

## Medical Error Events, Hospitals

Event Type	Rule
<b>Procedural Events</b>	<p><b>Surgery or other invasive procedure performed at the <u>wrong site</u>, on the <u>wrong patient</u>, or that is the <u>wrong procedure</u>, regardless of the type of procedure or the outcome.</b></p> <p>This event applies to all healthcare settings that perform surgery or other invasive procedures.</p>
<b>Procedural Events</b>	<p><b>Unintended retention of a foreign object in a patient after surgery or other invasive procedure, regardless of the type of procedure or the outcome.</b></p> <p>This event applies to all healthcare settings that perform surgery or other invasive procedures.</p>
<b>Procedural Events</b>	<p><b>Patient harm associated with perioperative or periprocedural anesthesia or sedation of an ASA Class I or ASA Class II patient.</b></p> <p>This event applies to all healthcare settings that administer perioperative or periprocedural anesthesia or sedation.</p>
<b>Procedural Events</b>	<p><b>Medically-assisted reproduction with the wrong donor sperm or egg, regardless of the outcome.</b></p> <p>This event applies to all healthcare settings that perform medically-assisted reproduction.</p>
<b>Procedural Events</b>	<p><b>Introduction of an unapproved, unscreened, or inappropriately approved device, implant, or object into an MR Zone IV area, regardless of the outcome.</b></p> <p>This event applies to all healthcare settings that perform MRI.</p>
<b>Procedural Events</b>	<p><b>Patient harm associated with an MRI-related thermal injury.</b></p> <p>This event applies to all healthcare settings that perform MRI.</p>
<b>Procedural Events</b>	<p><b>Delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or greater than 25% above the planned radiotherapy dose, regardless of the outcome.</b></p> <p>This event applies to all healthcare settings that provide radiotherapy services.</p>

<p><b>Product or Device Events</b></p>	<p><b>Patient harm associated with the use of contaminated drugs, devices, or biologics.</b></p> <p>This event applies to all healthcare settings that use drugs, devices, and biologics in the provision of patient care except virtual care.</p>
<p><b>Product or Device Events</b></p>	<p><b>Patient harm associated with the use or function of a medical device in patient care, in which the device is used or functions other than as intended.</b></p> <p>This event applies to all healthcare settings that use medical devices in the provision of patient care.</p>
<p><b>Product or Device Events</b></p>	<p><b>Patient harm occurring when systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas, or are contaminated by toxic substances.</b></p> <p>This event applies to all healthcare settings that have systems designated for oxygen, or other gas, to be delivered to a patient, except virtual care.</p>
<p><b>Product or Device Events</b></p>	<p><b>Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the healthcare setting, regardless of the outcome.</b></p> <p>This event applies to all healthcare settings that operate equipment during direct patient care, except virtual care.</p>
<p><b>Patient Protection Events</b></p>	<p><b>Discharge or release of a patient who does not have decision-making capacity to other than an authorized person or entity, regardless of the outcome.</b></p> <p>This event applies to all healthcare settings that provide care or services to patients who do not have decision-making capacity.</p>
<p><b>Patient Protection Events</b></p>	<p><b>Patient harm associated with the disappearance or unauthorized departure of a patient who does not have decision-making capacity.</b></p> <p>This event applies to all healthcare settings that provide care or services to patients who do not have decision-making capacity.</p>
<p><b>Patient Protection Events</b></p>	<p><b>Patient suicide or suicide attempt that occurs after presentation for care or within seven days of discharge or release, regardless of the outcome.</b></p>

	<p>This event applies to all healthcare settings that screen for suicide/suicide ideation. Although most commonly occurring in hospital and acute care settings, this event also applies to outpatient settings that provide primary care or mental health services.</p>
<b>Patient Protection Events</b>	<p><b>Patient harm associated with the use of chemical restraints, physical restraints, or seclusion.</b></p> <p>This event is applicable to all healthcare settings that use restraints or seclusion except home or virtual care.</p>
<b>Patient Protection Events</b>	<p><b>Sexual abuse or sexual assault within or on the grounds of a healthcare setting, regardless of the outcome.</b></p> <p>This event applies to all healthcare settings, with emphasis on newer care modalities where traditional physical boundaries may not apply but patient vulnerability exists.</p>
<b>Care Provision Events</b>	<p><b>Patient harm associated with a fall.</b></p> <p>This event applies to all healthcare settings except virtual care. Although most commonly occurring in inpatient and long-term care settings, this event should be reported by all healthcare settings, particularly those providing direct care for patients at higher risk of falling.</p>
<b>Care Provision Events</b>	<p><b>Patient harm associated with an unintended burn from any source.</b></p> <p>This event applies to all healthcare settings except virtual care.</p>
<b>Care Provision Events</b>	<p><b>Patient harm associated with a medication error.</b></p> <p>This event applies to all healthcare settings that prescribe, prepare, dispense, and administer medications.</p>
<b>Care Provision Events</b>	<p><b>Patient harm associated with unsafe processing or administration of blood products.</b></p> <p>This event applies to all healthcare settings where blood or blood-derived products are processed and/or administered.</p>
<b>Care Provision Events</b>	<p><b>Patient harm associated with a stage 3 pressure injury, stage 4 pressure injury, unstageable pressure injury, or deep tissue pressure injury acquired after admission.</b></p>

	<p>This event applies to all healthcare settings that provide round-the-clock observation, monitoring, and care. This event does not apply to ambulatory/outpatient, home, or virtual care.</p>
<b>Care Provision Events</b>	<p><b>Patient harm associated with the irretrievable loss of a biological specimen that is irreplaceable or is only replaceable through an invasive procedure.</b></p> <p>This event applies to all healthcare settings where the collection and management of a biological specimen occur except virtual care.</p>
<b>Care Provision Events</b>	<p><b>Patient harm resulting from failure to act on clinically significant laboratory, pathology, or radiology test results.</b></p> <p>This event applies to all healthcare settings where laboratory, pathology, or radiology test results are ordered, processed, resulted, and communicated to the ordering clinician or clinical care team and where results are interpreted, assessed, acted upon, and communicated to the patient, authorized person, or entity.</p>
<b>Care Provision Events</b>	<p><b>Patient harm associated with an intravascular air embolism.</b></p> <p>This event applies to all healthcare settings except virtual care.</p>
<b>Care Provision Events</b>	<p><b>Maternal patient harm associated with labor or delivery in a low-risk pregnancy.</b></p> <p>This event applies to all healthcare settings where labor or delivery occurs.</p>
<b>Care Provision Events</b>	<p><b>Neonatal patient harm associated with labor or delivery in a low-risk pregnancy.</b></p> <p>This event applies to all healthcare settings where labor or delivery occurs.</p>
<b>Care Provision Events</b>	<p><b>Patient harm associated with the care of a neonate.</b></p> <p>This event applies to all healthcare settings that provide neonatal care from birth to less than or equal to 28 days after delivery.</p>
<b>Care Provision Events</b>	<p><b>Patient harm associated with unrecognized clinical deterioration.</b></p> <p>This event applies to all healthcare settings.</p>

## Medical Error Events, Ambulatory Surgery Centers (ASCs)

Event Type	Rule
<b>Surgical Events</b>	<p><b>Surgery performed on the <u>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.</b></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 Events</b>	<p><b>Surgery performed on the <u>wrong patient</u>, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient.</b></p>
<b>Surgical Events</b>	<p><b><u>Wrong surgical procedure</u> performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient.</b></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 Events</b>	<p><b>Retention of a foreign object in a patient after surgery or other invasive procedure.</b></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 Events</b>	<p><b>Intraoperative or immediately postoperative death in an ASA Class I patient.</b></p> <p>Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p>

<p><b>Product or Device Events</b></p>	<p><b>Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the center.</b></p> <p>Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.</p>
<p><b>Product or Device Events</b></p>	<p><b>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.</b></p> <p>Included are, but not limited to, the following:</p> <ul style="list-style-type: none"> <li>• Catheters.</li> <li>• Drains and other specialized tubes.</li> <li>• Infusion pumps.</li> <li>• Ventilators.</li> </ul>
<p><b>Product or Device Events</b></p>	<p><b>Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the center.</b></p> <p>Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.</p>
<p><b>Patient Protection Events</b></p>	<p><b>Infant discharged to the wrong person.</b></p>
<p><b>Patient Protection Events</b></p>	<p><b>Patient death or serious disability associated with patient elopement.</b></p>
<p><b>Patient Protection Events</b></p>	<p><b>Patient suicide or attempted suicide resulting in serious disability, while being cared for in the center, defined as events that result from patient actions after admission to the center.</b></p> <p>Excluded are deaths resulting from self-inflicted injuries that were the reason for admission to the center.</p>
<p><b>Care Management Events</b></p>	<p><b>Patient death or serious disability associated with a medication error.</b></p> <p>For example, errors involving the wrong:</p> <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 Events</b>	<b>Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products.</b>
<b>Care Management Events</b>	<p><b>Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the center.</b></p> <p>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 Events</b>	<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>
<b>Care Management Events</b>	<b>Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates.</b>
<b>Care Management Events</b>	<p><b>Stage 3 or 4 pressure ulcers acquired after admission to the center.</b></p> <p>Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable because of the presence of eschar.</p>
<b>Care Management Events</b>	<b>Patient death or serious disability resulting from joint movement therapy performed in the center.</b>

<b>Care Management Events</b>	<b>Artificial insemination with the wrong donor sperm or wrong egg.</b>
<b>Environmental Events</b>	<b>Patient death or serious disability associated with an electric shock while being cared for in the center.</b> Excluded are events involving planned treatment, such as electrical countershock or elective cardioversion.
<b>Environmental Events</b>	<b>Any incident in which a line designated for oxygen or other gas to be delivered to a patient is contaminated.</b> For example, the 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>Environmental Events</b>	<b>Patient death or serious disability associated with a burn incurred from any source while being cared for in the center.</b>
<b>Environmental Events</b>	<b>Patient death or serious disability associated with a fall while being cared for in the center.</b>
<b>Environmental Events</b>	<b>Patient death or serious disability associated with the use of restraints or bed rails while being cared for in the center.</b>
<b>Criminal Events</b>	<b>Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.</b>
<b>Criminal Events</b>	<b>Abduction of a patient of any age.</b>
<b>Criminal Events</b>	<b>Sexual assault on a patient within or on the grounds of the center.</b>
<b>Criminal Events</b>	<b>Death or significant injury of a <u>patient</u> resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.</b>
<b>Criminal Events</b>	<b>Death or significant injury of a <u>staff member</u> resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the center.</b>