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CIRCULAR LETTER: DHCQ-12-9-570

TO: Hospital Chief Executive Officers
Ambulatory Surgery Center Administrators
Risk Managers

FROM: Madeleine Biondolillo, MD
Bureau Director

DATE: September 7, 2012

SUBJECT: Hospital and Ambulatory Surgery Center Serious Reportable Event (SRE) Updates

This letter provides updated instructions for the reporting of serious incidents and serious reportable events (SREs). This topic has been addressed previously in Circular Letters DHCQ 09-06-510, DHCQ 08-07-496, DHCQ 08-06-489 and DHCQ 07-12-478. These letters are available at http://www.mass.gov/dph/dhcq (see Related Links, Serious Reportable Events). Effective October 1, 2012 and consistent with updates to the National Quality Forum list of Serious Reportable Events, the Massachusetts Department of Public Health (DPH or the Department) will update its list of SREs as defined in Hospital Licensure Regulation 105 CMR 130.000 and Clinic Licensure Regulation 105 CMR 140.000 under the authority granted by M.G.L Chapter 111, §51H.

Hospitals and ambulatory surgical centers are required to report SREs to the Department and are prohibited from charging or seeking reimbursement for SRE-related services when a preventability analysis determines that the event was preventable. A revised reporting form for SREs has been developed to implement the new provisions (see attachment). These updated instructions should be used for cases occurring on or after October 1, 2012. The Department anticipates working closely with facilities to determine if certain adverse events meet definitional criteria to qualify as an SRE. We encourage facilities to actively reach out to our hospital complaints unit with questions. Simultaneously, the Department of Public Health is continuing to roll out implementation of the Health Care Facility Reporting System (HCFRS), and the transition from paper to electronic reporting is expected to be complete by January 1, 2013.

Pages 1-3 of this updated form are to be used for the reporting of incidents that are not SREs, using the Department's current process. The guidance that follows is intended to assist in determining whether an event that has occurred meets the definitions of an SRE. The guidance is not intended to be comprehensive. As clinical events are adjudicated throughout the year, commonly occurring themes will be identified. Examples of events illustrating these themes will be posted on the Bureau's website as Frequently Asked Questions (FAQs).

We recognize that expanding definitions of Serious Reportable Events will lead to increased reporting. The Department is committed to maintaining its philosophy of publicly reporting these events in a manner intended to drive improvement, not punish providers or facilities. SRE reporting is not meant to capture operator error or evaluate individual care providers. Specifically, our reporting philosophy is:

- *To catalyze facility-specific and statewide initiatives to address the most prevalent preventable events through identification of root causes and dissemination of best practices;*

- *To validate that the extensive work conducted across the health system often reduces the rate of preventable adverse health events, and to refocus interventions where such reduction is not seen;*

- *To further inform consumers, policy-makers, and providers on the frequency and setting of adverse events;*

- *To report the occurrence of events as a means to inform improvement as a core measure of quality and safety; these measures are not intended to be punitive; and*

- *Not all adverse events may be averted. However, our goal remains elimination of those events that are preventable. The long-term goal of public reporting is to minimize the number of these occurrences through increased awareness and development of robust systems for error tracking and prevention. Therefore, we seek to gain a greater understanding of how preventable events happen and how they can be prevented in the future.*

Definitional clarity is essential to ensuring appropriate capture of events and parity in reporting across systems. The Department has made great efforts to ensure that all aspects of SREs are clearly defined and uniformly applied, however there is bound to be additional clarification needed. The Department is committed to maintaining and updating Frequently Asked Questions (FAQs) on its website. Preliminary FAQs built upon questions that we have received in years past have been posted; we will work closely with Risk Managers, Quality Improvement leadership, administrative leadership, and providers to ensure that these definitions reflect necessary changes in standards of care. Please contact Chris Duerr at (617) 753-8204 if you have any questions regarding the regulations, policies, or a clinical definition.

Frequently Asked Questions Related to Serious Reportable Events

1. Has the Department of Public Health adopted the entire 2011 NQF SRE Update for the purposes of reporting serious events in Massachusetts hospitals and ambulatory surgical centers?

Yes, the Department of Public Health (DPH or the Department) has adopted the report with respect to hospital and ambulatory surgical center SRE reporting, but has added clarifications and definitions (see below).

2. When should providers begin to submit SRE reports using the updated guidance?

Events that occur on or after October 1 should be submitted using the new reporting requirements.

3. Whom should I contact if I have a question about reporting an SRE?

All content questions should be directed to Chris Duerr, Hospital Unit Complaint Manager. She can be reached at (617) 753-8204, or at chris.duerr@massmail.state.ma.us. Technical questions about the Health Care Facilities Reporting System can be directed to Guido Altomonte at (617)753-8180, or at galtomonte@massmail.state.ma.us.

4. I noticed that the term "serious disability" has been replaced with "serious injury." What constitutes serious injury?

The Massachusetts Department of Public Health defines *serious injury* as:

Physical or mental damage that substantially limits or results in loss of one or more of the major life activities (e.g., breathing; dressing/undressing; drinking; eating; eliminating waste products; getting into or out of bed, chair, etc.; hearing; seeing; sitting; sleeping; walking; and working) of an individual in the short term, which may become a disability if extended long term. A serious injury can result in death, loss of a body part, long or short term disability, loss of bodily function, or require a major intervention for correction (e.g., higher level of care, surgery, and dialysis). Serious injury includes a substantial change in the patient's risk status such that care or monitoring, based on national accepted standards, whether provided or not, is required that was not required before the event.

Examples include but are not limited to:

- The patient's discharge status or discharge plan was changed as a result of the serious injury

- As a result of the incident, there was a change in the treatment plan that required a change in the level of care provided to the patient
- Any incident requiring major intervention, such as resuscitation, surgical intervention in the OR, new dialysis treatment, a higher level of care, e.g., transfer to critical care unit, for correction
- The patient's length of stay was extended, either at the hospital or at their post-acute placement to address the serious injury
- Bone fractures including wrist and rib fractures. Excludes hairline fractures and fractures of the fingers, toes, thumbs and nose
- Loss of a body part
- Permanent or temporary loss or substantial limitation of bodily function
- Any potential exposure to blood borne pathogens (e.g., Hepatitis or HIV) through reuse or improper repurposing of medical equipment, e.g., endoscopy tubes, syringes, regardless of whether or not the patient is actually infected
- Laceration that requires repair by suture or staple
- Second-degree or more severe burn

5. Does death or serious injury associated with the use or function of a device include cases in which the provider attempted to used the device in a manner consistent with the manufacturer's literature, but failed due to inexperience or inability?

[Event 2B]

SRE reporting is not meant to capture operator error or evaluate individual care providers. If the provider attempted to use the device correctly, any resulting injury or death would not qualify as a Device Use or Function SRE. However, proper intention encompasses provider obligation to observe all protocols put in place around the use of a device. If a provider fails to follow an institutional protocol for using a device, and the patient experiences death or serious injury as a result, the event must be reported to DPH.

6. For the purposes of SRE reporting, what is considered an invasive procedure?

DPH is using the following list, which is taken directly from the Institute for Clinical Systems Improvement (ICSI), to determine when a procedure is considered invasive. **Please note that DPH is only adopting the list of procedures that ARE deemed to be invasive.** The Department of Public Health **has not adopted** the list of procedures that ICSI does not consider invasive. Questions about whether or not a procedure not included below is invasive should be directed to DPH. Updated guidance will be disseminated as DPH makes case-by-case determinations.

Examples of invasive procedures:

- Any procedures involving skin incision

- Any procedures involving general or regional anesthesia, monitored anesthesia care, or conscious sedation
- Injections of any substance into a joint space or body cavity
- Percutaneous aspiration of bodily fluids or air through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis, suprapubic catheterization, chest tube)
- Biopsy (e.g., bone marrow, breast, liver, muscle, kidney, genitourinary, prostate, bladder, skin)
- Cardiac procedures (e.g., cardiac catheterization, cardiac pacemaker implantation, angioplasty, stent-implantation, intra-aortic balloon catheter insertion, elective cardioversion)
- Endoscopy (e.g., colonoscopy, bronchoscopy, esophagogastric endoscopy, cystoscopy, percutaneous endoscopic gastronomy, J-tube placements, nephrostomy tube placements)
- Invasive radiologic procedures (e.g., angiography, angioplasty, percutaneous biopsy)
- Dermatology procedures (biopsy, excision and deep cryotherapy for malignant lesions- excluding cryotherapy for benign lesions)
- Invasive ophthalmic procedures including miscellaneous procedures involving implants
- Oral procedures including tooth extraction or gingival biopsy
- Podiatric invasive procedures (e.g., removal of ingrown toenail)
- Skin or wound debridement
- Electroconvulsive therapy
- Radiation oncology procedures
- Central line placements or PICC
- Kidney stone lithotripsy
- Colposcopy and/or endometrial biopsy

7. If a patient is admitted to a hospital with evidence of a deep tissue injury that becomes a Stage 3 pressure ulcer, is that a reportable SRE?

[Event 4F]

The chart below categorizes pressure ulcer staging and reporting requirements:

Patient is admitted to hospital with:	**During the hospital stay Pressure Ulcer becomes:**	**SRE or Not?**
No Pressure Ulcer	Stage 3, 4 or unstageable	SRE
Stage 1	Stage 3, 4 or unstageable	SRE
Stage 2	Stage 4 or unstageable	SRE
Stage 2	Stage 3	Not SRE
Stage 3	Stage 4 or unstageable	Reportable*
Stage 4	---	Not SRE

Unstageable	Stage 3 or 4	Reportable*
Deep Tissue Injury	Pressure Ulcer (any stage)	Not SRE

*In these cases, the pressure ulcer should be reported to DPH, which will decide on a case-by-case basis whether or not the pressure ulcer should be considered a Serious Reportable Event. A determination will be made within 7 days of reporting.

8. If a patient presents with a Stage 3, Stage 4 or unstageable pressure ulcer on admission, does my organization need to inform the Department of Public Health?

[Event 4F]

A hospital or ASC must file a report with DPH if there is reason to suspect that the pressure ulcer developed at another hospital or ASC in Massachusetts, and met the criteria for a reportable pressure ulcer at that facility. Reason to suspect would include statements from the patient or his/her family, the patient's medical record, or other sources such as the attending physician. If the hospital knows or has reason to believe that the pressure ulcer was already reported to DPH by the hospital or ASC where the pressure ulcer developed, the hospital does not need to report the same pressure ulcer again.

Please note that if hospitals and ASCs reasonably suspect that, as a result of neglect, a nursing home or rest home resident, or home health or hospice client has developed a pressure sore, that incident must be reported to the Department under the Massachusetts Patient Abuse Law.

9. My patient is critically ill, and routine turning and repositioning poses a significant risk to her cardiovascular and/or respiratory status. Does the otherwise-reportable pressure ulcer that my patient developed still qualify as an SRE?

[Event 4F]

DPH should be alerted to the occurrence of the pressure ulcer and will decide on a case-by-case basis whether or not the pressure ulcer qualifies as an SRE. As DPH considers these cases, it will develop and disseminate more exact guidance.

10. If a patient elopes, but returns to the facility unharmed, is that an SRE?

[Event 3B]

A patient elopement would only be reported as an SRE if the patient died or sustained a serious injury during the elopement. If no serious injury or harm occurs, the event does not need to be reported to the DPH as an SRE or as an incident.

11. If a health care practitioner inserts a central line into an artery instead of a vein, has the provider performed a wrong site surgery SRE?

[Event 1A]

Veins and arteries qualify as sites, and are therefore subject to wrong site surgery evaluation. If the provider introduces a product through the line, the event qualifies as an SRE. However, if the error is recognized and corrected before the line is utilized, the event would not be reportable.

12. A patient's cardiac monitor issued an alert, but staff did not notice it because the monitor's alarms had been muted. Does this qualify as an SRE?

[Event 2B]

Yes. If a monitor whose purpose is to provide audible, time-sensitive health data alerts has been purposely silenced, the device is not being used correctly. Any serious injury or death that results from the monitor's alarms being silenced should be reported as event 2B: use or function of a device.

13. A suicide has occurred at my facility; should I report this as an SRE?

[Event 3C]

If the person had been accepted into care by the facility (e.g., registered or been triaged for care), thus becoming a *patient*, the suicide is an SRE. If the person is not a patient at the facility, the suicide would not qualify as an SRE, but should still be reported to DPH. Please refer to the definition of *patient* in the Glossary of the NQF Serious Reportable Events in Healthcare –2011 Update for additional guidance.

14. When does a burn qualify as an SRE?

[Event 5C]

This event has been expanded to include burns experienced by staff members during the process of providing care. To qualify as an SRE, a burn must result in death or serious injury, and the burn must have been related to the provision (staff) or receiving (patient) of care. Second degree burns (and higher level) are considered serious injury, regardless of the intervention or care required to treat.

15. My facility treated a neonate for a complication related to labor/delivery in a low-risk pregnancy; the neonate experienced serious injury. If the labor/delivery did not occur at my hospital, should I report this as an SRE?

[Events 4D and 4C]

The incident should be reported to the DPH, but will not be recorded as an SRE at your facility.

16: I know that I must report an intraoperative or immediately postoperative/post procedure death in an ASA Class 1 patient. Can you define immediately postoperative?

[Event 1E]

All deaths that occur within 24 hours after surgery or other invasive procedure are considered immediately postoperative. If the procedure is completed, the 24-hour count begins after the surgery/procedure is complete (see definition of "surgery ends" in Glossary). If the surgery/procedure is not completed, the 24-hour count begins after the administration of anesthesia.

17. If an ASA Class 1 patient dies, but has a condition that was not known at the time of surgery that would have changed his or her classification, is that death reportable as event 1E, intraoperative or immediately postoperative death of an ASA Class 1 patient?

[Event 1E]

Yes. Although DPH recognizes that in some cases a condition may truly have been undetectable before the procedure, in many cases the pre-surgical patient evaluation was insufficient, and a more thorough examination could have determined that the patient was not ASA Class 1. All such cases should be reported to DPH as SREs.

18. While performing the first step of a multi-step laparoscopic procedure, a needle was retained in the patient, who was then closed and repositioned for the next step. The needle was removed during the second step of the procedure. Do I have to report this as a retained object SRE?

[Event 1D]

No. As long as the object was removed before the end of the entire procedure, the event does not qualify as an SRE. The NQF definition (which DPH has adopted) of when "surgery ends" states that the procedure is not complete until "the patient has been taken from the operating/procedure room."

19. I'm confused about when a person qualifies as a patient, specifically for events such as patient falls or suicide. Can you offer some insight?

The NQF glossary states that "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." Therefore, all SRE categories apply to outpatients while they are receiving care in the hospital/healthcare setting.

Please note the NQF differentiates between patients who do and do not need assistance. In practice, this means that if a person had multiple, pre-scheduled appointments in a hospital or ASC on the same day, and fell and sustained a serious injury in between these appointments, the event would NOT be considered an SRE. However, if a person requires supervision or assistance ambulating, he remains a patient until he has been delivered into the care of a family member or aide. Therefore, if the person experienced a fall with serious injury before being delivered to the adult responsible for his care, the event would qualify as an SRE, as the person would still be considered a patient.

20. A patient experienced an SRE at another hospital. My hospital is treating the effects of the SRE. Are we allowed to seek payment?

Yes, a hospital can seek payment for services required to treat the effects of an SRE, provided the hospital did not cause the SRE. However, please note that if the treating hospital and the original hospital share the same corporate parent, neither hospital can seek payment for related services.

21. A visitor to the hospital slipped and fell in a hallway. Should I report this as an SRE?

No, Serious Reportable Events apply only to patients and, in some cases, staff members. Any adverse events experienced by visitors to the hospital are not considered SREs. Please note, however, that suicides and attempted suicides that occur on a hospital's campus should be reported to DPH regardless of whether or not the person was a patient. Similarly, criminal events such as abuse should be reported to the appropriate authority.

22. A patient at my facility died after experiencing an SRE. How should I proceed with the reporting process?

If a patient dies after experiencing an SRE, the required 7-day and 30-day reports must be submitted to the DPH as usual. The same reports also must be submitted to the patient's insurer, because HIPAA and state law permit the release of protected health information without patient consent to the insurer for payment purposes.

SRE reports should be included in the patient's medical record and are subject to release under MGL c. 111, § 70. The medical record of a deceased patient may be released by the hospital to the duly appointed executor or administrator of the deceased patient's estate, or the executor or administrator's attorney. If a patient dies before a 7-day or 30-day report has been prepared, the court appointed executor or administrator may obtain a copy of the SRE report included in the medical record.

Massachusetts-Specific Guidance

Although the Massachusetts Department of Public Health adopted the NQF 2011 Updates in full, it has chosen to clarify and/or adopt state-specific guidelines for some events. This document summarizes those changes; healthcare providers should be aware that language in this document will always supersede guidance provided by the NQF.

1. DPH has adopted the NQF Update that replaces the term "serious disability" with "serious injury." In an effort to minimize confusion and individual attempts to interpret the NQF language, DPH offers the following, official interpretation of what constitutes "serious injury:"

The definition of <u>serious injury</u> shall include:

Physical or mental damage that substantially limits or results in loss of one or more of the major life activities (e.g., breathing; dressing/undressing; drinking; eating; eliminating waste products; getting into or out of bed, chair, etc.; hearing; seeing; sitting; sleeping; walking; and working) of an individual in the short term, which may become a disability if extended long term. A serious injury can result in death, loss of a body part, long or short term disability, loss of bodily function, or require a major intervention for correction (e.g., higher level of care, surgery, and dialysis). Serious injury includes a substantial change in the patient's risk status such that care or monitoring, based on national accepted standards, whether provided or not, is required that was not required before the event.

Examples include but are not limited to:

- The patient's discharge status or discharge plan was changed as a result of the serious injury
- As a result of the incident, there was a change in the treatment plan that required a change in the level of care provided to the patient
- Any incident requiring major intervention, such as resuscitation, surgical intervention in the OR, new dialysis treatment, a higher level of care, e.g., transfer to critical care unit, for correction
- The patient's length of stay was extended, either at the hospital or at their post-acute placement to address the serious injury
- Bone fractures including wrist and rib fractures. Excludes hairline fractures and fractures of the fingers, toes, thumbs and nose
- Loss of a body part
- Permanent or temporary loss or substantial limitation of bodily function
- Any potential exposure to blood borne pathogens (e.g., Hepatitis or HIV) through reuse or improper repurposing of medical equipment, e.g., endoscopy tubes, syringes, regardless of whether or not the patient is actually infected
- Laceration that requires repair by suture or staple
- Second-degree or more severe burn

Definitions for both "serious" and "injury" can be found in the Glossary of the NQF Serious Reportable Events in Healthcare –2011 Update, but this interpretation should be used when determining what qualifies as serious injury.

2. DPH is using the following list, which is taken directly from the Institute for Clinical Systems Improvement (ICSI), to determine when a procedure is considered invasive. **Please note that DPH is only adopting the list of procedures that ARE deemed to be invasive.** The Department of Public Health **has not adopted** the list of procedures that ICSI does not consider invasive. Questions about whether or not a procedure not included below is invasive should be directed to DPH. Updated guidance will be disseminated as DPH makes case-by-case determinations.

Examples of invasive procedures:

- Any procedures involving skin incision
- Any procedures involving general or regional anesthesia, monitored anesthesia care, or conscious sedation
- Injections of any substance into a joint space or body cavity
- Percutaneous aspiration of bodily fluids or air through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis, suprapubic catheterization, chest tube)
- Biopsy (e.g., bone marrow, breast, liver, muscle, kidney, genitourinary, prostate, bladder, skin)
- Cardiac procedures (e.g., cardiac catheterization, cardiac pacemaker implantation, angioplasty, stent-implantation, intra-aortic balloon catheter insertion, elective cardioversion)
- Endoscopy (e.g., colonoscopy, bronchoscopy, esophagogastric endoscopy, cystoscopy, percutaneous endoscopic gastronomy, J-tube placements, nephrostomy tube placements)
- Invasive radiologic procedures (e.g., angiography, angioplasty, percutaneous biopsy)
- Dermatology procedures (biopsy, excision and deep cryotherapy for malignant lesions- excluding cryotherapy for benign lesions)
- Invasive ophthalmic procedures including miscellaneous procedures involving implants
- Oral procedures including tooth extraction or gingival biopsy
- Podiatric invasive procedures (e.g., removal of ingrown toenail)
- Skin or wound debridement
- Electroconvulsive therapy
- Radiation oncology procedures
- Central line placements or PICC
- Kidney stone lithotripsy

- Colposcopy and/or endometrial biopsy

DPH will provide more guidance on invasive procedures as questions are received and areas of concern are identified.

3. Massachusetts has developed its own guidelines regarding the reporting of pressure ulcers. Please use the chart below to determine whether or not to report a pressure ulcer.

Patient is admitted to hospital with:	**During the hospital stay Pressure Ulcer becomes:**	**Is it and SRE/Not SRE?**
No Pressure Ulcer	Stage 3, 4 or unstageable	SRE
Stage 1	Stage 3, 4 or unstageable	SRE
Stage 2	Stage 4 or unstageable	SRE
Stage 2	Stage 3	Not SRE
Stage 3	Stage 4 or unstageable	Reportable*
Stage 4	---	Not SRE
Unstageable	Stage 3 or 4	Reportable*
Deep Tissue Injury	Pressure Ulcer (any stage)	Not SRE

*In these cases, the pressure ulcer should be reported to DPH, which will decide on a case-by-case basis whether or not the pressure ulcer should be considered a Serious Reportable Event. A determination will be made within 7 days.

4. Event 2B: Use or Function of a Device, is not meant to capture individual or operator error. Massachusetts does not require the reporting of critical incidents that result from health care staff's error in operating a medical device, provided that the staff member's intention was to use the device in a manner consistent with the device manufacturer's literature.

5. The NQF 2011 Update specifies that only suicide, attempted suicide, or self-harm that occurs at a healthcare facility and is committed by a patient qualifies as an SRE. Massachusetts is in agreement with this specification, but does require all hospitals and ambulatory surgical centers to report non-patient suicide, attempted suicide, or self-harm that occurs on their premises as an incident.

6. In Massachusetts, event 4I, Failure to Follow up or Communicate Test Results, includes communication among health care staff members and communication between health care staff and the patient.

Summary of Changes in the NQF List - 2011

Overall Changes	
Miscellaneous changes	1. Glossary of Terms added 2. Added Radiologic Events as 7th category
Definitions	1. Replaces the term "serious disability" with the term "serious injury" 2. Replaced the term "healthcare facility" with "healthcare setting"
Events Removed	1. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while patient being cared for in a healthcare facility 2. Patient death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates. 3. Patient death or serious disability due to spinal manipulative therapy
New Events Added	1. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy 2. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen 3. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results 4. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area
Surgical or Invasive Procedure Events	
Definitions	1. The term "invasive procedure" now accompanies the term "surgery" or "surgical" in events 1A-1D. 2. In event 1A, the term "body part" has been changed to "site," making the event Wrong Site Surgery.
Patient Protection Events	
Patient Discharge (event 3A)	"Infant discharged to the wrong person," event 3A, now includes the discharge of any patient or resident who is unable to make decisions (e.g. patients with Alzheimer's) to other than an authorized person.
Suicide (event 3C)	This event was expanded from "suicide or attempted suicide" to include "self-harm that results in serious injury."

Care Management Events	
Events Added	1. The Patient Fall event was moved from the Environmental Event category to the Care Management category. No substantive changes to the event were made.
Blood Products (event 4B)	The previous event specific to hemolytic reactions due to administration of ABO/HLA-incompatible blood/blood products has been broadened in 4B to: Patient death or serious injury associated with unsafe administration of blood products.
Pressure Ulcers (event 4F)	Unstageable pressure ulcers that were acquired after admission/presentation to the healthcare setting are now considered Serious Reportable Events.
Environmental Events	
Staff Injury or Death	The events related to electric shock (5A) and burns (5C) now include staff, i.e., patient *or staff* death or serious injury.
Gas Delivery (event 5B)	1. "Line designated for oxygen or other gas" has been changed to "systems designated for oxygen or other gas" to include remote and bedside systems. 2. The phrase "contains no gas" was added to the phrase "contains the wrong gas or is contaminated with toxic substances." The event now reads "...contain no gas, the wrong gas, or are contaminated by toxic substances."
Restraints (event 5D)	This event has been clarified to include only physical restraints; chemical restraints are not included.
Potential Criminal Events	
Definitions	1. The category name has been changed to include the word "potential." 2. In the Patient Abduction event (7B), the term "resident" has been included alongside "patient." 3. The term "significant injury" in the Physical Assault event (7D) has been changed to "serious injury."
Staff Assault	The Sexual Abuse/Assault Event (7C) now includes abuse or assault suffered by staff; the event was previously limited to patients.