**Section 235.110 Definitions**

For the purpose of this Part:

"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.

"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.

"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.

"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.

"Sexual Assault" includes, without limitation, acts prohibited under Sections 11‑1.20 through 11-1.60 of the Criminal Code of 2012.

"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.

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

"Unemancipated minor" means a minor who has not been granted the legal status of emancipated, pursuant to the Emancipation of Minors Act.

(Source: Amended at 40 Ill. Reg. 375, effective December 23, 2015)