DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

1) Heading of the Part: Adverse Health Care Event Reporting Code

2) Code Citation: 77 Ill. Adm. Code 235

3)

Section Numbers:	Proposed Action:
235.110	Amendment
235.120	Amendment
235.130	Amendment
235.160	Amendment
235.170	Amendment

4) Statutory Authority: Illinois Adverse Health Care Events Reporting Law of 2005 [410 ILCS 522]

5) A Complete Description of the Subjects and Issues Involved: The proposed rulemaking implements P.A. 98-683 which mandated the Department of Public Health to adopt a list of adverse health care events in accordance with the most recent National Quality Forum's identification of a serious reportable event.

The economic effect on this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: National Quality Forum (NQF), Serious Reportable Events in Healthcare 2011 Update: A Consensus Report, Washington, DC: NQF; 2011. (www.qualityforum.org/Publications/2011/12/Serious_Reportable_Events_in_Healthcare_2011.aspx)

7) Will this rulemaking replace any emergency rulemaking currently in effect? No

8) Does this rulemaking contain an automatic repeal date? No

9) Does this rulemaking contain incorporations by reference? No

10) Are there any other proposed rulemakings pending on this Part? No

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11) Statement of Statewide Policy Objectives: This rule making poses no additional monetary obligation on units of local government.

12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Interested persons may present their comments concerning this rulemaking within 45 days after this issue of the *Illinois Register* to:

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Assistant General Counsel
Department of Public Health
Division of Legal Services
535 W. Jefferson St., 5th Floor
Springfield, Illinois 62761

(217)782-2043
e-mail: dph.rules@illinois.gov

13) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities and not for profit corporations affected: None

B) Reporting, bookkeeping or other procedures required for compliance: None

C) Types of professional skills necessary for compliance: None

14) Regulatory Agenda on which this rulemaking was summarized: July 2015

The full text of the Proposed Amendments begins on the next page:

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NOTICE OF PROPOSED AMENDMENTS

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER b: HOSPITALS AND AMBULATORY CARE FACILITIES

PART 235
ADVERSE HEALTH CARE EVENTS~~EVENT~~ REPORTING CODE

Section

AUTHORITY: Implementing and authorized by the Illinois Adverse Health Care Events Reporting Law of 2005 [410 ILCS 522].

SOURCE: Adopted at 33 Ill. Reg. 15763, effective October 30, 2009; amended at 39 Ill. Reg. _____, effective _____.

Section 235.110 Definitions

For the purpose of this Part:

~~"ABO-incompatible blood or blood products" means blood or blood products that are inconsistent with a given patient's blood type.~~

"Act" means the Illinois Adverse Health Care Events Reporting Law of 2005 [410 ILCS 522].

"Admitting diagnosis code" means a standard medical code associated with an injury or illness of a patient, which is assigned to the patient at the time of admission to the health care facility.

"Adverse health care event" means any event identified as a serious reportable event as listed in Section 235.130 ~~of this Part~~.

"ASA Class I patient" as designated by the American Society of Anesthesiologists (ASA) Physical Status Classification System means a normal, healthy patient prior to surgery.

"Biologics" means products made from living organisms. Biologics are derived from living material (human, plant, animal or microorganism) and used for the treatment, prevention, or cure of disease in humans.

"Contamination" means the presence of a detectable foreign substance or material that renders a substance, preparation, device or equipment impure, unstable or unsuitable for use.

"Corrective action plan" means a document that describes the specific steps that the health care facility has taken or intends to take to resolve or reduce the risk of similar adverse health care events occurring in the facility. This document will address responsibility for implementation, oversight, time lines and strategies for measuring the effectiveness of the actions.

"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 Part *shall be reported even if the death might have otherwise occurred as the natural course of the patient's illness or underlying condition.* (Section 10-15(h) of the Act)

"Decisional capacity" means the ability to understand and appreciate the nature and consequences of a decision regarding medical treatment or forgoing life-sustaining treatment and the ability to reach and communicate an informed decision in the matter as determined by the attending physician as defined by Section 10 of the Health Care Surrogate Act. [755 ILCS 40/10]

"*Department" means the Illinois Department of Public Health.* (Section 10-10 of the Act)

"Device" includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, ventilators, and procedural and monitoring equipment.~~*"Device" includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps and ventilators.* (Section 10-15 of the Act)~~

"Findings of root cause analysis" means the conclusions of the organizational root cause analysis that summarize how the adverse event happened and reasons for

the adverse event occurrence. Reportable findings do not include investigatory notes, data, staff interviews and other unrelated documentation that led to the conclusions of the root cause analysis.

"Guardian" means a court appointed guardian of the person who serves as a representative of a minor or as a representative of a person under legal disability as defined by Section 10 of the Health Care Surrogate Act [755 ILCS 40/10]

"Health care facility" or "health care setting" *means a hospital maintained by the State or any department or agency of the State 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* [210 ILCS 85], *a hospital organized under the University of Illinois Hospital Act* [110 ILCS 330], *and an ambulatory surgical treatment center licensed under the Ambulatory Surgical Treatment Center Act* [210 ILCS 5]. (Section 10-10 of the Act)

"Health care facility environment" means the totality of the conditions of a health care facility, including infrastructure, services and physical plant.

~~"Hypoglycemia" is defined as blood glucose levels <70 milligrams/deciliter, based on National Institute of Health (NIH) guidelines and American Diabetes Association Standards of Medical Care, although severe hypoglycemia usually occurs with blood glucose levels <60 mg/dl. Hypoglycemia may occur with or without symptoms, as hypoglycemic unawareness can be present in some individuals. Patient death or serious disability related to hypoglycemia that occurs while the patient is being cared for in a health care facility for a condition unrelated to hypoglycemia (such as congestive heart failure or foot amputation) would qualify as an adverse event.~~

"Immediately post-operative" means within 24 hours after surgery or other invasive procedure was completed or after administration of anesthesia (if surgery/procedure not completed).

"Licensed health care provider" means any person licensed by the State to provide medical, nursing or other health care services.

"Low risk pregnancy" means a pregnancy that is anticipated to be free of problems based on a woman's past medical history, past gynecological and obstetric history and any other relevant issues as the pregnancy continues.

"Major life activity" means an activity of daily living that an individual can perform with little or no difficulty, such as walking, seeing, hearing, eating, speaking, breathing, learning, performing manual tasks or taking care of one's self.

"Principal procedure code" means a code that identifies the procedure performed for definitive treatment of a patient, rather than for diagnostic or exploratory purposes, or that is necessary to take care of a complication.

"Process" means a systematic sequence of actions used to produce something or achieve an end.

"Product" means something produced by human or mechanical effort or by a natural process.

"Restraint" means any method of restricting a patient's freedom of movement that: is not a usual and customary part of a medical diagnostic or treatment procedure to which the patient or his or her legal representative has consented; is not indicated to treat the patient's medical condition or symptoms; or does not promote the patient's independent functioning.

"Root cause" means a fundamental reason or reasons for an adverse event, without which the adverse health care event would not have occurred.

"Root cause analysis" means the process for determining how an error occurred.

"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 results in *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 10-15(h) of the Act)

"Serious injury" means an injury that can result in death, loss of a body part, disability, loss of bodily function, or require major intervention for correction (for example, higher level of care, surgery).

"Sexual abuse" includes criminal sexual abuse or criminal sexual assault as defined in Sections 11-1.20 through 11-1.60 of the Criminal Code of 2012 [720 ILCS 5]/.

"Sexual Assault" includes, without limitation, acts prohibited under Sections 11-1.20 through 11-1.60 of the Criminal Code of 2012 [720 ILCS 5] ~~means an act of nonconsensual forced sexual penetration or sexual conduct as defined in Section 12-12 of the Criminal Code of 1961 [720 ILCS 5], including, without limitation, acts prohibited under Sections 12-13 through 12-16 of the Criminal Code of 1961~~.

~~"Significant injury" means harm or hurt through damage inflicted on the body by an external force~~.

"Staff member" means any full-time or part-time employee, contractor, or volunteer who is authorized to work at the reporting facility, and who is responsible for carrying out the work of the reporting facility, whether in a paid or unpaid capacity.

"Surgery" means an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or the procedure is carried out using an instrument that is introduced through a natural body orifice. Surgery includes minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to Caesarian delivery to extensive multiorgan transplantation. Surgery does not include such things as otoscopes and drawing blood. ~~treatment of diseases or injuries by manual and/or instrumental methods. Such methods may include invasive, minimally invasive or non-invasive procedures, depending on the conditions treated and the nature of the instruments and technology used~~.

"System" means a set of interdependent elements, both human and nonhuman, interacting to achieve a common goal.

~~"Systemic disturbance" means a human or nonhuman malfunction, intrusion or interruption that affects multiple organs, tissues or processes, or affects the health care organization as a whole~~.

"Unemancipated minor" means a minor who has not been granted the legal status of emancipated, pursuant to the requirements of the Emancipation of Minors Act [750 ILCS 30].

(Source: Amended at 39 Ill. Reg. _____, effective _____)

Section 235.120 Referenced Materials

The following materials are referenced in this Part:

a) State of Illinois statutes:

1) Hospital Licensing Act [210 ILCS 85]

2) Ambulatory Surgical Treatment Center Act [210 ILCS 5]

3) University of Illinois Hospital Act [110 ILCS 330]

~~4~~) Criminal Code of 2012~~1961~~ [720 ILCS 5]

5) Code of Civil Procedure, Article VIII, Part 21 [735 ILCS 5/Art. VIII, Part 21]

6) Health Care Surrogate Act [755 ILCS 40]

7) Emancipation of Minors Act [750 ILCS 30]

b) State of Illinois Administrative Rules
Rules of Practice and Procedure in Administrative Hearings (Illinois Department of Public Health) (77 Ill. Adm. Code 100)

(Source: Amended at 39 Ill. Reg. _____, effective _____)

Section 235.130 Adverse Health Care Events

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

The following are "adverse health care events" for the purposes of ~~the requirements of~~ the Act and this Part:

a) Surgical or Invasive Procedure Events. Events reportable under this subsection are: ~~*Surgical events. Events reportable under this subsection are:*~~

1) Any surgery or other invasive procedure performed on the wrong body part or site and that is not consistent with the correct documented informed consent for that patient, excluding emergent situations that occur in the course of surgery or other invasive procedure when exigency precludes obtaining informed consents.~~*Surgery performed on a wrong body part that is not consistent with the documented informed consent for that patient. Reportable events under this* subsection *do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent*.~~

2) Surgery or other invasive procedure performed on the wrong patient.~~*Surgery performed on the wrong patient.*~~

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

4) Unintended retention of a foreign object in a patient after surgery or other invasive procedure, including medical or surgical items intentionally placed by medical providers that are unintentionally left in place. Unintended retention of a foreign object excludes:

A) Objects present prior to surgery or other invasive procedure that are intentionally left in place;

B) Objects intentionally implanted as part of a planned intervention; and

C) Objects not present prior to surgery or other invasive procedure that are intentionally left in when the risk of removal exceeds the

risk of retention (such as micro-needles, broken screws).~~*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) Intraoperative or immediately postoperative or post-procedure death in an ASA Class I patient, including all ASA Class I patient deaths in situations in which anesthesia was administered, regardless of whether or not the planned surgical procedure was performed.~~*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 10-15(b) of the Act~~)

b) Product or Device Events. Events reportable under this subsection are:~~*Product or device events. Events reportable under this subsection are:*~~

1) Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the health care setting, including contaminants in drugs, devices, or biologics regardless of the source of the contamination or the product.~~*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.* For example, devices and drugs that are intended to be sterile and are not, rather than devices that may be contaminated after use begins~~.~~

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 including but not limited to, catheters, drains, and other specialized tubes, infusion pumps, ventilators, and procedural and monitoring equipment.~~*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.* For example, use of a Foley catheter (for urinary drainage) to insert a central venous line, thus using the wrong equipment. Not, for

~~example, using the correct device incorrectly, such as inserting a naso-gastric tube in the larynx instead of the esophagus.~~

3) Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care setting, excluding deaths or serious injury associated with neurosurgical procedures known to present a high risk of intravascular air embolism.~~*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.* (Section 10-15(c) of the Act)~~

c) Patient Protection Events. Events reportable under this subsection are:~~*Patient protection events. Events reportable under this subsection are:*~~

1) Discharge or release of a patient or resident of any age, who lacks decisional capacity, to anyone other than a guardian or other legally authorized person.~~*An infant discharged to the wrong person.*~~

2) Patient death or serious injury associated with patient elopement (disappearance), excluding events involving competent adults with decision-making capacity who leave against medical advice or voluntarily leave without being seen.~~*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, attempted suicide, or self-harm that results in serious injury while being cared for in a health care setting. Deaths resulting from self-inflicted injuries that were the reason for admission or presentation to the health care facility are excluded from reporting requirements.~~*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.* (Section 10-15(d) of the Act)~~

d) Care Management Events. Events reportable under this subsection are:~~*Care management events. Events reportable under this subsection are:*~~

1) Patient death or serious injury associated with a medication error (for example, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration). ~~*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 injury associated with unsafe administration of blood products. ~~*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 injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting, including events that occur within 42 days post-delivery but not deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.~~*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) Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy, including for the office-based surgery, birthing center or "home" setting, unplanned admission to an inpatient setting within 24 hours of delivery.~~*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.* (Section 10-15(e) of the Act)~~

5) Patient death or serious injury associated with a fall while being cared for in a health care setting including, but not limited to fractures, head injuries, and intracranial hemorrhage.

6) Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission or presentation to a healthcare setting unless:

A) Stage 2 pressure ulcer, which was recognized upon admission, progresses to a Stage 3; or

B) A pressure ulcers develops in an area where deep tissue injury was documented as present upon admission~~/~~ or presentation.

7) Artificial insemination with the wrong donor sperm or wrong egg.

8) Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen including events where specimens are misidentified or where another procedure cannot be done to produce a specimen.

9) Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.

e) Environmental Events. Events reportable under this subsection are:~~*Environmental events. Events reportable under this subsection are:*~~

1) Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a health care facility, excluding events involving patients during planned treatments such as electric countershock or elective carioversion.~~*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 systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances.~~*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 or staff member death or serious injury associated with a burn incurred from any source in the course of a patient care process in a health care setting.~~*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* subsection *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* or serious disability *associated with a fall while being cared for in a health care facility*~~.

4~~5~~) Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a health care setting ~~*Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility*. (Section 10-15(f) of the Act)~~

f) Radiologic Events. Reportable under this subsection is: ~~*Physical security events. Events reportable under this subsection are:1)*~~death or serious injury of a patient or staff member associated with the introduction of a metallic object into the Magnetic Resonance Imaging area including events related to material inside the patient's body or projectiles outside the patient's body.~~*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.* (Section 10-15(g) of the Act)~~

~~5)~~ ~~In case of an event listed in subsection (f)(4) in which a staff member is harmed, the health care facility shall generate a report to the Department, substituting staff information for patient information.~~

g) Potential Criminal 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 or resident of any age.

3) Sexual abuse or sexual assault on a patient or staff member within or on the grounds of a health care setting.

4) Death or serious injury of a patient or staff member resulting from a physical assault (for example, battery) that occurs within or on the grounds of a health care setting.

(Source: Amended at 39 Ill. Reg. _____, effective _____)

Section 235.160 Communication and Annual Report

The Department will communicate with *health care facilities to maximize the use of the* adverse health care event *reporting system to improve health care quality.* (Section 10-30(b) of the Act)

a) The Department will collect and analyze data from adverse health care event reports *to determine patterns of* systems~~*system*~~ *failure in the health care system and successful methods to correct these failures.* (Section 10-30(b) of the Act)

b) The data collected will be used to provide adverse health care event prevention recommendations to Illinois health care facilities and to help to ensure a data base of adverse health care event reports that will provide greater understanding of adverse health care events and promote the reduction of risk for those events.

c) The Department will publish an annual report to increase general knowledge about adverse health care events, their causes, and strategies for prevention. This report will be made available to the public.

(Source: Amended at 39 Ill. Reg. _____, effective _____)

Section 235.170 Enforcement

a) A health care facility that fails to comply with the requirements of the Act and this Part shall be subject to enforcement action by the Department.

b) *After notice and opportunity for a hearing, the* Department *may deny, suspend, or revoke a license to open, conduct, operate, and maintain a hospital in any case in which the* Department *finds that there has been a substantial failure to comply with the provisions of* the~~*the*~~ Act or this Part. (Section 7(a) of the Hospital Licensing Act)

c) *When the* Department *determines that* an ambulatory surgical treatment center *has failed to comply with* the~~*the*~~ Act or this Part, *the Department may issue a notice of fine assessment which shall specify the violations for which the fine is assessed.*

(Section 10(d) of the Ambulatory Surgical Treatment Center Act) Fines will be assessed in accordance with Section 10(d) of the Ambulatory Surgical Treatment Center Act. The Department will provide notice and opportunity for hearing to the ambulatory surgical treatment center.

d) Hearings shall be conducted in accordance with the Department's Rules of Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100).

(Source: Amended at 39 Ill. Reg. _____, effective _____)