

Event Type	Rule
<b>Surgical</b>	<p><u>Surgery performed on the wrong body part</u>, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient.</p> <p>Excluded are emergent situations:</p> <ul style="list-style-type: none"> <li>• that occur in the course of surgery; or</li> <li>• whose exigency precludes obtaining informed consent;</li> </ul> <p>or both.</p>
<b>Surgical</b>	<p><u>Surgery performed on the wrong patient</u>, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.</p>
<b>Surgical</b>	<p><u>Wrong surgical procedure performed on a patient</u>, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient.</p> <p>Excluded are emergent situations:</p> <ul style="list-style-type: none"> <li>• that occur in the course of surgery; or</li> <li>• whose exigency precludes obtaining informed consent;</li> </ul> <p>or both.</p>
<b>Surgical</b>	<p><u>Retention of a foreign object in a patient after surgery or other invasive procedure.</u></p> <p>The following are excluded:</p> <ul style="list-style-type: none"> <li>• Objects intentionally implanted as part of a planned intervention.</li> <li>• Objects present before surgery that were intentionally retained.</li> <li>• Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws.</li> </ul>
<b>Surgical</b>	<p><u>Intraoperative or immediately postoperative death in a patient with no systemic disease(s).</u> Included are all patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p>

<b>Product/Device</b>	<u>Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center.</u> Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.
<b>Product/Device</b>	<u>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.</u> Included are, but not limited to, the following: <ul style="list-style-type: none"> <li>• Catheters.</li> <li>• Drains and other specialized tubes.</li> <li>• Infusion pumps.</li> <li>• Ventilators.</li> </ul>
<b>Product/Device</b>	<u>Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center.</u>  Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
<b>Patient Protection</b>	Infant discharged to the wrong person.
<b>Patient Protection</b>	Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person.
<b>Patient Protection</b>	Patient death or serious disability associated with patient elopement. Excludes adults with decision-making capacity.
<b>Patient Protection</b>	<u>Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center,</u> defined as events that result from patient actions after admission to the center.  Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the center.
<b>Care Management</b>	<u>Patient death or serious disability associated with a medication error,</u> for example, errors involving the wrong: <ul style="list-style-type: none"> <li>• drug;</li> <li>• dose;</li> </ul>

	<ul style="list-style-type: none"> <li>• patient;</li> <li>• time;</li> <li>• rate;</li> <li>• preparation; or</li> <li>• route of administration.</li> </ul> <p>Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient has a known allergy and drug-drug interactions for which there is known potential for death or serious disability.</p>
<b>Care Management</b>	Patient death or serious disability associated with a hemolytic reaction due to the administration of blood or blood products incompatible with the A, B, AB, and O blood group system/human leukocyte antigen (ABO/HLA).
<b>Care Management</b>	<p><u>Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center.</u> Included are events that occur within forty-two (42) days post-delivery.</p> <p>Excluded are deaths from any of the following:</p> <ul style="list-style-type: none"> <li>• Pulmonary or amniotic fluid embolism.</li> <li>• Acute fatty liver of pregnancy.</li> <li>• Cardiomyopathy.</li> </ul>
<b>Care Management</b>	Death or serious disability of a neonate associated with labor or delivery in a low-risk pregnancy.
<b>Care Management</b>	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the center.
<b>Care Management</b>	Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.
<b>Care Management</b>	<p><u>Stage three (3) or four (4) pressure ulcers acquired after admission to the center.</u></p> <p>Excluded is progression from stage two (2) or stage three (3) if the stage two (2) or stage three (3) pressure ulcer was recognized upon admission or unstageable because of the presence of eschar.</p>

<b>Care Management</b>	Patient death or serious disability resulting from joint movement therapy performed in the center.
<b>Care Management</b>	Artificial insemination with the wrong donor sperm or wrong egg.
<b>Care Management</b>	Patient death or serious disability resulting from the irretrievable loss of an irreplaceable biological specimen.
<b>Care Management</b>	Patient death or serious disability resulting from failure to follow-up or communicate laboratory, pathology, or radiology test results.
<b>Environment</b>	<u>Patient death or serious disability associated with an electric shock while being cared for in the center.</u> Excluded are events involving planned treatment, such as electrical countershock or elective cardioversion.
<b>Environment</b>	Any incident in which a line designated for oxygen or other gas to be delivered to a patient: <ul style="list-style-type: none"> <li>• contains the wrong gas; or</li> <li>• is contaminated by toxic substances.</li> </ul>
<b>Environment</b>	Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.
<b>Environment</b>	Patient death or serious disability associated with a fall while being cared for in the center.
<b>Environment</b>	Patient death or serious disability associated with the use of restraints or bed rails while being cared for in the center.
<b>Radiologic</b>	Death or serious disability of a patient or staff associated with the introduction of a metallic object into the magnetic resonance imaging (MRI) area.
<b>Criminal</b>	Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.
<b>Criminal</b>	Abduction of a patient of any age.
<b>Criminal</b>	Sexual assault on a patient within or on the grounds of the center.

<b>Criminal</b>	Death or significant injury of a patient resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.
<b>Criminal</b>	Death or significant injury of a staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.

Combine for aggregate data purposes.

## Definitions

"ASA Class I patient" means a normal, healthy patient.

"Biologics" means a biological product, such as:

- a globulin;
- a serum;
- a vaccine;
- an antitoxin;
- blood; or
- an antigen;

used in the prevention or treatment of disease.

"Burn" means any injury or damage to the tissues of the body caused by exposure to any of the following:

- Fire.
- Heat.
- Chemicals.
- Electricity.
- Radiation.
- Gases.

"Elopement" means any situation in which a registered or admitted patient, excluding events involving adults with decision-making capacity, leaves the hospital without staff being aware that the patient has done so.

"Hyperbilirubinemia" means total serum bilirubin levels greater than twenty-five (25) mg/dL in a neonate.

"Hypoglycemia" means a physiologic state in which:

- the blood sugar falls below sixty (60) mg/dL (forty [40] mg/dL in neonates); and
- physiological or neurological, or both, dysfunction begins.

"Immediately postoperative" means within twenty-four (24) hours after either of the following:

- Administration of anesthesia (if surgery or other invasive procedure is not completed).
- Completion of surgery or other invasive procedure.

"Informed consent" means the authorization or agreement of a patient to undergo surgery or other invasive procedure that is based upon communication between a patient and his or her physician regarding the surgery or other invasive procedure.

"Joint movement therapy" means all types of manual techniques, to include:

- mobilization (movement of the spine or a joint within its physiologic range of motion);
- manipulation (movement of the spine or a joint beyond its normal voluntary physiologic range of motion); or
- any other type of manual musculoskeletal therapy;

regardless of their precise anatomic and physiologic focus or their discipline of origin.

"Kernicterus" means the medical condition in which elevated levels of bilirubin cause brain damage.

"Low-risk pregnancy" means a woman sixteen (16) to thirty-nine (39) years of age with no previous diagnosis of any of the following:

- Essential hypertension.
- Renal disease.
- Collagen-vascular disease.
- Liver disease.
- Preeclampsia.
- Cardiovascular disease.
- Placenta previa.
- Multiple gestation.
- Intrauterine growth retardation.
- Smoking.
- Pregnancy-induced hypertension.
- Premature rupture of membranes.
- Other previously-documented condition that poses a high risk of pregnancy-related mortality.

"Neonates" means infants in the first twenty-eight (28) days of life.

"Serious disability" means either of the following:

- Significant loss of function including sensory, motor, physiologic, or intellectual impairment:
  - not present on admission and requiring continued treatment; or
  - for which there is a high probability of long-term or permanent lifestyle change at discharge.

- Unintended loss of a body part.

"Sexual assault" means a crime included under [IC 35-42-4](#) or [IC 35-46-1-3](#).

"Surgery or other invasive procedure" means surgical or other invasive procedures that involve a skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure begins at the time of the skin incision, puncture, or insertion of an instrument or foreign material into tissues, cavities, or organs. A procedure ends when the surgical incision has been closed or operative devices, such as probes, have been removed. The procedures include, but are not limited to, the following:

- Open or percutaneous surgical procedures.
- Percutaneous aspiration.
- Selected injections.
- Biopsy.
- Percutaneous cardiac and vascular diagnostic or interventional procedures.
- Laparoscopies.
- Endoscopies.
- Colonoscopies.

The term excludes intravenous therapy, venipuncture for phlebotomy, diagnostic tests without intravenous contrast agents, nasogastric tubes, or indwelling urinary catheters.

"Toxic substance" means chemicals that are present in sufficient concentration to pose a hazard to human health.