# NATIONAL QUALITY FORUM

TO: Consensus Standards Approval Committee

FR: Peter Angood, MD and Melinda Murphy, RN MS

RE: Results of Voting for *Serious Reportable Events in Healthcare-2011 Update: A Consensus Report*

DA: April 11, 2011

The CSAC will be reviewing voting results for the draft report *Serious Reportable Events in Healthcare-2011 Update: A Consensus Report* during the April 11 meeting. This memo includes summary information about the project, as well as the Member voting results. The complete voting draft report and supplemental materials are available on the project page.

## CSAC ACTION REQUIRED

Pursuant to the CDP, the CSAC may consider approval of the Serious Reportable Events and Additional Specifications specified in the "voting draft" of *Serious Reportable Events in Healthcare-2011 Update: A Consensus Report*.

Twenty-nine Serious Reportable Events and additional specifications were considered for approval. The Steering Committee recommended all twenty-nine events and additional specifications for endorsement. The voters approved endorsement.

Please see Appendix A for a listing of the Serious Reportable Events and additional specifications.

## BACKGROUND

The recommended report identifies 29 Serious Reportable Events in Healthcare, of which 25 have been brought forward from the 2006 list and updated and 4 are new. All of the Serious Reportable Events (SREs) have been reviewed in terms of their applicability to four specific settings of care— hospitals; outpatient or office-based surgery centers; long-term care settings, specifically, skilled nursing facilities; and ambulatory practice settings, specifically, office-based practices. The report focuses on identifying and specifying each event for public reporting within the applicable settings of care. It does not recommend implementation strategies for public reporting or for use in payment for performance initiatives.

### Comments and their Disposition

NQF received 220 comments from respondents representing 26 NQF Member organizations and 13 nonmember organizations or individuals during the comment period. The major themes of the comments included: 1) suggested modifications or revisions to definitions included in the event descriptions and glossary; 2) concern that SRE 4E: Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting, will capture unpreventable falls; 3) concern that SRE 4I: Death or serious injury resulting from failure to follow up or communicate clinical information, is too broad to implement; 4) concern about including staff in reporting requirements for six of the SREs; and 5) recommendations for additional SREs. Additionally, there were comments that the improved

specificity and clarity of the events would lead to an increased number of reports. The Steering Committee reviewed the comments and provided responses that are noted in the table of comments posted on the NQF web site and addressed within the report. With respect to the potential for increased reporting, this was addressed in the body of the report. A synopsis of the major concerns identified during the review period is provided below.

**Definitions related to the SREs**
Generally the comments called for further clarification of several definitions as well as the addition of definitions to the glossary in order to more clearly define the events.

*Action Taken:* The glossary was improved with modification and addition of definitions as determined appropriate by the Steering Committee. Effort was made to harmonize with appropriate guidelines and widely accepted sources (e.g., FDA, NCCMERP). The Steering Committee acknowledged that with increased clarity and specification of the events, an increase in the number of reports may occur that would not be indicative of a worsening of the safety of healthcare delivery. This has been addressed in the report.

**SRE 4E: Patient death or serious injury associated with a fall while being cared for in a healthcare setting**
This event was initially specified as "Patient death or serious injury associated with a fall during or after being cared for and prior to leaving the grounds of a healthcare setting" with the intent of capturing falls that might occur during such activities as attended transfers from facility to vehicles. Several commenters expressed concern that this event would be interpreted more broadly and capture incidents outside of the healthcare setting which could not be prevented by the healthcare setting, such as patients who linger on the grounds past discharge and then suffer a fall. Commenters were concerned that healthcare providers would be held accountable for such events over which they had no control.

*Action Taken:* The Steering Committee reviewed these comments, in terms of how to specify this event to capture falls that are preventable by the healthcare setting. The event description was modified to capture only patient falls that occur while the patient is being cared for in a healthcare setting. The definition of patient was clarified to note that a person becomes a patient at the point that they are being "cared for" in the facility, with "cared for" being defined as when the patient is first engaged by a member of the care team. It also provides examples of when a patient is no longer under care that speaks to safe assistance to a vehicle from an inpatient stay or, for the ambulatory outpatient, departure from a care location.

**SRE 4I: Death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results**

Originally specified as "Death or serious injury resulting from failure to follow up or communicate clinical information," several comments were made expressing concern that this event was too broad to implement. Commenters stated that "failure to follow up" needs to be clearly defined. Commenters also stated that "clinical information" was too broad to implement, as this could include anything from vital reports to patient allergies to abnormal test results.

*Action taken:* The Steering Committee acknowledged that the event needed to be narrowed in order for facilities to implement the event. The Steering Committee recommended changing the event description to capture failure to follow up or communicate laboratory, pathology, or radiology test results only, narrowing the scope of the clinical information. It was also clarified, though implementation guidance, that the directionality of failure to follow up or communicate is from physician to physician or from physician to patient.

**Inclusion of staff in reporting requirements**
Several comments were made requesting that staff not be included in event specifications for reporting of six of the SREs (5A, 5C, 7A, 7B, 7C, 7D) as there are other avenues for reporting staff harm, such as OSHA.

*Action taken:* The Steering Committee acknowledged that reporting of harm to staff can occur through OSHA; however, the primary focus of OSHA is not improving patient safety and the Steering Committee stated that occurrence of these specific SREs could just as easily happen to a patient as to staff. Such events, whether shock, burn, projectiles, or assaults have the potential to facilitate enterprise-wide learning and improvement to the benefit of patients and staff that is less likely to be forthcoming through organizations with fundamentally different goals.

**Recommendations for additional SREs**
A number of comments were made requesting that additional events be added to the SRE listing, including the CLABSI event which was reviewed by the Steering Committee but not recommended for endorsement.

*Action taken:* The Steering Committee reviewed suggestions for new SREs, and determined that the suggested events were not ready for endorsement at this time, due to a lack of persuasive evidence of the preventability of the suggested events. The Steering Committee recommended that these events be considered, with any new evidence, in the next update of the SREs.

The Steering Committee also noted that future SRE submissions should focus on preventable system errors by type, rather than on either single representative errors of a type or discipline-specific error.

**Additional Comments**

After the report was posted for Member vote, a representative for the Institute for Safe Medication Practices submitted a comment noting that the SRE related to medication errors did not address serious or fatal community pharmacy dispensing errors. NQF staff acknowledge the importance of this issue, and propose that the following language, italicized below, be added to the report at this time and that the issue be revisited by the Steering Committee at the next SRE update:

<u>Patient death or serious injury 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)</u>. The high rate of medication errors resulting in injury and death makes this event important to endorse again. With this update, two significant additions to the additional specifications have been made. One is the administration of a medication for which there is serious contraindication. The other relates to failure to observe safe injection practices

(i.e., the improper use of single dose/single use and multi-dose containers leading to injury or death as a result of dosages). *Because this update of the SREs focuses on hospitals, office-based practices, ambulatory surgery centers, and skilled nursing facilities, a significant number of serious and fatal events resulting from community pharmacy dispensing errors are not captured. When such events occur during dispensing of medications ordered from the identified sites of care, they should be included in analyses of causes, as appropriate.*

## NQF MEMBER VOTING

The 30-day voting period for the Serious Reportable Events in Healthcare project closed on March 18, 2011.

### Voting Results

Voting results for the Serious Reportable Events are provided below. The voters approved the Serious Reportable Events.

**Measure Event 1A-Surgery or other invasive procedure performed on the wrong site**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 9 | 0 | 2 | 11 | 100% |
| Provider Organizations | 8 | 1 | 0 | 9 | 89% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **38** | **1** | **2** | **41** | **97%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 98% |

*equation: Yes/ (Total - Abstain)

**Measure Event 1B-Surgery or other invasive procedure performed on the wrong patient**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 9 | 0 | 2 | 11 | 100% |
| Provider Organizations | 9 | 0 | 0 | 9 | 100% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |

| | | | | | |
|---|---|---|---|---|---|
| **All Councils** | **39** | **0** | **2** | **41** | **100%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 100% |

*equation: Yes/ (Total - Abstain)

**Measure Event 1C-Wrong surgical or other invasive procedure performed on a patient**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 9 | 0 | 2 | 11 | 100% |
| Provider Organizations | 9 | 0 | 0 | 9 | 100% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **39** | **0** | **2** | **41** | **100%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 100% |

*equation: Yes/ (Total - Abstain)

**Measure Event 1D-Unintended retention of a foreign object in a patient after surgery or other invasive procedure**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 9 | 0 | 0 | 9 | 100% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **38** | **0** | **3** | **41** | **100%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 100% |

*equation: Yes/ (Total - Abstain)

**Measure Event 1E-Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 7 | 0 | 2 | 9 | 100% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **36** | **0** | **5** | **41** | **100%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 100% |

*equation: Yes/ (Total - Abstain)

**Measure Event 2A-Patient death or serious injury associated with the use of contaminated drugs devices or biologics provided by the healthcare setting**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 10 | 0 | 1 | 11 | 100% |
| Provider Organizations | 7 | 2 | 0 | 9 | 78% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **38** | **2** | **1** | **41** | **95%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 97% |

*equation: Yes/ (Total - Abstain)

**Measure Event 2B-Patient death or serious injury associated with the use or function of a device in patient care in which the device is used or functions other than as intended**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 9 | 0 | 2 | 11 | 100% |
| Provider Organizations | 8 | 1 | 0 | 9 | 89% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |

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|---|---|---|---|---|---|
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **38** | **1** | **2** | **41** | **97%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 98% |

*equation: Yes/ (Total - Abstain)

**Measure Event 2C-Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 6 | 3 | 0 | 9 | 67% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **35** | **3** | **3** | **41** | **92%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 95% |

*equation: Yes/ (Total - Abstain)

**Measure Event 3A-Discharge or release of a patient/resident of any age who is unable to make decisions to other than an authorized person**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 9 | 1 | 1 | 11 | 90% |
| Provider Organizations | 7 | 2 | 0 | 9 | 78% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 2 | 1 | 0 | 3 | 67% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **36** | **4** | **1** | **41** | **90%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 91% |

*equation: Yes/ (Total - Abstain)

**Measure Event 3B-Patient death or serious injury associated with patient elopement**

**(disappearance)**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 9 | 1 | 1 | 11 | 90% |
| Provider Organizations | 8 | 1 | 0 | 9 | 89% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **38** | **2** | **1** | **41** | **95%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 97% |

*equation: Yes/ (Total - Abstain)

**Measure Event 3C-Patient suicide attempted suicide or self harm that results in serious injury while being cared for in a healthcare setting**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 1 | 2 | 11 | 89% |
| Provider Organizations | 6 | 3 | 0 | 9 | 67% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 2 | 1 | 0 | 3 | 67% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **34** | **5** | **2** | **41** | **87%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 89% |

*equation: Yes/ (Total - Abstain)

**Measure Event 4A-Patient death or serious injury 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)**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 10 | 0 | 1 | 11 | 100% |
| Provider Organizations | 9 | 0 | 0 | 9 | 100% |
| Public/Community Health | 0 | 0 | 0 | 0 | |

| | | | | | |
|---|---|---|---|---|---|
| Agency | | | | | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **40** | **0** | **1** | **41** | **100%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 100% |

*equation: Yes/ (Total - Abstain)

**Measure Event 4B-Patient death or serious injury associated with unsafe administration of blood products**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 9 | 0 | 0 | 9 | 100% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **38** | **0** | **3** | **41** | **100%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 100% |

*equation: Yes/ (Total - Abstain)

**Measure Event 4C-Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 7 | 0 | 2 | 9 | 100% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **36** | **0** | **5** | **41** | **100%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 100% |

*equation: Yes/ (Total - Abstain)

**Measure Event 4D-Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 6 | 1 | 2 | 9 | 86% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 3 | 1 | 0 | 4 | 75% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **34** | **2** | **5** | **41** | **94%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 94% |

*equation: Yes/ (Total - Abstain)

**Measure Event 4E-Patient death or serious injury associated with a fall while being cared for in a healthcare setting**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 10 | 0 | 1 | 11 | 100% |
| Provider Organizations | 7 | 2 | 0 | 9 | 78% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **38** | **2** | **1** | **41** | **95%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 97% |

*equation: Yes/ (Total - Abstain)

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|---|---|---|---|---|---|

**Measure Event 4F-Any Stage 3 Stage 4 and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |

| | | | | | |
|---|---|---|---|---|---|
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 6 | 3 | 0 | 9 | 67% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **35** | **3** | **3** | **41** | **92%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 95% |

*equation: Yes/ (Total - Abstain)

**Measure Event 4G-Artificial insemination with the wrong donor sperm or wrong egg**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 6 | 1 | 2 | 9 | 86% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **35** | **1** | **5** | **41** | **97%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 98% |

*equation: Yes/ (Total - Abstain)

**Measure Event 4H-Death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 7 | 1 | 1 | 9 | 88% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 3 | 1 | 0 | 4 | 75% |
| QMRI | 2 | 1 | 0 | 3 | 67% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **34** | **3** | **4** | **41** | **92%** |

| | |
|---|---|
| Percentage of councils approving (<50%) | 100% |
| Average council percentage approval | 90% |

*equation: Yes/ (Total - Abstain)

**Measure Event 4I-Death or serious injury resulting from failure to follow up or communicate laboratory pathology or radiology test results**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 6 | 3 | 0 | 9 | 67% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 3 | 1 | 0 | 4 | 75% |
| QMRI | 2 | 1 | 0 | 3 | 67% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **33** | **5** | **3** | **41** | **87%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 87% |

*equation: Yes/ (Total - Abstain)

**Measure Event 5A-Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 7 | 2 | 0 | 9 | 78% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **36** | **2** | **3** | **41** | **95%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 97% |

*equation: Yes/ (Total - Abstain)

**Measure Event 5B-Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas the wrong gas or is contaminated by toxic substances**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 7 | 2 | 0 | 9 | 78% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 2 | 1 | 0 | 3 | 67% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **35** | **3** | **3** | **41** | **92%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 92% |

*equation: Yes/ (Total - Abstain)

**Measure Event 5C-Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 1 | 2 | 11 | 89% |
| Provider Organizations | 6 | 3 | 0 | 9 | 67% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 2 | 1 | 0 | 3 | 67% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **34** | **5** | **2** | **41** | **87%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 89% |

*equation: Yes/ (Total - Abstain)

**Measure Event 5D-Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 9 | 0 | 0 | 9 | 100% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |

| | | | | | |
|---|---|---|---|---|---|
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **38** | **0** | **3** | **41** | **100%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 100% |

*equation: Yes/ (Total - Abstain)

**Measure Event 6A-Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 0 | 3 | 11 | 100% |
| Provider Organizations | 6 | 2 | 1 | 9 | 75% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 2 | 1 | 0 | 3 | 67% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **34** | **3** | **4** | **41** | **92%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 92% |

*equation: Yes/ (Total - Abstain)

**Measure Event 7A-Any instance of care ordered by or provided by someone impersonating a physician nurse pharmacist or other licensed healthcare provider**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 1 | 2 | 11 | 89% |
| Provider Organizations | 8 | 1 | 0 | 9 | 89% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 2 | 1 | 0 | 3 | 67% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **36** | **3** | **2** | **41** | **92%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 92% |

*equation: Yes/ (Total - Abstain)

**Measure Event 7B-Abduction of a patient/resident of any age**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 1 | 2 | 11 | 89% |
| Provider Organizations | 8 | 1 | 0 | 9 | 89% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **37** | **2** | **2** | **41** | **95%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 97% |

*equation: Yes/ (Total - Abstain)

**Measure Event 7C-Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 1 | 2 | 11 | 89% |
| Provider Organizations | 7 | 2 | 0 | 9 | 78% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |
| QMRI | 3 | 0 | 0 | 3 | 100% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **36** | **3** | **2** | **41** | **92%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 95% |

*equation: Yes/ (Total - Abstain)

**Measure Event 7D-Death or serious 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 setting**

| Measure Council | Yes | No | Abstain | Total Votes | % Approval* |
|---|---|---|---|---|---|
| Consumer | 8 | 0 | 0 | 8 | 100% |
| Health Plan | 5 | 0 | 0 | 5 | 100% |
| Health Professional | 8 | 1 | 2 | 11 | 89% |
| Provider Organizations | 7 | 2 | 0 | 9 | 78% |
| Public/Community Health Agency | 0 | 0 | 0 | 0 | |
| Purchaser | 4 | 0 | 0 | 4 | 100% |

| | | | | | |
|---|---|---|---|---|---|
| QMRI | 2 | 1 | 0 | 3 | 67% |
| Supplier/Industry | 1 | 0 | 0 | 1 | 100% |
| **All Councils** | **35** | **4** | **2** | **41** | **90%** |
| Percentage of councils approving (<50%) | | | | | 100% |
| Average council percentage approval | | | | | 90% |

*equation: Yes/ (Total - Abstain)

### Comments During Voting

No comments were received during the voting period.

## Appendix A
## PROPOSED SERIOUS REPORTABLE EVENTS IN HEALTHCARE

| 1. SURGICAL OR INVASIVE PROCEDURE EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| A. Surgery or other invasive procedure performed on the wrong site<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | 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.<br><br>Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints.<br><br>Excludes emergent situations that occur in the course of surgery or other invasive procedure and/or whose exigency precludes obtaining informed consent. | 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.<br><br>Although an incorrectly placed surgical mark could result in surgery being performed on the wrong body part, surgery does not begin at time the surgical mark is made on the patient. Placing a mark on the wrong body part or site does not in itself constitute wrong site surgery.<br><br>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.<br><br>This event is intended to capture instances of:<br>• surgery or other invasive procedure on the right body part but on the wrong location/site on the body; e.g. left/right (appendages/organs), wrong digit, level (spine), stent placed in wrong iliac artery, steroid injection into wrong knee, biopsy of wrong mole, burr hole on wrong side of skull;<br>• delivery of fluoroscopy or radiotherapy to the wrong region of the body;<br>• use of incorrectly placed vascular catheters;<br>• use of incorrectly placed tubes (for example, feeding tubes placed in the lung or ventilation tubes passed into the esophagus).<br><br>This event is not intended to capture:<br>• changes in plan upon entry into the patient with discovery of pathology in close proximity to the |

| 1. SURGICAL OR INVASIVE PROCEDURE EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| | | intended place where risk of a second surgery or procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae). |
| B. Surgery or other invasive procedure performed on the wrong patient<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | Defined as any surgery or invasive procedure on a patient that is not consistent with the correctly documented informed consent for that patient.<br><br>Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints. | 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.<br><br>This event is intended to capture:<br>• surgical procedures (whether or not completed) initiated on one patient intended for a different patient.<br><br>Use of accepted patient identification procedures is key to avoiding such events. |
| C. Wrong surgical or other invasive procedure performed on a patient<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | 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.<br><br>Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints.<br><br>Excludes emergent situations that occur in the course of surgery or other invasive procedures and/or whose exigency precludes obtaining informed consent. | 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.<br><br>This event is intended to capture:<br>• insertion of the wrong medical implant into the correct surgical site.<br><br>This event is not intended to capture:<br>• 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 adhesions, spine level/extra vertebrae). |

| 1. SURGICAL OR INVASIVE PROCEDURE EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | Includes medical or surgical items intentionally placed by provider(s) that are unintentionally left in place.<br><br>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). | This event is intended to capture:<br>• occurrences of unintended retention of objects at any point after the surgery/procedure ends regardless of setting (post anesthesia recovery unit, surgical suite, emergency department, patient bedside) and regardless of whether the object is to be removed after discovery;<br>• unintentionally retained objects (including such things as wound packing material, sponges, catheter tips, trocars, guide wires) in all applicable settings. |
| E. Intraoperative or immediately postoperative/ postprocedure death in an ASA Class I patient<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices | 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.<br><br>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). | This event is intended to capture:<br>• ASA Class I patient death associated with the administration of anesthesia whether or not the planned surgical procedure was carried out. |

| 2. PRODUCT OR DEVICE EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |

| 2. PRODUCT OR DEVICE EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | Includes contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.<br><br>Includes threat of disease that changes patient's risk status for life requiring medical monitoring not needed before the event | This event is intended to capture:<br>• 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 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)..*<br><br>This event is intended to capture:<br>• administration of contaminated vaccine or medication (e.g., intramuscular antibiotic);<br>• serious infection from contaminated drug or device used in surgery or an invasive procedure (e.g., a scalpel);<br>• occurrences related to use of improperly cleaned or maintained device. |

| 2. PRODUCT OR DEVICE EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended<br><br>Applicable settings:<br><br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | Includes, but is not limited to, catheters, drains and other specialized tubes, infusion pumps, ventilators, and procedural and monitoring equipment. | This event is intended to capture:<br><br>• occurrences whether or not the use is intended or described by the device manufacturers' literature;<br>• |

| 2. PRODUCT OR DEVICE EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers,<br>• Long-term Care/Skilled Nursing Facilities | Excludes death or serious injury associated with neurosurgical procedures known to present a high risk of intravascular air embolism. | This event is intended to capture:<br>• 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;<br>• low-risk procedures including those related to lines placed for infusion of fluids in vascular space. |

| 3. PATIENT PROTECTION EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |

| 3. PATIENT PROTECTION EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person.<br><br>Applicable settings:<br><br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | | 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.<br><br>Examples of individuals who do not have decision-making capacity include: newborns, minors, adults with Alzheimer’s.<br><br>Individual healthcare organizations or other relevant jurisdictional authorities may have specific requirements for assessing decision-making capacity. |

| 3. PATIENT PROTECTION EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| B. Patient death or serious injury associated with patient elopement (disappearance).<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | Includes events that occur after the individual presents him/herself for care in a healthcare setting.<br><br>Excludes events involving competent adults with decision-making capacity who leave against medical advice or voluntarily leave without being seen. | The term "elopement" and "competent" adult should be interpreted in accordance with prevailing legal standards in applicable jurisdictions.<br><br>~~*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*~~.~~<br><br>This is not intended to capture:<br>• death or serious injury that occurs (after the patient is located) due to circumstances unrelated to the elopement. |
| C. Patient suicide, attempted suicide, or selfharm that results in serious injury, while being cared for in a healthcare setting<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ | Includes events that result from patient actions after they present themselves for care in a healthcare setting.<br><br>Excludes deaths resulting from self-inflicted injuries that were the reason for admission/presentation to the healthcare facility. | 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. |

| 3. PATIENT PROTECTION EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | | |

| 4. CARE MANAGEMENT EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |

| 4. CARE MANAGEMENT EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| A. Patient death or serious injury 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)<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | Excludes reasonable differences in clinical judgment on drug selection and dose.<br><br>Includes, but is not limited to, death or serious injury associated with a) over- or 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, d) improper use of single-dose/single-use and multi-dose medication vials and containers leading to death or serious injury as a result of dose adjustment problems. | This event is intended to capture:<br>• 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 medications/ 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 assure availability of such information and prominently display such information within information systems, or other system failures that are determined through investigation to be cause of the adverse event.*<br>• occurrences in which a patient dies or suffers serious injury as a result of failure to administer a prescribed medication;<br>• 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”;<br>• occurrences in which a patient dies or suffers serious injury as a result of wrong administration technique.<br><br>This event is not intended to capture:<br>• patient death or serious injury associated with allergies that could not reasonably have been known or discerned in advance of the event. |

| 4. CARE MANAGEMENT EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| B. Patient death or serious injury associated with unsafe administration of blood products<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facility | | 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.<br><br>This event is not intended to capture :<br>• patient death or serious injury associated with organ rejection other than those attributable to a hyperacute hemolytic reaction<br>• patient death or injury when cause is not detectable by ABO/HLA matching. |
| C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers | Includes events that occur within 42 days post-delivery.<br>Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy. | This event is not intended to create a new obligation. The organization's obligation is to report the event when made aware of the maternal death or serious injury either by readmittance or by the patient's family. |

| 4. CARE MANAGEMENT EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers | Includes, for the office-based surgery, birthing center or "home" setting, unplanned admission to an inpatient setting within 24 hours of delivery | Unplanned admission to other than the birth setting should be verified with the identified birth setting. |
| E. Patient death or serious injury associated with a fall while being cared for in a healthcare setting<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | Includes but is not limited to fractures, head injuries, and intracranial hemorrhage | *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.* |

| 4. CARE MANAGEMENT EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/ presentation to a healthcare setting<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Long-term Care/ Skilled Nursing Facilities | 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. | 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. |
| G. Artificial insemination with the wrong donor sperm or wrong egg<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices | | The organization's obligation is to report the event when made aware of the occurrence. |
| H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen. | Includes events where specimens are misidentified, where another procedure cannot be done to produce a specimen<br>Includes progression of an undiagnosed disease or threat of disease that changes the patient's risk status for life, requiring | This event is not intended to capture:<br>• procedures where the specimen was properly handled, but the specimen proved to be nondiagnostic.<br>Inability to secure a replacement for a lost specimen can occur with excisional biopsy as well as in organ |

| 4. CARE MANAGEMENT EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | monitoring not needed before the event | removal. |
| I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | Includes events where failure to report increased neonatal bilirubin levels result in kernicterus. | Examples of serious injury are a new diagnosis, or an advancing stage of an existing diagnosis (e.g., cancer).<br><br>Failure to follow up or communicate can be limited to healthcare staff or can involve communication to the patient. . |

| 5. ENVIRONMENTAL EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | Excludes events involving patients during planned treatments such as electric countershock /elective cardioversion. | This event is intended to capture:<br>• patient death or injury associated with unintended electric shock during the course of care or treatment;<br>• staff death or injury associated with unintended electric shock while carrying out duties directly associated with a patient care process, including preparing for care delivery.<br><br>This event is not intended to capture:<br>• patient death or injury associated with emergency defibrillation in ventricular fibrillation or with electroconvulsive therapies;<br>• injury to staff who are not involved in patient care. |
| B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | | This event is intended to capture:<br>• events in which the line is attached to a reservoir distant from the patient care unit or in a tank near the patient such as E-cylinders, anesthesia machines. |

| 5. ENVIRONMENTAL EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| | | |
| C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | | This event is intended to capture burns that result from:<br>• operating room flash fires, including second degree burn in these cases;<br>• hot water;<br>• sunburn in the patient with decreased ability to sense pain;<br>• smoking in the patient care environment. |

| 5. ENVIRONMENTAL EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | | The event is intended to capture:<br>• instances where physical restraints are implicated in the death; e.g., lead to strangulation/entrapment, etc. |

| 6. RADIOLOGIC EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |

| | | |
|---|---|---|
| A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices | Includes events related to material inside the patient's body or projectiles outside the patient's body. | This event is intended to capture injury or death as a result of projectiles including:<br>• retained foreign object<br>• external projectiles<br>• pacemakers |

| **7. POTENTIAL CRIMINAL EVENTS** | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing | | This event is intended to capture:<br>• those without licensure to provide the care given;<br>• those with licensure who represent themselves and act beyond the scope of their licensure.<br><br>It is not intended to capture individuals who are practicing within the scope of their license whom patients or others mistakenly bestow titles beyond that scope when such is not encouraged by the provider. |

| 7. POTENTIAL CRIMINAL EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| Facilities | | |
| B. Abduction of a patient/resident of any age<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | | This event is intended to capture:<br>• removal of a patient/resident, who does not have decisionmaking capacity, without specific notification and approval by staff even when the person is otherwise authorized to be away from the setting.<br><br>Examples of individuals who do not have decisionmaking capacity include: newborns, minors, adults with Alzheimer's. |
| C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting<br><br>Applicable settings:<br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices | | Language and definitions may vary based on state statute; however, the principle and intent remain regardless of language required based on jurisdiction. |

| 7. POTENTIAL CRIMINAL EVENTS | | |
|---|---|---|
| **EVENT** | **ADDITIONAL SPECIFICATIONS** | **IMPLEMENTATION GUIDANCE** |
| • Long-term Care/Skilled Nursing Facilities | | |
| D. Death or serious 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 setting.<br><br>Applicable settings:<br><br>• Hospitals<br>• Outpatient/Office-based Surgery Centers<br>• Ambulatory Practice Settings/ Office-based Practices<br>• Long-term Care/Skilled Nursing Facilities | | 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”). |