LRB09406746DRJ37560b

94TH GENERAL ASSEMBLY

State of Illinois

2005 and 2006

HB1578

Introduced 2/15/2005, by Rep. Mary E. Flowers

SYNOPSIS AS INTRODUCED:

New Act	
210 ILCS 85/7	from Ch. 111 1/2, par. 148
225 ILCS 85/30	from Ch. 111, par. 4150

Creates the Adverse Health Care Event Reporting Act and amends the Hospital Licensing Act and the Pharmacy Practice Act of 1987. Requires hospitals to report to the Department of Public Health certain types of adverse health care events, including the following: (1) surgical events; (2) product or device events; (3) patient protection events; (4) care management events; (5) environmental events; and (6) criminal events. Requires pharmacies to report adverse events involving (i) dispensing of the wrong prescription medication or (ii) failing to warn a prescription drug purchaser of possible adverse drug interactions. Requires hospitals and pharmacies to conduct a root cause analysis of each adverse health care event. Requires the Department of Public Health to establish an adverse health care event reporting system designed to facilitate quality improvement in the health care system. Provides for sanctions against a hospital or pharmacy for violations of the Act.

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FISCAL NOTE ACT
MAY APPLY

A BILL FOR

AN ACT concerning health.

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

Section 1. Short title. This Act may be cited as the Adverse Health Care Event Reporting Act.

Section 5. Definitions. In this Act:

"Department" means the Department of Public Health.

"Facility" means a hospital licensed under the Hospital Licensing Act or a hospital subject to the University of Illinois Hospital Act.

"Pharmacy" means a pharmacy as defined in the Pharmacy Practice Act of 1987.

"Serious disability" means (i) a physical or mental impairment that substantially limits one or more of the major life activities of an individual, (ii) a loss of bodily function, if the impairment or loss lasts more than 7 days or is still present at the time of discharge from an inpatient health care facility, or (iii) loss of a body part.

"Surgery" means the treatment of disease, injury, or deformity by manual or operative methods. "Surgery" includes endoscopies and other invasive procedures.

Section 10. Reports of adverse health care events. Every facility or pharmacy must report to the Department the occurrence of any of the adverse health care events described in Sections 15 through 45 as soon as is reasonable and practicable, but no later than 15 working days after discovery of the event. The report must be filed in a format specified by the Department and must identify the facility or pharmacy but may not include any identifying information for any of the health care professionals, facility employees, or patients involved. The Department may consult with experts and

organizations familiar with patient safety when developing the format for reporting and in further defining events in order to be consistent with industry standards.

Section 15. Surgical events. A facility must report the following adverse health care events:

(1) Surgery performed on a wrong body part that is not consistent with the documented informed consent for that patient. Reportable events under this paragraph (1) do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent.

(2) Surgery performed on the wrong patient.

(3) The wrong surgical procedure performed on a patient that is not consistent with the documented informed consent for that patient. Reportable events under this paragraph (3) do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent.

(4) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

(5) Death, during or immediately after surgery, of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

Section 20. Product or device events. A facility must report the following adverse health care events:

(1) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the facility when the contamination is the

result of generally detectable contaminants in drugs, devices, or biologics, regardless of the source of the contamination or the product.

(2) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. "Device" includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.

(3) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

Section 25. Patient protection events. A facility must report the following adverse health care events:

(1) An infant discharged to the wrong person.

(2) Patient death or serious disability associated with patient disappearance for more than 4 hours, excluding events involving adults who have decision-making capacity.

(3) Patient suicide or attempted suicide resulting in serious disability while being cared for in a facility due to patient actions after admission to the facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the facility.

Section 30. Care management events. A facility must report the following adverse health care events:

(1) Patient death or serious disability associated with a medication error, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

(2) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(3) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

(4) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a facility.

(5) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. "Hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.

(6) Stage 3 or 4 ulcers acquired after admission to a facility, excluding progression from stage 2 to stage 3 if stage 2 was recognized upon admission.

(7) Patient death or serious disability due to spinal manipulative therapy.

Section 35. Environmental events. A facility must report the following adverse health care events:

(1) Patient death or serious disability associated with an electric shock while being cared for in a facility, excluding events involving planned treatments such as electric countershock.

(2) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.

(3) Patient death or serious disability associated with a burn incurred from any source while being cared for in a facility.

(4) Patient death associated with a fall while being

cared for in a facility.

(5) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a facility.

Section 40. Criminal events. A facility must report the following adverse health care events:

(1) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

(2) Abduction of a patient of any age.

(3) Sexual assault on a patient within or on the grounds of a facility.

(4) Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

Section 45. Pharmacy events. A pharmacy must report the following adverse health care events:

(1) Dispensing of the wrong prescription medication.

(2) Failing to warn a person to whom a prescription drug is dispensed of possible adverse drug interactions.

Section 50. Root cause analysis; corrective action plan. Following the occurrence of an adverse health care event, the facility or pharmacy must conduct a root cause analysis of the event. Following the analysis, the facility or pharmacy must: (i) implement a corrective action plan to implement the findings of the analysis or (ii) report to the Department any reasons for not taking corrective action. If the root cause analysis and the implementation of a corrective action plan are complete at the time an event must be reported, the findings of the analysis and the corrective action plan must be included in the report of the event. The findings of the root cause analysis and a copy of the corrective action plan must otherwise be filed with the Department within 60 days after the

event occurs.

Section 55. Relation to other law.

(a) Adverse health events described in Sections 15 through 35 or Section 45 do not constitute "abuse" or "neglect" under the Elder Abuse and Neglect Act, provided that the facility or pharmacy makes a determination within 24 hours after discovering the event that this Act is applicable and the facility or pharmacy files the reports required under this Act in a timely fashion.

(b) A facility that has determined that an event described in Sections 15 through 35 or Section 45 has occurred must inform persons who are mandated reporters under the Elder Abuse and Neglect Act of that determination. A mandated reporter otherwise required to report under that Act is relieved of the duty to report an event that the facility or pharmacy determines under subsection (a) to be reportable under this Act.

(c) The protections and immunities applicable to voluntary reports under the Elder Abuse and Neglect Act are not affected by this Act.

(d) Notwithstanding any provision of the Elder Abuse and Neglect Act, the Department on Aging is not required to conduct an investigation of an event described in Sections 15 through 35 or Section 45.

Section 60. Adverse health care event reporting system.

(a) The Department shall establish an adverse health care event reporting system designed to facilitate quality improvement in the health care system. The reporting system shall not be designed to punish errors by health care practitioners or health care facility or pharmacy employees.

(b) The reporting of adverse health care events system shall consist of the following:

(1) Mandatory reporting of adverse health care events by facilities and pharmacies.

(2) Mandatory completion of a root cause analysis and a corrective action plan by the facility or pharmacy and reporting of the findings of the analysis and the plan to the Department or reporting of reasons for not taking corrective action.

(3) Analysis of reported information by the Department to determine patterns of systemic failure in the health care system and successful methods to correct these failures.

(4) Sanctions against facilities and pharmacies for failure to comply with reporting system requirements.

(5) Communication from the Department to facilities, pharmacies, health care purchasers, and the public to maximize the use of the reporting system to improve health care quality.

(c) The Department must design the reporting system so that a facility or pharmacy may file by electronic means the reports required under Sections 15 through 45. The Department shall encourage a facility or pharmacy to use the electronic filing option when that option is feasible for the facility or pharmacy.

(d) The Department is not authorized to select from or between competing alternate acceptable medical practices.

Section 65. Analysis of reports of adverse health care events. The Department shall do the following:

(1) Analyze adverse health care event reports, corrective action plans, and findings of the root cause analyses to determine patterns of systemic failure in the health care system and successful methods to correct these failures.

(2) Communicate to an individual facility or pharmacy the Department's conclusions, if any, regarding an adverse health care event reported by the facility or pharmacy.

(3) Communicate with relevant health care facilities and pharmacies any recommendations for corrective action

resulting from the Department's analysis of submissions from facilities and pharmacies.

(4) Publish an annual report: (i) describing, by institution, adverse health care events reported; (ii) outlining, in aggregate, corrective action plans and the findings of root cause analyses; and (iii) making recommendations for modifications of State health care operations.

Section 70. Sanctions. The Department shall take steps necessary to determine whether adverse health care event reports, the findings of the root cause analyses, and corrective action plans are filed in a timely manner. If a facility or pharmacy (i) fails to file a timely adverse health care event report under Section 10, (ii) fails to conduct a root cause analysis, to implement a corrective action plan, or to provide the findings of a root cause analysis or corrective action plan in a timely fashion under Section 50, or (iii) fails to report to the Department why corrective action is not needed, the Department (A) in the case of a facility, may take action under Section 7 of the Hospital Licensing Act or (B) in the case of a pharmacy, shall refer the matter to the Department of Financial and Professional Regulation.

Section 75. Interstate coordination. The Department shall report the definitions and the list of reportable events adopted in this Act to the National Quality Forum and, working in coordination with the National Quality Forum, to the other states. The Department shall monitor discussions by the National Quality Forum of amendments to the forum's list of reportable events and shall report to the General Assembly whenever the list is modified. The Department shall also monitor implementation efforts in other states to establish a list of reportable events and shall make recommendations to the General Assembly as necessary for modifications to the list of reportable events in this Act or in the other components of the

reporting system to keep the system established under this Act as nearly uniform as possible with similar systems in other states.

Section 905. The Hospital Licensing Act is amended by changing Section 7 as follows:

(210 ILCS 85/7) (from Ch. 111 1/2, par. 148)

Sec. 7. (a) The Director after notice and opportunity for hearing to the applicant or licensee may deny, suspend, or revoke a permit to establish a hospital or deny, suspend, or revoke a license to open, conduct, operate, and maintain a hospital (i) in any case in which he finds that there has been a substantial failure to comply with the provisions of this Act or the Hospital Report Card Act or the standards, rules, and regulations established by virtue of either of those Acts or (ii) as provided in Section 70 of the Adverse Health Care Event Reporting Act.

(b) Such notice shall be effected by registered mail or by personal service setting forth the particular reasons for the proposed action and fixing a date, not less than 15 days from the date of such mailing or service, at which time the applicant or licensee shall be given an opportunity for a hearing. Such hearing shall be conducted by the Director or by an employee of the Department designated in writing by the Director as Hearing Officer to conduct the hearing. On the basis of any such hearing, or upon default of the applicant or licensee, the Director shall make a determination specifying his findings and conclusions. In case of a denial to an applicant of a permit to establish a hospital, such determination shall specify the subsection of Section 6 under which the permit was denied and shall contain findings of fact forming the basis of such denial. A copy of such determination shall be sent by registered mail or served personally upon the applicant or licensee. The decision denying, suspending, or revoking a permit or a license shall become final 35 days after

it is so mailed or served, unless the applicant or licensee, within such 35 day period, petitions for review pursuant to Section 13.

(c) The procedure governing hearings authorized by this Section shall be in accordance with rules promulgated by the Department and approved by the Hospital Licensing Board. A full and complete record shall be kept of all proceedings, including the notice of hearing, complaint, and all other documents in the nature of pleadings, written motions filed in the proceedings, and the report and orders of the Director and Hearing Officer. All testimony shall be reported but need not be transcribed unless the decision is appealed pursuant to Section 13. A copy or copies of the transcript may be obtained by any interested party on payment of the cost of preparing such copy or copies.

(d) The Director or Hearing Officer shall upon his own motion, or on the written request of any party to the proceeding, issue subpoenas requiring the attendance and the giving of testimony by witnesses, and subpoenas duces tecum requiring the production of books, papers, records, or memoranda. All subpoenas and subpoenas duces tecum issued under the terms of this Act may be served by any person of full age. The fees of witnesses for attendance and travel shall be the same as the fees of witnesses before the Circuit Court of this State, such fees to be paid when the witness is excused from further attendance. When the witness is subpoenaed at the instance of the Director, or Hearing Officer, such fees shall be paid in the same manner as other expenses of the Department, and when the witness is subpoenaed at the instance of any other party to any such proceeding the Department may require that the cost of service of the subpoena or subpoena duces tecum and the fee of the witness be borne by the party at whose instance the witness is summoned. In such case, the Department in its discretion, may require a deposit to cover the cost of such service and witness fees. A subpoena or subpoena duces tecum issued as aforesaid shall be served in the same manner as a

subpoena issued out of a court.

(e) Any Circuit Court of this State upon the application of the Director, or upon the application of any other party to the proceeding, may, in its discretion, compel the attendance of witnesses, the production of books, papers, records, or memoranda and the giving of testimony before the Director or Hearing Officer conducting an investigation or holding a hearing authorized by this Act, by an attachment for contempt, or otherwise, in the same manner as production of evidence may be compelled before the court.

(f) The Director or Hearing Officer, or any party in an investigation or hearing before the Department, may cause the depositions of witnesses within the State to be taken in the manner prescribed by law for like depositions in civil actions in courts of this State, and to that end compel the attendance of witnesses and the production of books, papers, records, or memoranda.

(Source: P.A. 93-563, eff. 1-1-04.)

Section 910. The Pharmacy Practice Act of 1987 is amended by changing Section 30 as follows:

(225 ILCS 85/30) (from Ch. 111, par. 4150)

(Section scheduled to be repealed on January 1, 2008)

Sec. 30. (a) In accordance with Section 11 of this Act, the Department may refuse to issue, restore, or renew, or may revoke, suspend, place on probation, reprimand or take other disciplinary action as the Department may deem proper with regard to any license or certificate of registration for any one or combination of the following causes:

1. Material misstatement in furnishing information to the Department.

2. Violations of this Act, or the rules promulgated hereunder.

3. Making any misrepresentation for the purpose of obtaining licenses.

4. A pattern of conduct which demonstrates incompetence or unfitness to practice.

5. Aiding or assisting another person in violating any provision of this Act or rules.

6. Failing, within 60 days, to respond to a written request made by the Department for information.

7. Engaging in dishonorable, unethical or unprofessional conduct of a character likely to deceive, defraud or harm the public.

8. Discipline by another U.S. jurisdiction or foreign nation, if at least one of the grounds for the discipline is the same or substantially equivalent to those set forth herein.

9. Directly or indirectly giving to or receiving from any person, firm, corporation, partnership or association any fee, commission, rebate or other form of compensation for any professional services not actually or personally rendered.

10. A finding by the Department that the licensee, after having his license placed on probationary status has violated the terms of probation.

11. Selling or engaging in the sale of drug samples provided at no cost by drug manufacturers.

12. Physical illness, including but not limited to, deterioration through the aging process, or loss of motor skill which results in the inability to practice the profession with reasonable judgment, skill or safety.

13. A finding that licensure or registration has been applied for or obtained by fraudulent means.

14. The applicant, or licensee has been convicted in state or federal court of any crime which is a felony or any misdemeanor related to the practice of pharmacy, of which an essential element is dishonesty.

15. Habitual or excessive use or addiction to alcohol, narcotics, stimulants or any other chemical agent or drug which results in the inability to practice with reasonable

judgment, skill or safety.

16. Willfully making or filing false records or reports in the practice of pharmacy, including, but not limited to false records to support claims against the medical assistance program of the Department of Public Aid under the Public Aid Code.

17. Gross and willful overcharging for professional services including filing false statements for collection of fees for which services are not rendered, including, but not limited to, filing false statements for collection of monies for services not rendered from the medical assistance program of the Department of Public Aid under the Public Aid Code.

18. Repetitiously dispensing prescription drugs without receiving a written or oral prescription.

19. Upon a finding of a substantial discrepancy in a Department audit of a prescription drug, including controlled substances, as that term is defined in this Act or in the Illinois Controlled Substances Act.

20. Physical illness which results in the inability to practice with reasonable judgment, skill or safety, or mental incompetency as declared by a court of competent jurisdiction.

21. Violation of the Health Care Worker Self-Referral Act.

22. Failing to sell or dispense any drug, medicine, or poison in good faith. "Good faith", for the purposes of this Section, has the meaning ascribed to it in subsection (u) of Section 102 of the Illinois Controlled Substances Act.

23. Interfering with the professional judgment of a pharmacist by any registrant under this Act, or his or her agents or employees.

<u>24. Violation of the Adverse Health Care Event Reporting Act, as provided in Section 70 of that Act.</u>

(b) The Department may refuse to issue or may suspend the

license or registration of any person who fails to file a return, or to pay the tax, penalty or interest shown in a filed return, or to pay any final assessment of tax, penalty or interest, as required by any tax Act administered by the Illinois Department of Revenue, until such time as the requirements of any such tax Act are satisfied.

(c) The Department shall revoke the license or certificate of registration issued under the provisions of this Act or any prior Act of this State of any person who has been convicted a second time of committing any felony under the Illinois Controlled Substances Act, or who has been convicted a second time of committing a Class 1 felony under Sections 8A-3 and 8A-6 of the Illinois Public Aid Code. A person whose license or certificate of registration issued under the provisions of this Act or any prior Act of this State is revoked under this subsection (c) shall be prohibited from engaging in the practice of pharmacy in this State.

(d) In any order issued in resolution of a disciplinary proceeding, the Board may request any licensee found guilty of a charge involving a significant violation of subsection (a) of Section 5, or paragraph 19 of Section 30 as it pertains to controlled substances, to pay to the Department a fine not to exceed $2,000.

(e) In any order issued in resolution of a disciplinary proceeding, in addition to any other disciplinary action, the Board may request any licensee found guilty of noncompliance with the continuing education requirements of Section 12 to pay the Department a fine not to exceed $1000.

(f) The Department shall issue quarterly to the Board a status of all complaints related to the profession received by the Department.

(Source: P.A. 92-880, eff. 1-1-04.)