

Serious Reportable Event	SKILLED NURSING FACILITY TAP Discussion/Recommendations	OFFICE-BASED SURGERY TAP Discussion/Recommendations	PHYSICIAN OFFICE TAP Discussion/Recommendation
1. SURGICAL EVENTS			
<p>A. Surgery performed on the wrong body part</p> <p>Defined as any surgery performed on a body part that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery includes endoscopies and other invasive procedures. Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p>	<p>When interpreted as invasive procedures (as noted in the additional specifications), the event is relevant in SNFs, as it would be in any other setting, though the level of injury and the typical procedure will be different in this setting.</p> <p>Preventability deserves specific consideration in the SNF setting due to the numbers of patients with problems related to cognition.</p> <p>Recommendations: 1) Consider revising event descriptor to Invasive procedure performed on wrong body part. 2) Revisit definition of surgery in light of change to invasive procedure & add setting specific examples</p>	<p>This event is relevant to the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event entirely preventable in the ambulatory or office-based surgery environment.</p> <p>Recommendations: TAP recommends inclusion of invasive procedures in reporting of this event, such as a stent placed in the wrong iliac artery. Likely the same process or system errors lead to these events.</p> <p>TAP recommends inclusion of language to capture wrong site procedures, such as those being done on the wrong digit or at the wrong level of the spine.</p> <p>TAP suggests inclusion of radiation therapy for when the wrong body part is irradiated.</p> <p>TAP recommends clarifying definition of when surgery ends. TAP suggests defining it by when the incisions are closed and counts have been completed. If the count leads to identification of a missing item and it is retrieved, this should not be reported as systems in place to catch retained objects have functioned correctly. If the specialty has in place a different process (i.e. use of films to identify missing items in orthopedics), identification of the item and retrieval also should not be reported when this process has occurred. TAP suggests language such as "and other system processes utilized to identify foreign objects have been concluded".</p>	<p>This event is relevant to Ambulatory Outpatient Environments.</p> <p>TAP notes that for the most part in ambulatory/office-based settings, a wrong site procedure may not meet the serious criteria. However, there are a lot of procedures that can be done on the wrong body part that are indicative of a system error. The definition may need to be broadened to recognize this.</p> <p>TAP considers this event entirely preventable in the ambulatory environment.</p> <p>Recommendations: TAP recommends use of the term "procedures" rather than "surgeries" to be more inclusive of what typically occurs in the ambulatory environment. TAP also recommends use of the term "site" rather than "body part" in order to clarify reporting of the event. TAP agrees with recommendation to change category name to "Surgical and Other Procedures."</p> <p>TAP recommends inclusion of examples relevant to the ambulatory environment in the implementation guidance.</p>

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<p>B. Surgery performed on the wrong patient</p> <p>Defined as any surgery on a patient that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery includes endoscopies and other invasive procedures.</p>	<p>See discussion and recommendations at 1.A. above.</p>	<p>This event is relevant to the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event entirely preventable in the ambulatory or office-based surgery environment.</p> <p>Recommendations: TAP recommends inclusion of an ophthalmological example in the implementation guidance as this is a significant issue.</p> <p>Please reference Surgery on the wrong body part for explanation of definition of when surgery ends.</p>	<p>This event is relevant to Ambulatory Outpatient Environments.</p> <p>TAP states that ambulatory environments will have more significant issues of patient misidentification, as patients are not identified by wristbands and other systems in place in the inpatient hospital environment. TAP recommends language reflecting this to be inserted into the implementation guidance. TAP discussed that prevention of patient misidentification may be accomplished through the use of at least two patient identifiers, per the Joint Commission Patient Identification Guidelines.</p> <p>TAP emphasized that many offices have invasive procedures and people don't realize this isn't limited to ambulatory surgery centers.</p> <p>TAP considers this event entirely preventable in the ambulatory environment.</p> <p>Recommendations: TAP recommends use of the term "procedures" rather than "surgeries" to be more inclusive of what typically occurs in the ambulatory environment. TAP also recommends use of the term "site" rather than "body part" in order to clarify reporting of the event. TAP agrees with recommendation to change category name to "Surgical and Other Procedures." TAP recommends inclusion of examples relevant to the ambulatory environment in the implementation guidance.</p>

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<p>C. Wrong surgical procedure performed on a patient</p> <p>Defined as any surgical procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient.</p> <p>Surgery includes endoscopies and other invasive procedures.</p> <p>Excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent.</p>	<p>See discussion and recommendations at 1.A. above.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event entirely preventable in the ambulatory or office-based surgery environment.</p> <p>TAP discussed whether this event should capture the correct implant being inserted into the wrong site or the right procedure at the wrong level of the spine.</p> <p>Please reference Surgery on the wrong body part for explanation of definition of when surgery ends.</p>	<p>This event is relevant to Ambulatory Outpatient Environments.</p> <p>TAP acknowledges that informed consent when performed in the ambulatory environment is less formal and is not documented as stringently. TAP recommends modification of language regarding informed consent to reflect this.</p> <p>TAP considers this event entirely preventable in the ambulatory environment.</p> <p>Recommendations: TAP recommends use of the term "procedures" rather than "surgeries" to be more inclusive of what typically occurs in the ambulatory environment. TAP also recommends use of the term "site" rather than "body part" in order to clarify reporting of the event. TAP agrees with recommendation to change category name to "Surgical and Other Procedures."</p> <p>TAP recommends inclusion of examples relevant to the ambulatory environment in the implementation guidance.</p>

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<p>D. Unintended retention of a foreign object in a patient after surgery or other procedure</p> <p>Excludes a) objects present prior to surgery that are intentionally left in place; b) objects intentionally implanted as part of a planned intervention; and c) objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention (such as microneedles, broken screws).</p>	<p>See discussion and recommendations at 1.A. above.</p> <p>TAP states that "unintended" retention bears further clarification and potentially examples to reduce ambiguity including as related to the definition for invasive procedure. (see suggested modifications 3 & 4) When doing so, consider suggested modification 1.</p> <p>Recommendations: Provide definition and/or examples of "unintended".</p> <p>TAP recommends using examples of retained wound packing materials in the implementation guidance.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP acknowledges that implementation of this event may be difficult as retained objects may not be found and recovered until years after they are left behind. It may be impossible to review the system errors that led to the object being unintentionally retained.</p> <p>TAP considers this event entirely preventable in the ambulatory or office-based surgery environment.</p> <p>Please reference Surgery on the wrong body part for explanation of definition of when surgery ends.</p>	<p>This event is relevant to Ambulatory Outpatient Environments.</p> <p>TAP discussed use of the term "medical or surgical item" rather than "foreign object" if it clarifies what is to be reported. TAP states that this event should capture occurrences that contribute to a less than optimal outcome that the provider contributed to.</p> <p>TAP considers this event entirely preventable in the ambulatory environment with the above clarifications.</p> <p>Recommendations: TAP recommends defining the surgical and procedural environment.</p> <p>TAP recommends inclusion of examples relevant to the ambulatory environment in the implementation guidance.</p>

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<p>E. Intraoperative or immediately postoperative death in an ASA Class I patient</p> <p>Includes all ASA Class I patient deaths in situations in which anesthesia was administered; the planned surgical procedure may or may not have been carried out.</p> <p>Immediately postoperative means within 24 hours after surgery or other invasive procedure was completed, or after administration of anesthesia (if surgery was not completed).</p>	<p>This event does not apply in the SNF setting.</p> <p>Recommendation: Do not include in SNF SRE event list.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment. TAP acknowledges that this event rarely occurs, but it should be reported when it does.</p> <p>TAP suggested that this event include reporting of death or unexpected hospital admission after a procedure in an ambulatory facility with regards to the ambulatory surgical environment. TAP acknowledges that causality may not be attributed to the ASC and that the event may not have been preventable, but state the importance of reporting these events and investigating them.</p> <p>TAP considers this event largely preventable in the ambulatory and office-based surgery environment.</p>	<p>This event is relevant to Ambulatory Outpatient Environments.</p> <p>TAP considers this event largely preventable, as death can occur as a result of unknown patient information, such as unknown drug allergies or sudden onset of cardiac symptoms without patient history.</p> <p>Recommendations: TAP recommends that any death associated with a procedure be reported with regards to the ambulatory setting. TAP suggests the following language: "Death during or immediately afer an ambulatory procedure."</p> <p>TAP recommends clarification of time window for reporting this event.</p> <p>TAP recommends inclusion of examples relevant to the ambulatory environment in the implementation guidance.</p>
<p>2. PRODUCT OR DEVICE EVENTS</p>			

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<p>A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility</p> <p>Includes detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.</p>	<p>This event is relevant to SNFs without need for change.</p> <p>Recommendation: Include on SNF SRE event list. Any change made to the event at other points in the process should be reviewed by the SNF TAP for continued appropriateness.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event largely preventable.</p>	<p>This event is relevant to Ambulatory Outpatient Environments.</p> <p>TAP considers this event largely preventable in ambulatory environments, as manufacturers could recall drugs due to contaminants after patients have already received them.</p> <p>Recommendations: TAP recommends use of term "healthcare setting" to be more inclusive of ambulatory environments.</p> <p>TAP recommends inclusion of examples relevant to the ambulatory environment in the implementation guidance. Such examples may include inadequate sterilization.</p>

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<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</p> <p>Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.</p>	<p>The event applies to SNF settings, though some changes should be considered.</p> <p>The NQF definition of "serious" specifies "disability or loss of bodily function lasting more than seven days"; SNF responsibility goes beyond 30 days so should be rethought for the setting. Complications of an event will likely impact SNF patients differently than acute care patients; they often do not return to pre-event levels of functioning/health.</p> <p>TAP considers this event largely preventable.</p> <p>Recommendations: 1) Consider modifying the event descriptor to "Patient death or additional disability..." 2) Consider including the issue of improper maintenance in the event.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event largely preventable.</p> <p>Recommendations: TAP recommends that when the device is used off-label that adverse outcomes still be captured with this event.</p>	<p>This event is relevant to the Ambulatory Outpatient Environment.</p> <p>TAP considers this event largely preventable, as a device malfunction cannot necessarily be prevented.</p> <p>Recommendations: TAP recommends inclusion of examples relevant to the ambulatory environment in the implementation guidance.</p> <p>With regards to recommendation to change from "associated with a device" to "caused by a device" TAP stated that causality may be difficult to attribute. Discussion around suggestion to change to "associated with the improper or inappropriate use of a device in patient care" ...TAP questioned whether this event was meant to capture device malfunction or improper/inappropriate use?</p> <p>TAP recommends language in the implementation guidance allowing for off-label use as well as exclusions for pediatric populations and potentially other populations.</p>

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<p>C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility</p> <p>Excludes death or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism</p>	<p>This event is relevant for SNFs.</p> <p>Nursing homes are increasingly using lines; however, the ability to diagnose this event creates ambiguity in that it would require autopsy. SNFs, for the most part, are not yet using "bundles". Including this event for SNFs is appropriate and could drive improvements. It would be useful to include examples that would illustrate the applicability.</p> <p>Recommendations: 1) Address issues of ambiguity. 2) Consider inclusion of examples or other ways to illustrate SNF applicability.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP acknowledges that this event happens infrequently in the ambulatory and office-based surgery environment.</p> <p>TAP considers this event largely preventable.</p>	<p>As stated, TAP does not consider this event to be relevant to the Ambulatory Outpatient Environment.</p>
<p>3. PATIENT PROTECTION EVENTS</p>			

Serious Reportable Event	SKILLED NURSING FACILITY TAP Discussion/Recommendations	OFFICE-BASED SURGERY TAP Discussion/Recommendations	PHYSICIAN OFFICE TAP Discussion/Recommendation
<p>A. Infant discharged to the wrong person</p>	<p>This event is applicable in the SNF setting though modifications are needed.</p> <p>TAP recommends that with respect to children, it is appropriate to change the term "infant" to "minor" or "person unable to make decisions". TAP also recommends that "wrong person" should be "unauthorized person". In considering "unauthorized" will need to define or clarify what that means; e.g., taking without permission or notification even if otherwise authorized. TAP acknowledges that staff responsibility in monitoring patients and visitors should be considered.</p> <p>Recommendations: 1) To avoid appearance of infantilizing adults, add a second new event that specifically addresses adults. 2) Change "wrong" to "unauthorized" and define it. 3) Address the matter of staff responsibility and meaning of authorization in implementation guidance. 4) In the infant-related event, use "minor" or other term to capture person's inability to make decisions rather than "infant". 5) Consider role of states in defining such events and provide for that role in implementation guidance.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event entirely preventable.</p>	<p>As stated, TAP does not consider this event to be relevant to the Ambulatory Outpatient Environment. Ambulatory environments are too porous and infants are discharged to whomever they are accompanied by without providers being aware of custodial situations.</p>

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<p>B. Patient death or serious disability associated with patient elopement (disappearance)</p>	<p>The event applies to SNF settings and they are prepared for attempts at elopement.</p> <p>However, the term should be defined and it should be noted that states' definition, where they exist, are to be used. The definition should not include competent patients who have SNF "permission" to be away from the facility.</p> <p>Recommendations: 1) Define elopement and include the caveat that in jurisdictions where states have defined it, the state's definition is to be used.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment. Patients can leave recovery before being discharged, or elope from the ASC before the procedure occurs.</p> <p>TAP considers this event entirely preventable.</p> <p>Recommendations: TAP recommends that the distinction between elopement and patients leaving against medical advice be clarified.</p> <p>TAP recommends clarification of a time limit associated with this event-24 hours.</p>	<p>This event is relevant to the Ambulatory Outpatient Environment.</p> <p>TAP considers this event largely preventable in the ambulatory environment.</p> <p>TAP recommends clarification of time window from elopement to patient death or disability.</p> <p>TAP recommends inclusion of examples relevant to the ambulatory environment in the implementation guidance.</p>
<p>C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility</p> <p>Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.</p>	<p>The event, as specified, applies to SNF settings and is appropriate for inclusion in a SNF SRE list. It was noted that the method most readily available and used in SNFs is water.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment. TAP acknowledges that this event is unlikely to occur but instances should be reported</p> <p>TAP considers this event largely preventable.</p>	<p>This event is relevant to the Ambulatory Outpatient Environment.</p> <p>TAP considers this event largely preventable in the ambulatory environment.</p> <p>Recommendations: TAP recommends use of the term "healthcare setting" rather than "healthcare facility" to be more inclusive of ambulatory environments.</p> <p>TAP recommends inclusion of examples relevant to the ambulatory environment in the implementation guidance.</p>
<p>4. CARE MANAGEMENT EVENTS</p>			

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<p>A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)</p> <p>Excludes reasonable differences in clinical judgment involving drug selection and dose.</p> <p>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>	<p>This event is relevant in the SNF environment.</p> <p>TAP acknowledges that movement to patient autonomy that includes self-medication creates ambiguity. It would be useful to provide exclusions for medication taken without staff knowledge whether self- or family- administered. Consideration must be given to including language regarding need for systems or mechanisms for knowing what patients are taking as well as the need for monitoring levels of medication and inclusion of the pharmacists' role in medication management.</p> <p>Recommendations: 1) Clarify meaning of error by addressing self medication directly or through exclusions. 2) Consider adding exclusions for medication taken without staff knowledge. 3) Add "failure to monitor" as an inclusion and consider guidance specific to the issue of monitoring related to self-medication; e.g., INR for the patient on coumadin. 4) Discuss facility responsibility with relation to systems to know what patients are taking. 5) Acknowledge role of phamacists in medication management including where this is specified; e.g., states operations manuals. 6) Include recommendations for future study about monitoring medication levels or physiologic parameters in places where self medication is used.</p>	<p>This event is relevant in the Ambulatory & Office-based Surgery environment.</p> <p>TAP acknowledges that implementation of this event will be more challenging in the ambulatory surgery environment as facilities don't have access to the same tools, such as CPOE.</p> <p>TAP considers this event largely preventable in the ambulatory surgery environment.</p>	<p>This event is relevant in the Ambulatory Outpatient Environment.</p> <p>TAP considers this event largely preventable. With proper systems in place this should be preventable; there are systems out there but they are not all in use now. There is a grey area about what is an error vs. "bad luck".</p> <p>Recommendations: TAP recommends inclusion of language to capture the following:</p> <ul style="list-style-type: none"> -Patients given the wrong prescription from the provider -Patient administered the wrong drug -Patients given another patient's prescription -Pharmacy dispensing errors -Drug-drug interactions and drug-disease interactions <p>TAP recommends exclusion of failure of patients to comply and patients who self medicate.</p> <p>TAP recommends inclusion of examples relevant to the ambulatory environment in the implementation guidance.</p>

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<p>B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products</p>	<p>This event is relevant in the SNF environment.</p> <p>Because blood is being provided in some nursing homes, though done rarely, the event does apply and should be included. TAP members do not have the data to show the frequency but determined that the fact that blood is given in nursing homes argues for event reporting. The event, as stated, is subject to interpretation perhaps more so as it relates to disability in the SNF setting.</p> <p>Recommendation: Include this event in the SNF SRE list and acknowledge that blood is given only rarely in the SNF setting.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP states that this event is uncommon but in the event of an occurrence is important enough to be reported.</p> <p>TAP considers this event entirely preventable.</p>	<p>This event is relevant to the Ambulatory Outpatient Environment, if ambulatory settings include infusion centers.</p> <p>TAP considers this event entirely preventable in the ambulatory environment.</p>
<p>C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility</p> <p>Includes events that occur within 42 days postdelivery.</p> <p>Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.</p>	<p>This event does not apply in the SNF setting. While there was discussion of the possibility of having a pregnant patient in the SNF setting suffer death or disability, such patients by virtue of warranting SNF care would not meet the definition of low risk.</p> <p>Recommendation: Do not include in SNF SRE event list.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP recommends that this event be reported for low risk patients at birthing centers.</p> <p>TAP considers this event largely preventable.</p>	<p>As stated, TAP does not consider this event to be relevant to the Ambulatory Outpatient Environment.</p>

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<p>D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility</p>	<p>The event is relevant in the SNF setting.</p> <p>It was noted that patients in SNFs often have reduced body mass and may tolerate drops in blood glucose levels less well than the patient with more "normal" body mass. However, there are patients who have chronically low blood sugar who may not show signs of hypoglycemia until the blood sugar is lower than the defined level. Also, some competent patients refuse blood sugar monitoring. What would otherwise be considered an event should generally not apply to those patients on "comfort measures only". The planned treatment for the patient should guide determination of whether such an occurrence is reportable.</p> <p>Recommendations: 1) Include this event in the SNF SRE list as specified. 2) In implementation guidance, include caveats about patient refusal of monitoring and that this event is not intended to apply to patients receiving terminal care "comfort measures only" absent planned treatment.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event entirely preventable in the ambulatory surgery environment.</p> <p>Recommendations: TAP recommends modification of blood glucose level definitions with regards to the pediatric population.</p>	<p>As stated, TAP does not consider this event to be relevant to the Ambulatory Outpatient Environment.</p>

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<p>E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates</p> <p>Hyperbilirubinemia is defined as bilirubin levels >30 mg/dL.</p> <p>Neonate refers to the first 28 days of life.</p>	<p>This event does not apply in the SNF setting.</p> <p>Recommendation: Do not include in SNF SRE event list.</p>	<p>This event is not relevant in the Ambulatory and Office-based Surgery environment. TAP states that the literature is not robust with regards to prevention and treatment of hyperbilirubinemia. Additionally, ambulatory surgery facilities rarely treat neonates.</p>	<p>This event is relevant in the Ambulatory Outpatient Environment.</p> <p>Recommendations: TAP recommends clarification of the definition of serious disability for this event.</p> <p>TAP recommends inclusion of the language "who are seen in a healthcare environment".</p> <p>TAP considers this event largely preventable in the ambulatory environment.</p>
<p>F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility</p> <p>The organization's obligation is to report the event when it is made aware of the death or serious disability either by re-admittance or by the patient's family.</p>	<p>This event applies to SNFs though modification for the setting is indicated.</p> <p>In addition to pressure ulcers, deep tissue injury (DTI) should be captured. When applicable, the definitions for DTI and other terms used as well as exclusionary definitions should be consistent with National Pressure Ulcer Advisory Panel's recommendations and relevant federal requirements. Issues related to stageability and preventability should be further address in the event specifications or implementation guidance to improve clarity. The event as currently specified excludes ulcers present on admission and should continue to do so.</p> <p>Recommendations: As noted above related to modification for the setting, harmonizing definitions, addressing staging and preventability.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment. TAP acknowledged that occurrence of this event would likely signify that the patient was in poor health prior to the procedure.</p> <p>TAP notes that monitoring occurrences of this event will be challenging in the ambulatory surgery environment as patients are not necessarily there for a long enough time period for pressure ulcers to develop and be discovered.</p> <p>TAP considers this event largely preventable in the ambulatory surgery environment.</p> <p>Recommendations: TAP recommends exclusions when documentation of tissue injury was present on admission.</p>	<p>As stated, TAP does not consider this event to be relevant to the Ambulatory Outpatient Environment.</p>

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G. Patient death or serious disability due to spinal manipulative therapy ENDORSEMENT REMOVAL RECOMMENDED	The event is relevant in some SNFs depending on the practitioners providing care; however, the anomalous nature of the event both in terms of fit within the SRE list and application argue for its deletion across the board. Recommendation: Retire the SRE.	This event is not relevant in the Ambulatory and Office-based Surgery environment. TAP states that this event likely wouldn't happen in an ambulatory surgery center.	This event is relevant in the Ambulatory Outpatient Environment.
H. Artificial insemination with the wrong donor sperm or wrong egg	The event is relevant in some SNFs depending on the practitioners providing care; however, the anomalous nature of the event both in terms of fit within the SRE list and application argue for its deletion across the board. Recommendation: This event is not appropriate for SNFs.	This event is relevant in the Ambulatory and Office-based Surgery environment. TAP acknowledges that there may be difficulties in attribution and discovery of the occurrence of this event. TAP considers this event entirely preventable in the ambulatory surgery environment.	This event is relevant in the Ambulatory Outpatient Environment.
5. Environmental Events			
A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility Excludes events involving planned treatments such as electric countershock/ elective cardioversion.	This event is relevant in SNFs based on the many electrical items in use in SNFs as well as some procedures that involve use of electrical current. Recommendation: Include in SRE list. The TAP disagrees with combining the burn and shock SREs.	This event is relevant in the Ambulatory and Office-based Surgery environment.	This event is relevant in the Ambulatory Outpatient Environment. TAP considers this event largely preventable in the ambulatory environment. Recommendations: TAP recommends use of the term "healthcare setting" rather than "healthcare facility" to be more inclusive of ambulatory environments.

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<p>B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances</p>	<p>The event is relevant in SNFs.</p> <p>The TAP suggested that the event description be modified to explicitly include tanks and suggested this could be done by substituting "...systems for delivering oxygen or other gas..." or similar language.</p> <p>Recommendation: Include in SNF SRE list with modification as noted.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p>	<p>This event is relevant in the Ambulatory Outpatient Environment.</p> <p>TAP considers this event largely preventable in the ambulatory environment, as long as all participants in the system are involved; e.g., a contractor could shut off a gas line without the provider being aware.</p> <p>Recommendations: TAP recommends use of the term "healthcare setting" rather than "healthcare facility" to be more inclusive of ambulatory environments.</p> <p>TAP recommends inclusion of the following language: "or death/serious disability associated with lack of delivery of gas."</p>
<p>C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility</p>	<p>The event is relevant in SNFs.</p> <p>To improve clarity of types of burns that would be reportable, the group recommends that consideration be given to providing specific inclusions or examples in the implementation guidance that speak to such things as hot water burns and serious sunburn in patients decreased ability to sense the pain; burn associated with smoking.</p> <p>Recommendation: Include in SNF SRE list with additional clarifying language as noted. As noted earlier, the TAP disagrees with combining this event with electric shock based on the differences in processes involved.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event largely preventable.</p> <p>Recommendations: TAP recommends language in the implementation guidance calling for second degree burns requiring treatment to be reported under this event, particularly those related to OR flash fires that burn patients.</p>	<p>This event is relevant in the Ambulatory Outpatient Environment.</p> <p>TAP considers this event largely preventable in the ambulatory environment.</p>

Serious Reportable Event	SKILLED NURSING FACILITY TAP Discussion/Recommendations	OFFICE-BASED SURGERY TAP Discussion/Recommendations	PHYSICIAN OFFICE TAP Discussion/Recommendation
<p>D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility</p> <p>Includes, but is not limited to, fractures, head injuries, and intracranial hemorrhage.</p>	<p>This event is particularly relevant in SNFs.</p> <p>The TAP does recommend that "fall" be defined and that the event be modified, at least for the SNF setting, to read "Patient death or additional injury associated with ..." to make it more consistent with regulatory language. Care planning and appropriate communication of the plan to patients and families is important; however, many formerly restrained patients are being ambulated and even with protective measures some will fall. Competent but fragile SNF patients who have been advised of risks may choose to walk with or without assistance and with or without family encouragement. Prescribed medications may also predispose to unsteadiness.</p> <p>This frequency of occurrence of this event is still significant for death and serious disability. Risk vs. patient autonomy contributes to this event not being entirely or largely preventable.</p> <p>Recommendation: Include in SNF SRE list with modification to include definition of fall. Consider adding language related to inclusions either in specification or guidance.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event largely preventable.</p> <p>Recommendations: TAP recommends guidance for where the perimeter ends that the healthcare facility is responsible for the fall. Does this only include the medical office space, or does this include the parking lot or curb outside of the facility?</p>	<p>This event is relevant in the Ambulatory Outpatient Environment.</p> <p>TAP considers this event largely preventable in the ambulatory environment, as patients can decline assistance or decline to use assistive devices.</p> <p>TAP discussed issues of where the responsibility of the provider ends. If the patient falls while walking from the office to the radiology department, who is accountable? Similarly, if the patient falls on the grounds of the facility, is that provider accountable?</p> <p>Recommendations: TAP recommends inclusion of the following language: "when the patient is in the direct care of the healthcare team in the healthcare setting" for the ambulatory environment.</p>

Serious Reportable Event	SKILLED NURSING FACILITY TAP Discussion/Recommendations	OFFICE-BASED SURGERY TAP Discussion/Recommendations	PHYSICIAN OFFICE TAP Discussion/Recommendation
<p>E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility</p>	<p>This event is relevant in SNFs.</p> <p><i>It was noted that SNF prevention of this event has improved significantly in the last 10 years, surpassing hospital performance.</i></p> <p>Suggestions were made for improvement of the event descriptor and the definition of restraint. The TAP did not feel strongly regarding moving the event to Care Management though they did appreciate the rationale.</p> <p>Recommendations: 1) Change the event descriptor to read "Patient death or serious injury..." 2) Revise the definition of restraint or bedrails to be consistent</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment. TAP notes that though this event likely doesn't happen with frequency, it should be reported when it does occur.</p> <p>TAP considers this event entirely preventable.</p> <p>Recommendations: TAP recommends consideration of use of chemical restraints in the context of this event.</p>	<p>TAP acknowledged that restraints may possibly used for young children or the elderly during imaging exams in the Ambulatory Outpatient Environment. TAP did not reach consensus on whether this event is relevant for the ambulatory environment.</p>
<p>6. CRIMINAL EVENTS</p>			
<p>A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider</p> <p>ENDORSEMENT REMOVAL RECOMMENDED</p>	<p>The event is relevant in the SNF setting where patients may be more vulnerable based on use of contract staff.</p> <p>It may be more difficult to implement in nursing homes due to use of "agency" contracts and potentially limited knowledge of the rigor with which credentials are verified.</p> <p>Recommendations: 1) Include this event on the SNF SRE list. 2) Add implementation guidance regarding vulnerability to misrepresentation.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event entirely preventable.</p> <p>Recommendations: TAP recommends language in the implementation guidance regarding people in the process of becoming physicians who fail to introduce themselves properly and confuse the patient.</p>	<p>This event is relevant in the Ambulatory Outpatient Environment.</p> <p>TAP acknowledges that these events are likely underreported.</p> <p>Recommendations: TAP recommended exclusions for medical assistants, other medical staff who are mistakenly given titles by patients or others visiting the facility.</p>

Serious Reportable Event	SKILLED NURSING FACILITY TAP Discussion/Recommendations	OFFICE-BASED SURGERY TAP Discussion/Recommendations	PHYSICIAN OFFICE TAP Discussion/Recommendation
<p>B. Abduction of a patient of any age ENDORSEMENT REMOVAL RECOMMENDED</p>	<p>The event is relevant in the SNF setting since they are generally more vulnerable thus more "at risk".</p> <p>To improve clarity "abduction" should be defined and should address inclusions and exclusions with consideration of who is authorized to take a competent or incompetent patient from a facility and under what circumstances; e.g., without staff knowledge.</p> <p>Recommendation: Include the event on the list with modifications/ as noted.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p>	<p>This event is relevant to the Ambulatory Outpatient Environment.</p> <p>TAP states that there is a distinction between a forcible abduction of a child and discharging to the wrong person.</p> <p>TAP considers this event largely preventable in the ambulatory environment.</p>
<p>C. Sexual assault on a patient within or on the grounds of a healthcare facility ENDORSEMENT REMOVAL RECOMMENDED</p>	<p>The event is relevant in the SNF setting.</p> <p>Consideration should be given to expanding the event from sexual assault to sexual abuse. The term used should be defined. Consider addressing the importance of ability to consent and actual consent in additional specifications or implementation guidance to clarify that competent patients may consent to sexual activity without triggering event reporting.</p> <p>Recommendation: 1) Include this event on the SNF list. 2) Consider replacing "assault" with "abuse" and define the term used. 3) Include language sensitive to consent between competent patients.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p>	<p>This event is relevant to the Ambulatory Outpatient Environment.</p> <p>TAP considers this event entirely preventable in the ambulatory environment.</p> <p>Recommendations: TAP recommends use of the term "office setting" rather than "on the grounds of a healthcare facility" as providers cannot be responsible for the parking lot or other external areas.</p>

Serious Reportable Event	SKILLED NURSING FACILITY TAP Discussion/Recommendations	OFFICE-BASED SURGERY TAP Discussion/Recommendations	PHYSICIAN OFFICE TAP Discussion/Recommendation
<p>D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility</p> <p>ENDORSEMENT REMOVAL RECOMMENDED</p>	<p>The event is relevant in the SNF setting.</p> <p>While this is an understudied area it is an increasing problem. In addition to patients and staff, it can involve other visitors to the facility.</p> <p>Recommendations: Revise the event to include death or significant injury to visitors (regardless of purpose of the visit; e.g., visiting patients, visiting to provide service to the facility, etc.) and be clear about the possible permutations.</p>	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p>	<p>This event is relevant to the Ambulatory Outpatient Environment.</p> <p>TAP considers this event largely preventable in the ambulatory environment.</p> <p>Recommendations: TAP recommends use of the term "office setting" rather than "on the grounds of a healthcare facility" as providers cannot be responsible for the parking lot or other external areas.</p>

	Submitter	New Serious Reportable Event	SKILLED NURSING FACILITY TAP Discussion/ Recommendations	OFFICE-BASED SURGERY TAP Discussion/ Recommendations	PHYSICIAN OFFICE TAP Discussion/Recommendations
1	OSF Healthcare System	Patient death or disability as a consequence of MRI error, defined as magnetizable material inside the MRI room	This event is not relevant to SNFs.	<p>This event is relevant in the Ambulatory and Office-based Surgery environment.</p> <p>Recommendations: TAP recommends inclusion of this event as stated.</p>	<p>This event is relevant in the Ambulatory Outpatient Environment.</p> <p>TAP considers this event entirely preventable in the ambulatory environment.</p> <p>Recommendations: TAP recommends clarifying the term "MRI error" as the event is not related to the MRI itself so much as a consequence of screening what enters the room. TAP suggests language such as: "Patient death or disability as a consequence of metal projectiles in the MRI area"</p> <p>TAP recommends consideration of broadening this event to capture "injury" rather than "death or disability" in order to capture events where patient may be injured as a consequence of metal being in the room.</p>

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2	Pennsylvania Patient Safety Authority	Patient death or serious injury associated with prolonged fluoroscopy with cumulative dose > 1500 rads to a single field or any delivery of radiotherapy to the wrong body region, or 25 percent above or below the planned radiotherapy dose	This event is not relevant to SNFs.	<p>This event is relevant in the Ambulatory and Office-based Surgery environment; however, TAP does not recommend this event as it is not auditable or feasible for the ambulatory surgery environment.</p> <p>TAP acknowledges that this event likely would not be captured at the time of occurrence in an ambulatory surgery environment.</p> <p>Recommendations: TAP recommends that a separate event be created to capture radiation overdoses.</p> <p>TAP recommends consideration of cumulative radiation doses.</p>	<p>This event is relevant in the Ambulatory Outpatient Environment.</p> <p>TAP considers this event entirely preventable in the ambulatory environment.</p> <p>Recommendations: TAP recommends clarifying death or serious injury, as the outcomes may occur years after the event. May need to use term “ionizing radiation” to clarify event.</p> <p>TAP suggests broadening the event to capture death or serious injury associated with radiation exposure.</p>

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3	Pennsylvania Patient Safety Authority	Patient death or serious injury related to a central line associated blood stream infection (CLABSI)	<p>This event is relevant to SNFs since lines, most commonly PICC lines, are used and have been forgotten.</p> <p>Most often, the line is inserted by an external consultant so consideration of attribution for purposes of learning and improvement may deserve special consideration in SNFs.</p> <p>TAP recommends that in further developing the event for inclusion on the SRE list(s), it should be defined and CLABSI compliance criteria should be referenced.</p>	<p>This event is not relevant in the Ambulatory and Office-based Surgery environment. TAP states that the event is important but not the same magnitude as other SREs.</p> <p>TAP does not think this event is auditable or preventable in the ambulatory surgery environment.</p>	As stated, this event is not relevant in the Ambulatory Outpatient Environment.
4	Pennsylvania Patient Safety Authority	Death among surgical patient with serious, treatable complications (failure to rescue)	This event, as described, is not relevant to SNFs.	TAP does not recommend this event for the Ambulatory and Office-based Surgery environment. TAP states that the event is unclear as written and would present implementation challenges, as it is likely that the patient would have left the site of the surgery prior to occurrence of the event.	As stated, this event is not relevant in the Ambulatory Outpatient Environment.

	Submitter	New Serious Reportable Event	SKILLED NURSING FACILITY TAP Discussion/ Recommendations	OFFICE-BASED SURGERY TAP Discussion/ Recommendations	PHYSICIAN OFFICE TAP Discussion/Recommendations
5	Minnesota Alliance for Patient Safety	Death of a neonate while being cared for in a healthcare facility following low-risk pregnancy and delivery and the absence of congenital abnormalities	This event, as described, is not relevant to SNFs.	<p>TAP recommends modifications to this event to make it relevant in the Ambulatory and Office-based Surgery environment.</p> <p>Recommendations: TAP recommends the event capture "Death or unplanned admission of a neonate in an ambulatory surgery center within 24 hours of delivery."</p> <p>TAP recommends including language about birthing centers in the implementation guidance of this event.</p>	As stated, this event is not relevant in the Ambulatory Outpatient Environment.
6	Brigham & Women's Hospital	Arterial misplacement and use of a central venous catheter	The event, as described, could be relevant to SNFs. If developed for use, the TAP suggests that it apply to hospitals only for an initial period.	TAP recommends inclusion of this event in the implementation guidance for misuse of a device or wrong site procedure.	<p>As stated, this event is not relevant in the Ambulatory Outpatient Environment.</p> <p>Recommendations: TAP recommends that this event possibly be included with wrong site procedure.</p>

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7	Pennsylvania Patient Safety Authority	Death or serious injury related to irretrievable, lost surgical specimens	<p>The event is relevant for SNFs. If developed for use, the TAP suggests that "Irretrievable" be broadened and defined more clearly in terms of both incomplete and complete loss of access to tissue.</p>	<p>This event is relevant to the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event entirely preventable.</p> <p>Recommendations: TAP recommends that this event capture when specimens are mixed up (lost or misidentified), as these are lost and irretrievable.</p> <p>TAP recommends specifying "death or serious injury" and reporting all occurrences of either, as when the procedure to obtain the specimen is warranted (excisional biopsy, organ removal, etc.), it is serious to lose the specimen and either miss or delay diagnosis.</p>	<p>This event is relevant to the Ambulatory Outpatient Environment.</p> <p>TAP acknowledges that there will be challenges with implementation as the time frame between loss of specimen and adverse outcome may be lengthy. To capture these events, TAP recommends adding language that the occurrence of death or potential serious injury be reported.</p> <p>TAP considers this event entirely preventable in the ambulatory environment.</p> <p>Recommendations: TAP recommends use of the term "procedural specimens" rather than "surgical specimens" to be more inclusive of what takes place in the ambulatory environment.</p> <p>TAP suggests insertion of language clarifying that the specimen is not only irretrievable but also that another procedure cannot be done to produce a like specimen.</p>

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8	Minnesota Alliance for Patient Safety	Diagnostic testing error resulting in unnecessary invasive procedure, serious disability or death	The event is relevant for SNFs. If accepted, it will require further clarification and specification.	<p>This event is relevant to the Ambulatory and Office-based Surgery environment.</p> <p>TAP considers this event entirely preventable.</p> <p>Recommendations: TAP recommends that the definition of diagnostic testing error be expanded. As written now this could include the wrong history taken, incorrect labeling of a specimen, errors in processing at the lab, etc.</p>	<p>This event is relevant to the Ambulatory Outpatient Environment.</p> <p>TAP considers this event entirely preventable in the ambulatory environment.</p> <p>Recommendations: TAP recommends that this event capture failure to have a necessary invasive procedure as well as having an unnecessary invasive procedure, as two patients will be involved in the mix up when this event occurs.</p> <p>TAP suggests using language to clarify this is capturing diagnostic result error resulting in unnecessary invasive procedure, serious disability or death. The types of events are as follows: Laboratory, pathology, and imaging. Includes wrong labeling of specimen, misreported result, etc.</p> <p>This event should capture all or most of the pre-analytical, analytical and post-analytical errors.</p>

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9	Minnesota Alliance for Patient Safety	Patient death or serious disability associated with failure to communicate or follow-up on test results	<p>The event is relevant for SNFs and is a significant problem.</p> <p>TAP recommends consideration be given to expanding this event or adding an event to include failure to carry out test orders. The potential for such events is heightened as patients move between settings of care and as transient providers enter orders and plans and depart the setting prior to their completion.</p>	<p>This event is relevant to the Ambulatory and Office-based Surgery environment.</p> <p>TAP states concerns about the feasibility of reporting this event. TAP believes this is a good area to explore as relates to SREs, but this SRE may not be well enough defined as stated.</p>	<p>This event is relevant in the Ambulatory Outpatient Environment. This is the number 1 cause of malpractice in the ambulatory setting (missed or delayed diagnosis).</p> <p>TAP acknowledges that providers may not know about these for years (abnormal mammogram that no one saw for years, etc.)</p> <p>TAP considers this event entirely preventable in the ambulatory environment.</p> <p>Recommendations: TAP recommends consideration of serious harm or injury that goes to patients that may not be serious disability.</p> <p>TAP recommends exclusions when there is documentation that the provider attempted to follow up with the patient, as well as when the patient doesn't adhere to the follow-up plan.</p>

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10	Pennsylvania Patient Safety Authority	Death or serious injury resulting from care provided by an impaired healthcare worker	<p>The event is relevant for SNFs and is sufficiently similar to the proposed event which follows to consider the two together.</p> <p>TAP acknowledges that the issue is very complex given the range of substances that could be involved, the types of impairments other than substance that could be involved, the ability to determine/verify the impairment objectively which suggest enforcement difficulty and the potential unintended consequences in any care setting.</p>	<p>TAP does not recommend this event for the Ambulatory and Office-based Surgery environment. TAP states that the event would present implementation challenges as impairment is not quantitatively defined or measurable.</p> <p>TAP is concerned that this event would lead to false accusations, as impairment would be challenging to prove after the fact/when the report was being filed.</p> <p>Legalization of marijuana in some states will make implementation of this event difficult as there are no "blood levels" or quantitative measurements that indicate impairment.</p> <p>TAP notes that the event is important; concerns solely stem from feasibility of implementation.</p> <p>TAP suggests a modification to "Patient harm as a result of any criminal behavior on behalf of the provider" in order to capture this and like events.</p>	<p>This event is relevant in the Ambulatory Outpatient Environment.</p> <p>TAP notes that legalization of marijuana in some states will make implementation of this event difficult as there are no "blood levels" or quantitative measurements that indicate impairment.</p> <p>TAP notes that the event is important; concerns solely stem from feasibility of implementation. There are difficulties in quantating impairment.</p> <p>Recommendations: TAP recommends defining impairment to include drug, alcohol, depression, medical illness and sleep deprivation.</p>

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11	OSF Healthcare System	Death or significant injury of a patient as a consequence of staff impaired by recreational drugs or alcohol use	See notes above.	TAP states same concerns for this event as the one preceding it.	TAP recommends combining this event with the preceding event.