S T A T E O F N E W Y O R K

11180

I N A S S E M B L Y

May 24, 2010

Introduced by M. of A. GOTTFRIED -- (at request of the Department of Health) -- read once and referred to the Committee on Health

AN ACT to amend the public health law and the education law, in relation to adverse event reporting and notification by hospitals and diagnostic and treatment centers; and to amend part X2 of chapter 62 of the laws of 2003, amending the public health law relating to allowing for the use of funds of the office of professional medical conduct for activities of the patient health information and quality improvement act of 2000, in relation to omitting sunset provisions for enhanced penalties

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Section 2805-l of the public health law, as added by chapter 266 of the laws of 1986, subdivision 3 as amended by chapter 542 of the laws of 2000, subdivision 4 as added and subdivision 5 as renumbered by chapter 632 of the laws of 2006, is amended to read as follows:

S 2805-l. [Incident] ADVERSE EVENT reporting. 1. (A) FOR PURPOSES OF THIS SECTION, "HOSPITAL" MEANS ANY GENERAL HOSPITAL OR DIAGNOSTIC AND TREATMENT CENTER.

(B) All hospitals[, as defined in subdivision ten of section twenty-eight hundred one of this article,] shall be required to report [incidents] ADVERSE EVENTS described by subdivision two of this section to the department WITHIN TWENTY-FOUR HOURS OF OBTAINING KNOWLEDGE OF ANY INFORMATION WHICH REASONABLY APPEARS TO SHOW THAT SUCH AN ADVERSE EVENT HAS OCCURRED. SUCH REPORT SHALL BE MADE in a manner [and within time periods] as may be specified by regulation of the department.

2. The following [incidents] ADVERSE EVENTS shall be reported to the department:

(a) patients' deaths or impairments of bodily functions in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards;

(b) fires in the hospital which disrupt the provision of patient care services or cause harm to patients or staff;

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [ ] is old law to be omitted.

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(c) equipment malfunction during treatment or diagnosis of a patient which did or could have adversely affected a patient or hospital personnel;

(d) poisoning occurring within the hospital;

(e) strikes by hospital staff;

(f) disasters or other emergency situations external to the hospital environment which affect hospital operations; [and]

(g) termination of any services vital to the continued safe operation of the hospital or to the health and safety of its patients and personnel, including but not limited to the anticipated or actual termination of telephone, electric, gas, fuel, water, heat, air conditioning, rodent or pest control, laundry services, food or contract services[.];

(H) SERIOUS CRIMES OCCURRING ON HOSPITAL PREMISES OR GROUNDS, AS DEFINED BY THE COMMISSIONER; AND

(I) OTHER SERIOUS ADVERSE EVENTS AS DETERMINED BY THE COMMISSIONER AFTER CONSIDERATION OF NATIONAL STANDARDS AND EXPERT ADVICE PROVIDED PURSUANT TO SUBDIVISION SIX OF THIS SECTION.

3. (A)(I) The hospital shall conduct an investigation of [incidents] ADVERSE EVENTS described in paragraphs (a) [through (d)] AND (C) of subdivision two of this section. THE HOSPITAL SHALL COMPLETE SUCH INVESTIGATION AND PROVIDE TO THE DEPARTMENT A WRITTEN REPORT THEREOF within thirty days of obtaining knowledge of any information which reasonably appears to show that such an [incident] ADVERSE EVENT has occurred[, provided that, if the hospital reasonably expects such investigation to extend beyond such thirty day period, the hospital shall notify the department of such expectation and the reason therefor, and shall inform the department of the expected completion date of the investigation. The hospital shall provide to the department a copy of the investigation report within twenty-four hours of completion. Nothing herein shall limit the authority of the department to conduct an investigation of incidents occurring in general hospitals].

(II) IF DIRECTED TO DO SO BY THE DEPARTMENT, THE HOSPITAL SHALL CONDUCT AN INVESTIGATION OF ADVERSE EVENTS DESCRIBED IN PARAGRAPHS (B) AND (D) THROUGH (I) OF SUBDIVISION TWO OF THIS SECTION AND SHALL COMPLETE SUCH INVESTIGATION AND PROVIDE TO THE DEPARTMENT A WRITTEN REPORT THEREOF WITHIN THIRTY DAYS OF RECEIVING SUCH DIRECTION FROM THE DEPARTMENT.

(B) A HOSPITAL MAY SUBMIT TO THE COMMISSIONER A WRITTEN REQUEST FOR AN EXTENSION OF TIME TO COMPLETE AN INVESTIGATION AND SUBMIT AN INVESTIGATION REPORT PURSUANT TO PARAGRAPH (A) OF THIS SUBDIVISION. SUCH REQUEST SHALL STATE THE LENGTH OF THE EXTENSION REQUESTED, WHY SUCH EXTENSION IS NECESSARY, AND WHAT STEPS HAVE BEEN OR WILL BE TAKEN BY THE HOSPITAL TO ENSURE THAT PATIENT SAFETY WOULD NOT BE COMPROMISED BY APPROVAL OF SUCH EXTENSION. THE COMMISSIONER MAY GRANT AN EXTENSION IF HE OR SHE FINDS IT TO BE REASONABLE AFTER CONSIDERATION OF THE INFORMATION SUBMITTED BY THE HOSPITAL AND FACTORS INCLUDING BUT NOT LIMITED TO THE SERIOUSNESS OF THE EVENT, THE MAGNITUDE AND URGENCY OF THE RISK IT PRESENTS, THE LIKELIHOOD OF REPETITION AND THE IMPACT AN EXTENSION MAY HAVE UPON PATIENT SAFETY. THE COMMISSIONER MAY, IN HIS OR HER DISCRETION, GRANT AN EXTENSION OF TIME WHICH IS OF LONGER OR SHORTER DURATION THAN THAT REQUESTED BY THE HOSPITAL AND MAY, IN HIS OR HER DISCRETION, GRANT ADDITIONAL EXTENSIONS UNDER THE SAME CRITERIA LISTED HEREIN.

4. NOTHING HEREIN SHALL LIMIT THE AUTHORITY OF THE DEPARTMENT TO CONDUCT INVESTIGATIONS OF ADVERSE EVENTS OCCURRING IN HOSPITALS, NOR TO ENFORCE THE PROVISIONS OF THIS CHAPTER BASED ON SUCH EVENTS.

5. THE DEPARTMENT SHALL ANALYZE REPORTS OF INVESTIGATIONS OF ADVERSE EVENTS AND USE SUCH ANALYSES IN THE DEVELOPMENT, DISSEMINATION AND TRACKING OF PATIENT SAFETY GOALS AND BEST PRACTICES IN PATIENT SAFETY. THE DEPARTMENT MAY ALSO RELEASE TO HOSPITALS OR TO THE PUBLIC OR BOTH ANALYSES AND FINDINGS DERIVED FROM THE ADVERSE EVENT DATA IN A FORMAT THAT DOES NOT IDENTIFY SPECIFIC PATIENTS.

6. THE DEPARTMENT SHALL CONSULT, AS APPROPRIATE, WITH CLINICIANS, HOSPITAL ADMINISTRATORS, RESEARCHERS AND CONSUMERS WITH EXPERTISE IN THE AREA OF PATIENT SAFETY AND QUALITY IMPROVEMENT CONCERNING:

(A) IMPROVEMENTS TO THE ADVERSE EVENT REPORTING SYSTEM, INCLUDING BUT NOT LIMITED TO, CHANGES IN THE TYPES OF ADVERSE EVENTS AND OTHER RELEVANT PATIENT DATA THAT SHOULD BE REPORTED;

(B) INTEGRATION OF ADVERSE EVENT DATA WITH OTHER DATA REPORTING SYSTEMS FOR PURPOSES OF IMPROVING PATIENT SAFETY;

(C) COLLABORATIVE STRATEGIES TO IMPROVE PATIENT SAFETY WHICH MAY INCLUDE, BUT ARE NOT LIMITED TO, CONSULTATION WITH HOSPITALS TO IDENTIFY EFFECTIVE STRATEGIES DEPLOYED TO PROMOTE PATIENT SAFETY AND DEVELOPMENT OF EDUCATION PROGRAMS TO TARGET AREAS IN NEED OF IMPROVEMENT BASED ON FINDINGS OF THE ADVERSE EVENT REPORTING SYSTEM;

(D) THE TYPES OF ADVERSE EVENT DATA THAT SHOULD BE DISCLOSED TO THE PUBLIC; AND

(E) STRATEGIES TO ENCOURAGE REPORTING UNDER THIS SECTION.

7. (A) EACH GENERAL HOSPITAL, AND EACH DIAGNOSTIC AND TREATMENT CENTER THAT PROVIDES AMBULATORY SURGERY, DIAGNOSTIC OR THERAPEUTIC RADIATION OR END STAGE RENAL DISEASE SERVICES, SHALL ESTABLISH A PATIENT SAFETY COMMITTEE WHICH SHALL BE CHARGED WITH:

(I) CONDUCTING ONGOING ANALYSIS AND APPLICATION OF EVIDENCE-BASED PATIENT SAFETY PRACTICES IN ORDER TO REDUCE THE PROBABILITY OF ADVERSE EVENTS;

(II) CONDUCTING ANALYSES OF ADVERSE EVENTS AND NEAR-MISS EVENTS THAT OCCUR WITHIN THE FACILITY; AND

(III) DEVELOPING AND PROMOTING THE IMPLEMENTATION OF RISK REDUCTION STRATEGIES TO PREVENT THE OCCURRENCE OF ADVERSE OR NEAR-MISS EVENTS.

(B) THE RESPONSIBILITIES OF THE PATIENT SAFETY COMMITTEE MAY BE ASSUMED BY AN EXISTING COMMITTEE OF THE HOSPITAL, PROVIDED THAT SUCH COMMITTEE SATISFIES THE REQUIREMENTS SET FORTH IN THIS SECTION AND IN REGULATIONS PROMULGATED BY THE COMMISSIONER.

(C) THE PATIENT SAFETY COMMITTEE SHALL BE CHAIRED BY A PATIENT SAFETY OFFICER WHO SHALL REPORT DIRECTLY TO THE CHIEF EXECUTIVE OFFICER OR ADMINISTRATOR, AS APPLICABLE, AND SHALL PRESENT ON AT LEAST A QUARTERLY BASIS TO THE GOVERNING BODY OF THE HOSPITAL A REPORT ON THE COMMITTEE'S ACTIVITIES, FINDINGS AND RECOMMENDATIONS AND THE STATUS OF EFFORTS TO IMPLEMENT THOSE RECOMMENDATIONS PREVIOUSLY MADE BY THE COMMITTEE AND ADOPTED.

(D) FOR PURPOSES OF THIS SUBDIVISION, "NEAR-MISS EVENT" MEANS AN EVENT OR SITUATION THAT COULD HAVE RESULTED IN AN ADVERSE EVENT BUT DID NOT, EITHER BY CHANCE OR THROUGH TIMELY INTERVENTION.

[4.] 8. The commissioner shall establish protocols for hospital personnel where a patient under the age of eighteen years dies during transportation to the hospital or while at the hospital, under circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards. Such protocols shall address matters including, but not limited to, the following:

(a) medical and social history, and examination of the patient;

(b) preservation of evidence and chain of custody;

(c) questioning of the patient's family, guardian or person in parental authority;
(d) circumstances surrounding the injury resulting in death;
(e) determination of the cause of death;
(f) notification of law enforcement personnel; and
(g) reporting requirements under title six of article six of the social services law.
In developing such protocols, the commissioner shall consult with the office of children and family services, local departments of social services, coordinators of child fatality review teams established pursuant to section four hundred twenty-two-b of the social services law, law enforcement agencies, pediatricians preferably with expertise in the area of child abuse and maltreatment or forensic pediatrics, and such other persons as the commissioner deems necessary.
[5.] 9. The commissioner shall make, adopt, promulgate and enforce such rules and regulations as he may deem appropriate to effectuate the purposes of this section.
10. (A) NOTWITHSTANDING ANY INCONSISTENT PROVISION OF SECTION TWELVE OF THIS CHAPTER OR ANY OTHER LAW, THE COMMISSIONER MAY IMPOSE A CIVIL PENALTY NOT TO EXCEED FIVE THOUSAND DOLLARS FOR EACH VIOLATION OF THE REQUIREMENTS OF THIS SECTION OR THE RULES AND REGULATIONS PROMULGATED PURSUANT TO SUCH SECTION PERTAINING TO THE TIMELY REPORTING AND INVESTIGATION OF ADVERSE EVENTS AND THE SUBMISSION OF INVESTIGATION REPORTS CONCERNING SUCH EVENTS.
(B) THE PENALTY PROVIDED FOR IN PARAGRAPH (A) OF THIS SUBDIVISION MAY BE INCREASED TO AN AMOUNT NOT TO EXCEED SEVEN THOUSAND FIVE HUNDRED DOLLARS FOR A SUBSEQUENT VIOLATION IF THE PERSON COMMITTED THE SAME VIOLATION, WITH RESPECT TO THE SAME OR ANY OTHER PERSON OR PERSONS, WITHIN TWELVE MONTHS OF THE INITIAL VIOLATION FOR WHICH A PENALTY WAS ASSESSED PURSUANT TO PARAGRAPH (A) OF THIS SUBDIVISION.
(C) THE PENALTY PROVIDED FOR IN PARAGRAPH (A) OF THIS SUBDIVISION MAY BE INCREASED TO AN AMOUNT NOT TO EXCEED TEN THOUSAND DOLLARS FOR EACH VIOLATION IF THE ADVERSE EVENT DIRECTLY RESULTED IN SERIOUS PHYSICAL HARM TO A PATIENT OR PATIENTS.
(D) IN ADDITION TO THE PENALTIES AVAILABLE UNDER SUBDIVISIONS (A), (B) AND (C) OF THIS SUBDIVISION, THE COMMISSIONER MAY IMPOSE A CIVIL PENALTY OF FIVE HUNDRED DOLLARS FOR EACH DAY THAT A HOSPITAL FAILS TO SUBMIT AN INVESTIGATION REPORT AS REQUIRED PURSUANT TO PARAGRAPH (A) OF SUBDIVISION THREE OF THIS SECTION, IF THE COMMISSIONER HAS NOT AUTHORIZED AN EXTENSION OF TIME PURSUANT TO PARAGRAPH (B) OF SUBDIVISION THREE OF THIS SECTION.
(E) THE COMPTROLLER IS HEREBY AUTHORIZED AND DIRECTED TO DEPOSIT AMOUNTS COLLECTED UNDER THIS SUBDIVISION TO THE PATIENT SAFETY CENTER ACCOUNT TO BE USED FOR PURPOSES OF THE PATIENT SAFETY CENTER CREATED BY TITLE TWO OF ARTICLE TWENTY-NINE-D OF THIS CHAPTER.
(F) ANY CIVIL PENALTIES AVAILABLE UNDER THIS SUBDIVISION SHALL BE ASSESSED SUBJECT TO THE APPLICABLE PROVISIONS OF SECTIONS TWELVE AND TWELVE-A OF THIS CHAPTER.
S 2. Section 2805-m of the public health law, as amended by chapter 808 of the laws of 1987, is amended to read as follows:
S 2805-m. Confidentiality. 1. The information required to be collected and maintained pursuant to sections twenty-eight hundred five-j and twenty-eight hundred five-k of this article[,] AND THE reports required to be submitted pursuant to section twenty-eight hundred five-l of this article [and any incident reporting requirements imposed upon diagnostic and treatment centers pursuant to the provisions

of this chapter] shall be kept confidential and shall not be released except to the department or pursuant to subdivision four of section twenty-eight hundred five-k of this article.

2. Notwithstanding any other provisions of law, none of the records, documentation or committee actions or records required pursuant to sections twenty-eight hundred five-j [and], twenty-eight hundred five-k OR TWENTY-EIGHT HUNDRED FIVE-L of this article[,] NOR the reports required pursuant to section twenty-eight hundred five-l of this article [nor any incident reporting requirements imposed upon diagnostic and treatment centers pursuant to the provisions of this chapter] shall be subject to disclosure under article six of the public officers law or article thirty-one of the civil practice law and rules, except as hereinafter provided or as provided by any other provision of law. No person in attendance at a meeting of any such committee shall be required to testify as to what transpired thereat. The prohibition relating to discovery of testimony shall not apply to the statements made by any person in attendance at such a meeting who is a party to an action or proceeding the subject matter of which was reviewed at such meeting.

3. There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any person, partnership, corporation, firm, society, or other entity on account of the communication of information in the possession of such person or entity, or on account of any recommendation or evaluation, regarding the qualifications, fitness, or professional conduct or practices of a physician, to any governmental agency, medical or specialists society, or hospital as required by sections twenty-eight hundred five-j, twenty-eight hundred five-k and twenty-eight hundred five-l of this article [or any incident reporting requirements imposed upon diagnostic and treatment centers pursuant to the provisions of this chapter]. The foregoing shall not apply to information which is untrue and communicated with malicious intent.

S 3. Subdivision 3 of section 6527 of the education law, as amended by chapter 257 of the laws of 1987, is amended to read as follows:

3. No individual who serves as a member of (a) a committee established to administer a utilization review plan of a hospital, including a hospital as defined in article twenty-eight of the public health law or a hospital as defined in subdivision ten of section 1.03 of the mental hygiene law, or (b) a committee having the responsibility of the investigation of an incident reported pursuant to section 29.29 of the mental hygiene law or the evaluation and improvement of the quality of care rendered in a hospital as defined in article twenty-eight of the public health law or a hospital as defined in subdivision ten of section 1.03 of the mental hygiene law, or (c) any medical review committee or subcommittee thereof of a local, county or state medical, dental, podiatry or optometrical society, any such society itself, a professional standards review organization or an individual when such committee, subcommittee, society, organization or individual is performing any medical or quality assurance review function including the investigation of an incident reported pursuant to section 29.29 of the mental hygiene law, either described in clauses (a) and (b) of this subdivision, required by law, or involving any controversy or dispute between (i) a physician, dentist, podiatrist or optometrist or hospital administrator and a patient concerning the diagnosis, treatment or care of such patient or the fees or charges therefor or (ii) a physician, dentist, podiatrist or optometrist or hospital administrator and a provider of medical, dental, podiatric or optometrical services concerning any

medical or health charges or fees of such physician, dentist, podiatrist or optometrist, or (d) a committee appointed pursuant to section twenty-eight hundred five-j of the public health law to participate in the medical and dental malpractice prevention program, or (e) any individual who participated in the preparation of [incident] ADVERSE EVENT reports required by the department of health pursuant to section twenty-eight hundred five-l of the public health law, or (f) a committee established to administer a utilization review plan, or a committee having the responsibility of evaluation and improvement of the quality of care rendered, in a health maintenance organization organized under article forty-four of the public health law or article forty-three of the insurance law, including a committee of an individual practice association or medical group acting pursuant to a contract with such a health maintenance organization, shall be liable in damages to any person for any action taken or recommendations made, by him within the scope of his function in such capacity provided that (a) such individual has taken action or made recommendations within the scope of his function and without malice, and (b) in the reasonable belief after reasonable investigation that the act or recommendation was warranted, based upon the facts disclosed.

Neither the proceedings nor the records relating to performance of a medical or a quality assurance review function or participation in a medical and dental malpractice prevention program nor any report required by the department of health pursuant to section twenty-eight hundred five-l of the public health law described herein, including the investigation of an incident reported pursuant to section 29.29 of the mental hygiene law, shall be subject to disclosure under article thirty-one of the civil practice law and rules except as hereinafter provided or as provided by any other provision of law. No person in attendance at a meeting when a medical or a quality assurance review or a medical and dental malpractice prevention program or an incident reporting function described herein was performed, including the investigation of an incident reported pursuant to section 29.29 of the mental hygiene law, shall be required to testify as to what transpired thereat. The prohibition relating to discovery of testimony shall not apply to the statements made by any person in attendance at such a meeting who is a party to an action or proceeding the subject matter of which was reviewed at such meeting.

S 4. Section 4 of part X2 of chapter 62 of the laws of 2003, amending the public health law relating to allowing for the use of funds of the office of professional medical conduct for activities of the patient health information and quality improvement act of 2000, as amended by chapter 21 of the laws of 2010, is amended to read as follows:

S 4. This act shall take effect immediately; provided that the provisions of section one of this act shall be deemed to have been in full force and effect on and after April 1, 2003[, and shall expire March 31, 2011 when upon such date the provisions of such section shall be deemed repealed].

S 5. This act shall take effect on the one hundred eightieth day after it shall have become law; provided, however, that effective immediately, the addition, amendment and repeal of any rule or regulation necessary for the implementation of this act on its effective date is authorized and directed to be made and completed on or before such effective date.