DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED RULES

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	New
235.120	New
235.130	New
235.140	New
235.150	New
235.160	New
235.170	New
235.180	New

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 rules set forth a health care facility reporting system for adverse health care events, as such events are defined in the Illinois Adverse Health Care Events Reporting Law of 2005. The Law defines "health care facilities" as hospitals and ambulatory surgical treatment centers. The proposed rules set forth definitions; time frames for reporting events; the required elements of the report; and necessary follow-up reporting, which includes a root cause analyses and corrective action plan. The Department's communication with the health care facilities and the Annual Report are described. Enforcement provisions for noncompliance are also included, as well as a confidentiality provision.

The economic effect of 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: None

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

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

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9) Does this rulemaking contain incorporations by reference? No

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

11) Statement of Statewide Policy Objectives: This rulemaking does not create or expand a State mandate.

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 the publication of this issue of the *Illinois Register* to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
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: Not-for-profit health care facilities

B) Reporting, bookkeeping or other procedures required for compliance: Reporting of adverse health care events and necessary follow-up reporting, as applicable, including root cause analyses and corrective action plans

C) Types of professional skills necessary for compliance: Information gathering, reporting, conducting root cause analyses and developing corrective action plans

14) Regulatory Agenda on which this rulemaking was summarized: January 2008

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

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NOTICE OF PROPOSED RULES

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

PART 235
ADVERSE HEALTH CARE 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. _____, 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 listed in Section 235.130 of this Part.

"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)

"*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 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.

"Health care facility" 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 <60 milligrams/deciliter (mg/dl).

"Inpatient" means a patient who is admitted to a health care facility for treatment that requires at least one overnight stay.

"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 central importance to a person's daily life.

"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)

"Sexual Assault" 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.

"Surgery" means 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 body or organization as a whole.

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 1961 [720 ILCS 5]

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

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

Section 235.130 Adverse Health Care Events

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

a) *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* 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 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* subsection *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 10-15(b) of the Act)

b) *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.* (Section 10-15(c) of the Act)

c) *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.* (Section 10-15(d) of the Act)

d) *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.* (Section 10-15(e) of the Act)

e) *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* 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.*

5) *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) *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.* (Section 10-15(g) of the Act)

Section 235.140 Adverse Health Care Event Reporting System

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 Section 235.130 of this Part *no later than 30 days after discovery of the event.* (Section 10-15(a) of the Act) The reports required by the Act and this Part may be filed by electronic means. Reports of adverse health care events shall include:

1) The name, address and Department-assigned unique identifier of the health care facility making the report;

2) The name, title and contact information of the person making the report;

3) The exact location within the health care facility where the adverse health care event occurred;

4) The date and time that the adverse health care event occurred;

5) The date and time that any employee, contractor or representative of the health care facility was notified of the occurrence of the adverse health care event;

6) If the patient or patients involved in the adverse health care event reside in this State, the county in which the patient resides;

7) If the patient or patients involved in the adverse health care event do not reside in this State, the state or country in which the patient resides;

8) Gender and date of birth of the patient;

9) Race or ethnicity of the patient;

10) Language spoken by patient; if the language was not English, was a translator present;

11) Date on which the patient was admitted;

12) Admitting diagnosis code of the patient;

13) Principal procedure code of the patient if the event involved surgery;

14) Description of the adverse health care event, including number and type of staff present at time of the event;

15) Any immediate or emergency remedial actions taken prior to filing the adverse health care event report, including an apology to the patient and/or patient's family; and

16) The outcome for the patient from the adverse event.

Section 235.150 Root Cause Analysis and Corrective Action Plan

a) *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*:

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1) *Implement a corrective action plan to address the findings of the analysis; or*

2) *Report to the Department any reasons for not taking corrective action.*

b) *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.* (Section 10-20 of the Act)

c) The root cause analysis shall:

1) Focus primarily on systems and processes;

2) Progress from specific direct causes in clinical processes to contributing causes in organizational processes;

3) Use flow charts and cause and effect diagrams to describe the sequence of the reportable events;

4) Contain the following key elements:

A) Details of the adverse health care event;

B) Identification of any human factors related to the adverse health care event;

C) Examination of any related processes and systems in place during the adverse health care event;

D) Analysis of staffing levels at the times before, during and after the adverse health care event;

E) Analysis of staff communication before, during and after the adverse health care event;

F) Analysis of the training and education of staff in connection with the systems and processes associated with the root cause analysis of the adverse health care event;

G) Analysis of any actions, inactions, literacy or knowledge gaps of the patient that may have contributed to the adverse health care event;

H) Assessment of the equipment involved in the adverse health care event, if any;

I) Analysis of the health care facility environment before, during and after the adverse health care event;

J) Identification of any external factors beyond the control of the health care facility; and

K) Identification of any other factors related to the adverse health care event;

5) Describe contributing and underlying factors to the root cause; and

6) Identify changes that could be made in systems and processes, either through redesign of existing systems or processes or development of new systems or processes, that would reduce the risk of such events occurring in the future.

d) The corrective action shall include:

1) Specific actions to correct the identified causes of the event to prevent a similar event occurring in the future;

2) Identified and measurable outcomes;

3) A designated person responsible for implementation and evaluation; and

4) A specific implementation plan with the following:

A) Completion dates;

B) Provisions for education of and communication with appropriate hospital staff; and

C) A description of how the hospital's performance will be assessed and evaluated following full implementation.

e) The Department will determine whether the root cause analysis and corrective action plan are acceptable, based on the requirements of this Section. If the root cause analysis and corrective action plan are acceptable, the Department will instruct the facility to begin follow-up activity to measure the success of the corrective action plan.

f) If the Department determines that the root cause analysis and corrective action plan are unacceptable, based on the requirements of this Section, the Department will provide consultation on the criteria that have not been met and will allow an additional time period (up to 30 calendar days) for resubmission.

g) A health care facility shall report to the Department regarding the outcome of the corrective action plans at four and eight months following the initiation of the plan.

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 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.

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* 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* 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).

Section 235.180 Confidentiality

Other than the annual report required under paragraph (4) of Section 10-35 of the Act, *adverse health care event reports, findings of root cause analyses, and corrective action plans filed by a health care facility under* the Act *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* the Act and this Part *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.* (Section 10-25 of the Act)