

## 93RD GENERAL ASSEMBLY State of Illinois 2003 and 2004

Introduced 2/6/2004, by Jacqueline Y. Collins - Barack Obama

## SYNOPSIS AS INTRODUCED:

New Act 30 ILCS 105/5.625 new

Creates the Patient Safety Act. Creates the Patient Safety Authority that, among other duties, works with medical facilities and the Department of Public Health to reduce the number and severity of serious events and incidents that occur at the facility and receives reports from health care workers regarding serious events. Provides funding for the Authority and the administration of the Act through a surcharge on the medical facilities' licensing fees, which shall be deposited into the Patient Safety Trust Fund, a special fund in the State treasury. Requires medical facilities to develop, implement, and comply with an internal patient safety plan, designate a patient safety officer, and establish a patient safety committee. Provides that a health care worker who reasonably believes that a serious event or incident has occurred shall report the serious event or incident according to the patient safety plan of the medical facility, unless the health care worker knows that a report has already been made. Requires that the medical facility notify the patient or a family member of the patient of a serious event. Contains other provisions. Amends the State Finance Act to create the Patient Safety Authority Trust Fund. Effective January 1, 2005.

LRB093 20971 AMC 46958 b

FISCAL NOTE ACT MAY APPLY

1 AN ACT concerning patient safety.

## Be it enacted by the People of the State of Illinois, represented in the General Assembly:

- 4 Section 1. Short title. This Act may be cited as the
- 5 Patient Safety Act.
- 6 Section 5. Definitions. As used in this Act:
- 7 "Ambulatory surgical treatment center" means an ambulatory
- 8 surgical treatment center licensed under the Ambulatory
- 9 Surgical Treatment Center Act.
- 10 "Authority" means the Patient Safety Authority established
- in this Act.
- "Board" means the board of directors of the Patient Safety
- 13 Authority.
- "Department" means the Department of Public Health.
- "Fund" means the Patient Safety Trust Fund.
- 16 "Health care worker" means an employee, independent
- 17 contractor, licensee, or other individual authorized to
- 18 provide services in a medical facility.
- "Incident" means an event, occurrence, or situation
- 20 involving the clinical care of a patient in a medical facility
- 21 that could have injured the patient but did not either cause an
- 22 unanticipated injury or require the delivery of additional
- 23 health care services to the patient. "Incident" does not
- 24 include a serious event.
- "Licensee" means an individual who is licensed or certified
- 26 to provide professional services in this State and is employed
- 27 by or authorized to provide professional services in a medical
- 28 facility.
- "Medical facility" means an ambulatory surgical treatment
- 30 center or hospital.
- 31 "Patient safety officer" means an individual designated by
- 32 a medical facility under section 40.

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"Serious event" means an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. "Serious event" does not include an incident.

7 Section 10. Patient Safety Authority.

- (a) There is established an entity to be known as the Patient Safety Authority. The powers and duties of the Authority shall be vested in and exercised by a board of directors.
- 12 (b) The board of the Authority shall consist of 11 members 13 as follows:
  - (1) Two physicians who are licensed in Illinois and reside in Illinois appointed by the Governor, who shall serve initial terms of 3 years.
  - (2) A nurse who is licensed in Illinois and resides in Illinois appointed by the Governor, who shall serve an initial term of 3 years.
  - (3) A pharmacist who is licensed in Illinois and resides in Illinois appointed by the Governor, who shall serve an initial term of 2 years.
  - (4) A health care worker who is employed by a hospital located in Illinois and resides in Illinois appointed by the Governor, who shall serve an initial term of 2 years.
  - (5) Six residents of Illinois appointed by the Governor, one of whom is a health care worker, who shall each serve an initial term of 4 years.
  - (c) Members of the board shall serve for terms of 4 years after completion of the initial terms designated in subsection (b) and shall not be eligible to serve more than 2 full consecutive terms.
  - (d) A majority of the members of the board shall constitute a quorum. Notwithstanding any other provision of law, action may be taken by the board at a meeting upon a vote of the

- 1 majority of its members present in person.
- 2 (e) The board shall meet at the call of the chairperson.
- 3 The board shall hold meetings at least quarterly. The meetings
- 4 shall be subject to the requirements of the Open Meetings Act.
- 5 (f) The chairperson shall be one of the physicians 6 appointed under item (1) of subsection (b), as determined by
- 7 the Governor.

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- (g) The Authority shall be formed within 60 days after the effective date of this Act.
- 10 Section 15. Powers and duties of the Authority.
- 11 (a) The Authority shall have all of the following powers
  12 and duties:
  - (1) Employ staff as necessary to implement this Act.
  - (2) Make, execute, and deliver contracts and other instruments.
  - (3) Apply for, solicit, receive, establish priorities for, allocate, disburse, contract for, administer, and spend funds in the Fund and other funds that are made available to the Authority from any source consistent with the purposes of this Act.
  - (4) Contract with a for-profit or registered nonprofit entity, other than a health care provider, to do any of the following:
    - (A) Collect, analyze, and evaluate data regarding reports of serious events and incidents, including the identification of performance indicators and patterns in frequency or severity at certain medical facilities or in certain regions of Illinois.
    - (B) Transmit to the Authority recommendations for changes in health care practices and procedures that may be instituted for the purpose of reducing the number and severity of serious events and incidents.
    - (C) Directly advise reporting medical facilities of immediate changes that can be instituted to reduce serious events and incidents.

- 1 (D) Conduct reviews in accordance with subsection 2 (b).
  - (5) Receive and evaluate recommendations made by the entity contracted with in accordance with item (4) and report those recommendations to the Department. The Department shall approve or disapprove the recommendations within 30 days.
  - Department, issue recommendations to medical facilities on a facility-specific or on a Statewide basis regarding changes, trends, and improvements in health care practices and procedures for the purpose of reducing the number and severity of serious events and incidents. Prior to issuing recommendations, consideration shall be given to the following factors: expectation of improved quality care, implementation feasibility, other relevant implementation practices, and the cost impact to patients, payors, and medical facilities. Statewide recommendations shall be issued to medical facilities on a continuing basis and shall be published and posted on the Department's and the Authority's publicly accessible World Wide Web site.
  - (7) Meet with the Department for purposes of implementing this Act.
  - (b) A health care worker who has complied with the reporting requirements of subsection (a) of the Section 35 may file an anonymous report regarding a serious event with the Authority. Upon receipt of the report, the Authority shall give notice to the affected medical facility that a report has been filed. The Authority shall conduct its own review of the report, unless the medical facility has already commenced an investigation of the serious event. The medical facility shall provide the Authority with the results of its investigation no later than 30 days after receiving notice pursuant to this subsection. If the Authority is dissatisfied with the adequacy of the investigation conducted by the medical facility, the Authority shall perform its own review of the serious event and

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- 1 may refer a medical facility and any involved licensee to the 2 Department for failure to report.
- 3 (c) The Authority shall report no later than December 31, 4 2005 and annually thereafter to the Department and the General 5 Assembly on the Authority's activities in the preceding year.
- 6 The report shall include:
  - (1) A schedule of the year's meetings.
  - (2) A list of contracts entered into pursuant to this Section, including the amounts awarded to each contractor.
  - (3) A summary of the Fund receipts and expenditures, including a financial statement and balance sheet.
  - (4) The number of serious events and incidents reported by medical facilities on a geographical basis.
  - (5) The information derived from the data collected including any recognized trends concerning patient safety.
  - (6) The number of anonymous reports filed and reviews conducted by the Authority.
  - (7) The number of referrals to licensure boards for failure to report under this Act.
  - (8) Recommendations for statutory or regulatory changes that may help improve patient safety in Illinois.
  - The annual report shall be made available for public inspection and shall be posted on the Authority's publicly accessible World Wide Web site.
  - Section 20. Patient Safety Trust Fund.
  - (a) There is created a special fund in State treasury to be known as the Patient Safety Trust Fund. The monies in the Fund shall be used by the Authority for the administration of this Act. All interest earned from the investment or deposit of moneys accumulated in the Fund shall be deposited in the Fund for the same use.
- 32 (b) Commencing July 1, 2005, each medical facility shall 33 pay the Department a surcharge on its licensing fee as provided 34 by rule in an amount necessary to provide sufficient revenues 35 to operate the Authority. The total assessment for all medical

- 1 facilities shall not exceed \$5,000,000. The Department shall
- 2 transfer the total assessment amount to the Fund within 30 days
- 3 of receipt.
- 4 (c) In the event that the Fund is discontinued or the
- 5 Authority is dissolved by operation of law, any balance
- 6 remaining in the Fund, after deducting administrative costs of
- 7 liquidation, shall be returned to the medical facilities in
- 8 proportion to their financial contributions to the Fund in the
- 9 preceding licensing period.
- 10 (d) If, after 30 days' notice, a medical facility fails to
- 11 pay a surcharge levied by the Department under this Act, the
- 12 Department may assess an administrative penalty of \$1,000 per
- day until the surcharge is paid.
- 14 Section 25. Responsibilities of the Department of Public
- 15 Health.
- 16 (a) The Department shall have all of the following
- 17 responsibilities:
- 18 (1) Review and approve patient safety plans in
- 19 accordance with section 30.
- 20 (2) In conjunction with the Authority, analyze and
- 21 evaluate existing health care procedures and approve
- recommendations issued by the Authority under items (6) and
- 23 (7) of subsection (a) of Section 15.
- 24 (3) Meet with the Authority for purposes of
- 25 implementing this Act.
- 26 (b) The recommendations made to medical facilities
- 27 pursuant to item (2) of subsection (a) may be considered by the
- Department for licensure purposes under the the Ambulatory
- 29 Surgical Treatment Center Act and the Hospital Licensing Act,
- 30 but shall not be considered mandatory unless adopted by the
- 31 Department as rules.
- 32 Section 30. Patient safety plans.
- 33 (a) A medical facility must develop, implement, and comply
- 34 with an internal patient safety plan that shall be established

- 1 for the purpose of improving the health and safety of patients.
- 2 The plan shall be developed in consultation with the licensees
- 3 providing health care services in the medical facility.
  - (b) A patient safety plan shall:
  - (1) Designate a patient safety officer as set forth in Section 40.
  - (2) Establish a patient safety committee as set forth in Section 45.
  - (3) Establish a system for the health care workers of a medical facility to report serious events and incidents that shall be accessible 24 hours a day, 7 days a week.
  - (4) Prohibit any retaliatory action against a health care worker for reporting a serious event or incident in accordance with the Whistleblower Act.
  - (5) Provide for written notification to patients in accordance with subsection (b) of Section 35.
  - (c) Within 60 days after the effective date of this Act, a medical facility shall submit its patient safety plan to the Department for approval consistent with the requirements of this Section. If the Department does not approve or reject the plan within 60 days after receipt, the plan shall be deemed approved.
  - (d) Upon approval of the patient safety plan, a medical facility shall notify all health care workers of the medical facility of the patient safety plan. Compliance with the patient safety plan shall be required as a condition of employment or credentialing at the medical facility.
    - Section 35. Reporting and notification.
  - (a) A health care worker who reasonably believes that a serious event or incident has occurred shall report the serious event or incident according to the patient safety plan of the medical facility, unless the health care worker knows that a report has already been made. The report shall be made immediately or as soon thereafter as reasonably practicable, but in no event later than 24 hours after the occurrence or

discovery of a serious event or incident.

- (b) A medical facility, through an appropriate designee, shall provide written notification to a patient affected by a serious event or, with the consent of the patient, to an available family member or designee, within 7 days of the occurrence or discovery of a serious event. If the patient is unable to give consent, the notification shall be given to an adult member of the immediate family. If an adult member of the immediate family cannot be identified or located, notification shall be given to the closest adult family member. For unemancipated patients who are under 18 years of age, the parent or guardian shall be notified in accordance with this subsection. The notification requirements of this subsection shall not be subject to the provisions of subsection (a) of Section 50. Notification under this subsection shall not constitute an acknowledgment or admission of liability.
- (c) A health care worker who reports the occurrence of a serious event or incident in accordance with subsection (a) or (b) shall not be subject to any retaliatory action for reporting the serious event or incident and shall have the protections and remedies set forth in the Whistleblower Act.
- (d) Nothing in this Section shall limit a medical facility's ability to take appropriate disciplinary action against a health care worker for failure to meet defined performance expectations or to take corrective action against a licensee for unprofessional conduct, including making false reports or failure to report serious events under this Act.
- Section 40. Patient safety officer. A patient safety officer of a medical facility shall do all of the following:
  - (1) Serve on the patient safety committee.
- 31 (2) Ensure the investigation of all reports of serious 32 events and incidents.
  - (3) Take such action as is immediately necessary to ensure patient safety as a result of any investigation.
    - (4) Report to the patient safety committee regarding

any action taken to promote patient safety as a result of investigations commenced pursuant to this Section.

Section 45. Patient safety committee.

(a) A hospital's patient safety committee shall be composed of the medical facility's patient safety officer, at least 3 health care workers of the medical facility, and at least 2 residents of the community served by the medical facility who are not agents, employees, or contractors of the medical facility. No more than one member of the patient safety committee shall be a member of the medical facility's board of trustees. The committee shall include members of the medical facility's medical and nursing staff. The committee shall meet at least monthly.

An ambulatory surgical treatment center's patient safety committee shall be composed of the medical facility's patient safety officer, at least one health care worker of the medical facility, and at least one resident of the community served by the ambulatory surgical facility who is not an agent, employee or contractor of the ambulatory surgical facility. No more than one member of the patient safety committee shall be a member of the medical facility's board of governance. The committee shall include members of the medical facility's medical and nursing staff. The committee shall meet at least quarterly.

- (b) A patient safety committee of a medical facility shall do all of the following:
  - (1) Receive reports from the patient safety officer.
  - (2) Evaluate investigations and actions of the patient safety officer on all reports.
  - (3) Review and evaluate the quality of patient safety measures utilized by the medical facility. A review shall include the consideration of reports made under item (4) of subsection (a) and subsection (b) of Section 15 and subsection (a) of Section 35.
  - (4) Make recommendations to eliminate future serious events and incidents.

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(5) Report to the administrative officer and governing 1 2 body of the medical facility on a quarterly basis regarding number of serious events and incidents and its 3 recommendations to eliminate future serious events and 5 incidents.

Section 50. Confidentiality and compliance.

- Any documents, materials, or information solely prepared or created for the purpose of compliance with subsection (b) of Section 45 or of reporting under item (4) of subsection (a) and subsection (b) of Section 15 and subsection (a) of Section 35 that arise out of matters reviewed by the patient safety committee or the governing board of a medical facility pursuant to subsection (b) of Section 45 are confidential and shall not be discoverable or admissible as evidence in any civil or administrative action or proceeding. Any documents, materials, records, or information that would otherwise be available from original sources shall not be construed as immune from discovery or use in any civil or administrative action or proceeding merely because they were presented to the patient safety committee or governing board of a medical facility.
- person who performs responsibilities for or participates in meetings of the patient safety committee or governing board of a medical facility pursuant to subsection (b) of Section 45 shall be allowed to testify as to any matters within the knowledge gained by the person's responsibilities or participation on the patient safety committee or governing board of a medical facility, provided that the person shall be allowed to testify as to any matters within the person's knowledge that was gained outside of the responsibilities or participation on the patient committee or governing board of a medical facility.
- The confidentiality protections set forth in subsections (a) and (b) shall only apply to the documents, materials, or information prepared or created pursuant to the

- 1 responsibilities of the patient safety committee or governing
- 2 board of a medical facility set forth in subsection (b) of
- 3 Section 45.
- 4 (d) Any documents, materials or information made
- 5 confidential by subsection (a) shall not be subject to requests
- 6 under the Freedom of Information Act.
- 7 (e) Notwithstanding any other provision of law, no person
- 8 providing information or services to the patient safety
- 9 committee, governing board of a medical facility, Authority, or
- 10 Department shall be held, by reason of having provided such
- information or services, to have violated any criminal law or
- to be civilly liable under any law, unless such information is
- false and the person providing such information knew, or had
- 14 reason to believe, that such information was false and was
- motivated by malice toward any person directly affected by such
- 16 action.
- 17 Section 90. The State Finance Act is amended by adding
- 18 Section 5.625 as follows:
- 19 (30 ILCS 105/5.625 new)
- Sec. 5.625. The Patient Safety Trust Fund.
- 21 Section 99. Effective date. This Act takes effect January
- 22 1, 2005.