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ASSEMBLY, No. 4327

STATE OF NEW JERSEY
212th LEGISLATURE

INTRODUCED JUNE 11, 2007

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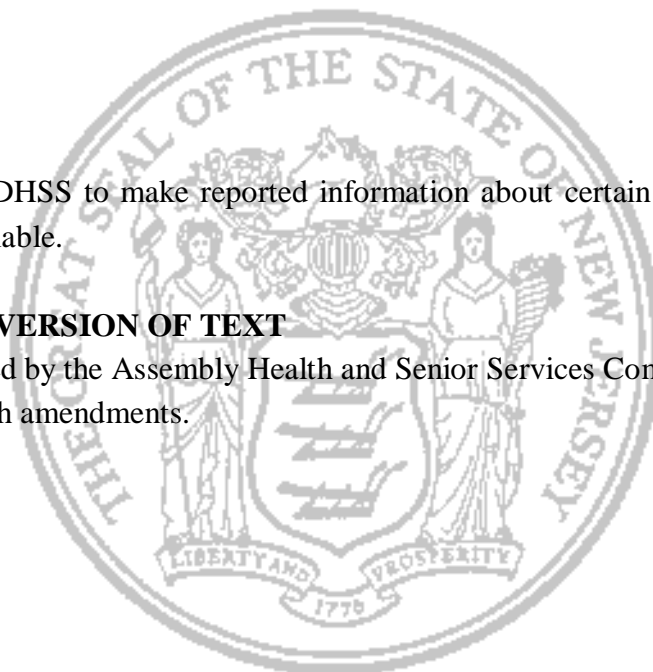
Scalera, Schaer and Prieto

SYNOPSIS

Requires DHSS to make reported information about certain adverse events publicly available.

CURRENT VERSION OF TEXT

As reported by the Assembly Health and Senior Services Committee on June 14, 2007, with amendments.



(Sponsorship Updated As Of: 11/9/2007)

1 AN ACT concerning information about adverse events in health care
2 facilities and amending P.L.2004, c.9.

3

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

6

7 1. Section 3 of P.L.2004, c.9 (C.26:2H-12.25) is amended to
8 read as follows:

9 3. a. As used in this act:

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

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

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

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

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

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

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

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

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

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

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

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

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

¹Assembly AHE committee amendments adopted June 14, 2007.

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

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

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

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

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

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

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

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

47 e. (1) A health care professional or other employee of a health
48 care facility is encouraged to make anonymous reports to the

1 department or, in the case of a State psychiatric hospital, to the
2 Department of Human Services, in a form and manner established
3 by the commissioner, regarding near-misses, preventable events and
4 adverse events that are otherwise not subject to mandatory reporting
5 pursuant to subsection c. of this section.

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

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

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

21 (2) considered a public record under P.L.1963, c.73 (C.47:1A-1
22 et seq.) or P.L.2001, c.404 (C.47:1A-5 et al.) ‘[, except to the
23 extent utilized by the department for the purposes of subsection l. of
24 this section]’; or

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

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

45 In using the information to exercise oversight, the department,
46 Department of Human Services and Attorney General, as
47 applicable, shall place primary emphasis on assuring effective
48 corrective action by the facility or health care professional,

1 reserving punitive enforcement or disciplinary action for those
2 cases in which the facility or the professional has displayed
3 recklessness, gross negligence or willful misconduct, or in which
4 there is evidence, based on other similar cases known to the
5 department, Department of Human Services or the Attorney
6 General, of a pattern of significant substandard performance that
7 has the potential for or actually results in harm to patients.

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

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

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

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

40 i. The investigative and disciplinary powers conferred on the
41 boards and commissions established pursuant to Title 45 of the
42 Revised Statutes, the Director of the Division of Consumer Affairs
43 in the Department of Law and Public Safety and the Attorney
44 General under the provisions of P.L.1978, c.73 (C.45:1-14 et seq.)
45 or any other law, rule or regulation, as well as the investigative and
46 enforcement powers conferred on the department and the
47 commissioner under the provisions of Title 26 of the Revised
48 Statutes or any other law, rule or regulation, shall not be exercised

1 in such a manner so as to unduly interfere with a health care
2 facility's implementation of its patient safety plan established
3 pursuant to this section. However, this act shall not be construed to
4 otherwise affect, in any way, the exercise of such investigative,
5 disciplinary and enforcement powers.

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

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

32 k. Nothing in this act shall be construed to increase or decrease
33 the discoverability, in accordance with *Christy v. Salem*, No. A-
34 6448-02T3 (Superior Court of New Jersey, Appellate Division,
35 February 17, 2004)(2004 WL291160), of any documents, materials
36 or information if obtained from any source or context other than
37 those specified in this act.

38 1. (1) The commissioner, in consultation with the Commissioner
39 of Human Services, shall make available to members of the public,
40 on the official Internet website of the Department of Health and
41 Senior Services, a '[list of the number]' report on hospital
42 performance on patient safety measures with appropriate statistical
43 risk adjustments based upon significant hospital characteristics and
44 covariates of patient clinical outcomes.

45 (a) The report shall include, at a minimum, the risk-adjusted rate
46 of occurrence¹ of serious preventable adverse events that ¹[are
47 reported to the appropriate department pursuant to this section, by
48 health care facility, without providing] have resulted in death or

1 loss of a body part, or disability or loss of bodily function lasting
2 more than seven days or still present at the time of discharge from a
3 health care facility. In providing this information, the
4 commissioner shall take into consideration not only the number of
5 events but their rate of occurrence and how this rate compares
6 nationwide, if applicable.¹

7 ‘(b) The report shall not provide’ any identifying information
8 about any person connected with any such event ‘and shall not
9 include the day or month on which any such event occurred’.

10 ‘(c)’ The ‘[list] report’ shall be presented in such a format as
11 the commissioner deems appropriate to enable comparison among
12 health care facilities in particular facility categories with respect to
13 the information, and, as it pertains to general hospitals, shall be
14 included in the New Jersey Hospital Performance Report annually
15 issued by the commissioner that measures the performance of
16 general hospitals in the State.

17 (2) The commissioner and the Commissioner of Human Services
18 shall jointly issue an annual report to the Governor, and to the
19 Legislature pursuant to section 2 of P.L.1991, c.164 (C.52:14-19.1),
20 to be made available on the official Internet website of the
21 department, which assesses the progress made by health care
22 facilities in effectuating the purposes of P.L.2004, c.9 (C.26:2H-
23 12.23 et seq.) and makes such recommendations for operational
24 changes in health care facilities, and specifically for changes by
25 regulation or legislation, as either or both commissioners determine
26 appropriate.

27 (cf: P.L.2004, c.9, s.3)

28
29 2. This act shall take effect ‘[immediately] one year after the
30 date of enactment or one year after the adoption of regulations by
31 the Commissioner of Health and Senior Services to implement the
32 provisions of P.L.2004, c.9 (C.26:2H-12.23 et seq.) in all health
33 care facilities to which the provisions of that act apply, whichever
34 date is later’.