to subsection c. of this section, shall not be:

(1) subject to discovery or admissible as evidence or otherwise disclosed in any civil, criminal or administrative action or proceeding;

(2) considered a public record under P.L.1963, c.73 (C.47:1A-1 et seq.) or P.L.2001,

c.404 (C.47:1A-5 et al.); or

(3) used in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing or licensing of an individual, which is based on the individual's participation in the development, collection, reporting or storage of information in accordance with this section. The provisions of this paragraph shall not be construed to limit a health care facility from taking disciplinary action against a health care professional in a case in which the professional has displayed recklessness, gross negligence or willful misconduct, or in which there is evidence, based on other similar cases known to the facility, of a pattern of significant substandard performance that resulted in serious preventable adverse events.

The information received by the department, or the Department of Human Services, as applicable, shall be shared with the Attorney General in accordance with rules and regulations adopted pursuant to subsection j. of this section, and may be used by the department, the Department of Human Services and the Attorney General for the purposes of this act and for oversight of facilities and health care professionals; however, the departments and the Attorney General shall not use the information for any other purpose.

In using the information to exercise oversight, the department, Department of Human Services and Attorney General, as applicable, shall place primary emphasis on assuring effective corrective action by the facility or health care professional, reserving punitive enforcement or disciplinary action for those cases in which the facility or the professional has displayed recklessness, gross negligence or willful misconduct, or in which there is evidence, based on other similar cases known to the department, Department of Human Services or the Attorney General, of a pattern of significant substandard performance that has the potential for or actually results in harm to patients.

g. Any documents, materials or information developed by a health care facility as part of a process of self-critical analysis conducted pursuant to subsection b. of this section concerning preventable events, near-misses and adverse events, including serious preventable adverse events, and any document or oral statement that constitutes the disclosure provided to a patient or the patient's family member or guardian pursuant to subsection d. of this section, shall not be:

(1) subject to discovery or admissible as evidence or otherwise disclosed in any civil, criminal or administrative action or proceeding; or

(2) used in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing or licensing of an individual, which is based on the individual's participation in the development, collection, reporting or storage of information in accordance with subsection b. of this section. The provisions of this paragraph shall not be construed to limit a health care facility from taking disciplinary action against a health care professional in a case in which the professional has displayed recklessness, gross negligence or wilful misconduct, or in which there is evidence, based on other similar cases known to the facility, of a pattern of significant substandard performance that resulted in serious preventable adverse events.

h. Notwithstanding the fact that documents, materials or information may have been considered in the process of self-critical analysis conducted pursuant to subsection b. of this section, or received by the department or the Department of Human Services pursuant to the provisions of subsection c. or e. of this section, the provisions of this act shall not be construed to increase or decrease, in any way, the availability, discoverability, admissibility or use of any such documents, materials or information if obtained from any source or context other than those specified in this act.

i. The investigative and disciplinary powers conferred on the boards and commissions established pursuant to Title 45 of the Revised Statutes, the Director of the Division of Consumer Affairs in the Department of Law and Public Safety and the Attorney General under the provisions of P.L.1978, c.73 (C.45:1-14 et seq.) or any other law, rule or regulation, as well as the investigative and enforcement powers conferred on the department and the commissioner under the provisions of Title 26 of the Revised Statutes or any other law, rule or regulation, shall not be exercised in such a manner so as to unduly interfere with a health care facility's implementation of its patient safety plan established pursuant to this section. However, this act

shall not be construed to otherwise affect, in any way, the exercise of such investigative, disciplinary and enforcement powers.

j. The commissioner shall, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), adopt such rules and regulations necessary to carry out the provisions of this act. The regulations shall establish: criteria for a health care facility's patient safety plan and patient safety committee; the time frame and format for mandatory reporting of serious preventable adverse events at a health care facility; the types of events that qualify as serious preventable adverse events and adverse events specifically related to an allergic reaction; the circumstances under which a health care facility is not required to inform a patient or the patient's family about a serious preventable adverse event or adverse event specifically related to an allergic reaction; and a system for the sharing of information received by the department and the Department of Human Services pursuant to subsections c. and e. of this section with the Attorney General. In establishing the criteria for reporting serious preventable adverse events, the commissioner shall, to the extent feasible, use criteria for these events that have been or are developed by organizations engaged in the development of nationally recognized standards.

The commissioner shall consult with the Commissioner of Human Services with respect to rules and regulations affecting the State psychiatric hospitals and with the Attorney General with respect to rules and regulations regarding the establishment of a system for the sharing of information received by the department and the Department of Human Services pursuant to subsections c. and e. of this section with the Attorney General.

k. Nothing in this act shall be construed to increase or decrease the discoverability, in accordance with *Christy v. Salem*, No. A-6448-02T3 (Superior Court of New Jersey, Appellate Division, February 17, 2004)(2004 WL291160), of any documents, materials or information if obtained from any source or context other than those specified in this act.

4. This act shall take effect 180 days after the date of enactment.

Approved April 27, 2004.