26:2H-12.23

LEGISLATIVE HISTORY CHECKLIST
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LAWS OF: 2004 **CHAPTER:** 9

NJSA: 26:2H-12.23 ("Patient Safety Act")

BILL NO: S557 (Substituted for A2214)

SPONSOR(S): Vitale and others

DATE INTRODUCED: Pre-filed

COMMITTEE: **ASSEMBLY:** Health and Human Services

SENATE: Health, Human Services and Senior Citizens

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: **ASSEMBLY:** March 15, 2004

SENATE: March 29, 2004

DATE OF APPROVAL: April 27, 2004

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL Senate Committee Substitute (1R) enacted

S557

SPONSOR'S STATEMENT: (Begins on page 7 of original bill) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: Yes

SENATE: Yes

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: No

A2214

SPONSOR'S STATEMENT: (Begins on page 7 of original bill) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: Yes
Identical to Assembly Statement to S557

SENATE: No

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: No

(continued)

VETO MESSAGE: No

GOVERNOR'S PRESS RELEASE ON SIGNING: Yes

FOLLOWING WERE PRINTED:

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REPORTS: No

HEARINGS: Yes

974.90 H434 2002b New Jersey. Legislature. Assembly Health and Human Services Committee
Testimony concerning issues and recommendations….patient safety, held August 1, 2002. Trenton, 2002

974.90 H434 2004 New Jersey. Legislature. Health and Human Services Committee
Meeting on S.557, held 1-26-2004. Trenton, 2004

NEWSPAPER ARTICLES: Yes

"McGreevey signs law for safety of patients," 4-28-2004 Philadelphia Inquirer, p.B3
"McGreevey signs Patient Safety Act," 4-28-2004 The Press, p.A8
"Medical errors to be reported under new law," The Record p.A3
"State tales mew approach to hospital error reports," 4-28-2004 Star Ledger p16

§§1-3
C.26:2H-12.23 to
26:2H-12.25
§4
Note to §§1-3

P.L. 2004, CHAPTER 9, ***approved April 27, 2004***
Senate Committee Substitute (***First Reprint***) for Senate, No. 557

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:*

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

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

EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and intended to be omitted in the law.

Matter underlined thus is new matter.
Matter enclosed in superscript numerals has been adopted as follows:
[1] Assembly AHH committee amendments adopted March 4, 2004.

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.

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.

[1]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.[1]

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 [1]**[**and date**]**, date, participants and content[1] of the notification shall be documented in the patient's medical record in accordance with rules and regulations adopted by the commissioner. [1]The content of the documentation shall be determined in accordance with the rules and regulations of the commissioner.[1] If the patient's physician determines[1]**[**, in accordance with criteria established by the commissioner by regulation**]**[1] that the disclosure would seriously and adversely affect the patient's health, then the facility shall [1]**[**notify**]** assure that [1]the family member, if available, [1]is notified in accordance with rules and regulations adopted by the commissioner[1]. 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 **[1]**[affect]**[1]** 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.

[1]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.[1]

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

"Patient Safety Act"; establishes medical error reporting system.

SENATE, No. 557

STATE OF NEW JERSEY

211th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2004 SESSION

Sponsored by:
Senator JOSEPH F. VITALE
District 19 (Middlesex)

Co-Sponsored by:
Senators Littell, Turner and Allen

SYNOPSIS

"Patient Safety Act"; establishes medical error reporting system and provides "Good Samaritan" protections to certain health care professionals.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.

AN ACT concerning patient safety and supplementing Title 26 of the Revised Statutes and Title 2A of the New Jersey Statutes.

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

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

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, the current punitive medical malpractice environment, with its focus on assigning blame and fixing liability, is not particularly effective in promoting accountability and increasing patient safety, and is actually 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.

3. a. As used in this section:

"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 section, 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. The commissioner may permit a facility to use its existing quality improvement committee for this purpose if the existing committee meets the requirements established for a patient safety committee;

(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.

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, 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, 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. If the patient's physician determines, in accordance with criteria established by the commissioner by regulation that the disclosure would seriously and adversely affect the patient's health, then the facility shall notify the family member, if available. In the event that an adult patient is not informed of the serious preventable adverse event, 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, 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. 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 section. 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; and the types of events that qualify as serious preventable adverse events; and 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. 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.

4. a. If an individual's actual health care facility duty, including on-call duty, does not require a response to a patient emergency situation, a health care professional who, in good faith, responds to a life-threatening emergency or responds to a request for emergency assistance in a life-threatening emergency within a hospital or other health care facility, is not liable for civil damages as a result of an act or omission in the rendering of emergency care. The immunity granted pursuant to this section shall not apply to acts or omissions constituting gross negligence, recklessness or willful misconduct.

b. The provisions of subsection a. of this section do not apply to a health care professional if a provider-patient relationship existed before the emergency, or if consideration in any form is provided to the health care professional for the service rendered.

c. The provisions of subsection a. of this section do not diminish a general hospital's responsibility to comply with all Department of Health and Senior Services licensure requirements concerning medical staff availability at the hospital.

d. A health care professional shall not be liable for civil damages for injury or death caused in an emergency situation occurring in the health care professional's private practice or in a health care facility on account of a failure to inform a patient of the possible consequences of a medical procedure when the failure to inform is caused by any of the following:

(1) the patient was unconscious;

(2) the medical procedure was undertaken without the consent of

the patient because the health care professional reasonably believed that a medical procedure should be undertaken immediately and that there was insufficient time to fully inform the patient; or

(3) a medical procedure was performed on a person legally incapable of giving informed consent, and the health care professional reasonably believed that a medical procedure should be undertaken immediately and that there was insufficient time to obtain the informed consent of the person authorized to give such consent for the patient.

The provisions of this subsection are applicable only to actions for damages for an injury or death arising as a result of a health care professional's failure to inform, and not to actions for damages arising as a result of a health care professional's negligence in rendering or failing to render treatment.

e. As used in this section:

(1) "Health care professional" means a physician, dentist, nurse or other health care professional whose professional practice is regulated pursuant to Title 45 of the Revised Statutes and an emergency medical technician or paramedic certified by the Commissioner of Health and Senior Services pursuant to Title 26 of the Revised Statutes; and

(2) "Health care facility" means a health care facility licensed by the Department of Health and Senior Services pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.).

5. This act shall take effect immediately, except that sections 2 and 3 shall take effect 180 days after the date of enactment.

STATEMENT

This bill, the "Patient Safety Act," establishes a medical error reporting system for health care facilities that seeks to minimize the occurrence of errors, as well as to detect those that do occur, and to incorporate mechanisms to continually improve the performance of facilities to enhance patient safety by minimizing, to the greatest extent feasible, the harm to patients that results from the delivery system itself. In this regard, the bill establishes a system that both mandates the confidential disclosure to the Department of Health and Senior Services (DHSS) or the Department of Human Services (DHS), in the case of State psychiatric hospitals, of the most serious preventable adverse events, and also encourages the voluntary, anonymous and confidential disclosure to the respective departments of less serious adverse events, as well as near-misses.

Specifically, the bill requires all licensed health care facilities in the State and State psychiatric hospitals to develop and implement a patient safety plan, which includes a patient safety committee, for the purpose of improving the health and safety of patients at the facility.

Components of the plan would include a process for teams of facility staff, 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 to reduce the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures; and analyses of near-misses, with particular attention to serious preventable adverse events and adverse events.

A health care facility would be required to report to DHSS or DHS, as applicable, in a form and manner established by the Commissioner of Health and Senior Services, every serious preventable adverse event that occurs in that facility. The bill defines "adverse event" as an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable. "Serious preventable adverse event" is defined as an adverse event that is preventable 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.

The bill also provides that a health care professional or other employee of a health care facility is encouraged to make anonymous reports to the applicable department, 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.

A health care facility would be required to assure that the patient affected by a serious preventable adverse event, 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, 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 bill provides that any documents, materials or information received by the department concerning serious preventable adverse events, near-misses, preventable events and adverse events that are otherwise not subject to mandatory reporting, 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 N.J.S.A.47:1A-1 et seq. or N.J.S.A.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. The bill provides, however, that this provision 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.

Similarly, any documents, materials or information developed by a health care facility as part of a process of self-critical analysis conducted pursuant to this bill, 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 the bill, 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. The bill provides, however, that this provision 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 bill also expands the State's "Good Samaritan" law to provide immunity from civil damages to licensed health care professionals, paramedics and emergency medical technicians (whose duty does not require a response to a patient emergency situation) who, in good faith, respond to a life-threatening emergency or respond to a request for emergency assistance in a life threatening emergency within a hospital or other licensed health care facility. The immunity shall not apply:

-- to acts or omissions constituting gross negligence, recklessness or willful misconduct;

-- if a provider-patient relationship existed before the emergency; or

-- if consideration in any form is provided to the health care professional for the service rendered.

Further, the bill provides that a health care professional shall not be liable for civil damages for injury or death caused in an emergency situation occurring in the health care professional's private practice or in a health care facility on account of a failure to inform a patient of the possible consequences of a medical procedure when the failure to inform is caused by any of the following:

- the patient was unconscious;

- the medical procedure was undertaken without the consent of the

patient because the health care professional reasonably believed that a medical procedure should be undertaken immediately and that there was insufficient time to fully inform the patient; or

- a medical procedure was performed on a person legally incapable of giving informed consent, and the health care professional reasonably believed that a medical procedure should be undertaken immediately and that there was insufficient time to obtain the informed consent of the person authorized to give such consent for the patient.

The immunity provided is applicable only to actions for damages for an injury or death arising as a result of a health care professional's failure to inform, and not to actions for damages arising as a result of a health care professional's negligence in rendering or failing to render treatment.

ASSEMBLY HEALTH AND HUMAN SERVICES COMMITTEE

STATEMENT TO

SENATE COMMITTEE SUBSTITUTE FOR

SENATE, No. 557

with committee amendments

STATE OF NEW JERSEY

DATED: MARCH 4, 2004

The Assembly Health and Human Services Committee reports favorably and with committee amendments the Senate Committee Substitute for Senate Bill No. 557.

As amended by the committee, this committee substitute, which is designated the "Patient Safety Act," establishes a medical error reporting system for health care facilities that seeks to minimize the occurrence of errors, as well as to detect those that do occur, and to incorporate mechanisms to continually improve the performance of facilities to enhance patient safety by minimizing, to the greatest extent feasible, the harm to patients that results from the delivery system itself. The substitute establishes a system that requires confidential disclosure to the Department of Health and Senior Services (DHSS), or the Department of Human Services (DHS) in the case of State psychiatric hospitals, of the most serious preventable adverse events, and also encourages voluntary, anonymous and confidential disclosure to the respective departments of less serious adverse events, as well as near-misses.

Specifically, the substitute requires all licensed health care facilities in the State and State psychiatric hospitals to develop and implement a patient safety plan, which includes a patient safety committee, for the purpose of improving the health and safety of patients at the facility. The plan would include a process for teams of facility staff, 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 to reduce the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures; and analyses of near-misses, with particular attention to serious preventable adverse events and adverse events.

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

A health care facility would be required to report to DHSS or

DHS, as applicable, in a form and manner established by the Commissioner of Health and Senior Services, every serious preventable adverse event that occurs in that facility. In that regard, the substitute defines:

-- "adverse event" as an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable; and

-- "serious preventable adverse event" as an adverse event that is preventable 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.

The substitute also provides that a health care professional or other employee of a health care facility is encouraged to make anonymous reports to the applicable department, in a form and manner established by the Commissioner of Health and Senior Services, regarding near-misses, preventable events and adverse events that are otherwise not subject to mandatory reporting.

A health care facility would be required to 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 of Health and Senior Services by regulation.

The substitute provides that any documents, materials or information received by DHSS or DHS concerning serious preventable adverse events, near-misses, preventable events and adverse events that are otherwise not subject to mandatory reporting, will not be:

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

-- considered a public record under N.J.S.A.47:1A-1 et seq. or N.J.S.A.47:1A-5 et al.; or

-- 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.

The substitute provides, however, that this provision is not to 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.

Similarly, any documents, materials or information developed by

a health care facility as part of a process of self-critical analysis conducted pursuant to this substitute, 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 the substitute, will not be:

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

-- 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.

The substitute provides, however, that this provision is not to 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 substitute specifies that, notwithstanding the fact that documents, materials or information may have been considered in the process of self-critical analysis conducted pursuant to this substitute, or received by DHSS or DHS pursuant to the provisions of this substitute, the provisions of the substitute are not to 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 the substitute.

The substitute further provides that 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 N.J.S.A.45:1-14 et seq. or any other law, rule or regulation, as well as the investigative and enforcement powers conferred on DHSS and the Commissioner of Health and Senior Services under the provisions of Title 26 of the Revised Statutes or any other law, rule or regulation, are not to 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 substitute. The substitute is not, however, to be construed to otherwise affect, in any way, the exercise of such investigative, disciplinary and enforcement powers.

The substitute also provides that nothing in the substitute is to be construed to increase or decrease the discoverability, in accordance with Christy v. Salem, of any documents, materials or information if obtained from any source or context other than those specified in this

substitute.

As reported by the committee, this substitute is identical to Assembly Bill No. 2214 Aca (Weinberg/Manzo), which the committee also reported on this date.

COMMITTEE AMENDMENTS

The committee amendments to the substitute provide as follows:

-- The provisions of the substitute are not to be construed to eliminate or lessen a hospital's obligation under current law or regulation to have a continuous quality improvement program;

-- The notification to a patient or his family member, when applicable, of a serious preventable adverse event or an adverse event specifically related to an allergic reaction, shall include the time, date, participants and content of the notification, as required by regulations of the Department of Health and Senior Services;

-- The word "discoverability" is added in subsection h. of section 3 of the substitute; and

-- Nothing in the substitute is to be construed to increase or decrease the discoverability, in accordance with Christy v. Salem, of any documents, materials or information if obtained from any source or context other than those specified in this substitute.

SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

STATEMENT TO

SENATE COMMITTEE SUBSTITUTE FOR
SENATE, No. 557

STATE OF NEW JERSEY

DATED: JANUARY 26, 2004

The Senate Health, Human Services and Senior Citizens Committee reports favorably a Senate Committee Substitute for Senate Bill No. 557.

This substitute, the "Patient Safety Act," establishes a medical error reporting system for health care facilities that seeks to minimize the occurrence of errors, as well as to detect those that do occur, and to incorporate mechanisms to continually improve the performance of facilities to enhance patient safety by minimizing, to the greatest extent feasible, the harm to patients that results from the delivery system itself. In this regard, the substitute establishes a system that both mandates the confidential disclosure to the Department of Health and Senior Services (DHSS), or the Department of Human Services (DHS) in the case of State psychiatric hospitals, of the most serious preventable adverse events and also encourages the voluntary, anonymous and confidential disclosure to the respective departments of less serious adverse events, as well as near-misses.

Specifically, the substitute requires all licensed health care facilities in the State and State psychiatric hospitals to develop and implement a patient safety plan, which includes a patient safety committee, for the purpose of improving the health and safety of patients at the facility. Components of the plan would include a process for teams of facility staff, 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 to reduce the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures; and analyses of near-misses, with particular attention to serious preventable adverse events and adverse events.

A health care facility would be required to report to DHSS or DHS, as applicable, in a form and manner established by the Commissioner of Health and Senior Services, every serious preventable adverse event that occurs in that facility. The substitute defines "adverse event" as an event that is a negative consequence of

care that results in unintended injury or illness, which may or may not have been preventable. "Serious preventable adverse event" is defined as an adverse event that is preventable 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.

The substitute also provides that a health care professional or other employee of a health care facility is encouraged to make anonymous reports to the applicable department, 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.

A health care facility would be required to 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 substitute provides that any documents, materials or information received by DHSS or DHS concerning serious preventable adverse events, near-misses, preventable events and adverse events that are otherwise not subject to mandatory reporting, 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 N.J.S.A.47:1A-1 et seq. or N.J.S.A.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. The substitute provides, however, that this provision 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.

Similarly, any documents, materials or information developed by a health care facility as part of a process of self-critical analysis conducted pursuant to this substitute, 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 the substitute, 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. The substitute provides, however, that this provision 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 substitute specifies, however, that notwithstanding the fact that documents, materials or information may have been considered in the process of self-critical analysis conducted pursuant to this substitute, or received by DHSS or DHS pursuant to the provisions of this substitute, the provisions of the substitute shall not be construed to affect, in any way, the availability, admissibility or use of any such documents, materials or information if obtained from any source or context other than those specified in the substitute.

The substitute further provides that 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 N.J.S.A.45:1-14 et seq. or any other law, rule or regulation, as well as the investigative and enforcement powers conferred on DHSS and the Commissioner of Health and Senior Services 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 substitute. The substitute shall not, however, be construed to otherwise affect, in any way, the exercise of such investigative, disciplinary and enforcement powers.

ASSEMBLY, No. 2214

STATE OF NEW JERSEY

211th LEGISLATURE

INTRODUCED FEBRUARY 9, 2004

Sponsored by:
Assemblywoman LORETTA WEINBERG
District 37 (Bergen)
Assemblyman LOUIS MANZO
District 31 (Hudson)
Assemblyman ROBERT GORDON
District 38 (Bergen)

SYNOPSIS

"Patient Safety Act"; establishes medical error reporting system.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 3/5/2004)

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:*

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

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.

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.

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 and date of the notification shall be documented in the patient's medical record in accordance with rules and regulations adopted by the commissioner. If the patient's physician determines, in accordance with criteria established by the commissioner by regulation that the disclosure would seriously and adversely affect the patient's health, then the facility shall notify the family member, if available. 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 affect, in any way, the availability, 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.

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

STATEMENT

This bill, the "Patient Safety Act," establishes a medical error reporting system for health care facilities that seeks to minimize the occurrence of errors, as well as to detect those that do occur, and to incorporate mechanisms to continually improve the performance of facilities to enhance patient safety by minimizing, to the greatest extent feasible, the harm to patients that results from the delivery system itself. In this regard, the bill establishes a system that both mandates the confidential disclosure to the Department of Health and Senior Services (DHSS), or the Department of Human Services (DHS) in the case of State psychiatric hospitals, of the most serious preventable adverse events and also encourages the voluntary, anonymous and confidential disclosure to the respective departments of less serious adverse events, as well as near-misses.

Specifically, the bill requires all licensed health care facilities in the State and State psychiatric hospitals to develop and implement a patient safety plan, which includes a patient safety committee, for the purpose of improving the health and safety of patients at the facility. Components of the plan would include a process for teams of facility staff, 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 to reduce the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures; and analyses of near-misses, with particular attention to serious preventable adverse events and adverse events.

A health care facility would be required to report to DHSS or DHS, as applicable, in a form and manner established by the Commissioner of Health and Senior Services, every serious preventable adverse event that occurs in that facility. The bill defines "adverse event" as an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable. "Serious preventable adverse event" is defined as an adverse event that is preventable 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.

The bill also provides that a health care professional or other employee of a health care facility is encouraged to make anonymous reports to the applicable department, 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.

A health care facility would be required to 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 bill provides that any documents, materials or information received by DHSS or DHS concerning serious preventable adverse events, near-misses, preventable events and adverse events that are otherwise not subject to mandatory reporting, 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 N.J.S.A.47:1A-1 et seq. or N.J.S.A.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. The bill provides, however, that this provision 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.

Similarly, any documents, materials or information developed by a health care facility as part of a process of self-critical analysis conducted pursuant to this bill, 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 the bill, 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. The bill provides, however, that this provision 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 bill specifies, however, that notwithstanding the fact that documents, materials or information may have been considered in the process of self-critical analysis conducted pursuant to this bill, or received by DHSS or DHS pursuant to the provisions of this bill, the provisions of the bill shall not be construed to affect, in any way, the availability, admissibility or use of any such documents, materials or information if obtained from any source or context other than those specified in the bill.

The bill further provides that 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 N.J.S.A.45:1-14 et seq. or any other law, rule or regulation, as well as the investigative and enforcement powers conferred on DHSS and the Commissioner of Health and Senior Services 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 bill. The bill shall not, however, be construed to otherwise affect, in any way, the exercise of such investigative, disciplinary and enforcement powers.

ASSEMBLY HEALTH AND HUMAN SERVICES COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2214

with committee amendments

STATE OF NEW JERSEY

DATED: MARCH 4, 2004

The Assembly Health and Human Services Committee reports favorably and with committee amendments Assembly Bill No. 2214.

As amended by the committee, this bill, which is designated the "Patient Safety Act," establishes a medical error reporting system for health care facilities that seeks to minimize the occurrence of errors, as well as to detect those that do occur, and to incorporate mechanisms to continually improve the performance of facilities to enhance patient safety by minimizing, to the greatest extent feasible, the harm to patients that results from the delivery system itself. The bill establishes a system that requires confidential disclosure to the Department of Health and Senior Services (DHSS), or the Department of Human Services (DHS) in the case of State psychiatric hospitals, of the most serious preventable adverse events, and also encourages voluntary, anonymous and confidential disclosure to the respective departments of less serious adverse events, as well as near-misses.

Specifically, the bill requires all licensed health care facilities in the State and State psychiatric hospitals to develop and implement a patient safety plan, which includes a patient safety committee, for the purpose of improving the health and safety of patients at the facility. The plan would include a process for teams of facility staff, 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 to reduce the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures; and analyses of near-misses, with particular attention to serious preventable adverse events and adverse events.

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

A health care facility would be required to report to DHSS or DHS, as applicable, in a form and manner established by the Commissioner of Health and Senior Services, every serious preventable adverse event that occurs in that facility. In that regard, the bill defines:

-- "adverse event" as an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable; and

-- "serious preventable adverse event" as an adverse event that is preventable 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.

The bill also provides that a health care professional or other employee of a health care facility is encouraged to make anonymous reports to the applicable department, in a form and manner established by the Commissioner of Health and Senior Services, regarding near-misses, preventable events and adverse events that are otherwise not subject to mandatory reporting.

A health care facility would be required to 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 of Health and Senior Services by regulation.

The bill provides that any documents, materials or information received by DHSS or DHS concerning serious preventable adverse events, near-misses, preventable events and adverse events that are otherwise not subject to mandatory reporting, will not be:

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

-- considered a public record under N.J.S.A.47:1A-1 et seq. or N.J.S.A.47:1A-5 et al.; or

-- 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.

The bill provides, however, that this provision is not to 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.

Similarly, any documents, materials or information developed by a health care facility as part of a process of self-critical analysis conducted pursuant to this bill, 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 the bill, will not be:

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

-- 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.

The bill provides, however, that this provision is not to 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 bill specifies that, notwithstanding the fact that documents, materials or information may have been considered in the process of self-critical analysis conducted pursuant to this bill, or received by DHSS or DHS pursuant to the provisions of this bill, the provisions of the bill are not to 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 the bill.

The bill further provides that 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 N.J.S.A.45:1-14 et seq. or any other law, rule or regulation, as well as the investigative and enforcement powers conferred on DHSS and the Commissioner of Health and Senior Services under the provisions of Title 26 of the Revised Statutes or any other law, rule or regulation, are not to 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 bill. The bill is not, however, to be construed to otherwise affect, in any way, the exercise of such investigative, disciplinary and enforcement powers.

The bill also provides that nothing in the bill is to be construed to increase or decrease the discoverability, in accordance with Christy v. Salem, of any documents, materials or information if obtained from any source or context other than those specified in this bill.

As reported by the committee, this bill is identical to the Senate Committee Substitute for Senate Bill No. 557 (Aca) (Vitale/Girgenti), which the committee also reported on this date.

COMMITTEE AMENDMENTS

The committee amendments to the bill provide as follows:

-- The provisions of the bill are not to be construed to eliminate or lessen a hospital's obligation under current law or regulation to have a continuous quality improvement program;

-- The notification to a patient or his family member, when applicable, of a serious preventable adverse event or an adverse event specifically related to an allergic reaction, shall include the time, date, participants and content of the notification, as required by regulations of the Department of Health and Senior Services;

-- The word "discoverability" is added in subsection h. of section 3 of the bill; and

-- Nothing in the bill is to be construed to increase or decrease the discoverability, in accordance with Christy v. Salem, of any documents, materials or information if obtained from any source or context other than those specified in this bill.

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RELEASE: April 27, 2004

Office of the Governor

News Releases

Previous Screen

McGreevey Signs Landmark Law Protecting NJ's Families

Patient Safety Act Establishes Medical Error Reporting System

(PERTH AMBOY) –Governor James E. McGreevey today signed landmark legislation designed to improve patient safety and save lives through comprehensive reporting of medical errors by hospitals, nursing homes and other health care facilities.

"As we strive to protect the health of New Jersey's families, we must first and foremost, ensure the safety of our patients," said Governor James E. McGreevey. "Today, I am proud to sign into law – the New Jersey Patient Safety Act. This landmark legislation will help keep our families safe by establishing a non-punitive medical error reporting system. It will allow for better reporting; better, more thorough, investigation; and better solutions that keep our families safe.
It empowers health care professionals to do the right thing and come forward to report mistakes. It will help us fix the systemic problems that lead to errors. But most of all, it saves lives."

The Patient Safety Act (S-557), sponsored by Sen. Joseph F. Vitale (D-Middlesex) and Assemblywoman Loretta Weinberg (D-Hudson), requires health care facilities to report serious, preventable adverse events to the state Department of Health and Senior Services. It also allows anonymous reporting of less serious errors and near misses.

"This law will save lives – it's that simple," said Senator Joseph V. Vitale (D-Middlesex). "Today, New Jersey has taken a momentous step to improve patient safety, renewing our commitment and dedication to ensuring that all New Jerseyans are provided with the highest quality of care.''

Governor McGreevey signed the measure into law during a ceremony at Raritan Bay Medical Center in Perth Amboy. Governor McGreevey was joined for the bill signing by

Commissioner of Health and Senior Services Clifton R. Lacy, M.D., Sen. Vitale, and Betsy Ryan, general counsel of the New Jersey Hospital Association.

“Patient safety is one of the hallmarks of the McGreevey administration,’’ said Health and Senior Services Commissioner Clifton R. Lacy, M.D.“The majority of medical errors occur as a result of problems inherent in complex systems. It is through recognition and understanding of underlying causes that effective preventive measures can be identified and implemented.”

This legislation creates a culture of safety that encourages health care professionals to disclose serious, preventable adverse events within their facilities, where the root causes can be carefully analyzed, as well as to the state Department of Health and Senior Services. It gives health care professionals the legal protection they need to be able to report and more openly discuss medical errors without of litigation.

“The New Jersey Hospital Association has been proud to support legislation that now will require all hospitals to report serious errors and near misses, analyze them in a broader context and make the improvements and changes that will enhance patient safety,” said Gary Carter, president and chief executive officer of the New Jersey Hospital Association.

"Patient safety must be paramount for legislators, doctors, and medical facilities," said Assemblywoman Loretta Weinberg (D-Bergen), chairwoman of the Assembly Health and Human Services Committee. "This medical error reporting will not only save lives, it will better enable the medical community to work collaboratively on performance improvements."

Dr. Lacy said the department will analyze the reported data in an effort to identify trends as well as best practices that would be shared with health care professionals and facilities statewide to prevent the future occurrence of similar problems.

“We must understand what, why and how errors occur so that they can be prevented,’’ said Dr. Lacy.

A 1999 Institute of Medicine report estimated that between 44,000 and 98,000 Americans die every year as a result of preventable medical errors. Medical errors cost the health care industry about 8.8 billion.