**Section 235.130 Adverse Health Care Events**

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

a) Surgical or Invasive Procedure 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.

2) Surgery or other invasive procedure 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.

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).

5) Intraoperative or immediately postoperative or postprocedure death in an ASA Class I patient, including all ASA Class I patient deaths in situations in which anesthesia was administered, regardless of whether the planned surgical procedure was performed.

b)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.

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.

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.

c)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.

2)Patient death or serious injury associated with patient elopement (disappearance), excluding events involving competent adults with decisionmaking capacity who leave against medical advice or voluntarily leave without being seen.

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.

d)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).

2) Patient death or serious injury associated with unsafe administration of 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.

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 after delivery.

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 ulcer 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 in which specimens are misidentified or when 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:

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 cardioversion.

2)Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, or 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.

4)Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a health care setting.

f) Radiologic Events. Reportable under this subsection is 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.

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 40 Ill. Reg. 375, effective December 23, 2015)