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Yes

FOLLOWING WERE PRINTED:

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No

REPORTS:

HEARINGS:

Yes

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

974.90 New Jersey. Legislature. Health and Human Services Committee
H434 Meeting on S.557, held 1-26-2004. Trenton, 2004
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 takes new approach to hospital error reports," 4-28-2004 Star Ledger p16

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

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

3
4 **BE IT ENACTED** by the Senate and General Assembly of the State
5 of New Jersey:

6
7 1. This act shall be known and may be cited as the "Patient Safety
8 Act."

9
10 2. The Legislature finds and declares that:

11 a. Adverse events, some of which are the result of preventable
12 errors, are inherent in all systems, and the health care literature
13 demonstrates that the great majority of medical errors result from
14 systems problems, not individual incompetence;

15 b. Well-designed systems have processes built in to minimize the
16 occurrence of errors, as well as to detect those that do occur; they
17 incorporate mechanisms to continually improve their performance;

18 c. To enhance patient safety, the goal is to craft a health care
19 delivery system that minimizes, to the greatest extent feasible, the
20 harm to patients that results from the delivery system itself;

21 d. An important component of a successful patient safety strategy
22 is a feedback mechanism that allows detection and analysis not only of
23 adverse events, but also of "near-misses";

24 e. To encourage disclosure of these events so that they can be
25 analyzed and used for improvement, it is critical to create a non-
26 punitive culture that focuses on improving processes rather than
27 assigning blame. Health care facilities and professionals must be held
28 accountable for serious preventable adverse events; however, punitive
29 environments are not particularly effective in promoting accountability
30 and increasing patient safety, and may be a deterrent to the exchange
31 of information required to reduce the opportunity for errors to occur
32 in the complex systems of care delivery. Fear of sanctions induces
33 health care professionals and organizations to be silent about adverse
34 events, resulting in serious under-reporting; and

35 f. By establishing an environment that both mandates the
36 confidential disclosure of the most serious, preventable adverse events,
37 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.

1 disclosure of less serious adverse events, as well as preventable events
2 and near misses, the State seeks to increase the amount of information
3 on systems failures, analyze the sources of these failures and
4 disseminate information on effective practices for reducing systems
5 failures and improving the safety of patients.

6 3. a. As used in this act:

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

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

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

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

16 "Event" means a discrete, auditable and clearly defined occurrence.

17 "Health care facility" or "facility" means a health care facility
18 licensed pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) and a State
19 psychiatric hospital operated by the Department of Human Services
20 and listed in R.S.30:1-7.

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

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

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

31 "Serious preventable adverse event" means an adverse event that
32 is a preventable event and results in death or loss of a body part, or
33 disability or loss of bodily function lasting more than seven days or
34 still present at the time of discharge from a health care facility.

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

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

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

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

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

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

8 ¹The provisions of this subsection shall not be construed to
9 eliminate or lessen a hospital's obligation under current law or
10 regulation to have a continuous quality improvement program.¹

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

15 d. A health care facility shall assure that the patient affected by a
16 serious preventable adverse event or an adverse event specifically
17 related to an allergic reaction, or, in the case of a minor or a patient
18 who is incapacitated, the patient's parent or guardian or other family
19 member, as appropriate, is informed of the serious preventable adverse
20 event or adverse event specifically related to an allergic reaction, no
21 later than the end of the episode of care, or, if discovery occurs after
22 the end of the episode of care, in a timely fashion as established by the
23 commissioner by regulation. The time ¹[and date], date, participants
24 and content¹ of the notification shall be documented in the patient's
25 medical record in accordance with rules and regulations adopted by
26 the commissioner. ¹The content of the documentation shall be
27 determined in accordance with the rules and regulations of the
28 commissioner.¹ If the patient's physician determines¹ [, in accordance
29 with criteria established by the commissioner by regulation]¹ that the
30 disclosure would seriously and adversely affect the patient's health,
31 then the facility shall ¹[notify] assure that ¹the family member, if
32 available, ¹is notified in accordance with rules and regulations adopted
33 by the commissioner¹. In the event that an adult patient is not
34 informed of the serious preventable adverse event or adverse event
35 specifically related to an allergic reaction, the facility shall assure that
36 the physician includes a statement in the patient's medical record that
37 provides the reason for not informing the patient pursuant to this
38 section.

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

46 (2) The commissioner shall establish procedures for and a system

1 to collect, store and analyze information voluntarily reported to the
2 department pursuant to this subsection. The repository shall function
3 as a clearinghouse for trend analysis of the information collected
4 pursuant to this subsection.

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

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

14 (2) considered a public record under P.L.1963, c.73 (C.47:1A-1
15 et seq.) or P.L.2001, c.404 (C.47:1A-5 et al.); or

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

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

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

46 g. Any documents, materials or information developed by a health

1 care facility as part of a process of self-critical analysis conducted
2 pursuant to subsection b. of this section concerning preventable
3 events, near-misses and adverse events, including serious preventable
4 adverse events, and any document or oral statement that constitutes
5 the disclosure provided to a patient or the patient's family member or
6 guardian pursuant to subsection d. of this section, shall not be:

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

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

22 h. Notwithstanding the fact that documents, materials or
23 information may have been considered in the process of self-critical
24 analysis conducted pursuant to subsection b. of this section, or
25 received by the department or the Department of Human Services
26 pursuant to the provisions of subsection c. or e. of this section, the
27 provisions of this act shall not be construed to ¹[affect] increase or
28 decrease¹, in any way, the availability¹, discoverability¹, admissibility
29 or use of any such documents, materials or information if obtained
30 from any source or context other than those specified in this act.

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

45 j. The commissioner shall, pursuant to the "Administrative
46 Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), adopt such

1 rules and regulations necessary to carry out the provisions of this act.
2 The regulations shall establish: criteria for a health care facility's
3 patient safety plan and patient safety committee; the time frame and
4 format for mandatory reporting of serious preventable adverse events
5 at a health care facility; the types of events that qualify as serious
6 preventable adverse events and adverse events specifically related to
7 an allergic reaction; the circumstances under which a health care
8 facility is not required to inform a patient or the patient's family about
9 a serious preventable adverse event or adverse event specifically
10 related to an allergic reaction; and a system for the sharing of
11 information received by the department and the Department of Human
12 Services pursuant to subsections c. and e. of this section with the
13 Attorney General. In establishing the criteria for reporting serious
14 preventable adverse events, the commissioner shall, to the extent
15 feasible, use criteria for these events that have been or are developed
16 by organizations engaged in the development of nationally recognized
17 standards.

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

25 ¹k. Nothing in this act shall be construed to increase or decrease
26 the discoverability, in accordance with Christy v. Salem, No. A-6448-
27 02T3 (Superior Court of New Jersey, Appellate Division, February 17,
28 2004)(2004 WL291160), of any documents, materials or information
29 if obtained from any source or context other than those specified in
30 this act.¹

31

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

33

34

35

36

37 "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.



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

3
4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

6
7 1. This act shall be known and may be cited as the "Patient Safety
8 Act."

9
10 2. The Legislature finds and declares that:

11 a. Adverse events, some of which are the result of preventable
12 errors, are inherent in all systems, and the health care literature
13 demonstrates that the great majority of medical errors result from
14 systems problems, not individual incompetence;

15 b. Well-designed systems have processes built in to minimize the
16 occurrence of errors, as well as to detect those that do occur; they
17 incorporate mechanisms to continually improve their performance;

18 c. To enhance patient safety, the goal is to craft a health care
19 delivery system that minimizes, to the greatest extent feasible, the
20 harm to patients that results from the delivery system itself;

21 d. An important component of a successful patient safety strategy
22 is a feedback mechanism that allows detection and analysis not only of
23 adverse events, but also of "near-misses";

24 e. To encourage disclosure of these events so that they can be
25 analyzed and used for improvement, it is critical to create a non-
26 punitive culture that focuses on improving processes rather than
27 assigning blame. Health care facilities and professionals must be held
28 accountable for serious preventable adverse events; however, the
29 current punitive medical malpractice environment, with its focus on
30 assigning blame and fixing liability, is not particularly effective in
31 promoting accountability and increasing patient safety, and is actually
32 a deterrent to the exchange of information required to reduce the
33 opportunity for errors to occur in the complex systems of care
34 delivery. Fear of sanctions induces health care professionals and
35 organizations to be silent about adverse events, resulting in serious
36 under-reporting; and

37 f. By establishing an environment that both mandates the
38 confidential disclosure of the most serious, preventable adverse events,
39 and also encourages the voluntary, anonymous and confidential
40 disclosure of less serious adverse events, as well as preventable events
41 and near misses, the State seeks to increase the amount of information
42 on systems failures, analyze the sources of these failures and
43 disseminate information on effective practices for reducing systems
44 failures and improving the safety of patients.

45
46 3. a. As used in this section:

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

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

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

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

9 "Event" means a discrete, auditable and clearly defined occurrence.

10 "Health care facility" or "facility" means a health care facility
11 licensed pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) and a State
12 psychiatric hospital operated by the Department of Human Services
13 and listed in R.S.30:1-7.

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

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

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

24 "Serious preventable adverse event" means an adverse event that is
25 a preventable event and results in death or loss of a body part, or
26 disability or loss of bodily function lasting more than seven days or
27 still present at the time of discharge from a health care facility.

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

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

33 (1) a patient safety committee, as prescribed by regulation. The
34 commissioner may permit a facility to use its existing quality
35 improvement committee for this purpose if the existing committee
36 meets the requirements established for a patient safety committee;

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

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

1 and adverse events; and

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

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

8 d. A health care facility shall assure that the patient affected by a
9 serious preventable adverse event, or, in the case of a minor or a
10 patient who is incapacitated, the patient's parent or guardian or other
11 family member, as appropriate, is informed of the serious preventable
12 adverse event, no later than the end of the episode of care, or, if
13 discovery occurs after the end of the episode of care, in a timely
14 fashion as established by the commissioner by regulation. If the
15 patient's physician determines, in accordance with criteria established
16 by the commissioner by regulation that the disclosure would seriously
17 and adversely affect the patient's health, then the facility shall notify
18 the family member, if available. In the event that an adult patient is
19 not informed of the serious preventable adverse event, the facility shall
20 assure that the physician includes a statement in the patient's medical
21 record that provides the reason for not informing the patient pursuant
22 to this section.

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

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

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

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

44 (2) considered a public record under P.L.1963, c.73 (C.47:1A-1 et
45 seq.) or P.L.2001, c.404 (C.47:1A-5 et al.); or

46 (3) used in an adverse employment action or in the evaluation of

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

12 The information received by the department, or the Department of
13 Human Services, as applicable, may be used by the department, the
14 Department of Human Services and the Attorney General for the
15 purposes of this act and for oversight of facilities and health care
16 professionals; however, the departments and the Attorney General
17 shall not use the information for any other purpose.

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

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

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

38 (2) used in an adverse employment action or in the evaluation of
39 decisions made in relation to accreditation, certification, credentialing
40 or licensing of an individual, which is based on the individual's
41 participation in the development, collection, reporting or storage of
42 information in accordance with subsection b. of this section. The
43 provisions of this paragraph shall not be construed to limit a health
44 care facility from taking disciplinary action against a health care
45 professional in a case in which the professional has displayed
46 recklessness, gross negligence or wilful misconduct, or in which there

1 is evidence, based on other similar cases known to the facility, of a
2 pattern of significant substandard performance that resulted in serious
3 preventable adverse events.

4 h. The commissioner shall, pursuant to the "Administrative
5 Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), adopt such
6 rules and regulations necessary to carry out the provisions of this
7 section. The regulations shall establish: criteria for a health care
8 facility's patient safety plan and patient safety committee; the time
9 frame and format for mandatory reporting of serious preventable
10 adverse events at a health care facility; and the types of events that
11 qualify as serious preventable adverse events; and the circumstances
12 under which a health care facility is not required to inform a patient or
13 the patient's family about a serious preventable adverse event. In
14 establishing the criteria for reporting serious preventable adverse
15 events, the commissioner shall, to the extent feasible, use criteria for
16 these events that have been or are developed by organizations engaged
17 in the development of nationally recognized standards.

18 The commissioner shall consult with the Commissioner of Human
19 Services with respect to rules and regulations affecting the State
20 psychiatric hospitals.

21

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

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

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

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

45 (1) the patient was unconscious;

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

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

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

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

14 e. As used in this section:

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

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

23
24 5. This act shall take effect immediately, except that sections 2 and
25 3 shall take effect 180 days after the date of enactment.

26
27
28 STATEMENT

29
30 This bill, the "Patient Safety Act," establishes a medical error
31 reporting system for health care facilities that seeks to minimize the
32 occurrence of errors, as well as to detect those that do occur, and to
33 incorporate mechanisms to continually improve the performance of
34 facilities to enhance patient safety by minimizing, to the greatest extent
35 feasible, the harm to patients that results from the delivery system
36 itself. In this regard, the bill establishes a system that both mandates
37 the confidential disclosure to the Department of Health and Senior
38 Services (DHSS) or the Department of Human Services (DHS), in the
39 case of State psychiatric hospitals, of the most serious preventable
40 adverse events, and also encourages the voluntary, anonymous and
41 confidential disclosure to the respective departments of less serious
42 adverse events, as well as near-misses.

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

1 Components of the plan would include a process for teams of facility
2 staff, comprised of personnel who are representative of the facility's
3 various disciplines and have appropriate competencies, to conduct:
4 ongoing analysis and application of evidence-based patient safety
5 practices to reduce the probability of adverse events resulting from
6 exposure to the health care system across a range of diseases and
7 procedures; and analyses of near-misses, with particular attention to
8 serious preventable adverse events and adverse events.

9 A health care facility would be required to report to DHSS or DHS,
10 as applicable, in a form and manner established by the Commissioner
11 of Health and Senior Services, every serious preventable adverse event
12 that occurs in that facility. The bill defines "adverse event" as an event
13 that is a negative consequence of care that results in unintended injury
14 or illness, which may or may not have been preventable. "Serious
15 preventable adverse event" is defined as an adverse event that is
16 preventable and results in death or loss of a body part, or disability or
17 loss of bodily function lasting more than seven days or still present at
18 the time of discharge from a health care facility.

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

24 A health care facility would be required to assure that the patient
25 affected by a serious preventable adverse event, or, in the case of a
26 minor or a patient who is incapacitated, the patient's parent or
27 guardian or other family member, as appropriate, is informed of the
28 serious preventable adverse event, no later than the end of the episode
29 of care, or if discovery occurs after the end of the episode of care, in
30 a timely fashion as established by the commissioner by regulation.

31 The bill provides that any documents, materials or information
32 received by the department concerning serious preventable adverse
33 events, near-misses, preventable events and adverse events that are
34 otherwise not subject to mandatory reporting, shall not be:

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

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

39 (3) used in an adverse employment action or in the evaluation of
40 decisions made in relation to accreditation, certification, credentialing
41 or licensing of an individual, which is based on the individual's
42 participation in the development, collection, reporting or storage of
43 information. The bill provides, however, that this provision shall not
44 be construed to limit a health care facility from taking disciplinary
45 action against a health care professional in a case in which the
46 professional has displayed recklessness, gross negligence or willful

1 misconduct, or in which there is evidence, based on other similar cases
2 known to the facility, of a pattern of significant substandard
3 performance that resulted in serious preventable adverse events.

4 Similarly, any documents, materials or information developed by a
5 health care facility as part of a process of self-critical analysis
6 conducted pursuant to this bill, concerning preventable events, near-
7 misses and adverse events, including serious preventable adverse
8 events, and any document or oral statement that constitutes the
9 disclosure provided to a patient or the patient's family member or
10 guardian pursuant to the bill, shall not be:

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

14 (2) used in an adverse employment action or in the evaluation of
15 decisions made in relation to accreditation, certification, credentialing
16 or licensing of an individual, which is based on the individual's
17 participation in the development, collection, reporting or storage of
18 information. The bill provides, however, that this provision shall not
19 be construed to limit a health care facility from taking disciplinary
20 action against a health care professional in a case in which the
21 professional has displayed recklessness, gross negligence or willful
22 misconduct, or in which there is evidence, based on other similar cases
23 known to the facility, of a pattern of significant substandard
24 performance that resulted in serious preventable adverse events.

25 The bill also expands the State's "Good Samaritan" law to provide
26 immunity from civil damages to licensed health care professionals,
27 paramedics and emergency medical technicians (whose duty does not
28 require a response to a patient emergency situation) who, in good
29 faith, respond to a life-threatening emergency or respond to a request
30 for emergency assistance in a life threatening emergency within a
31 hospital or other licensed health care facility. The immunity shall not
32 apply:

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

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

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

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

45 - the patient was unconscious;

46 - the medical procedure was undertaken without the consent of the

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

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

9 The immunity provided is applicable only to actions for damages for
10 an injury or death arising as a result of a health care professional's
11 failure to inform, and not to actions for damages arising as a result of
12 a health care professional's negligence in rendering or failing to render
13 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)

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

3

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

6

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

9

10 2. The Legislature finds and declares that:

11 a. Adverse events, some of which are the result of preventable
12 errors, are inherent in all systems, and the health care literature
13 demonstrates that the great majority of medical errors result from
14 systems problems, not individual incompetence;

15 b. Well-designed systems have processes built in to minimize the
16 occurrence of errors, as well as to detect those that do occur; they
17 incorporate mechanisms to continually improve their performance;

18 c. To enhance patient safety, the goal is to craft a health care
19 delivery system that minimizes, to the greatest extent feasible, the
20 harm to patients that results from the delivery system itself;

21 d. An important component of a successful patient safety strategy
22 is a feedback mechanism that allows detection and analysis not only of
23 adverse events, but also of "near-misses";

24 e. To encourage disclosure of these events so that they can be
25 analyzed and used for improvement, it is critical to create a non-
26 punitive culture that focuses on improving processes rather than
27 assigning blame. Health care facilities and professionals must be held
28 accountable for serious preventable adverse events; however, punitive
29 environments are not particularly effective in promoting accountability
30 and increasing patient safety, and may be a deterrent to the exchange
31 of information required to reduce the opportunity for errors to occur
32 in the complex systems of care delivery. Fear of sanctions induces
33 health care professionals and organizations to be silent about adverse
34 events, resulting in serious under-reporting; and

35 f. By establishing an environment that both mandates the
36 confidential disclosure of the most serious, preventable adverse events,
37 and also encourages the voluntary, anonymous and confidential
38 disclosure of less serious adverse events, as well as preventable events
39 and near misses, the State seeks to increase the amount of information
40 on systems failures, analyze the sources of these failures and
41 disseminate information on effective practices for reducing systems
42 failures and improving the safety of patients.

43

44 3. a. As used in this act:

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

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

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

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

6 "Event" means a discrete, auditable and clearly defined occurrence.

7 "Health care facility" or "facility" means a health care facility
8 licensed pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) and a State
9 psychiatric hospital operated by the Department of Human Services
10 and listed in R.S.30:1-7.

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

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

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

21 "Serious preventable adverse event" means an adverse event that is
22 a preventable event and results in death or loss of a body part, or
23 disability or loss of bodily function lasting more than seven days or
24 still present at the time of discharge from a health care facility.

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

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

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

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

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

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

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

1 d. A health care facility shall assure that the patient affected by a
2 serious preventable adverse event or an adverse event specifically
3 related to an allergic reaction, or, in the case of a minor or a patient
4 who is incapacitated, the patient's parent or guardian or other family
5 member, as appropriate, is informed of the serious preventable adverse
6 event or adverse event specifically related to an allergic reaction, no
7 later than the end of the episode of care, or, if discovery occurs after
8 the end of the episode of care, in a timely fashion as established by the
9 commissioner by regulation. The time and date of the notification
10 shall be documented in the patient's medical record in accordance with
11 rules and regulations adopted by the commissioner. If the patient's
12 physician determines, in accordance with criteria established by the
13 commissioner by regulation that the disclosure would seriously and
14 adversely affect the patient's health, then the facility shall notify the
15 family member, if available. In the event that an adult patient is not
16 informed of the serious preventable adverse event or adverse event
17 specifically related to an allergic reaction, the facility shall assure that
18 the physician includes a statement in the patient's medical record that
19 provides the reason for not informing the patient pursuant to this
20 section.

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

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

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

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

42 (2) considered a public record under P.L.1963, c.73 (C.47:1A-1 et
43 seq.) or P.L.2001, c.404 (C.47:1A-5 et al.); or

44 (3) used in an adverse employment action or in the evaluation of
45 decisions made in relation to accreditation, certification, credentialing
46 or licensing of an individual, which is based on the individual's

1 participation in the development, collection, reporting or storage of
2 information in accordance with this section. The provisions of this
3 paragraph shall not be construed to limit a health care facility from
4 taking disciplinary action against a health care professional in a case
5 in which the professional has displayed recklessness, gross negligence
6 or willful misconduct, or in which there is evidence, based on other
7 similar cases known to the facility, of a pattern of significant
8 substandard performance that resulted in serious preventable adverse
9 events.

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

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

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

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

38 (2) used in an adverse employment action or in the evaluation of
39 decisions made in relation to accreditation, certification, credentialing
40 or licensing of an individual, which is based on the individual's
41 participation in the development, collection, reporting or storage of
42 information in accordance with subsection b. of this section. The
43 provisions of this paragraph shall not be construed to limit a health
44 care facility from taking disciplinary action against a health care
45 professional in a case in which the professional has displayed
46 recklessness, gross negligence or wilful misconduct, or in which there

1 is evidence, based on other similar cases known to the facility, of a
2 pattern of significant substandard performance that resulted in serious
3 preventable adverse events.

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

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

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

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

8
9 4. This act shall take effect 180 days after the date of enactment.

10
11
12 STATEMENT

13
14 This bill, the "Patient Safety Act," establishes a medical error
15 reporting system for health care facilities that seeks to minimize the
16 occurrence of errors, as well as to detect those that do occur, and to
17 incorporate mechanisms to continually improve the performance of
18 facilities to enhance patient safety by minimizing, to the greatest extent
19 feasible, the harm to patients that results from the delivery system
20 itself. In this regard, the bill establishes a system that both mandates
21 the confidential disclosure to the Department of Health and Senior
22 Services (DHSS), or the Department of Human Services (DHS) in the
23 case of State psychiatric hospitals, of the most serious preventable
24 adverse events and also encourages the voluntary, anonymous and
25 confidential disclosure to the respective departments of less serious
26 adverse events, as well as near-misses.

27 Specifically, the bill requires all licensed health care facilities in the
28 State and State psychiatric hospitals to develop and implement a
29 patient safety plan, which includes a patient safety committee, for the
30 purpose of improving the health and safety of patients at the facility.
31 Components of the plan would include a process for teams of facility
32 staff, comprised of personnel who are representative of the facility's
33 various disciplines and have appropriate competencies, to conduct:
34 ongoing analysis and application of evidence-based patient safety
35 practices to reduce the probability of adverse events resulting from
36 exposure to the health care system across a range of diseases and
37 procedures; and analyses of near-misses, with particular attention to
38 serious preventable adverse events and adverse events.

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

1 loss of bodily function lasting more than seven days or still present at
2 the time of discharge from a health care facility.

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

8 A health care facility would be required to assure that the patient
9 affected by a serious preventable adverse event or an adverse event
10 specifically related to an allergic reaction, or, in the case of a minor or
11 a patient who is incapacitated, the patient's parent or guardian or other
12 family member, as appropriate, is informed of the serious preventable
13 adverse event or adverse event specifically related to an allergic
14 reaction, no later than the end of the episode of care, or if discovery
15 occurs after the end of the episode of care, in a timely fashion as
16 established by the commissioner by regulation. The bill provides that
17 any documents, materials or information received by DHSS or DHS
18 concerning serious preventable adverse events, near-misses,
19 preventable events and adverse events that are otherwise not subject
20 to mandatory reporting, shall not be:

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

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

25 (3) used in an adverse employment action or in the evaluation of
26 decisions made in relation to accreditation, certification, credentialing
27 or licensing of an individual, which is based on the individual's
28 participation in the development, collection, reporting or storage of
29 information. The bill provides, however, that this provision shall not
30 be construed to limit a health care facility from taking disciplinary
31 action against a health care professional in a case in which the
32 professional has displayed recklessness, gross negligence or willful
33 misconduct, or in which there is evidence, based on other similar cases
34 known to the facility, of a pattern of significant substandard
35 performance that resulted in serious preventable adverse events.

36 Similarly, any documents, materials or information developed by a
37 health care facility as part of a process of self-critical analysis
38 conducted pursuant to this bill, concerning preventable events, near-
39 misses and adverse events, including serious preventable adverse
40 events, and any document or oral statement that constitutes the
41 disclosure provided to a patient or the patient's family member or
42 guardian pursuant to the bill, shall not be:

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

45 or

1 (2) used in an adverse employment action or in the evaluation of
2 decisions made in relation to accreditation, certification, credentialing
3 or licensing of an individual, which is based on the individual's
4 participation in the development, collection, reporting or storage of
5 information. The bill provides, however, that this provision shall not
6 be construed to limit a health care facility from taking disciplinary
7 action against a health care professional in a case in which the
8 professional has displayed recklessness, gross negligence or willful
9 misconduct, or in which there is evidence, based on other similar cases
10 known to the facility, of a pattern of significant substandard
11 performance that resulted in serious preventable adverse events.

12 The bill specifies, however, that notwithstanding the fact that
13 documents, materials or information may have been considered in the
14 process of self-critical analysis conducted pursuant to this bill, or
15 received by DHSS or DHS pursuant to the provisions of this bill, the
16 provisions of the bill shall not be construed to affect, in any way, the
17 availability, admissibility or use of any such documents, materials or
18 information if obtained from any source or context other than those
19 specified in the bill.

20 The bill further provides that investigative and disciplinary powers
21 conferred on the boards and commissions established pursuant to Title
22 45 of the Revised Statutes, the Director of the Division of Consumer
23 Affairs in the Department of Law and Public Safety and the Attorney
24 General under the provisions of N.J.S.A.45:1-14 et seq. or any other
25 law, rule or regulation, as well as the investigative and enforcement
26 powers conferred on DHSS and the Commissioner of Health and
27 Senior Services under the provisions of Title 26 of the Revised
28 Statutes or any other law, rule or regulation, shall not be exercised in
29 such a manner so as to unduly interfere with a health care facility's
30 implementation of its patient safety plan established pursuant to this
31 bill. The bill shall not, however, be construed to otherwise affect, in
32 any way, the exercise of such investigative, disciplinary and
33 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.

Office of the Governor

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News Releases

RELEASE: April 27, 2004

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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.

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