

## ARTICLE 10.

**Section 10-1.** Short title.

This Article may be cited as the Illinois Adverse Health Care Events Reporting Law of 2005. References in this Article to "this Law" mean this Article.

**Section 10-5.** Purpose.

The sole purpose of this Law is to establish an adverse health care event reporting system designed to facilitate quality improvement in the health care system through communication and collaboration between the Department and health care facilities. The reporting system established under this Law shall not be designed or, except as provided in this Law, used to punish errors or to investigate or take disciplinary action against health care facilities, health care practitioners, or health care facility employees.

**Section 10-10.** Definitions. As used in this Law, the following terms have the following meanings:

"Adverse health care event" means any event described in subsections (b) through (g) of Section 10-15.

"Department" means the Illinois Department of Public Health.

"Health care facility" means a hospital maintained by the State or any department or agency thereof where such department or agency has authority under law to establish and enforce standards for the hospital under its management and control, a hospital maintained by any university or college established under the laws of this State and supported principally by public funds raised by taxation, a hospital licensed under the Hospital Licensing Act, a hospital organized under the University of Illinois Hospital Act, and an ambulatory surgical treatment center licensed under the Ambulatory Surgical Treatment Center Act.

**Section 10-15.** Health care facility requirements to report, analyze, and correct.

(a) Reports of adverse health care events required. Each health care facility shall report to the Department the occurrence of any of the adverse health care events described in subsections (b) through (g) no later than 30 days after discovery of the event. The report shall be filed in a format specified by the Department and shall identify the health care facility, but shall not include any information identifying or that tends to identify any of the health care professionals, employees, or patients involved.

(b) Surgical events. Events reportable under this subsection are:

(1) Surgery performed on a wrong body part that is not consistent with the documented informed consent for that patient. Reportable events under this clause 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 clause 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.

(c) Product or device events. Events reportable under this subsection are:

(1) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care 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 health care facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(d) Patient protection events. Events reportable under this subsection are:

(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 health care facility due to patient actions after admission to the health care facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health care facility.

(e) Care management events. Events reportable under this subsection are:

(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 health care facility, 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 health care facility for a condition unrelated to hypoglycemia.

(f) Environmental events. Events reportable under this subsection are:

(1) Patient death or serious disability associated with an electric shock while being cared for in a health care 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 health care facility that is not consistent with the documented informed consent for that patient. Reportable events under this clause do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent.

(4) Patient death associated with a fall while being cared for in a health care facility.

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

(g) Physical security events. Events reportable under this subsection are:

(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 health care 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 health care facility.

(h) Definitions. As used in this Section 10-15:

"Death" means patient death related to an adverse event and not related solely to the natural course of the patient's illness or underlying condition. Events otherwise reportable under this Section 10-15 shall be reported even if the death might have otherwise occurred as the natural course of the patient's illness or underlying condition.

"Serious disability" means a physical or mental impairment, including loss of a body part, related to an adverse event and not related solely to the natural course of the patient's illness or underlying condition, that substantially limits one or more of the major life activities of an individual or a loss of bodily function, if the impairment or loss lasts more than 7 days prior to discharge or is still present at the time of discharge from an inpatient health care facility.

#### **Section 10-20.** Root cause analysis; corrective action plan.

Following the occurrence of an adverse health care event, the health care facility must conduct a root cause analysis of the event. Following the analysis, the health care facility must (i) implement a corrective action plan to address the findings of the analysis or (ii) report to the Department any reasons for not taking corrective action. A copy of the findings of the root cause analysis and a copy of the corrective action plan must be filed with the Department within 90 days after the submission of the report to the Department under Section 10-15.

#### **Section 10-25.** Confidentiality.

Other than the annual report required under paragraph (4) of Section 10-35 of this Law, adverse health care event reports, findings of root cause analyses, and corrective action plans filed by a health care facility under this Law and records created or obtained by the Department in reviewing or investigating these reports, findings, and plans shall not be available to the public and shall not be discoverable or admissible in any civil, criminal, or administrative proceeding against a health care facility or health care professional. No report or Department disclosure under this Law may contain information identifying a patient, employee, or licensed professional. Notwithstanding any other provision of law, under no circumstances shall the Department disclose information obtained from a health care facility that is confidential under Part 21 of Article VIII of the Code of Civil Procedure. Nothing in this Law shall preclude or alter

the reporting responsibilities of hospitals or ambulatory surgical treatment centers under existing federal or State law.

**Section 10-30.** Establishment of reporting system.

(a) The Department shall establish an adverse health event reporting system that will be fully operational by January 1, 2008 and designed to facilitate quality improvement in the health care system through communication and collaboration among the Department and health care facilities. The reporting system shall not be designed or used to punish errors or, except to enforce this Law, investigate or take disciplinary action against health care facilities, health care practitioners, or health care facility employees. The Department may not use the adverse health care event reports, findings of the root cause analyses, and corrective action plans filed under this Law for any purpose not stated in this Law, including, but not limited to, using such information for investigating possible violations of the reporting health care facility's licensing act or its regulations. The Department is not authorized to select from or between competing alternate health care treatments, services, or practices.

(b) The reporting system shall consist of:

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

(2) Mandatory completion of a root cause analysis and a corrective action plan by the health care facility 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 health care facilities for failure to comply with reporting system requirements.

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

(c) In establishing the adverse health event reporting system, including the design of the reporting format and annual report, the Department must consult with and seek input from experts and organizations specializing in patient safety.

(d) The Department must design the reporting system so that a health care facility may file by electronic means the reports required under this Law. The Department shall encourage a health care facility to use the electronic filing option when that option is feasible for the health care facility.

(e) Nothing in this Section prohibits a health care facility from taking any remedial action in response to the occurrence of an adverse health care event.

**Section 10-35.** Analysis of reports; communication of findings.

The Department shall do the following:

(1) Analyze adverse 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 individual health care facilities the Department's conclusions, if any, regarding an adverse event reported by the health care facility.

(3) Communicate to relevant health care facilities any recommendations for corrective action resulting from the Department's analysis of submissions from facilities.

(4) Publish an annual report that does the following:

- (i) Describes, by institution, adverse health care events reported.
- (ii) Summarizes, in aggregate form, the corrective action plans and findings of root cause analyses submitted by health care facilities.
- (iii) Describes adopted recommendations for quality improvement practices.

**Section 10-40.** Health Care Event Reporting Advisory Committee.

The Department shall appoint a 9-person Health Care Event Reporting Advisory Committee with at least one member from each of the following statewide organizations: one representing hospitals; one representing ambulatory surgical treatment centers; and one representing physicians licensed to practice medicine in all its branches. The committee shall also include other individuals who have expertise and experience in system-based quality improvement and safety and shall include one public member. At least 3 of the 9 members shall be individuals who do not have a financial interest in, or a business relationship with, hospitals or ambulatory surgical treatment centers. The Health Care Event Reporting Advisory Committee shall review the Department's recommendations for potential quality improvement practices and modifications to the list of reportable adverse health care events consistent with national standards. In connection with its review of the Department's recommendations, the committee shall conduct a public hearing seeking input from health care facilities, health care professionals, and the public.

**Section 10-45.** Testing period.

(a) Prior to the testing period in subsection (b), the Department shall adopt rules for implementing this Law in consultation with the Health Care Event Reporting Advisory Committee and individuals who have experience and expertise in devising and implementing adverse health care event or other health care quality reporting systems. The rules shall establish the methodology and format for health care facilities reporting information under this Law to the Department and shall be finalized before the beginning of the testing period under subsection (b).

(b) The Department shall conduct a testing period of at least 6 months to test the reporting process to identify any problems or deficiencies with the planned reporting process.

(c) None of the information reported and analyzed during the testing period shall be used in any public report under this Law.

(d) The Department must substantially address the problems or deficiencies identified during the testing period before fully implementing the reporting system.

(e) After the testing period, and after any corrections, adjustments, or modifications are finalized, the Department must give at least 30 days written notice to health care facilities prior to full implementation of the reporting system and collection of adverse event data that will be used in public reports.

(f) Following the testing period, 4 calendar quarters of data must be collected prior to the Department's publishing the annual report of adverse events to the public under paragraph (4) of Section 10-35.

(g) The process described in subsections (a) through (e) must be completed by the Department no later than July 1, 2007.

(h) Notwithstanding any other provision of law, the Department may contract with an entity for receiving all adverse health care event reports, root cause analysis findings, and corrective action plans that must be reported to the Department under this Law and for the compilation of

the information and the provision of quarterly and annual reports to the Department describing such information according to the rules adopted by the Department under this Law.

**Section 10-50.** Validity of public reports.

None of the information the Department discloses to the public may be made available in any form or fashion unless such information is shared with the health care facilities under review prior to public dissemination of such information. Those health care facilities shall have 30 days to make corrections and to add helpful explanatory comments about the information before the publication.

## ARTICLE 90.

**Section 90-5.** The Ambulatory Surgical Treatment Center Act is amended by changing Section 10d as follows:

(210 ILCS 5/10d)(from Ch. 111 1/2, par. 157-8.10d)

**Sec. 10d.** Fines and penalties.

(a) When the Director determines that a facility has failed to comply with this Act or the Illinois Adverse Health Care Events Reporting Law of 2005 or any rule adopted under either of those Acts hereunder, the Department may issue a notice of fine assessment which shall specify the violations for which the fine is assessed. The Department may assess a fine of up to \$500 per violation per day commencing on the date the violation was identified and ending on the date the violation is corrected, or action is taken to suspend, revoke or deny renewal of the license, whichever comes first.

(b) In determining whether a fine is to be assessed or the amount of such fine, the Director shall consider the following factors:

- (1) The gravity of the violation, including the probability that death or serious physical or mental harm to a patient will result or has resulted, the severity of the actual or potential harm, and the extent to which the provisions of the applicable statutes or rules were violated;
- (2) The reasonable diligence exercised by the licensee and efforts to correct violations;
- (3) Any previous violations committed by the licensee; and
- (4) The financial benefit to the facility of committing or continuing the violation.

(Source: P.A. 86-1292.)

**Section 90-10.** 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 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 Illinois Adverse Health Care Events Reporting Law of 2005 or the standards, rules, and regulations established by virtue of any either of those Acts.

(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.)