Texas Reportable Preventable Adverse Events Definitions and Guidance v1.7 (04/01/18)

Texas Note **Texas Department of State Health Services**	**The following document includes definitions, specifications and guidance as provided by the National Quality Forum (NQF), Appendix A and B; the Agency for Healthcare Research and Quality (AHRQ) Common Formats Users Guide; the AHRQ Common Format Forms; and the diagnosis codes that have been identified on the FY 2013 Final Healthcare Acquired Condition (HAC) List by CMS.** **Texas DSHS Preventable Adverse Event (PAE) program agrees with the following definitions and explanations unless otherwise noted in a Texas Note. In addition, other clarifying comments will be included in a Texas Note if indicated.**

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	Appendix A--Specifications of the Serious Reportable Events In Healthcare—2011 Update[1]	**Appendix B--Glossary Specifications of the Serious Reportable Events In Healthcare—2011 Update[2]**	**Common Formats[3] (CF) or Appendix 2 Glossary AHRQ Users Guide 1.2 – 2013[4]**	**Diagnosis Codes as Identified by CMS for HACs[5]**
PREVENTABLE ADVERSE EVENT REPORTING EFFECTIVE JANUARY 1, 2015.	Definitions of key terms are included in the Glossary (Appendix B) and, where the terms are used in the event description or additional specifications are considered part of the specifications of the events. Implementation Guidance is not proposed for endorsement. It amplifies statements in the Event and Additional Specifications, which are proposed for endorsement, with examples and explanations based on experience of those organizations / entities that have implemented event reporting as well as recommendations of the NQF Serious Reportable Events Steering Committee. It does not purport to be either comprehensive or even across the events and is not a requirement of either.	The following terms are defined as they apply to the NQF list of serious reportable events. To the extent practicable, they have been harmonized with definitions used in other NQF safety-related products, the Agency for Healthcare Research and Quality's Common Formats, and the World Health Organization's evolving International Classification for Patient Safety. The Common Formats are a product of the requirements of the Patient Safety and Quality Improvement Act of 2005 that provides a structure for reporting adverse events, while the latter provides structure for classifying such events.		
(1a) Surgery or invasive procedure involving wrong procedure. **This event must be reported**	WRONG PROCEDURE: Additional Specifications: Defined as any surgery or other invasive procedure performed on a body part or site that is not consistent with the correctly documented informed consent for that patient.	*Informed Consent* involves a process of shared decision making in which discussion between a person who would receive a treatment, including surgery or invasive procedure, and the caregiver/professional person who explains the treatment, provides information about possible benefits,		

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regardless of level of harm assessed.	Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, and injection into joints. Excludes emergent situations that occur in the course of surgery or other invasive procedures and/or whose exigency precludes obtaining informed consent. Implementation Guidance: It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a "surgical consent form"; however, it does require informed consent be documented in the patient record. This event is intended to capture: • insertion of the wrong medical implant into the correct surgical site. This event is not intended to capture: • changes in plan upon entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery/ procedure outweighs benefit of patient consultation, or unusual physical configuration (for example	risks and alternatives, and answers questions that result in the person's authorization or agreement to undergo a specific medical intervention. Documentation of this discussion should result in an accurate and meaningful entry in the patient record, which could include a signed "consent form". Signing a consent form does not constitute informed consent; it provides a record of the discussion. *Surgery* is 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. It 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 vaginal birth or Caesarian delivery to extensive multi-organ transplantation. It does not include use of such things as otoscopes and drawing blood.		

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	adhesions, spine level/extra vertebrae)			
(1b) Surgery or invasive procedure involving a surgery on the wrong site. **This event must be reported regardless of level of harm assessed.**	Additional Specifications: Defined as any surgery or other invasive procedure performed on a body part or site that is not consistent with the correctly documented informed consent for that patient. Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, and injection into joints. Excludes emergent situations that occur in the course of surgery or other invasive procedure and/or whose exigency precludes obtaining informed consent. Implementation Guidance: It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a "surgical consent form"; however, it does require informed consent be documented in the patient record. Although an incorrectly placed surgical mark could result in surgery being performed on the wrong body part,			

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	surgery does not begin at time the surgical mark is made on the patient. Placing a marked on the wrong body part or site does not in itself constitute wrong site surgery. Wrong site surgery or invasive procedure, corrected during the procedure, is still a wrong site procedure if the surgery/procedure had begun, based on the definition in glossary. This event in intended to capture instances of: • Surgery or other invasive procedure on the right body part but on the wrong locations/site on the body; e.g., left/right (appendages/organs), wrong digit, level (spine), stent placed in wrong iliac artery, steroid injection into the wrong knee, biopsy of wrong mole, burr hole on wrong side of skull: • Delivery of fluoroscopy or radiotherapy to the wrong region of the body; • Use of incorrectly placed vascular catheters: • Use of incorrectly placed tubes (for example, feeding tubes place in the lung or ventilation tubes passed into the esophagus). This event is NOT intended to capture:			

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	• Changes in plan upon entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery or procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesion, spine level/extra vertebrae).			
(1c) Surgery or invasive procedure involving a surgery on the wrong patient. **This event must be reported regardless of level of harm assessed.**	WRONG PATIENT: Additional Specifications: Defined as any surgical or other invasive procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient. Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, and injection into joints. Implementation Guidance: It should be noted that a correctly documented informed consent for patients whose procedures will not be carried out in an operating room may not involve a "surgical consent form"; however, it does require informed consent be documented in the patient record. This event is intended to capture:			

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	• surgical procedures (whether or not completed) initiated on one patient intended for a different patient. Use of accepted patient identification procedures is key to avoiding such events.			
(2) Foreign object retained after surgery. **This event must be reported regardless of level of harm assessed.**	RETAINED FOREIGN OBJECT: Additional Specifications: Includes medical or surgical items intentionally placed by provider(s) that are unintentionally left in place. 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/procedure that are intentionally left in when the risk of removal exceeds the risk of retention (such as microneedles, broken screws). Implementation Guidance: This event is intended to capture: • occurrences of unintended retention of objects at any point after the surgery/procedure ends regardless of setting (post anesthesia recovery unit, surgical	*Unintended retention* of a foreign object refers to a foreign object introduced into the body during a surgical or other invasive procedure, without removal prior to the end of the surgery or procedure, which the surgeon or other practitioner did not intend to leave in the body. *Surgery begins,* regardless of setting, at point of surgical incision, tissue puncture, or insertion of instrument into tissues, cavities, or organs. *Surgery ends* after all incisions or procedural access routes have been closed in their entirety, device(s) such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded and the patient has been taken from the operating/procedure room.	Unintentionally retained item: Foreign object introduced into the body during a surgical operation or another invasive procedure, without removal prior to finishing the surgery or procedure. The surgeon or other practitioner did not intend to leave the object in the body.	For ICD-10-CM codes refer to CMS.[5] See References on Page 40 #5.

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	suite, emergency department, patient bedside) and regardless of whether the object is to be removed after discovery; • unintentionally retained objects (including such things as wound packing material, sponges, catheter tips, trocars, guide wires) in all applicable settings.			
(2) Texas Note	Upon recommendation by the HAI/PAE Advisory Panel, Texas DSHS PAE Reporting Program will not follow the above NQF reference to the patient being taken from the operating/procedure room for this event to be reportable. For Texas PAE reporting, a foreign object is considered to be retained if it is not intended to remain, and is incidentally found to be in any part of the patient's body after all incisions or procedural access routes have been closed in their entirety and device(s) such as probes or instruments have been removed. A wound would be considered closed after application of a negative-pressure wound therapy (NPWT) vacuum dressing. For bedside procedures, an item is considered to be retained if it is not intended to remain, and is incidentally found to be in any part of the patient's body after the procedure is complete. This is consistent with Joint Commission Object Retained Sentinel Event.			
(3) Intraoperative or immediately postoperative postprocedure death of an ASA Class 1 Patient.	Additional Specifications: Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. 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). Implementation Guidance: This event is intended to capture:			

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	• ASA Class I patient death associated with the administration of anesthesia whether or not the planned surgical procedure was carried out.			
(3) Texas Note	This PAE is applicable for any intraoperative or immediately post-operative/post-procedure death of an ASA Class 1 patient where anesthesia was administered including general anesthesia, regional anesthesia, monitored anesthesia care (MAC), deep sedation/analgesia, and moderate sedation/analgesia ("Conscious Sedation").			
(4) Discharge or release of a patient of any age, who is unable to make decisions, to someone other than an authorized person. **This event must be reported regardless of level of harm assessed.**	Implementation Guidance: The terms "authorized" and "decision-making capacity" are defined in the glossary. Release to "other than an authorized person" includes removing the patient/resident without specific notification and approval by staff, even when the person is otherwise authorized. Examples of individuals who do not have decision-making capacity include: newborns, minors, adults with Alzheimer's. Individual healthcare organizations or other relevant jurisdictional authorities may have specific requirements for assessing decision-making Capacity.	*Authorized* means the guardian or other individual(s) having the legally recognized ability to consent on behalf of a minor or incapacitated individual (surrogate), or person designated by the surrogate to release or consent for the patient. *Decision-making capacity* is the ability to understand information relevant to a decision and the ability to appreciate the reasonably foreseeable consequences of a decision (or lack of a decision).		
(5) Any incident in which systems designated for	Implementation Guidance: This event is intended to capture: • events in which the line is attached to a reservoir distant			

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oxygen or other gas to be delivered to a patient contains no gas, wrong gas, or are contaminated by toxic substances. **This event must be reported regardless of level of harm assessed.**	from the patient care unit or in a tank near the patient such as E-cylinders, anesthesia machines.			
(6) Abduction of a patient of any age. **This event must be reported regardless of level of harm assessed.**	Implementation Guidance: This event is intended to capture: • removal of a patient/resident, who does not have decision-making capacity, without specific notification and approval by staff even when the person is otherwise authorized to be away from the setting. Examples of individuals who do not have decision-making capacity include: newborns, minors, adults with Alzheimer's.	*Abduction* means the taking away of a person by persuasion, by fraud, or by open force or violence. It includes convincing someone, particularly a minor or a woman he/she is better off leaving with the persuader, telling the person he/she is needed, or that the mother or father wants him/her to come with the abductor. (NQF Glossary) *Authorized* means the guardian or other individual having the legally recognized ability to consent on behalf of a minor or incapacitated individual (surrogate), or person designated by the surrogate to release or consent for the patient. (NQF Glossary)		

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		Decision-making capacity is the ability to understand information relevant to a decision and the ability to appreciate the reasonably foreseeable consequences of a decision (or lack of a decision).		
(7) Sexual abuse or assault of a patient within or on the grounds of a health care facility. **This event must be reported regardless of level of harm assessed.**	Implementation Guidance: Language and definitions may vary based on state statute; however, the principle and intent remain regardless of language required based on jurisdiction.	*Sexual abuse* is defined as the forcing of unwanted sexual activity by one person on another, as by the use of threats or coercion or sexual activity that is deemed improper or harmful, as between an adult and a minor or with a person of diminished mental capacity.		
(7) Texas Note	Texas will consider the following definitions and criteria for reporting (7) Sexual abuse or assault of a patient within or on the grounds of a health care facility. • Sexual Abuse or Assault: Nonconsensual sexual contact involving patient and another patient, staff member, or other perpetrator within or on the grounds of the healthcare facility. • Sexual Contact: Oral, vaginal, or anal penetration or touching/fondling of a patient's sex organ(s) by another individual's hand, sex organ, mouth or object. In the case of a child victim, sexual contact is: • Any touching by a person, including touching through clothing, of the anus, breast, or any part of the genitals of a child; or • Any touching of any part of the body of a child, including touching through clothing, with the anus, breast, or any part of the genitals of a person. In addition, one or more of the following criteria must be present to make the event reportable: • Any staff-witnessed sexual contact, as described above. • Admission by the perpetrator that sexual contact, as described above, did occur. • Sufficient clinical evidence obtained by the facility to support allegations of non-consensual sexual contact.			

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	(This guidance was developed in consideration of Texas Penal Codes Title 5, Chapter 21 and 22; Title 9, Chapter 43; and The Joint Commission Sexual Abuse/Assault Sentinel Event guidelines.)			
(8) Patient death or severe harm of a patient resulting from a physical assault that occurs within or on the grounds of a health care facility.	Implementation Guidance: Language and definitions may vary based on state statute (e.g., many states have existing statutes that use the terms "first degree assault" or "second degree assault" or "battery").			
(9) Patient death or severe harm associated with a fall in a health care facility resulting in a fracture, dislocation, intracranial injury, crushing injury, burn or other injury.	Additional Specifications: Includes but is not limited to fractures, head injuries, and intracranial hemorrhage. Implementation Guidance: Of note, an assessment that identifies patients at "risk" of fall, findings of risk accompanied by organizationally defined measures to be taken when risk is identified could be useful in both prevention and event analysis.		For purposes of patient safety, a fall is a sudden, unintended, uncontrolled, downward displacement of a patient's body to the ground or other object (e.g., onto a bed, chair, or bedside mat). This definition includes unassisted falls and assisted falls (i.e., when a patient begins to fall and is assisted to the ground by another person). (CF—Fall)	For ICD-10-CM codes refer to CMS.[5] See References on Page 40 #5.

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(9) Texas Note	This PAE is the combination of NQF's Serious Reportable Event (SRE) for fall and the HAC fall with injury. The fall SRE intends that any patient death or severe harm associated with a fall is reportable. The HAC is not dependent on a level of harm; however, Texas DSHS reportable events include any patient death or severe harm that is associated with a fall is reportable. The reporting system Texas Health Care Safety Network (TxHSN) provides choices dependent on the type of resultant injury (fracture, dislocation, intracranial, crushing, burn or other) as denoted in the HAC.			
(10) Patient death or severe harm associated with unsafe administration of blood or blood products.	Implementation Guidance: Unsafe administration includes, but is not limited to, hemolytic reactions and administering: a) blood or blood products to the wrong patient; b) the wrong type; or c) blood or blood products that have been improperly stored or handled. This event is not intended to capture: • patient death or serious injury associated with organ rejection other than those attributable to a hyperacute hemolytic reaction • patient death or injury when cause is not detectable by ABO/HLA matching.		Use this Common Format form to report any patient safety event or unsafe condition involving the processing and/or administration of blood or a blood product. This CF form is not intended for reporting blood or blood product collection and other processes prior to receipt of the product by the blood bank. (CF—Blood/Blood Product)	ICD-9-CM Codes:[5] 999.60 (CC) 999.61 (CC) 999.62 (CC) 999.63 (CC) 999.69 (CC) For ICD-10-CM codes refer to CMS.[5] See References on Page 40 #5.
(11) Patient death or severe harm resulting from the irretrievable loss of an irreplaceable biological specimen.	Additional Specifications: Includes events where specimens are misidentified, where another procedure cannot be done to produce a specimen. Includes progression of an undiagnosed disease or threat of disease that changes the patient's risk status for life, requiring monitoring not needed before the event. Implementation Guidance: This event is not intended to capture:			

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	• procedures where the specimen was properly handled, but the specimen proved to be nondiagnostic. Inability to secure a replacement for a lost specimen can occur with excisional biopsy as well as in organ removal.			
(12) Patient death or severe harm resulting from failure to follow up or communicate laboratory, pathology or radiology test results.	Additional Specifications: Includes events where failure to report increased neonatal bilirubin levels result in kernicterus. Implementation Guidance: Examples of serious injury are a new diagnosis, or an advancing stage of an existing diagnosis (e.g., cancer).			
(12) Texas Note	The NQF A Implementation Guidance states that failure to follow up or communicate can be limited to healthcare staff or can involve communication to the patient. Texas DSHS PAE Reporting Program requires that this PAE not be limited and that a failure to follow up or communicate includes failure to communicate to healthcare staff and/or the patient.			
(13) Patient death or severe harm associated with use of physical restraints or bedrails while	Implementation Guidance: The event is intended to capture: • instances where physical restraints are implicated in the death, e.g., lead to strangulation/entrapment, etc.	*Restraints* is defined by The Joint Commission, the Centers for Medicare & Medicaid Services, and by some states. The appropriate source(s) should be consulted for the definition required by the setting and/or jurisdiction in which a presumptive event occurs. In the event none of those definitions		

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being cared for in a health care facility.		apply to an institution, the following definition, which is intended to capture definitions from the named organizations, is offered: *Restraints* 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.		
(14) Perinatal death or severe harm (maternal or neonatal) associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility.	MATERNAL: Additional Specifications: Includes events that occur within 42 days post-delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy. Implementation Guidance: This event is not intended to create a new obligation. The organization's obligation, under this event, is to report only maternal death or serious injury associated with labor or delivery in a low risk pregnancy when made aware of the maternal death or serious injury either by readmittance or by the patient's family.	*Low-risk pregnancy* refers to a woman aged 18-39, with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome. *Neonate* is a newborn less than 28 days of age. (NQF Glossary)	Use this Common Format form to report any patient safety event associated with the birthing process or intrauterine procedures that occur during the perinatal period to the mother, fetus(es), or neonate(s). The perinatal period extends from the 20th week of gestation through 4 weeks (28 days) postpartum. (CF—Perinatal)	

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(14) Texas Note	For Texas DSHS Preventable Adverse Event Reporting, Texas agrees with the National Quality Forum's (NQF) definition of low-risk pregnancy in Appendix B Glossary as shown above. Other conditions for consideration that may pose a high risk of poor pregnancy outcome would include, but not be limited to, the following: uncontrolled or poorly controlled diabetes, morbid obesity, fetus/neonate congenital anomaly that is incompatible with life unless the severe harm or death was associated with labor and delivery and not the anomaly, fetus/neonate with osteogenesis imperfecta, non-vertex fetal presentation in labor/delivery, preterm infant with gestational age less than 37 weeks and/or birthweight less than 2500 grams.			
(14) Texas Note	For Texas DSHS Preventable Adverse Event Reporting: • Maternal death or severe harm that occurs within 42 days postpartum and the death or severe harm is associated with a labor or delivery that occurred in a general hospital, in a low risk pregnancy, is reportable by the facility where the labor and delivery occurred. ✓ For mothers who labored and delivered in a setting other than a general hospital and then transferred into the hospital, Texas PAE reporting does NOT apply. ✓ For mothers who began labor and delivery in another setting but is transferred to a hospital prior to the neonate's birth, PAE reporting would apply if an event occurred. • Neonatal death or severe harm that occurs to a newborn less than 28 days of age and the death or severe harm is associated with a labor or delivery that occurred in a general hospital, in a low risk pregnancy, is reportable by the facility where the labor and delivery occurred. ✓ For neonates that were born in a setting other than a general hospital and transferred into the hospital, Texas PAE reporting does NOT apply. ✓ For neonates whose mother began labor and delivery in another setting and completed labor and delivery in the hospital, PAE reporting would apply if an event occurred. For completion of the Perinatal PAE report: • When reporting a perinatal event that affects the mother, enter the mother's demographics when creating the event. • When reporting a perinatal event that affects the mother and neonate, enter the mother's demographics when creating the event. • When reporting a perinatal event that affects the neonate, enter the neonate's demographics when creating the event. • If a single event affects more than one neonate, enter the demographics for the most severely affected neonate and note injury to other neonate(s) in the narrative.			

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(15) Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) after total knee replacement or after hip replacement. **This event must be reported regardless of level of harm assessed.**			DVT and PE are two presentations of the same disease: venous thromboembolism (VTE). DVT refers to partial or total thrombotic occlusion of a deep vein of the lower extremity or pelvis (e.g., inferior vena cava, iliac, femoral, popliteal, tibial, gastrocnemial, soleal, or peroneal vein) or a deep vein of the upper extremity or upper thorax (e.g., internal jugular, brachiocephalic, superior vena cava, axillary, brachial, or subclavian). Symptomatic DVT is an objectively confirmed DVT that results in symptoms including pain and/or swelling of the affected limb. PE refers to a partial or total thromboembolic occlusion of one or more pulmonary arteries that causes symptoms or death. Symptomatic PE is an objectively confirmed PE that results in symptoms or signs such as shortness of breath, pleuritic chest pain,	For ICD-10-CM codes refer to CMS.[5] See References on Page 40 #5.

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			hemoptysis, oxygen desaturation, or death. (CF—VTE)	
(15) Texas Note	Chapter 98 of the Texas Health and Safety Code states that facilities shall report a healthcare associated adverse condition or event for which the Medicare program will not provide additional payment to the facility under a policy adopted by the federal Centers for Medicare and Medicaid Services. Therefore, report the following PAEs if they meet the coding qualifications for a Hospital Acquired Condition as noted in CMS column 5: (15) Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) after total knee replacement or after hip replacement, (16) Iatrogenic Pneumothorax with venous catheterization, (24) Surgical site infections following a spinal procedure, shoulder procedure, elbow procedure, laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery or cardiac implantable electronic device, (26) Poor glycemic control: diabetic ketoacidosis, (27) Poor glycemic control: diabetic ketoacidosis, (28) Poor glycemic control: nonketotic hyperosmolar coma, (29) Poor glycemic control: secondary diabetes with ketoacidosis, (30) Poor glycemic control: secondary diabetes with hyperosmolarity. NOTE: these events are to be reported if they occur during the episode of care, and not reported if they are present on admission.			
(16) Iatrogenic Pneumo-thorax with venous catheteriza-tion. **This event must be reported regardless of level of harm assessed.**				For ICD-10-CM codes refer to CMS.[5] See References on Page 40 #5.

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(17) Stage III, Stage IV, or Unstageable pressure ulcer acquired after admission / presentation to a health care facility. **This event must be reported regardless of level of harm assessed.**	Additional Specifications: Excludes progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission and excludes pressure ulcers that develop in areas where deep tissue injury is documented as present on admission/presentation. Implementation Guidance: Although this event could occur in the ambulatory surgery environment based on patient condition and surgery time, it will be difficult to discern. Pre- and post- skin assessment will be key.	*Pressure Ulcer, Stage 3* is defined as full thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon, or muscle is not exposed. Slough may be present. May include undermining and tunneling. The depth of a Stage 3 pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue and Stage 3 ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Stage 3 pressure ulcers. Bone/tendon is not visible or directly palpable. *Pressure Ulcer, Stage 4* is defined as full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present. Often includes undermining and tunneling. The depth of a Stage 4 pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Stage 4 ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon, Or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed bone/tendon is visible or directly palpable. *Pressure Ulcer, Unstageable* is defined as full thickness tissue loss in which the	Report a pressure ulcer or suspected deep tissue injury that was 1) not present on admission (i.e., newly-developed) or 2) worsened during the patient's stay. Report only an event that occurred prior to patient discharge. Exclude mucosal, arterial, or venous ulcers, diabetic foot ulcers. If a pressure ulcer is reported at a certain stage and gets worse before improvement, do not complete a new Pressure Ulcer Event Report. Instead, edit the existing event report to reflect the new stage and save the report. (CF—Pressure Ulcer)	For ICD-10-CM codes refer to CMS.[5] See References on Page 40 #5.

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		actual depth of the ulcer is completely obscured by slough and/or eschar in the wound bed. Until enough slough and/or eschar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either Stage 3 or Stage 4. *Deep tissue injury* presents as a purple or maroon localized area of discolored intact skin or blood-filed blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.		
(17) Texas Note	Texas DSHS has determined that reporting of Deep Tissue Injury is not required at this time. Therefore the NQF and AHRQ definitions and recommendation for DTI are not included in this document. If a DTI that has occurred during hospitalization progresses or is found to be a Stage 3, 4, or Unstageable Pressure Ulcer, then it becomes reportable. Effective January 1, 2017, exclusions for Pressure Ulcer Stage 3, 4, and Unstageable include: Stage 2 pressure ulcer on admission that progresses to Stage 3; ulcers that develop in areas of deep tissue injury that is present on admission and documented; and mucosal, arterial, venous, diabetic ulcers. See Pressure Ulcer Reporting Guidance Table at http://www.dshs.texas.gov/IDCU/health/preventable-adverse-events/PAE-Resources.aspx			

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(18) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed health care provider. **This event must be reported regardless of level of harm assessed.**	Implementation Guidance: This event is intended to capture: • those without licensure to provide the care given; • those with licensure who represent themselves and act beyond the scope of their licensure. It is not intended to capture individuals who are practicing within the scope of their license on whom patients or others mistakenly bestow titles beyond that scope when such is not encouraged by the provider.			
(19) Patient suicide, attempted suicide or self-harm that results in severe harm, while being cared for in a health care facility. **This event must be reported regardless of**	Additional Specifications: Includes events that result from patient actions after they present themselves for care in a healthcare setting. Excludes deaths resulting from self-inflicted injuries that were the reason for admission/presentation to the healthcare facility. Implementation Guidance: This event is not intended to capture patient suicide or attempted suicide when the patient is not physically present in the "healthcare setting" as defined in the glossary. (See			

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level of harm assessed.	healthcare setting in the Additional Definitions section page 31 below.)			
(20) Patient death or severe harm associated with patient elopement.	Additional Specifications: Includes events that occur after the individual presents him/herself for care in a healthcare setting. Excludes events involving competent adults with decision-making capacity who leave against medical advice or voluntarily leave without being seen. Implementation Guidance: The term "elopement" and "competent" adult should be interpreted in accordance with prevailing legal standards in applicable jurisdictions. Of note, an assessment that identifies patients at "risk" of elopement or a chief complaint and findings of risk accompanied by organizationally defined measures to be taken when risk is identified could be useful in both prevention and event analysis. This is not intended to capture: • death or serious injury that occurs (after the patient is located) due to circumstances unrelated to the elopement.	*Elopement* refers to a situation where a patient or resident who is cognitively, physically, mentally, emotionally, and/or chemically impaired wanders/walks/runs away, escapes, or otherwise leaves a caregiving institution or setting unsupervised, unnoticed, and/or prior to their scheduled discharge.		
(21) Patient death or severe harm associated	Additional Specifications: Excludes events involving patients during planned treatments such as electric countershock/elective cardioversion.			

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with an electric shock while being cared for in a health care facility.	Implementation Guidance: This event is intended to capture: • patient death or injury associated with unintended electric shock during the course of care or treatment. This event is not intended to capture: • patient death or injury associated with emergency defibrillation in ventricular fibrillation or with electroconvulsive therapies.			
(22) Patient death or severe harm associated with a burn incurred from any source while being cared for in a health care facility.	Implementation Guidance: This event is intended to capture burns that result from: • operating room flash fires, including second-degree burn in these cases; • hot water; • sunburn in the patient with decreased ability to sense pain; • smoking in the patient care environment.			
(23) Patient death or severe harm associated with the introduction of a metallic object into the MRI area.	Additional Specifications: Includes events related to material inside the patient's body or projectiles outside the patient's body. Implementation Guidance: This event is intended to capture injury or death as a result of projectiles including:			

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	• retained foreign object • external projectiles • pacemakers			
(24) Surgical site infections following a spinal procedure, shoulder procedure, elbow procedure, laparoscopic gastric bypass, gastroenter-ostomy, laparoscopic gastric restrictive surgery or cardiac implantable electronic device. **This event must be reported regardless of level of harm assessed.**				For ICD-10-CM codes refer to CMS.[5] See References on Page 41 #5.

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(25) Artificial insemination with the wrong donor sperm or wrong egg. **This event must be reported regardless of level of harm assessed.**	Implementation Guidance: The organization's obligation is to report the event when made aware of the occurrence.			
(26) Poor glycemic control: hypoglycemic coma. **This event must be reported regardless of level of harm assessed.**				For ICD-10-CM codes refer to CMS.[5] See References on Page 41 #5. See also Texas Poor Glycemic Control Crosswalk at www.paetexas.org
(27) Poor glycemic control: diabetic ketoacidosis. **This event must be reported regardless of level of harm assessed.**				For ICD-10-CM codes refer to CMS.[5] See References on Page 41 #5. See also Texas Poor Glycemic Control Crosswalk at www.paetexas.org

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(28) Poor glycemic control: nonketotic hyperosmolar coma. **This event must be reported regardless of level of harm assessed.**				For ICD-10-CM codes refer to CMS.[5] See References on Page 41 #5. See also Texas Poor Glycemic Control Crosswalk at www.paetexas.org
(29) Poor glycemic control: secondary diabetes with ketoacidosis. **This event must be reported regardless of level of harm assessed.**				For ICD-10-CM codes refer to CMS.[5] See References on Page 41 #5. See also Texas Poor Glycemic Control Crosswalk at www.paetexas.org
(30) Poor glycemic control: secondary diabetes with hyperosmo-larity. **This event must be reported regardless of**				For ICD-10-CM codes refer to CMS.[5] See References on Page 41 #5. See also Texas Poor Glycemic Control Crosswalk at

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level of harm assessed.				www.paetexas.org
(31) Patient death or severe harm associated with the use of contaminated drugs/devices or biologics provided by the health care facility.	Additional Specifications: Includes contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product. Includes threat of disease that changes patient's risk status for life requiring medical monitoring not needed before the event. Implementation Guidance: This event is intended to capture: • contaminations that can be seen with the naked eye or with use of detection mechanisms in general use. These contaminations are to be reported at such time as they become known to the provider or healthcare organization. Contaminants may be physical, chemical, or biological in nature. Not all contaminations can be seen with the naked eye (e.g., hepatitis and HIV) or readily detected using generally available or more specialized testing mechanisms (e.g., cultures, nucleic acid testing, mass spectrometry, and tests that signal changes in pH or glucose levels). Contamination that is inferred and changes risk status for life (e.g., consider a syringe or needle		For Contaminated Devices, see AHRQ CF instructions below for (32) Patient death or severe harm associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For Contaminated Drugs/Biologics, see AHRQ CF instructions below for (34) Patient death or severe harm associated with a medication error.	

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	contaminated once it has been used to administer medication to a patient by injection or via connection to a patient's intravenous infusion bag or administration set); • administration of contaminated vaccine or medication (e.g., intramuscular antibiotic); • serious infection from contaminated drug or device used in surgery or an invasive procedure (e.g., a scalpel); • occurrences related to use of improperly cleaned or maintained device.			
(32) Patient death or severe harm associated with the use or function of a device in patient care in which the device is used or functions other than as intended.	Additional Specifications: Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, ventilators, and procedural and monitoring equipment. Implementation Guidance: This event is intended to capture: • occurrences whether or not the use is intended or described by the device manufacturers' literature.		Report patient safety events involving a defect, failure, or incorrect use of a device, including an HIT device. A device includes an implant, medical equipment, or medical/surgical supply (including disposable product). An HIT device incudes hardware or software that is used to electronically create, maintain, analyze, store, or receive information to aid in the diagnosis, cure, mitigation, treatment, or prevention of disease and	

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			that is not an integral part of (1) an implantable device or (2) an item of medical equipment. (CF—Device or Medical/Surgical Supply, Including Health Information Technology (HIT))	
(33) Patient death or severe harm associated with intravascular air embolism that occurs while being cared for in a health care facility.	Additional Specifications: Excludes death or serious injury associated with neurosurgical procedures known to present a high risk of intravascular air embolism. Implementation Guidance: This event is intended to capture: • high-risk procedures, other than neurosurgical procedures, that include, but are not limited to, procedures involving the head and neck, vaginal delivery and caesarean section, spinal instrumentation procedures, and liver transplantation; • low-risk procedures, including those related to lines placed or infusion of fluids in vascular space.	As noted on page 8 in the National Quality Forum (NQF), *Serious Reportable Events In Healthcare—2011 Update: A Consensus Report* (See References page 40 #1), the neurosurgical procedures known to present a high risk of intravascular air embolism are those cases where surgery is performed in a position that puts the head above the heart to reduce venous pressure.		For ICD-10-CM codes refer to CMS.[5] See References on Page 41 #5.
(34) Patient death or severe harm associated with a	Additional Specifications: Excludes reasonable difference in clinical judgement on drug selection and dose. Includes, but is not limited to, death or serious injury associated with: a) over- or		Report patient safety events involving a substance such as medications, biological products, nutritional products, expressed human breast milk, medical gases, or	

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medication error.	under-dosing; b) administration of a medication to which a patient has a known allergy or serious contraindication, c) drug-drug interactions for which there is known potential for death or serious injury, and d) improper use of single-dose and multi-dose medication vials and containers leading to death or serious injury as a result of dose adjustment problems. Implementation Guidance: This event is intended to capture: • the most serious medication errors including occurrences in which a patient receives a medication for which there is a contraindication, or a patient known to have serious allergies to specific medication/agents, receives those medications/agents, resulting in serious injury or death. These events may occur as a result of failure to collect information about contraindications or allergies, failure to review such information available in information systems, failure of the organization to ensure availability of such information and prominently display such information within information		contrast media. (CF—Medication or Other Substance)	

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	systems, or other system failures that are determined through investigation to be cause of the adverse event; • occurrences in which a patient dies or suffers serious injury as a result of failure to administer a prescribed medication; • occurrences in which a patient is administered an over- or under-dose of a medication including insulin, heparin, and any other high alert medication including but not limited to medications listed on the Institute for Safe Medication Practices "High Alert Medication List"; • occurrences in which a patient dies or suffers serious injury as a result of wrong administration technique. This event is NOT intended to capture: • patient death or serious injury associated with allergies that could not reasonably have been known or discerned in advance of the event.	High alert medications are those medications that have a high risk of causing serious injury or death to a patient if they are misused. Examples of high-alert medications include anticoagulants and IV antithrombotics, insulin, cytotoxic chemotherapy, concentrated electrolytes, IV digoxin, opiate narcotics, neuromuscular blocking agents, and adrenergic agonists. The recommended "High Alert Medication List" is available at the Institute for Safe Medication Practices' website http://www.ismp.org.		

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ADDITIONAL DEFINTIONS				
Associated with		*Associated with* means that it is reasonable to initially assume that the adverse event was due to the referenced course of care; further investigation and/or root cause analysis of the unplanned event may be needed to confirm or refute the presumed relationship.		
Contributing factor			A circumstance determined retrospectively to have increased the likelihood of the event and that is generally external to the patient. They frequently relate to the physical environment or to the care delivery. (AHRQ App 2)	
Devices		*Medical device* is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, which is recognized in the official national formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other	Medical device: a medical device is an instrument, apparatus, implement, machine implant, in vitro reagent, or other similar or related article, including a component part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or	

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		animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.	intended to affect the structure or any function of the body, and which does not achieve any of its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes (e.g., walker, hearing aid, and medical/surgical supply, including disposable product (e.g., incontinence supply)). (AHRQ App 2)	
Duration of Harm			The period over which disease, disability, disfigurement, dysfunction, etc. may be evident; often denoted as none, transient, temporary (short-term), or permanent (life-long). (AHRQ App 2)	
Handover/ Handoff			The process when one health care professional updates another on the status of one or more patients for the purpose of taking over their care. Typical examples involve a physician who has	

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			been on call overnight telling an incoming physician about patients she has admitted so he can continue with their ongoing management, know what immediate issues to watch out for, and so on. Nurses similarly conduct a handover at the end of their shift, updating their colleagues about the status of the patients under their care and tasks that need to be performed. When the outgoing nurses return for their next duty period, they will in turn receive new updates during the change of shift handover. In addition, it is often used to refer to the information transfer that occurs from one clinical setting to another (e.g., from hospital to nursing home). (AHRQ App 2)	
Healthcare setting		*Healthcare setting* is defined as a general hospital or ambulatory surgery center licensed under Chapter 133 and 135 of the Texas Administrative Code and required to report Preventable Adverse Events. The boundary of the healthcare setting (the "grounds" is the		

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		physical area immediately adjacent to the setting's main buildings. It does not include nonmedical businesses such as shops and restaurants located close to the setting.		
Healthcare worker			Healthcare worker, including nursing assistant, patient transport/retrieval personnel, assistant/orderly, clerical/administrative personnel, interpreter/translator, technical/laboratory personnel, pastoral care personnel, biomedical engineer, housekeeping, maintenance, patient care assistant, or administrator/manager. (AHRQ App 2)	
HIT device			An HIT device includes hardware or software that is used to electronically create maintain, analyze, store, or receive information to aid in the diagnosis, cure, mitigation, treatment, or prevention of disease and that is not an integral part of (1) an implantable device or	

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			(2) an item of medical equipment. (CF – Device or Medical/Surgical Supply, Including Health Information Technology)	
Levels of Harm Related to question "After any intervention to reduce harm, what was the degree of residual harm to the patient from the incident (and subsequent intervention)?			**Death:** Dead at time of assessment. **Severe harm:** Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life. **Moderate harm:** Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm. **Mild harm:** Bodily or psychological injury resulting in minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay. **No harm:** Event reached patient, but no harm was evident. (CF--PIF)	

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Texas Note:	For Texas DSHS Preventable Adverse Event Reporting, Texas agrees with the AHRQ Common Format definition of severe harm as shown above. In addition, a determination of severe harm would be indicated, but not be limited to: injuries requiring a major intervention e.g. surgery, transfer to a higher level of care, and/or injuries resulting in bone fractures or loss of body part, (excluding minor fractures that do not require surgical intervention and that do not significantly interfere with functional ability or quality of life).			
Patient		*Patient* means a person who is a recipient of healthcare. *A person becomes a patient at the point that they are being "cared for" in the facility. Being "cared for" begins when they are first engaged by a member of the care team, e.g. assessment by the triage nurse in the E.D., walking with the phlebotomist to the lab for a lab draw. A patient is no longer considered a patient at the point that they are no longer under the care of a member of the care team, e.g. the nursing assistant has safely assisted the patient to the car from an inpatient stay; the ambulating patient that does not need assistance leaves the radiology department following an outpatient test.*		
Principal diagnosis			The condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital. (AHRQ App 2)	

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Principal procedure			The procedure performed for definitive treatment rather than diagnostic or exploratory purposes, or which is necessary to take care of a complication. (AHRQ App 2)	
Psychological injury			Harm or damage to a person's psyche, psychological functioning, or mental well-being. (AHRQ App 2)	
Reporter			Person in a health care organization who reports a patient safety concern; may (or may not) be the person who discovered the concern. (AHRQ App 2)	
Rescue Action			Action taken or started within the first 24 hours after the discovery of a patient safety incident that is intended to prevent, to minimize, or to reverse harm to the affected patient. (AHRQ App 2)	

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Texas Note regarding Severe Harm / Serious Injury	NQFs Serious Reportable Events use the phrase "serious injury". AHRQ's Common formats use the term "severe harm" for assessing the level of harm for adverse events. The Texas DSHS Preventable Adverse Event Reporting program elected to be consistent with AHRQ since the reporting model uses AHRQ's Common Formats. Therefore, the Texas Administrative Code, Chapter 200.7, uses the term "severe harm" in the list of PAEs. In an attempt to reconcile this difference, the Texas DSHS agrees with these definitions from both NQF and AHRQ and finds that severe harm and serious injury are similar enough to be considered synonymous for reporting purposes.			
Injury		*Injury,* as used in this report has a broad meaning. It includes physical or mental damage that substantially limits one or more of the major life activities of an individual in the short term, which may become a disability if extended long term. Further, injury includes a substantial change in the patient's long-term risk status such that care or monitoring, based on accepted national standards, is required that was not required before the event. *(Of note, states and other entities may use alternate definitions for the term "disability.")*	Bodily Injury: Physical harm or damage to a person's body. (AHRQ App 2) Psychological injury: Harm or damage to a person's psyche, psychological functioning, or mental well-being. (AHRQ App 2)	
Harm			Harm: Physical or psychological injury (including increased anxiety), inconvenience (such as prolonged treatment), monetary loss, and/or social impact, etc. suffered by a person, (AHRQ App 2)	

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Serious		*Serious* describes an event that can result in death, loss of a body part, disability, loss of bodily function, or require major intervention for correction (e.g., higher level of care, surgery).	Severe harm: Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life. (CF-PIF)	

DOCUMENT REFERENCES

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2. National Quality Forum (NQF), *Serious Reportable Events In Healthcare—2011 Update: A Consensus Report, Appendix B Glossary,* Washington, DC: NQF; 2011. Copyright © 2014 National Quality Forum. **http://www.qualityforum.org/Topics/SREs/Serious_Reportable_Events.aspx**

3. Agency for Healthcare Research and Quality (AHRQ), *Common Formats,* Washington, DC: NQF; 2012. **https://www.psoppc.org/psoppc_web/publicpages/commonFormatsV1.2**

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