

NATIONAL CONFERENCE OF INSURANCE LEGISLATORS Patient Safety Model Act

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Sponsored by Rep. George Keiser (ND) and Assem. Nancy Calhoun (NY)

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Purpose.

The purpose of this Act is to establish programs to:

- A. promote public accountability through the detection of statewide trends in the occurrence of certain medical errors by:
 - 1. requiring hospitals, ambulatory surgical centers, and mental hospitals to report errors
 - 2. providing the public with access to statewide summaries of the reports
 - 3. requiring hospitals, ambulatory surgical centers, and mental hospitals to implement risk-reduction strategies
- B. require reporting of hospital infection statistics in order to improve patient safety

[Drafting Note: A further purpose of the Act is to reduce the rising medical liability insurance premiums that are charged to medical professionals and that reflect, in part, the costs of medical errors.]

Short Title.

This act may be called the *Patient Safety Model Act*.

Part I. Patient Safety Program.

Section A. Hospitals

Subpart 1. Duties of Department

- (a) The department shall develop a patient safety program for hospitals. The program must:
 - (1) be administered by the hospital licensing program within the department
 - (2) serve as an information clearinghouse for hospitals concerning best practices and quality improvement strategies
- (b) The department shall group hospitals by size for the reports required by this Part as follows:

- (1) less than 50 beds
 - (2) 50 to 99 beds
 - (3) 100 to 199 beds
 - (4) 200 to 399 beds
 - (5) 400 beds or more
- (c) The department shall combine two or more categories described by Subsection (b) if the number of hospitals in any category falls below 40.

Subpart 2. Annual report

- (a) On renewal of a license under this chapter, a hospital shall submit to the department an annual report that lists the number and frequency of occurrences at the hospital or at an outpatient facility owned or operated by the hospital of each of the following events during the preceding year:
- (1) a medication error resulting in a patient's unanticipated death or major permanent loss of bodily function in circumstances unrelated to the natural course of the illness or underlying condition of the patient
 - (2) a perinatal death unrelated to a congenital condition in an infant with a birth weight greater than 2,500 grams
 - (3) the suicide of a patient in a setting in which the patient received care 24 hours a day
 - (4) the abduction of a newborn infant patient from the hospital or the discharge of a newborn infant patient from the hospital into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the infant
 - (5) the sexual assault of a patient during treatment or while the patient was on the premises of the hospital or facility
 - (6) a hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities
 - (7) a surgical procedure on the wrong patient or on the wrong body part of a patient
 - (8) a foreign object accidentally left in a patient during a procedure
 - (9) a patient death or serious disability associated with the use or function of a device designed for patient care that is used or functions other than as intended
- (b) The department may not require the annual report to include any information other than the number of occurrences of each event listed in Subsection (a) of this section.

Section B. Ambulatory Surgical Centers

Subpart 1. Duties of department

The department shall develop a patient safety program for ambulatory surgical centers. The program must:

- (a) be administered by the ambulatory surgical center licensing program within the department

- (b) serve as an information clearinghouse for ambulatory surgical centers concerning best and quality improvement strategies

Subpart 2. Annual report

- (a) On renewal of a license under this chapter, an ambulatory surgical center shall submit to the department an annual report that lists the number and frequency of occurrences at the center or at an outpatient facility owned or operated by the center of each of the following events during the preceding year:
 - (1) a medication error resulting in a patient's unanticipated death or major permanent loss of bodily function in circumstances unrelated to the natural course of the illness or underlying condition of the patient
 - (2) the suicide of a patient
 - (3) the sexual assault of a patient during treatment or while the patient was on the premises of the center or facility
 - (4) a hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities
 - (5) a surgical procedure on the wrong patient or on the wrong body part of a patient
 - (6) a foreign object accidentally left in a patient during a procedure
 - (7) a patient death or serious disability associated with the use or function of a device designed for patient care that is used or functions other than as intended
- (b) The department may not require the annual report to include any information other than the number of occurrences of each event listed in Subsection (a).

Section C. Mental Hospitals

Subpart 1. Duties of department

The department shall develop a patient safety program for mental hospitals licensed by the department. The program must:

- (a) be administered by the licensing program within the department
- (b) serve as an information clearinghouse for hospitals concerning best practices and quality improvement strategies

Subpart 2. Annual report

- (a) On renewal of a license under this chapter, a mental hospital shall submit to the department an annual report that lists the number and frequency of occurrences at the hospital or at an outpatient facility owned or operated by the hospital of each of the following events during the preceding year:
 - (1) a medication error resulting in a patient's unanticipated death or major permanent loss of bodily function in circumstances unrelated to the natural course of the illness or underlying condition of the patient
 - (2) the suicide of a patient in a setting in which the patient received care 24 hours a day

- (3) the sexual assault of a patient during treatment or while the patient was on the premises of the hospital or facility
 - (4) a hemolytic transfusion reaction in a patient resulting from the administration of blood or blood products with major blood group incompatibilities
 - (5) a patient death or serious disability associated with the use or function of a device designed for patient care that is used or functions other than as intended
- (b) The department may not require the annual report to include any information other than the number of occurrences of each event listed in Subsection (a) of this section.

Section D. General Requirements

Subpart 1. Root cause analysis and action plan

- (a) In this section, "root cause analysis" means the process that identifies basic or causal factors underlying a variation in performance leading to an event listed in Subparts 2 of Sections A, B, or C and that:
- (1) focuses primarily on systems and processes
 - (2) progresses from special causes in clinical processes to common causes in organizational processes
 - (3) identifies potential improvements in processes or systems
- (b) Not later than the 45th day after the date a hospital, ambulatory surgical center, or mental hospital becomes aware of an event listed in Subparts 2 of Sections A, B, or C, the facility shall:
- (1) conduct a root cause analysis of the event
 - (2) develop an action plan that identifies strategies to reduce the risk of a similar event occurring in the future
- (c) The department may review a root cause analysis or action plan related to an event listed in Subparts 2 of Sections A, B, or C during a survey, inspection, or investigation of a hospital, ambulatory surgical center, or mental hospital.
- (d) The department may not require a root cause analysis or action plan to be submitted to the department.
- (e) The department or an employee or agent of the department may not in any form, format, or manner remove, copy, reproduce, redact, or dictate from all or any part of a root cause analysis or action plan.

Subpart 2. Annual department summary

- (a) The department annually shall compile and make available to the public a summary of the events reported by mental hospitals as required by Subpart 2 of Sections A, B, or C of this part. The summary shall identify events by specific hospital, ambulatory surgical center, or mental hospital but shall not directly or indirectly identify:
- (1) an individual, or

- (2) a specific reported event or the circumstances or individuals surrounding the event

Subpart 3. Best practices report and department summary

- (a) A hospital, ambulatory surgical center, or mental hospital shall provide to the department at least one report of best practices and safety measures related to a reported event.
- (b) A hospital, ambulatory surgical center, or mental hospital may provide to the department a report of other best practices and the safety measures that are effective in improving patient safety.
- (c) The department by rule may prescribe the form and format of a best practices report. The department may not require a best practices report to exceed one page in length. The department shall accept, in lieu of a report in the form and format prescribed by the department, a copy of a report submitted by a hospital, ambulatory surgical center, or mental hospital to a patient safety organization.
- (d) The department periodically shall:
 - (1) review the best practices reports
 - (2) compile a summary of the best practices reports determined by the department to be effective and recommended as best practices
 - (3) make the summary available to the public by posting it on the Department's Web site and distributing its availability to interested parties as widely as practical
- (e) The summary shall identify best practices by specific hospital, ambulatory surgical center, or mental hospital but shall not directly or indirectly identify:
 - (1) an individual, or
 - (2) a specific reported event or the circumstances or individuals surrounding the event

Subpart 4. Confidentiality

The provisions of this section regarding the confidentiality of information or materials compiled or reported by a hospital, ambulatory surgical center, or mental hospital in compliance with or as authorized under this part do not restrict access, to the extent authorized by law, by the patient or the patient's legally authorized representative to records of the patient's medical diagnosis or treatment or to other primary health records.

Subpart 5. Report to legislature

- (a) Not later than [*insert practical date*], the commissioner of public health shall:
 - (1) evaluate the patient safety program established under Subpart 3 and
 - (2) report the results of the evaluation and make recommendations to the legislature

- (b) The commissioner of public health shall conduct the evaluation in consultation with hospitals, ambulatory surgical centers, or mental hospitals licensed under *[insert reference to licensing statute]*.
- (c) The evaluation must address:
 - (1) the degree to which the department was able to detect statewide trends in errors based on the types and numbers of events reported
 - (2) the degree to which the statewide summaries of events compiled by the department were accessed by the public
 - (3) the effectiveness of the department's best practices summary in improving patient care
 - (4) the impact of national studies on the effectiveness of state or federal systems of reporting medical errors
 - (5) the Department shall publicize the report and its availability as widely as practical to interested parties, including, but not limited to, hospitals, providers, media organizations, health insurers, health maintenance organizations, purchasers of health insurance, organized labor, consumer or patient advocacy groups, and individual consumers. The annual report shall be made available to any person upon request.

Subpart 6. Gifts, grants, and donations

The department may accept and administer a gift, grant, or donation from any source to carry out the purposes of this part.

Subpart 7. Whistleblower Protection

- (a) No employer shall take retaliatory action against any employee because the employee does any of the following:
 - (1) Discloses or threatens to disclose to any person or entity any activity, policy, practice, procedure, action, or failure to act of the employer or agent of the employer that the employee reasonably believes is a violation of any law or that the employee reasonably believes constitutes improper quality of patient care
 - (2) Provides information to, or testifies before, any public body conducting an investigation, a hearing, or an inquiry that involves allegations that the employer has violated any law or has engaged in behavior constituting improper quality of patient care
 - (3) Objects to or refuses to participate in any activity, policy, or practice of the employer or agent that the employee reasonably believes is in violation of a law or constitutes improper quality of patient care
- (b) Subdivisions (a)(1) and (3) of this section shall not apply unless an employee first reports the alleged violation of law or improper quality of patient care to the employer, supervisor, or other person designated by the employer to address reports by employees of improper quality of patient care, and the employer has had a reasonable opportunity to address the violation. The employer shall address the violation under its compliance plan, if one exists. The employee shall not be required to make

a report under this Subsection if the employee reasonably believes that doing so would be futile because making the report would not result in appropriate action to address the violation.

Subpart 8. Administrative penalty

- (a) The department may assess an administrative penalty against a person who violates this part or a rule adopted under this part.
- (b) The penalty may not exceed \$1,000 for each violation. Each day of a continuing violation constitutes a separate violation.
- (c) In determining the amount of an administrative penalty assessed under this section, the department shall consider:
 - (1) the seriousness of the violation
 - (2) the history of previous violations
 - (3) the amount necessary to deter future violations
 - (4) efforts made to correct the violation
 - (5) any hazard posed to the public health and safety by the violation
 - (6) any other matters that justice may require
- (d) All proceedings for the assessment of an administrative penalty under this Subpart are considered to be contested cases under *[insert reference to state administrative procedure act]*.

Subpart 9. Notice; request for hearing

- (a) If, after investigation of a possible violation and the facts surrounding that possible violation, the department determines that a violation has occurred, the department shall give written notice of the violation to the person alleged to have committed the violation. The notice shall include:
 - (1) a brief summary of the alleged violation
 - (2) a statement of the amount of the proposed penalty based on the factors set forth in Subpart 8(c) of this section
 - (3) a statement of the person's right to a hearing on the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty
- (b) Not later than the 20th day after the date on which the notice is received, the person notified may accept the determination of the department made under this section, including the proposed penalty, or make a written request for a hearing on that determination.
- (c) If the person notified of the violation accepts the determination of the department, the commissioner of public health or the commissioner's designee shall issue an order approving the determination and ordering that the person pay the proposed penalty.

Subpart 10. Hearing; order

- (a) If the person notified fails to respond in a timely manner to the notice

under Subpart 9(b) of this section, or if the person requests a hearing, the department shall:

- (1) set a hearing
 - (2) give written notice of the hearing to the person
 - (3) designate a hearings examiner to conduct the hearing
- (b) The hearings examiner shall make findings of fact and conclusions of law and shall promptly issue to the commissioner of public health or the commissioner's designee a proposal for decision as to the occurrence of the violation and a recommendation as to the amount of the proposed penalty if a penalty is determined to be warranted.
- (c) Based on the findings of fact and conclusions of law and the recommendations of the hearings examiner, the commissioner of public health or the commissioner's designee by order may find that a violation has occurred and may assess a penalty or may find that no violation has occurred.

Subpart 11. Notice and payment of administrative penalty; judicial review; refund

- (a) The department shall give notice of the order under Subpart 12(c) to the person notified. The notice must include:
- (1) separate statements of the findings of fact and conclusions of law
 - (2) the amount of any penalty assessed
 - (3) a statement of the right of the person to judicial review of the order
- (b) Not later than the 30th day after the date on which the decision is final as provided by *[insert reference to state administrative procedure code]*, the person shall either:
- (1) pay the penalty
 - (2) pay the penalty and file a petition for judicial review contesting the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty, or
 - (3) without paying the penalty, file a petition for judicial review contesting the occurrence of the violation, the amount of the penalty, or both the occurrence of the violation and the amount of the penalty
- (c) Within the 30-day period, a person who acts under Subsection (b)(3) of this section may:
- (1) stay enforcement of the penalty by:
 - (i) paying the penalty to the court for placement in an escrow account, or
 - (ii) giving to the court a supersedeas bond that is approved by the court for the amount of the penalty and that is effective until all judicial review of the order is final, or
 - (2) request the court to stay enforcement of the penalty by:
 - (i) filing with the court a sworn affidavit of the person stating that the person is financially unable to pay the amount of the penalty and is financially unable to give the supersedeas bond and
 - (ii) giving a copy of the affidavit to the department by certified mail
- (d) If the department receives a copy of an affidavit under Subsection (c)(2) of

this Subpart, the department may file with the court, within five days after the date the copy is received, a contest to the affidavit. The court shall hold a hearing on the facts alleged in the affidavit as soon as practicable and shall stay the enforcement of the penalty on finding that the alleged facts are true. The person who files an affidavit has the burden of proving that the person is financially unable to pay the penalty and to give a supersedeas bond.

- (e) If the person does not pay the penalty and the enforcement of the penalty is not stayed, the department may refer the matter to the attorney general for collection of the penalty.
- (f) Judicial review of the order:
 - (1) is instituted by filing a petition as provided by *[insert reference to state administrative procedure code]*, and
 - (2) is under the substantial evidence rule
- (g) If the court sustains the occurrence of the violation, the court may uphold or reduce the amount of the penalty and order the person to pay the full or reduced amount of the penalty. If the court does not sustain the occurrence of the violation, the court shall order that no penalty is owed.
- (h) When the judgment of the court becomes final, the court shall proceed under this Subsection. If the person paid the amount of the penalty under Subsection (b)(2) of this Subpart and if that amount is reduced or is not upheld by the court, the court shall order that the department pay the appropriate amount plus accrued interest to the person. The rate of the interest is the rate charged on loans to depository institutions by the New York Federal Reserve Bank, and the interest shall be paid for the period beginning on the date the penalty was paid and ending on the date the penalty is remitted. If the person paid the penalty under Subsection (c)(1)(i) or gave a supersedeas bond under Subsection (c)(1)(ii) and if the amount of the penalty is not upheld by the court, the court shall order the release of the escrow account or bond. If the person paid the penalty under Subsection (c)(1)(i) and the amount of the penalty is reduced, the court shall order that the amount of the penalty be paid to the department from the escrow account and that the remainder of the account be released. If the person gave a supersedeas bond and if the amount of the penalty is reduced, the court shall order the release of the bond after the person pays the amount.

Subpart 12. Expiration

Unless continued in existence, this part expires *[four years after the effective date of this act]*.

Subpart 13. Effective dates

[State may want to consider amount of time necessary for entities to comply with the provisions of this act.]

Part II. Hospital Infections Disclosure.

Section A. Definitions

For purposes of this act:

1. "Department" means the Department of _____ *[State may have several possible agencies to collect the data. These could be the state hospital licensing agency, state health care data collection agency, or state public health agency. This would minimize the state's cost to implement the bill, as the hospital-acquired infection data can be gathered in the course of collecting other patient data.]*
2. "Hospital" means an acute care health care facility licensed under the Hospital Licensing Act *[insert a cross-reference and/or citation to the definition of "acute care hospital" in your state hospital licensing law. You may also consider including hospital-affiliated and freestanding outpatient surgical centers.]*
3. "Hospital-acquired infection" means a localized or systemic condition (a) that results from adverse reaction to the presence of an infectious agent(s) or its toxin(s) as determined by clinical examination and (b) that was not present or incubating at the time of admission to the hospital unless the infection was related to a previous admission to the same facility.

1. **Section B. Hospital Reports**(a) Each hospital shall maintain a program capable of identifying and tracking hospital acquired infections for the purpose of public reporting under this section and quality improvement.
 - (b) Such programs shall have the capacity to identify the following elements: the specific infectious agents or toxins and site of each infection; the clinical department or unit within the facility where the patient first became infected; and the patient's diagnoses and any relevant specific surgical, medical or diagnostic procedure performed during the current admission.
 - (c) The department shall establish guidelines, definitions, criteria, standards and coding for hospital identification, tracking and reporting of hospital acquired infections that shall be consistent with the recommendations of recognized centers of expertise in the identification and prevention of hospital acquired infections including, but not limited to the National Health Care Safety Network of the Centers for Disease Control and Prevention or its successor. The department shall solicit and consider public comment prior to such establishment.
 - (d) Hospitals initially shall be required to identify, track and report hospital acquired infections that occur in critical care units to include surgical wound infections, central line related bloodstream infections, and ventilator associated pneumonia.
 - (e) Subsequent to the initial requirements identified in paragraph (d) of this subdivision the department may, from time to time, require the tracking and reporting of other types of hospital acquired infections that occur in hospitals in consultation with technical advisors who are regionally or nationally recognized experts in the prevention, identification and control of hospital acquired infection and the public reporting of performance data.

2. Each hospital shall regularly report to the department the hospital infection data it has collected. The department shall establish data collection and analytical methodologies that meet accepted standards for validity and reliability. In no case shall the frequency of reporting be required to be more frequently than once every six months, and reports shall be submitted not more than 60 days after the close of the reporting period.
3. The commissioner shall establish a state-wide database of all reported hospital acquired infection information for the purpose of supporting quality improvement and infection control activities in hospitals. The database shall be organized so that consumers, hospitals, healthcare professionals, purchasers and payers may compare individual hospital experience with that of other individual hospitals as well as regional and state-wide averages and, where available, national data.
4. (a) Subject to paragraph (c) of this subdivision, on or before [*choose date*] of each year the commissioner shall submit a report to the governor and the legislature, which shall simultaneously be published in its entirety on the department's Web site, that includes, but is not limited to, hospital acquired infection rates adjusted for the potential differences in risk factors for each reporting hospital, an analysis of trends in the prevention and control of hospital acquired infection rates in hospitals across the state, regional and, if available, national comparisons for the purpose of comparing individual hospital performance, and a narrative describing lessons for safety and quality improvement that can be learned from leadership hospitals and programs.
(b) The commissioner shall consult with technical advisors who have regionally or nationally acknowledged expertise in the prevention and control of hospital acquired infection and infectious disease in order to develop the adjustment for potential differences in risk factors to be used for public reporting.
(c) (i) No later than one year subsequent to the effective date of this act, the department shall establish a hospital acquired infection reporting system capable of receiving electronically transmitted reports from hospitals. Hospitals shall begin to submit such reports as directed by the commissioner but in no case later than six months subsequent to the establishment of such reporting system.
(ii) The first year of data submission under this section shall be considered the “pilot phase” of the statewide hospital acquired infection reporting system. The purpose of the pilot phase is to ensure, by various means, including any audit process referred to in Subdivision 6 of this section, the completeness and accuracy of hospital acquired infection reporting by hospitals. For data reported during the pilot phase, hospital identifiers shall be encrypted by the department in any and all public databases and reports. The department shall provide each hospital with an encryption key for that hospital only to permit access to its own performance data for internal quality improvement purposes.
(iii) No later than 180 days after the conclusion of the pilot phase, the department shall issue a report to hospitals assessing the overall accuracy of the data submitted in the pilot phase and provide guidance for improving the

accuracy of hospital acquired infection reporting. The department shall issue a report to the governor and the legislature assessing the overall completeness and accuracy of the data submitted by hospitals during the pilot phase and make recommendations for the improvement or modification of hospital acquired infection data reporting based on the pilot phase, as well as share lessons learned in prevention of hospital acquired infections. No hospital-identifiable data shall be included in the pilot phase report, but aggregate or otherwise de-identified data may be included.

(iv) After the pilot phase is completed, all data submitted under this section and compiled in the statewide hospital acquired infection database established herein and all public reports derived therefrom shall include hospital identifiers.

5. Subject to Subdivision 4 of this section, a summary table, in a format designed to be easily understood by lay consumers, that includes individual facility hospital acquired infection rates adjusted for potential differences in risk factors and comparisons with regional and/or state averages shall be developed and posted on the department's Web site. The commissioner shall consult with consumer and patient advocates and representatives of reporting facilities for the purpose of ensuring that such summary table report format is easily understandable by the public, and clearly and accurately portrays comparative hospital performance in the prevention and control of hospital acquired infections.
6. To assure the accuracy of the self-reported hospital acquired infection data and to assure that public reporting fairly reflects what actually is occurring in each hospital, the department shall develop and implement an audit process.
7. For the purpose of ensuring that hospitals have the resources needed for ongoing staff education and training in hospital acquired infection prevention and control, the department may make such grants to hospitals within amounts appropriated therefor.

Section C. Privacy

- (1) The provisions of this section regarding the confidentiality of information or materials compiled or reported by a hospital in compliance with or as authorized under this part do not restrict access, to the extent authorized by law, by the patient or the patient's legally authorized representative to records of the patient's medical diagnosis or treatment or to other primary health records.
- (2) It is the expressed intent of the Legislature that a patient's right of confidentiality shall not be violated in any manner. Patient social security numbers and any other information that could be used to identify an individual patient shall not be released notwithstanding any other provision of law.

Section D. Whistleblower Protection

- (a) No employer shall take retaliatory action against any employee because the employee does any of the following:
 - (1) Discloses or threatens to disclose to any person or entity any activity, policy, practice, procedure, action, or failure to act of the employer or agent of the employer that the employee reasonably believes is a violation of any law or

that the employee reasonably believes constitutes improper quality of patient care

- (2) Provides information to, or testifies before, any public body conducting an investigation, a hearing, or an inquiry that involves allegations that the employer has violated any law or has engaged in behavior constituting improper quality of patient care
 - (3) Objects to or refuses to participate in any activity, policy, or practice of the employer or agent that the employee reasonably believes is in violation of a law or constitutes improper quality of patient care
- (b) Subdivisions (a)(1) and (3) of this section shall not apply unless an employee first reports the alleged violation of law or improper quality of patient care to the employer, supervisor, or other person designated by the employer to address reports by employees of improper quality of patient care, and the employer has had a reasonable opportunity to address the violation. The employer shall address the violation under its compliance plan, if one exists. The employee shall not be required to make a report under this Subsection if the employee reasonably believes that doing so would be futile because making the report would not result in appropriate action to address the violation.

Section E. Penalties

A determination that a hospital has violated the provisions of this Act may result in any of the following:

1. termination of licensure or other sanctions relating to licensure under the Hospital Licensing Act *[insert name and citation of state hospital licensing act]*.
2. a civil penalty of up to \$1,000 per day per violation for each day the hospital is in violation of the Act

Section F. Regulatory oversight

The Department shall be responsible for ensuring compliance with this Act as a condition of licensure under the Hospital Licensing Act and shall enforce such compliance according to the provisions of the Hospital Licensing Act. *[insert name and citation of state hospital licensing act]*.

Section G. Amendments

The Hospital Licensing Act is amended as follows: *[Amend state hospital licensing act to add that violations of the Infections Disclosure Act are grounds for license termination or sanctions under the state licensing act.]*

¹Based on Texas House Bill 1614, enacted during the 2003-2004 session.

²Based on a combination of New York State chapter amendments 284 and 239 (2005).