Frequently Asked Questions on:

The Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements under the Medical Care Availability and Reduction of Error Act


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PRINCIPLE 1
The concepts of human error and preventability do not appear in the Serious Event definition. It is not necessary for an error to be involved, nor for the harm to be preventable, for a death or unanticipated injury to constitute a Serious Event.

QUESTIONS
In reference to the concept “Human error and preventability do not appear in the Serious Events definition. It is not necessary for an error to be involved, nor for the harm to be preventable, for a death or unanticipated injury to constitute a Serious Event.” In the following example, would this be reportable as a Serious Event?

Adverse Drug Reaction
A patient reports for an outpatient CT scan; they have no known drug allergies. After being administered Omnipaque IV, the patient develops itching and hives. The physician examines the patient and orders Benadryl, and the patient is monitored until the hives dissipate and then discharged. The reaction is submitted as an adverse drug reaction and added to the patient’s database as an allergy/reaction. This is an appropriate plan of care—I am having a hard time finding an event that led to the unanticipated injury that requires additional healthcare services.

What about an ADR where the patient has hives and gets Benadryl?

RESPONSE
The event is an adverse drug reaction (ADR); ADRs are reportable as Incidents or Serious Events (depending on level of harm). Whether or not there was an appropriate plan of care is irrelevant to the determination of whether or not this event is reportable. The facility will need to determine if the event is an Incident or Serious Event. This is a multifaceted question. A Serious Event involves an unanticipated injury requiring additional healthcare services. The facility should consider two things. First, was there an unanticipated injury? Second, did it require additional healthcare services? So first, was the Benadryl used to treat an unanticipated injury or was it used to prevent an injury? In other words, does the facility consider itching and hives an injury? Second, was the Benadryl “additional healthcare services”? When evaluating the administration of medication, one must consider a multitude of factors, such as route, comorbidity, and interactions. See Principle 1 from the final guidelines.
**QUESTIONS**

**Patient removing PICC line**
If a confused patient is admitted to a long-term acute care hospital with a PICC line in place and the patient partially removes the PICC line (without injury), requiring complete removal by nursing staff and reinsertion of a PICC or EPIV line, does this meet the standard of a Serious Event for reporting purposes?

If the same patient completely removes the PICC line without injury in the scenario above, does this meet the standard of a Serious Event for reporting purposes? These scenarios above assume a standard informed consent for PICC was completed but did not address the increased likelihood of PICC removal by the patient due to confusion.

If a patient unintentionally removes the PICC line and the PICC line is not replaced or is replaced with a peripheral IV, does this meet the standard for Serious Event reporting?

**RESPONSE**

The reinsertion of the PICC line may be considered an unnecessary invasive procedure (requiring informed consent) and thereby is generally considered a Serious Event if the dislodgement is unanticipated.

If there is no injury related to the dislodgement and no unnecessary invasive procedure (requiring informed consent), then this would not meet the definition of a Serious Event. However, if the patient experiences an event related to the lack of a PICC line, this event may meet the criteria of an Incident or Serious Event—for example, if IV dopamine cannot be administered and the patient’s blood pressure cannot be maintained and this leads to hypotensive shock and death.
PRINCIPLE 2
The unanticipated nature of the injury is from the perspective of a reasonably prudent patient. While every provider anticipates some rate of complications from the procedures they perform, infrequent complications are rarely anticipated by the patient unless the patient is somehow at increased risk. While we do not specify an exact threshold for the frequency of complications that makes a particular complication transition from unanticipated to anticipated, complications that occur rarely would be unanticipated by most reasonably prudent patients.

QUESTION
Unintended Diagnosis
Patient presented with a large bowel obstruction and had a Hartmann procedure eight weeks ago. He is scheduled for a laparoscopic extensive lysis of adhesion, partial colectomy, and mobilization of splenic flexure, and a small serosal tear occurred at the small bowel. This was repaired with a Lembert suture. Would this be considered an Incident, due to the unintended diagnosis not requiring an invasive procedure requiring its own informed consent?

RESPONSE
The facility should consider if this is an unanticipated injury and if it required additional healthcare services (services beyond first aid). See Principles 2, 3, and 4 from the Final Guidance.

- 2. The unanticipated nature of the injury is from the perspective of a reasonably prudent patient. While every provider anticipates some rate of complications from the procedures they perform, infrequent complications are rarely anticipated by the patient unless the patient is somehow at increased risk. While the Authority does not specify an exact threshold for the frequency of complications that makes a particular complication transition from unanticipated to anticipated, complications that occur rarely would be unanticipated by most reasonably prudent patients.
- 3. The disclosure of a potential complication on a patient consent form does not, in itself, constitute anticipation of the complication by the patient. Informing the patient of a risk does not mean the patient or the provider anticipates that the untoward outcome will actually occur.
- 4. Complications may be considered anticipated (and therefore not meeting the Serious Event definition) when they occur frequently or the risk of the complication is considered high for a particular patient and the high probability of this complication was disclosed to the patient in the informed consent discussion and documented either on the consent form or medical record.

If the facility determines that the injury was unanticipated, the repair with a Lembert suture would be considered additional healthcare services, therefore making this event reportable as a Serious Event.
**PRINCIPLE 4**
Complications may be considered anticipated (and therefore not meeting the Serious Event definition) when they occur frequently or the risk of the complication is considered high for a particular patient and the high probability of this complication was disclosed to the patient in the informed consent discussion and documented either on the consent form or medical record.

**QUESTION**
Definition of Frequently
Has the Authority or Department offered any definition as to what “frequently” means?

**RESPONSE**
The Authority and the Department do not define the term “frequently.” Refer to Principles 2 and 4 from the Final Guidance.

- 2. The unanticipated nature of the injury is from the perspective of a reasonably prudent patient. While every provider anticipates some rate of complications from the procedures they perform, infrequent complications are rarely anticipated by the patient unless the patient is somehow at increased risk. While the Authority does not specify an exact threshold for the frequency of complications that makes a particular complication transition from unanticipated to anticipated, complications that occur rarely would be unanticipated by most reasonably prudent patients.
- 4. Complications may be considered anticipated (and therefore not meeting the Serious Event definition) when they occur frequently or the risk of the complication is considered high for a particular patient and the high probability of this complication was disclosed to the patient in the informed consent discussion and documented either on the consent form or medical record.

**QUESTION**
Operative Tears
A patient is returning for a colostomy reversal, and the surgeon encounters expected adhesions. During the operation, the surgeon carefully dissects the adhesions and encounters small intestinal tears resulting from adhesions dissection that are immediately recognized and repaired by suture. Is this a Serious Event? Similarly, a patient who has had prior abdominal surgeries is in need of additional abdominal surgery. The surgeon encounters expected adhesions. During the operation, the surgeon carefully dissects the adhesions and encounters small intestinal tears that are immediately recognized and repaired by suture. Is either of these a Serious Event?

**RESPONSE**
There are several questions that should be answered in order to determine if either of these scenarios meets the definition of a Serious Event. The first question is if there is an unanticipated injury. It is stated that the surgeon encounters expected adhesions. Did the surgeon anticipate that with the
expected adhesions the patient would experience small intestinal tears? Did he or she discuss this with the patient? Remember, the unanticipated nature of the injury is from the perspective a reasonably prudent patient. Complications may be considered anticipated (and therefore not meeting the Serious Event definition) when they occur frequently or the risk of the complication is considered high for a particular patient and this high probability was also disclosed to the patient and documented on the consent form or medical record. If complication was anticipated by the patient because of a discussion with the physician and was documented in the consent or medical record, then it would not meet the definition of a Serious Event.

QUESTIONS

Complications

- An inpatient s/p small bowel resection requires a return to the OR to repair a bowel leak at suture line. Is this considered a rare complication and needs to be reported as a SE b/c of the additional healthcare services or would bowel leak be considered a common complication and not reportable?
- A patient undergoes lung biopsy and on x-ray the patient has 20% pneumothorax and a decision is made to place chest tubes. Is this considered a rare complication and needs to be reported as a SE because of the additional healthcare services or would pneumothorax be considered a common complication and not reportable?

RESPONSE

The terms "rare" complication and "common" complication appear in this inquiry for the case cited. This would relate to principles 2, 3, 4, and 5.

Principle 4 discusses “anticipated” in terms of the frequency or risk of complication for a particular patient and the high probability of the complication being disclosed in the informed consent discussion and documented on either the consent form or medical record. What was the likelihood or probability (versus possible or conceivable) for this particular patient? If it was likely or probable and it was communicated and documented as described in the principle, then it would not meet the definition of a Serious Event.

Principle 5 discusses the use of statistical norms or benchmarks when making Serious Event determinations. It states that “a SE that is within statistical norms or within benchmarks available in the clinical literature must still be reported. There is nothing in the law which allows for reporting SEs only when they exceed a statistical norm or benchmark.” This relates back to principle 2, which states, “Complications that occur rarely would be unanticipated by most reasonably prudent patients.” Furthermore, the final guidance on this principle states, “If a patient anticipates an injury from a medical procedure . . . and they still choose to undergo the procedure anyway . . . it is most likely because the provider conveyed the risk of injury to the patient.” The disclosure, however, of the potential complication on a patient consent form does not, in itself, constitute anticipation of the complication by the patient. Informing the patient of the risk does not mean the patient or provider anticipates that the untoward outcome will actually occur (principle 3). So ask these questions: Was this a high-probability
complication that was anticipated for this patient? Did this reasonably prudent patient anticipate this would occur? Was it discussed and documented?

QUESTION

A patient is critical with multiple comorbidities s/p AMI emergently taken to Cardiac Cath for interventions and expires during procedure. Is this reportable as a SE?

RESPONSE

Principle 4 discusses “anticipated” in terms of the frequency or risk of complication for a particular patient and the high probability of complication being disclosed in the informed consent discussion and documented on either the consent form or medical record. What was the likelihood or probability (versus possible or conceivable) for this particular patient? If it was likely or probable and that was communicated and documented as described in the principle, then it would not meet the definition of a Serious Event.
PRINCIPLE 9
Additional Healthcare Services:

Principle 9a
If a patient sustains an unanticipated injury for which no additional healthcare services are possible but treatment would be provided if options were available, this is considered a Serious Event.

QUESTION
An Injury with No Additional Treatment Ordered
If a patient falls and has rib fractures and this is confirmed via x-ray but no additional treatment is ordered, is this considered a Serious Event?

RESPONSE
Please refer to Principles 9a-c.

9. Additional healthcare services:

   a. If a patient sustains an unanticipated injury for which no additional healthcare services are possible but treatment would be provided if options were available, this is considered a Serious Event.

   b. If a patient sustains an unanticipated injury and additional healthcare services are possible but the risk of those services outweigh the negative consequences of the injury, this is considered a Serious Event.

   c. If additional healthcare services are required to treat an unanticipated injury and these additional healthcare services are not provided either because of unintentional omission or because the patient declines treatment, the occurrence is still a Serious Event.
PRINCIPLE 11
It is not necessary to report a Serious Event that occurred in another healthcare setting. If your facility discovers a Serious Event that occurred in another facility, you are strongly encouraged to notify the other facility.

QUESTION
Reporting an event at another facility
Can you help to clarify when reports should be entered into PSRS – you stated that if the patient comes in from another facility with a pressure ulcer this is not reportable under the MCARE act and should not be entered because it is not hospital acquired? When you look at the taxonomy in PSRS there is a field to submit this “admitted from other facility” – do you know why – I think this leads to confusion.

RESPONSE
The field "admitted from another facility" has been in PA-PSRS since the beginning of the program. Originally, all hospital-acquired events, including pressure ulcers, were reported, regardless of where the event occurred. Principle 11, in the new Final Guidance on Reporting Standardization document, clarifies that events that occurred at another facility should be reported by that facility, and you are strongly encouraged to notify the other facility. The field in PA-PSRS is not something that can be removed right now, but it may be removed in the future.
PRINCIPLE 12
A mid-procedure change in the plan of care in response to new information discovered during the procedure does not constitute an injury.

QUESTIONS

Intraoperative Plan of Care Change
Do all intraoperative changes in the plan of care require reporting?
If the surgical removal of a tumor requires the unplanned surgical resection of adjacent structures, is this reportable?

RESPONSE

A revised plan of care based upon new information encountered during a procedure, even when not discussed with the patient in advance of the procedure, does not, in itself, constitute an injury. If the new information was not expected, healthcare facilities have processes in place to address such circumstances and endeavor to inform the patient's representative to obtain consent.
PRINCIPLE 13
Exclusions—Additional Healthcare Services:

Principle 13a
Healthcare services provided to prevent an injury from occurring are excluded from this term for the purpose of Serious Event determinations.

Principle 13b
Services that could be provided by someone other than a licensed healthcare practitioner outside the clinical setting—essentially, first aid care—do not constitute additional healthcare services.

QUESTIONS

Intravenous Extravasation
Would giving Regitine to prevent dermal necrosis and sloughing from extravasation be reportable?

In reference to patient harm: a patient has an extravasation of a medication that is identified timely, the IV medication is stopped, and the policy is followed for administration of an antidote to prevent the extravasation from causing additional injury. The patient experiences no injury. On page 13 of the Final Guidance, it seems as if it fits under the area that states it is being used to prevent further harm, not treating harm that has already occurred (Incident). However, when you read the next paragraph regarding interventions to stop the harmful event, which uses terms of treatment and additional complications and higher levels of severity, I am unsure. Can you provide some clarity using the example provided?

RESPONSE

If the antidote was administered to prevent an infiltrate or extravasation from occurring (i.e., the antidote was administered prophylactically and before the infiltrate or extravasation occurred) then this would not meet the definition of a Serious Event.

If the infiltrate or extravasation began and the antidote was administered to prevent the injury from occurring, extending, or getting worse, then this would not meet the definition of a Serious Event; however, it is still reportable as an Incident. If the antidote was given in response to an injury, this would meet the definition of a Serious Event. See Principle 13a: Healthcare services provided to prevent an injury from occurring are excluded from this term for the purpose of Serious Event determinations.
QUESTION
Intravenous Infiltrate
Are IV infiltrates/extravasations reported only as a Serious Event if treatment is beyond 1st aid and invasive?

RESPONSE
A Serious Event involves an unanticipated injury requiring additional healthcare services. First, you must determine if the infiltration or extravasation was an unanticipated injury. Second, you must determine if the injury required additional healthcare services. To determine if additional healthcare services can be excluded from the Serious Event determination, one must determine on a case-by-case basis if the services required to treat an injury could be provided by someone other than a healthcare professional. When evaluating the administration of medication, one must consider a multitude of factors, such as route, comorbidity, and interactions. If you determine the infiltration or extravasation does not meet the definition of a Serious Event, it would still be reportable as an Incident. Please refer to the Serious Event Algorithm.

QUESTION
Hospital Acquired Pressure Ulcers
Do all hospital-acquired pressure ulcers need to be classified as a SE [Serious Event] or only stage III or IV if invasive treatment such as debridement or wound vacuum is required? Are stage I and II pressure ulcers only considered Incidents because treatment is not beyond first aid or invasive?

RESPONSE
A Serious Event involves an unanticipated injury requiring additional healthcare services. First, you must determine if the pressure ulcer was an unanticipated injury. Second, you must determine if the injury required additional healthcare services. To determine if additional healthcare services can be excluded from the Serious Event determination, one must determine on a case-by-case basis if the services required to treat the pressure ulcer could be provided outside the clinical setting by someone other than a healthcare professional. If you determine the pressure ulcer does not meet the definition of a Serious Event, it would still be reportable as an Incident. Please refer to the Serious Event Algorithm.
**PRINCIPLE 14**  
Reporting of Specific Types of Events

**QUESTION**

Restraints and Seclusion  
There now exists a restraints and seclusion other category with subcategories: Does this category need to be reported in 24 hours? For example, a patient death in restraint (restraint not considered to play a role). A patient death with restraint use in prior 24 hours (restraint not considered to play a role). A patient death in seclusion (seclusion not considered to play a role). A patient death with seclusion use in prior 24 hours (seclusion not considered to play a role).

**RESPONSE**

These events need to be reported within 24 hours of discovery. This is the same requirement as when they were reported as Serious Events or Infrastructure Failures prior to the addition of the category.

**Principle 14a**  
Restraint- or seclusion-related death or injury (i.e., in which the restraints or seclusion played a role in the death or injury) are reportable as Serious Events.

**QUESTION**

If a patient suffers an abrasion from soft-limb restraints or a superficial scratch as a result of physical restraint, is this considered a “restraint Injury” and thereby reportable as a Serious Event, even if no additional care beyond first aid was required?

**RESPONSE**

An injury that does not rise to the level of care beyond first aid does not meet the definition of a Serious Event. Please refer to the Serious Event definition below and the exclusion in 13b. This type of event may meet the definition of an Incident. Please refer to 14b.

Serious Event definition. An event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient.”

13b. Services that could be provided by someone other than a licensed healthcare practitioner outside the clinical setting—essentially, first aid care—do not constitute additional healthcare services.

14b. Restraints or seclusion may be involved in Incidents in which there is no death or injury requiring additional healthcare services.
**Principle 14b**
Restraints or seclusion may be involved in Incidents in which there is no death or injury requiring additional healthcare services (e.g., failure to timely remove restraints or end seclusion following physician order, finding patients in unsafe position while in restraints).

**QUESTION**

**Restraints**
When submitting restraint and seclusion reports which indicate no harm and restraints not contributing to death, why do questions 15-20 require answers and not allow us to choose “based on harm score no response needed,” especially if default of B1 is being used?

**RESPONSE**
Changes have been made to the system to accommodate the new taxonomy. The default harm score has been changed to B2, and questions 15 through 20 have been changed to eliminate the required fields.

**Principle 14c**
Any death in restraints or in which restraints were used within 24 hours of death (other than soft wrist restraints) but are not suspected of playing a role is reportable as “Other.”

**QUESTION**

**Death in Restraints**
Under the new reporting requirements, are facilities required to report the patient’s death within 24 hours of soft wrist restraint use? Or if the patient died while soft wrist restraints were in use but the restraints had nothing to do with the patient death? What harm score must I choose for this?

**RESPONSE**
The original design of the system was set to default to a harm score of I regardless of whether restraints or seclusion played a role in the death. The PA-PSRS system has been reconfigured to default to a harm score of B2. Please see Principle 14c. Please note that the requirement excludes soft wrist restraints.

**QUESTION**

**CMS Death in Restraint Reporting**
Definitions on the event reporting page state: “CMS requires hospitals to report to DOH any death in restraints or seclusion or in which restraints or seclusion were used within 24 hours of death (other than soft wrist restraints). Deaths in which the restraints or seclusion are suspected or confirmed as having played a role in the death should be reported as Serious Events (i.e., Serious Events J.4 or J.5). Other deaths in which the restraint or seclusion use was incidental or not suspected should be reported under
this ‘Other’ category.” Does the new reporting through PSRS take the place of hospital reporting to CMS?

RESPONSE

Reporting deaths in restraints (other than soft wrist restraints) or seclusion within 24 hours of death is not a new reporting requirement. Reporting through PA-PSRS does not take the place of the hospital reporting to CMS.

QUESTION

Since the new reporting through PSRS covers only restraints/seclusion within 24 hours of death, are hospitals expected to report deaths with restraints/seclusion greater than 24 hours but less than one week from death, where the Incident does not meet the definition of a Serious Event?

RESPONSE

Deaths that occur more than 24 hours after restraint use, where the death was related to the restraint use, would be reportable as a Serious Event. If it is a death that is related to the restraint use, it would always meet the definition of Serious Event. Other deaths are reported as Serious Events if they otherwise meet the definition of a Serious Event. If the event meets the definition of an Incident, it would be reported as such. If the event does not meet the definition of an Incident, then the event is not reportable. Reporting through PA-SRS does not relieve a facility of their obligation to also report to CMS.
**PRINCIPLE 15**

Suicide attempts that result in death or injury requiring additional healthcare services are reportable as Serious Events.

**QUESTIONS**

**Suicide attempt**

Principle 15 indicates that Suicide – attempt “must be a Serious Event.” There could be suicide attempts with injuries that require no treatment or only first aid treatment – is the reporting of these an exception to the definitions provided for “additional healthcare”?

**Suicide attempt with injury**

For suicide attempt with injury, it states it is always a Serious Event. Is this [true] regardless of whether the injury requires additional healthcare? For example, a [patient tries] to kill themselves by cutting wrists but is caught and there is only a minor cut that requires a bandaid.

**RESPONSE**

Suicide attempts that do not result in an injury requiring additional healthcare services are reportable as Infrastructure Failures.

Suicide attempts that result in injury requiring additional healthcare services, as described in principle 9, would require reporting as a Serious Event. Principle 9 is as follows: “9a. If a patient sustains an unanticipated injury for which no additional healthcare services are possible, but treatment would be provided if options were available, this is considered a Serious Event. 9b. If a patient sustains an unanticipated injury, and additional healthcare services are possible, but the risk of those services outweigh the negative consequences of the injury, this is considered a Serious Event. 9c. If additional healthcare services are required to treat an unanticipated injury, and these additional healthcare services are not provided either because of unintentional omission or because the patient declines treatment, the occurrence is still a Serious Event.”

Additionally, refer to Principle 13 when addressing the exclusions to additional healthcare services. Specifically 13b: “Services that could be provided by someone other than a licensed healthcare practitioner outside the clinical setting—essentially, first aid care—do not constitute additional healthcare services.”

**Principle 15b**

Other forms of intentional self-harm not resulting in injury requiring additional healthcare services may be reportable as Incidents.
**QUESTION**

Self-harm
Self-harm is now considered an Incident. How is the Department of Health receiving these events? Do they no longer want to receive them unless it is a serious self-harm?

**RESPONSE**

This is correct, only self-harm that is a Serious Event goes to the Department of Health.

**PRINCIPLE 16**

Principle 16a
Patient transfers are reportable only when they involve an event that meets one of the three definitions in MCARE: Serious Event, Incident, or Infrastructure Failure. Routine intra-hospital transfers to higher levels of care due to changes in the patient’s condition—in the absence of a precipitating event that would meet the definition of a Serious Event, Incident, or Infrastructure Failure—are not reportable.

**QUESTIONS**

Inter/intra hospital transfers
Regarding interfacility transfers, do these include behavioral health patients who suffer an injury (e.g., a fall) and who require transfer to the ED for evaluation?

Does this include primary care physicians (PCPs) who transfer their patients to the ED via ambulance for evaluation?

**RESPONSES**

Patient transfers, including behavioral health patients, are reportable when they involve an event that meets one of the three definitions in MCARE for a Serious Event, Incident, or Infrastructure Failure.

The facility must determine whether or not the transfer involves an event that meets the definition of one of the three definitions in MCARE for a Serious Event, Incident, or Infrastructure Failure. If it does, then it would be reportable. If it does not, it would not be reportable. Also refer to principle 16d: “Inpatient transfers from a specialty hospital to an acute care hospital or from one acute hospital to another acute hospital, due to the patient requiring clinical service not offered in the transferring hospital are not reportable.”

The key phrase of this principle is "in the absence of a precipitating event that would meet the definition of a . . . " One must determine if the transfer to a higher level of care due to changes in the patient's condition involved a precipitating event that meets the definition of a Serious Event, an Incident, or an Infrastructure Failure. If so, then the transfer is reportable.

Transfers from the PCP, when the PCP practice is under the facility license, would be reportable if the transfer meets the criteria outlined in this principle.
QUESTION

Unanticipated transfers
Given all the components of principle 16, under which circumstances would I use the following classification: Event type level 1 is J. Other/Misc. and sub-category level 2 is 6; unanticipated transfer to a higher level of care, and then I have 3 choices from which to select under the sub-category level 3?

RESPONSE

An unanticipated transfer to a higher level of care (either intrafacility or interfacility) would have to be precipitated by an event that meets one of the definitions in MCARE for a Serious Event, Incident, or Infrastructure Failure. If the precipitating event can be classified according to a non-other/miscellaneous event type (e.g., complication of procedure/treatment/test), then it would assigned to that event type and its subsequent subtype.

Principle 16c
Unanticipated intra-hospital transfers to higher levels of care due to an error or unanticipated complication of care are reportable as Serious Events.

QUESTION

Unanticipated Intra-hospital Transfers
Unanticipated intra-hospital transfers to higher levels of care due to an error or unanticipated complication of care are reportable as Serious Events. This is only if it meets the definition of a Serious Event, including a requirement of additional healthcare services that are not provided to prevent injury (i.e., patients who may be transferred to monitor for an injury but receive no additional treatment). Is this correct?

RESPONSE

Patient transfers are reportable when they involve an event that meets the definition of a Serious Event, Incident, or Infrastructure Failure. Transfers to a higher level of care due to a change in the patient’s condition are only reportable if there is a precipitating event that would meet the definition of a Serious Event, Incident, or Infrastructure Failure. The example in this question is of a patient who is transferred to monitor for an injury but who receives no additional treatment. To determine if this injury was a Serious Event, one first needs to evaluate if the injury was unanticipated. Second, one needs to determine what services are required for “monitoring” and if they fit the definition of additional healthcare services in response to the injury. Refer to the Serious Event Algorithm.
QUESTION

NICU Transfer (NAS Scores)
Infants who are transferred to the NICU due to increasing NAS scores (drug withdrawal): Are these considered unanticipated transfers that need to be reported and if so, as Incidents or Serious Events?

RESPONSE

Patient transfers are reportable when they involve an event that meets the definition of a Serious Event, Incident, or Infrastructure Failure. Transfers to a higher level of care due to a change in the patient’s condition are only reportable if there is a precipitating event that would meet the definition of a Serious Event, Incident, or Infrastructure Failure. The example in this question is of a patient with increasing NAS scores due to withdrawal. Refer to Principle 16a. One would need to determine if the precipitating event for the transfer, which in this case is the increasing NAS scores from withdrawal, meets the definition of a Serious Event, Incident, or Infrastructure Failure. Refer to 16c. One would need to determine if the increasing NAS scores from withdrawal was an unanticipated complication of care leading to an unanticipated transfer to a higher level of care.

QUESTION

Medical Event After Surgery
If a patient is admitted for an appendectomy and while recovering has an MI (either a patient with no known cardiac history or one who does have a cardiac history) and is transferred to the critical care unit, is that a Serious Event?

RESPONSE

First, the facility will need to determine if an unanticipated injury occurred. This will be specific to the case. Guidelines to consider are Principles 2, 3, 4, 7, and 10.
2. The unanticipated nature of the injury is from the perspective of a reasonably prudent patient. While every provider anticipates some rate of complications from the procedures they perform, infrequent complications are rarely anticipated by the patient unless the patient is somehow at increased risk. While the Authority does not specify an exact threshold for the frequency of complications that makes a particular complication transition from unanticipated to anticipated, complications that occur rarely would be unanticipated by most reasonably prudent patients.
3. The disclosure of a potential complication on a patient consent form does not, in itself, constitute anticipation of the complication by the patient. Informing the patient of a risk does not mean the patient or the provider anticipates that the untoward outcome will actually occur.
4. Complications may be considered anticipated (and therefore not meeting the Serious Event definition) when they occur frequently or the risk of the complication is considered high for a particular patient and the high probability of this complication was disclosed to the patient in the informed consent discussion and documented either on the consent form or medical record.
7. The event, occurrence, or situation that caused the death or unanticipated injury may be unknown but may still constitute a Serious Event. For example, a healthy (ASA I) patient undergoing elective surgery dies unexpectedly during the procedure and the cause of death is unknown.
10. Deaths or injuries resulting from the patient’s disease, in the absence of a contributing event, occurrence or situation, are not Serious Events.

QUESTION

Worsening Condition
If a patient is on the medical floor for possible stroke, the condition worsens, and the patient is transferred to the critical care unit, is this reportable?

RESPONSE

The facility will need to determine if the patient’s worsening condition was attributed to a precipitating event that meets the definition of a Serious Event, Incident, or Infrastructure Failure. If the transfer was due to changes in the patient’s condition without a precipitating event, then this transfer would not be reportable.

See Principles 16a and 16c.

16 a. Patient transfers are reportable only when they involve an event that meets one of the three definitions in MCARE: Serious Event, Incident, or Infrastructure Failure. Routine intra-hospital transfers to higher levels of care due to changes in the patient’s condition—without a precipitating event—that would meet the definition of a Serious Event, Incident or Infrastructure Failure—are not reportable. 16c. Unanticipated intra-hospital transfers to higher levels of care due to an error or unanticipated complication of care are reportable as Serious Events.

QUESTION

If a patient is on a MH or rehab unit and needs to be transferred to the medical/critical care floor, would that need to be reported as a serious condition? The assumption is that none of these situations had any kind of error involved. Based on what is listed as information in 16a and d, I would say no to this question.

RESPONSE

The facility will need to determine if the patient’s worsening condition was attributed to a precipitating event that meets the definition of a Serious Event, Incident, or Infrastructure Failure. If the transfer was due to changes in the patient’s condition without a precipitating event, then this transfer would not be reportable.

See Principles 16a and 16c. 16a. Patient transfers are reportable only when they involve an event that meets one of the three definitions in MCARE: Serious Event, Incident, or Infrastructure Failure. Routine intra-hospital transfers to higher levels of care due to changes in the patient’s condition—without a precipitating event—that would meet the definition of a Serious Event, Incident, or Infrastructure Failure—are not reportable. 16c. Unanticipated intra-hospital transfers to higher levels of care due to an error or unanticipated complication of care are reportable as Serious Events.
**Principle 16d**
Inpatient transfers from a specialty hospital to an acute care hospital, or from one acute hospital to another acute hospital, due to the patient requiring a clinical service not offered in the transferring hospital are not reportable.

**QUESTION**

**Transfer from a Specialty Hospital**
I do have a question in respect to acute care transfers [from specialty hospital to acute care hospital] and whether we need to report any longer. As it currently stands, if a patient exhibits a change in condition and we transfer to the acute care hospital, I enter a report for an Infrastructure Failure for the acute care transfer. Examples would be change in mental status, respiratory distress, and hypernatremia (patient admitted day prior from a skilled nursing facility). Given the language from Principle 16, how do I now report?

**RESPONSE**
The key phrase of this Principle is "in the absence of a precipitating event that would meet the definition of a . . . ." One must determine if the transfer to a higher level of care due to changes in the patient’s condition involved a precipitating event that meets the definition of a Serious Event, an Incident, or an Infrastructure Failure. If so, then the transfer is reportable. Refer to 16c: Unanticipated intra-hospital transfers to higher levels of care due to an error or unanticipated complication of care are reportable as a Serious Event.

**QUESTION**

**Transfers due to Bed Availability or Specialty**
In the Final Guidance document of 9/27/14, I interpret the following, am I correct? If you have a specialized unit (e.g., mental health) and you do not have bed capacity to take a patient who is in your ED (or, for example, the patient is in the ICU on an overdose) and the patient must be transferred from either an IP unit or the ED to another hospital with MH unit, it would not need to be reported as an Infrastructure Failure. If it took >6 hours to facilitate the transfer from the ED, then it would be reported as an ED boarding Incident.

**RESPONSE**
This is reportable because there is an issue with the infrastructure, in that the facility is at capacity and not able to accommodate those who need a service that the hospital otherwise provides. If wait time exceeded six hours, it would also be a separate report. Please see Principle 16d: Inpatient transfers from a specialty hospital to an acute care hospital or from one acute hospital to another acute hospital due to the patient requiring a clinical service not offered in the transferring hospital are not reportable.
QUESTION

If a pediatric patient needs intensive care, we do not have a PICU, and the patient needs to be transferred to another facility, is this reportable?

RESPONSE

See Principle 16d: Inpatient transfers from a specialty hospital to an acute care hospital or from one acute hospital to another acute hospital due to the patient requiring a clinical service not offered in the transferring hospital are not reportable.
PRINCIPLE 17
Consistent with the National Quality Forum-endorsed measure “percentage of Ambulatory Surgery Center (ASC) admissions requiring a hospital transfer or hospital admission upon discharge from the ASC,” when a patient admitted to an Ambulatory Surgery Facility (ASF) requires transfer to a hospital, these events are reportable as Incidents unless criteria for Serious Event are present.

QUESTION

Cancellations/transfers/admissions from Pre-op
Do ASFs have to report cancellations and transfers or admissions of patients [to the hospital] for conditions (e.g., Atrial Fib) that are identified in the pre-op area on day of surgery? If so, is that 2 reports (one for cancellation and one for transfer)?

RESPONSE

These events are reportable as Incidents unless criteria for a Serious Event are present. One report, submitted as a transfer, will suffice.

Principle 17A
Hospital Transfer/Admission: Any transfer/admission from an ASF directly to an acute care hospital, including hospital emergency room.

QUESTION

Emergency room after colonoscopy
We are an ASF that specializes in GI and on occasion have patients go to the Emergency [Department] for evaluation of pain post colonoscopy or EGD. This usually occurs after discharge within 24 hours of the procedure. Is this reported as an Incident? If they are admitted for 23 hours observation, is this an Incident? If surgery or another procedure such as another colonoscopy is required—is this a Serious Event?

RESPONSE

A facility’s obligation to report a transfer ends at discharge. However, that does not negate the obligation to report other events such as Incidents or Serious Events that they become aware of after discharge. The determination as to whether an event, occurrence, or situation meets the definition of an Incident or Serious Event lies with the facility. Refer to Program Memorandum No. 2015-02: Interpretation of the Definition of Serious Events Used by the Pennsylvania Patient Safety Reporting System Analysts.
**Principle 17b**
Intra-operative transfer from an ASF to a hospital is reportable as a Serious Event.

**QUESTION**

Intra-operative transfer from an ASF to a hospital
Any patient transferred from ASC is Incident (Intraoperative - Serious). Is it reportable as a transfer regardless if the patient goes to ED by ambulance or by family car?

**RESPONSE**

Principle 17 identifies that "Consistent with the National Quality Forum-endorsed measure ‘percentage of Ambulatory Surgery Center (ASC) admissions requiring a hospital transfer or hospital admission upon discharge from the ASC,’ when a patient admitted to an Ambulatory Surgery Facility (ASF) requires transfer to a hospital, these events are reportable as Incidents unless criteria for Serious Event are present.” Principle 17b states "Intra-operative transfer from an ASF to a hospital is reportable as Serious Event." The method of transportation is not a determinant.

**Principle 17c**
The Ambulatory Surgical Facility’s reporting obligation ends after discharge.

**QUESTIONS**

**Ambulatory Surgical Facility Reporting Obligation**
Does the wording “The ASF’s reporting obligation ends at discharge” apply only to transfers or does it apply to any/all events that may occur after discharge in which there are complications associated with the surgical procedure (e.g., surgical site infection), whether or not they require transfer?

Still unclear about what ASC reporting requirement ends after discharge means in light of the training that says a patient who is discharged from ASC and then next day is admitted for complication is a Serious Event. I thought the reporting requirement ends at discharge. REPHRASED: If a patient was admitted next day with event, it would still need to be reported as Serious Event. What is the point of the statement? If it is as indicated, the reporting requirement for transfer ends at discharge, that makes no sense either—the transfer is the discharge—it is a redundant statement.

**RESPONSE**
The facility’s obligation to report a transfer ends at discharge. However, the Principle does not negate the facility's responsibility to report other events that meet the definition of a Serious Event, including those it becomes aware of after discharge.
PRINCIPLE 18

Elopement of a patient who has been involuntarily committed or is in the process of being involuntarily committed is reportable as an Infrastructure Failure. If the patient is injured during the elopement, this is reportable as a Serious Event.

QUESTION

Non 302 Elopements
I have a question regarding ED elopement (for a patient NOT in 302 process). This option is no longer available. Is it still reportable to the DOH? I got the impression from a JCR update that it was no longer reportable, but have gotten other feedback from colleagues. Can you clarify for me or at the very least direct me to how it should be entered?

RESPONSE

Elopements from the ED that involve a patient in the 302 process are reportable. While not specified, it is implied that other elopements (those not involving a 302) from the ED are not reportable. However, this does not relieve a facility of its responsibility to take other measures it deems appropriate to ensure patient or public safety.

Principle 18a: Patients leaving the ED waiting room or treatment area without being seen are not reportable unless they are in the 302 process.

Principle 18b: Elopement of a patient who has been involuntarily committed or is in the process of being involuntarily committed is reportable as an Infrastructure Failure. If the patient is injured during the elopement, this is reportable as a Serious Event.

An ED patient in the 302 process who eloped with injury would be a Serious Event and classified as F.3.C. A patient in the 302 process who eloped with no injury would be an Infrastructure Failure and classified as T.4. –Elopement/AWOL-no injury.

Principle 18a

Patients leaving the ED waiting room or treatment area without being seen are not reportable unless they are in the 302 process.

QUESTION

302 Elopements
The training stated that only 302 patients who elope are reportable. For all others, they use the language patients who leave the waiting room/treatment [area] "without being seen." If the patient was seen by the physician and elopes (but does not sign AMA), is this reportable?
RESPONSE

Patients who leave the ED without being seen are not reportable unless they are in the 302 process. The patient has the right to leave the facility unless they are in the 302 process. Refer also to Principle 20. Patients who leave against medical advice, regardless of whether they sign a waiver or not, are not reportable. This does not relieve the facility of its responsibility to take other measures it deems appropriate to ensure patient or public safety.

Principle 18b

 Elopement of a patient who has been involuntarily committed or is in the process of being involuntarily committed is reportable as an Infrastructure Failure. If the patient is injured during the elopement, this is reportable as a Serious Event.

QUESTION

A facility has a psych patient in the ED for over 24 hours until the facility is able to locate an accepting facility and occasionally has patients elope from the treatment rooms. The facility has been reporting all elopements as Infrastructure Failures but is questioning this practice after reading the new guidance.

RESPONSE

Refer to Principle 18b, if a patient has been involuntarily committed or is in the 302 process, the elopement is reportable as an Infrastructure Failure. In the example given in this question, patients are being boarded in the ED for over 24 hours until an accepting facility is located. Refer to principle 22. Boarding patients in the ED more than six hours after the physician has determined they meet discharge criteria is reportable as an Infrastructure Failure. Discharge refers to discharge from the ED and includes admission to the hospital or specialty unit and/or transfer to another facility. Discharge in this principle actually refers to disposition decision.

QUESTIONS

Are all elopements from the ED an Infrastructure Failure or only those which involve a psych patient? Also the new principle states that ED elopements are NOT reportable unless the patient is committed or in process of being committed. However, inpatient elopements ARE Infrastructure events. Are these assumptions correct? (18a talks about ED left without being seen; 18b discusses ED involuntary elopements—I didn’t see “regular” ED elopements; 20 discusses AMA.)

Scenario: ED patient left the facility after treatment was started and did not notify staff. The patient is not involved in a 302 commitment process, and the elopement did not result in an injury. This scenario is not addressed by Principle 18, which applies to ED patients who have not been seen/treated. This scenario is not addressed by Principle 19, which applies to inpatients. This scenario is not addressed by Principle 20, which applies to patients who leave against medical advice. Under what circumstances would this scenario be reportable?
RESPONSE

If the patient has been involuntarily committed or is in the process of being involuntarily committed (the 302 process), the elopement is reportable as an Infrastructure Failure. Elopements from the ED that involve a patient in the 302 process are reportable. While not specified, it is implied that other elopements (those not involving a 302) from the ED are not reportable. However, this does not relieve a facility of its responsibility to take other measures it deems appropriate to ensure patient or public safety. Inpatient elopements are reportable. Patients who leave against medical advice, regardless of whether they sign a waiver or not, are not reportable. The patient has the right to leave the facility unless they are in the 302 process. This does not relieve the facility of its responsibility to take other measures it deems appropriate to ensure patient or public safety.

Again, this does not relieve a facility of its responsibility to take appropriate measures to ensure patient or public safety. Please see Principles 18a, 18b, 19, and 20.

18. Patients leaving the emergency department (ED) without being seen/treated: a. Patients leaving the ED waiting room or treatment area without being seen are not reportable unless they are in the 302 process. b. Elopement of a patient who has been involuntarily committed or is in the process of being involuntarily committed is reportable as an Infrastructure Failure. If the patient is injured during the elopement, this is reportable as a Serious Event.

19. Inpatient elopements are reportable as Infrastructure Failures. If an eloped patient is injured during an elopement, this is reportable as a Serious Event.

20. Events in which a patient leaves against medical advice (AMA), whether or not they sign a waiver, are not reportable.
**PRINCIPLE 21**

Use of unlicensed beds for patient care or patients receiving treatment in an area not designated for patient care (e.g., hallways, atrium, quiet room, tent on grounds) is reportable as an Infrastructure Failure. One report may cover multiple patients, provided the number of patients is specified.

**QUESTION**

**Capacity Event Involving Multiple Patients**

Could you provide guidance on the following scenario: When entering a Capacity event involving multiple patients, what harm score should be selected? There is the possibility of varying degrees of harm—which should be reported?

**RESPONSE**

The definition of an Infrastructure Failure is an undesirable or unintended event, occurrence, or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service that could seriously compromise patient safety. By the nature of this definition, any level of harm that could be assigned to an Infrastructure Failure would be anticipatory, because harm has not actually occurred to a patient. If a level of harm above a harm score of A is being considered, one should evaluate whether the event is an Incident or Serious Event.

**QUESTION**

**Capacity Event Involving Providing Care in the Hallway of the ED**

Request further clarification of Principle 21. Scenario: ED exceeds capacity of available beds for a period of several hours in a day. Several patients receive treatment in beds located in a hallway of the ED. How do we report the number of patients affected? In an example, the condition of being over capacity may start at 11:00 a.m., which currently triggers the need to file a report to the hospital’s in-house incident reporting system at that time. Since the condition will continue for several hours after the report is filed internally, the total number of patients affected will not be known until the end of that 24-hour period. Should the internal incident reporting be held until after midnight so that a total number of affected patients can be obtained for the previous day, rather than filing a report when the exceeded capacity condition begins? Do they report every shift or once per day?

**RESPONSE**

Reporting on a daily basis is acceptable. The reporting is from midnight to midnight. Thus, if a patient is admitted at 11:59 p.m. and stays until 1:00 a.m. the next day, they would be counted on both daily censuses. Reports for capacity may be entered on a daily basis in order to capture a full 24-hour period.
QUESTION

The term “unlicensed”
When submitting unlicensed bed infrastructures, does the term “unlicensed” refer to unlicensed inpatient beds and not refer to outpatient care areas?

RESPONSE

A hospital license covers all the services billed under the hospital provider number, which would include any inpatient or outpatient services provided and billed under that provider number.

Refer to principle 21: use of unlicensed beds for patient care or patients receiving treatment in an area not designated for patient care is reportable as an Infrastructure Failure. There are two distinct considerations when evaluating the use of unlicensed beds: licensed beds and designated treatment areas.

The first question one must ask is whether the patient receiving treatment or care in a bed that is not covered by the license. If the patient is receiving care in a bed not covered under the license, then you would submit an Infrastructure Failure report. Second, is the patient receiving care in an area not designated for patient care? This criterion is not dependent on the number of licensed beds. If a patient is receiving care or treatment in an area not designed for providing treatment (such as a hallway, tent, atrium, or quiet room), then you would submit an Infrastructure Failure report.
PRINCIPLE 22

Boarding patients in the emergency department (ED) or post anesthesia care unit (PACU) more than six hours after the ED or PACU physician has written the discharge order is reportable as an Infrastructure Failure.

QUESTION

Boarding Patient in an Non-Patient Care Area
If a patient is boarded in the ED and is in an area not designated for patient care, should that patient be reported twice? (Once for boarding patients and once for treating patients in an area not designated for patient care.)

RESPONSE

The patient who is boarded in the ED and is also being treated in an area not designated for patient care (e.g., hallway) should be reported as an Infrastructure Failure for boarding and as an Infrastructure Failure for treating patients in an area not designated for patient care. In other words, there should be two Infrastructure Failure reports. As a reminder, these reports are to be submitted daily.

QUESTION

Boarding Applicability and Duration
Our interpretation of this infrastructure reporting requirement is [that it is] not applicable to admitted patients from ED/PACU but for “boarded patients” who are “discharged” from the ED/PACU and have not left the ED/PACU. There is no mention of admission in the language of this requirement, and physicians in the ED do not write a discharge order for patients who are admitted into the hospital. Examples may be homeless patients, natural disaster in the community, or no one available to care for/pick up patient.

RESPONSE

Boarding patients in the ED or PACU more than six hours after the ED or PACU physician has written the discharge order is reportable as an Infrastructure Failure. For the purposes of this Principle, transfer, discharge, and admission orders are synonymous. The duration of the "boarding" condition should start when the patient meets physiologic criteria for transfer or discharge, and waiting for a bed to become available is an infrastructure issue unrelated to the patient's transfer, discharge, or admission criteria.
**QUESTIONS**

**Applicability**
Does this principle apply hospital-wide (i.e., not just in the ED)? For example, for boarding - it states PACU, would it also include boarding in other post procedure recovery areas like Cath Lab? For boarding [in the] ED, would psych patients waiting for placement in a psychiatric facility be counted in the boarding numbers? If a patient is boarded in the ED for >24 hours, should they be included on each day’s report?

**RESPONSE**
While this principle specifically mentions the ED and PACU, other postprocedure recovery areas such as the cardiac catheterization lab, endoscopy recovery areas, and interventional radiology recovery areas would be included as applicable.

**QUESTION**
We noted that PSRS did not take the opportunity to create an IF [Infrastructure Failure] type for patients in ASC >4 hours. Is that still required to be reported?

**RESPONSE**
Extensions of surgery or recovery time beyond the four-hour window are reportable. The facility would need to evaluate why the four-hour window was exceeded and determine whether the event meets the definition of a Serious Event or Infrastructure Failure.

**QUESTION**
Conditional Order
What if it's a conditional order - e.g., discharge after taking p.o. well - does the time limit (the 6 hours) begin when the order is written or when the criteria for discharge, admission, or transfer (e.g., patient is taking p.o. well) are fulfilled?

**RESPONSE**
Boarding patients in the ED or PACU more than 6 hours after the ED or PACU physician has written the discharge order is reportable as an Infrastructure Failure. In those instances in which the order is conditional (e.g., “Discharge when tolerating oral liquids”) and once the physiologic criteria for discharge are fulfilled, that time should not be considered a delay caused by an Infrastructure Failure. The duration of the "boarding" condition should start when the patient meets physiologic criteria for transfer or discharge, and waiting for a bed to become available is an infrastructure issue unrelated to the patient’s transfer, discharge, or admission criteria.
QUESTION
Boarding in Licensed ED/PACU Beds
My question is about boarding patients in LICENSED beds in PACU and ED. Can one IF report indicating how many patients suffice for IF re: boarding pts in ED or PACU >6 hours or do we need to enter one for each patient?

RESPONSE
This principle refers to patients being boarded in the ED or PACU for more than six hours after the ED or PACU physician has written the discharge order as reportable as an Infrastructure Failure. Reports for capacity may be entered daily in order to capture a full 24-hour period. Reporting daily is acceptable. The reporting is from midnight to midnight. Thus, if a patient is admitted at 11:59 p.m. and stays until 1:00 a.m. the next day, they would be counted on both daily censuses. One report may cover multiple patients, provided the number of patients is specified. Please refer to FAQs related to Principle 21.

QUESTIONS
Boarding Psychiatric patients & Elopements
For Boarding - ED - would psychiatric patients waiting for placement in a psychiatric facility be counted in the boarding numbers? If a patient is boarded in the ED for >24 hours, should they be included on each day’s report?

Should I report all transfers/admissions as an infrastructure which take longer than 6 hours for the patient to be moved out of the ED and/or transferred? Ex) A facility that has a psych patient in the ED for over 24 hours until facility is able to locate an accepting facility and occasionally has patients elope from the treatment rooms. The facility has been reporting all elopements as infrastructures but questioning this practice after reading the new guidance.

RESPONSE
The psychiatric patient that is boarded (waiting for placement) in the ED for greater than 6 hours should be reported as an Infrastructure Failure for boarding. Additionally, as covered in Principle 18 and 18a: “Patients leaving the ED waiting room or treatment area without being seen are not reportable unless they are in the 302 process. Elopement of a patient who has been involuntarily committed or is in the process of being involuntarily committed is reportable as an Infrastructure Failure.” In other words, that patient should be counted on both reports. Furthermore, if the patient is injured during the elopement, this is reportable as a Serious Event. For further information on elopements refer to previous FAQs on principle 18 and 18a.

QUESTION
When submitting boarding infrastructures, does the term “discharged” patient include patients being discharged to another facility or home or only to an inpatient unit? When patients are in outpatient care
areas (example interventional radiology or cardiac catheterization labs) and have procedures and are then boarded greater than 6 hours in the outpatient care area, is that an Infrastructure Failure?

RESPONSE

While this principle specifically mentions the ED and PACU, other postprocedure recovery areas such as the cardiac catheterization lab, endoscopy recovery areas, and interventional radiology recovery areas would be included as applicable.

QUESTION

Typically, the ED uses “disposition orders,” not discharge orders. Can that suffice to track potential boarders (>6 hours), and is the intent of this required reporting to address admitted patients?

RESPONSE

Boarding patients in the ED or PACU for more than six hours after the ED or PACU physician has written the discharge order is reportable as an Infrastructure Failure. For the purposes of this principle, “transfer,” “discharge,” “disposition,” and “admission order” are synonymous.
**Principle 24b**
Fire alarms that warrant activation of a facility’s internal fire response plan are reportable as Infrastructure Failures. A fire alarm resulting from an occurrence or cause that is clearly and immediately identified and does not require activation of the facility’s internal fire response plan is not reportable.

**QUESTIONS**

Fire alarms
Internal activation of hospital responders can occur for many reasons that do not include actual smoke or fire. Does any activation of hospital responders require reporting?

What if a young child pulls the fire alarm? Is this reported as an IF or not? If it’s immediately identified?

**RESPONSE**
If the occurrence or cause is clearly and immediately identified and does not require activation of the facility’s internal fire response plan, then the occurrence is not reportable.

Please reference case studies and rationale slides for principle 24a and 24b found in the online curriculum for Final Guidance for MCARE reporting. These slides provide scenarios that will further help to understand reporting requirements for this principle.

Case study examples and rationales are below:
24a: A small fire starts at the grill area in the kitchen. The facility staff are present and are able to extinguish the fire immediately. There is no damage, and the fire alarm did not activate. This is reportable as an Infrastructure Failure because any fire of any kind is reportable.

24b 1: The facility fire alarm is activated by the smoke detector system. Facility staff respond to the area as outlined in their emergency response plan. The source of the activation is identified as a toaster in the nursing lounge. There is no actual fire. This is reportable as an Infrastructure Failure because the fire alarm activated the facility’s internal fire response plan.

24b 2: While cleaning the smoke detectors, a facility maintenance staff member inadvertently activates the alarm system. The switchboard operator is immediately notified, and an “all clear” message is sent before facility staff respond to the alarm. This is not reportable because the cause was immediately identified and the facility’s internal emergency plan was not activated.
Principle 25a
Many patient safety concerns involving health IT are already reported under Event Types associated with Serious Events and Incidents, such as medication errors, laboratory test-related errors, and radiology errors.

QUESTION

HIT
Provide a definition of what health IT means (operational definition)

RESPONSE

Health information technology (IT) encompasses a technical system of computers, software, and devices that operate in the context of a larger sociotechnical system—a collection of hardware and software working in concert within an organization that includes people, processes, and workflows (IOM. Health IT and Patient Safety: Building Safer Systems for Better Care, 2012, p. 21). Health IT is not one specific product that, once implemented, can automatically result in highly safe and effective healthcare. In general, health IT is composed of components that include, but are not limited to, computerized provider order entry (CPOE) systems, clinical decision support (CDS) systems, laboratory information systems (LIS), picture archiving and communications systems (PACS), and more. Please refer to the Final Guidance for MCARE reporting curriculum slides 1.18 to 1.21 in module 3. These include screenshots of health IT–related questions for submitted event reports.
PRINCIPLE 26
Healthcare-associated infections that meet CDC definitions/criteria and that a hospital reports into NHSN should not also be reported through PA-PSRS.

QUESTION
Reporting Healthcare-associated Infections
Does an HAI treated empirically that doesn’t meet the CDC surveillance definition also not need to be reported in PSRS?

RESPONSE
This principle exists to prevent hospitals from having to report HAIs (which meet CDC definitions/criteria) through both NHSN and PA-PSRS. If the HAI meets the CDC definition/criteria and you are reporting it to NHSN, then you do not also have to report it through PA-PSRS.

CDC sets the national criteria standards for surveillance of HAIs. A hospital would apply the current CDC HAI criteria in order to determine an HAI for reporting into NHSN. When an infection is encountered, that through careful review falls outside CDC/NHSN reporting criteria, it would not be reported through NHSN or PA-PSRS. Pennsylvania hospitals are required to confer NHSN rights to the Authority; NHSN is the accepted mechanism for reporting hospital HAIs to the Authority.

Depending on the infection type (reportable or not), the infection may be reportable to the local or state department of health if the infection is listed on the state communicable disease reporting list.

PRINCIPLE 27
Unplanned power failures involving backup generator deployment or in which the backup generator fails to deploy are reportable as Infrastructure Failures.

QUESTION
Power Failure in an ASF After Hours
If an ASF experiences a power failure after hours and they are unable to open the following day because the power failure continues, is this a reportable Infrastructure Failure? Assume patients were all notified before the day of service that they would need to be rescheduled.
RESPONSE

Unplanned power failures are reportable as Infrastructure Failures. See Principle 27: Unplanned power failures involving backup generator deployment or in which the backup generator fails to deploy are reportable as Infrastructure Failures.

OTHER QUESTIONS

Certificate of Training

QUESTION

I just completed the training modules for the new standards of reporting requirements under the MCARE act. I received my certification online; however, I was also completing/learning the modules with two other individuals. How can they receive their own certification?

RESPONSE

In order to receive a CE certificate, each person must register and successfully complete the required modules for the Final Guidance for MCARE Reporting curriculum. The certificate is only issued to the name of the person that is entered in the registration profile. Multiple names cannot be supplied here.

QUESTION

Does a certificate need to be produced at time of survey for all PSRS users?

RESPONSE

The LMS training on Final Guidance for MCARE Reporting is not mandatory for users. We recommend that the training certificates are treated in the same manner as any other continuing education in your organization. In addition, please remember that as a licensed registered nurse in Pennsylvania, your continuing education credits may be audited by the licensing board.

Blank Event Forms

QUESTIONS

Will there be updated blank event forms on the PA-PSRS site to reflect the taxonomy changes and can you tell me if the new PSRS entry forms will be asking any additional questions that we need to add to our system? For example, when you changed the fall forms, we were told that there would be new questions. Since we were not told of any additional questions (ex. Self Harm), does that mean there will not be any? We are concerned about going live with our system changes until we see the PSRS changes on April 1. But if you can tell us before April 1, that would be helpful.
RESPONSE

The blank PSRS event forms have been updated to reflect the new reporting requirements and taxonomy changes. They are located under the Resources tab in PA-PSRS.

Taxonomy

QUESTION

Would you have the updated PA - Event type taxonomy list available to share with me so that I can share with staff? It is at the end of the previous PA training manual but is currently not updated.

RESPONSE

The new PA-PSRS taxonomy is available on the PSA website and is located under the Resources tab in PA-PSRS.

Printing of Final Guidance LMS Training Slides

QUESTIONS

Do you know if there is a way we can have the new training in a format that is easy to print out? Some of the girls have been trying to print out the presentations for reference, and you have to print out the slides one by one. Just wondering if there is a better way to do this so we have it for quick reference.

Is there a document that contains the examples/questions/scenarios provided in the training modules? These would be very beneficial to use during the training of our physicians and administrative leaders.

RESPONSE

Currently, printing functionality is not available for this LMS publication and there is not a document that contains the examples from the online learning. This request will be taken into consideration for future online learning events. Please note that anyone can take the online training, you will just need to forward the registration link to them. If you have additional training needs in your facility, please contact your PSL and we will work with you to meet your facility's needs.
**Principles Clarification re: June 2009 12 Principles**

**QUESTION**

The Final Guidance document—in the training modules offered, #’s 1-28 are referred to as “Principles.” Do these “Principles” replace previous 12 Principles that were agreed upon by the Patient Safety Authority Board June 9, 2009?

**RESPONSE**

The principles that were agreed upon by the Patient Safety Authority Board in June 2009 were never agreed upon by the Pennsylvania Department of Health; therefore, there was no final resolution on those principles. However, the 2009 principles were used as the basis for the Final Guidance reporting standardization project. To keep it simple and not get caught up in semantics, the principles published in September 2014 do replace the guidance from 2009.

**Information Regarding New Fields**

**QUESTION**

Is there any further information/guidance regarding the following new fields: a. Infrastructure Failure – Administration management – incomplete/incorrect order entry information b. Incident/Serious Event-Other – Inappropriate discharge?

**RESPONSE**

These events, incomplete/incorrect order entry information and inappropriate discharge, are not new to PA-PSRS per se. They were either renumbered or recategorized in the taxonomy. The Final Guidance was published to address some of our most common inconsistencies in reporting; it did not address these specific event types.

**Unplanned EMR downtime**

**QUESTION**

Unplanned EMR downtime is an Infrastructure Failure (new subcategory S. Physical Plant... 5. Unplanned EMR downtime). Is this regardless of whether patient care was affected? Is it regardless of the length of time it was down?

**RESPONSE**

Any unplanned EMR downtime is reportable as an Infrastructure Failure. We consider EMR an essential piece of the patient care infrastructure and thus treat the reporting as we would reports of generator failure.
Narcotic Discrepancy

QUESTION

Under the category of “V. Criminal / Potentially Criminal or Illegal Activity, revised subtype, 6. Narcotics discrepancy,” are new subcategories “a. Solved” and “b. Unsolved.” This subtype now includes solved discrepancies even if handled appropriately (for example, a miscount in Pyxis that is fixed, the drawer is shut accidentally). Is this reportable?

RESPONSE

This is reportable under the new section because there was a narcotic discrepancy but it has been appropriately handled and all narcotics are accounted for.

QUESTION

I am e-mailing to ask a question please, regarding F-Medication Safety. I am aware that this option/report has been retired in PSRS. Are missing narcotics still considered a 24-hour reportable event? If so, can you please direct me as to where I might find this option?

RESPONSE

Narcotics discrepancies are still reportable as Infrastructure Failures. They can be found in section V. Criminal/Potentially Criminal or Illegal activity 6. Narcotics discrepancies or 7. Drug diversion/theft. All Infrastructure Failures are reportable within 24 hours.

Request for Final Guidance Program Memorandum

QUESTION

How can I obtain the Final Guidance–related program memorandum and training information?

RESPONSE

Thank you for contacting the PA-PSRS help desk. I have included some links that will be helpful regarding the Final Guidance for acute healthcare facilities. On April 1, 2015, PA-PSRS was modified to address 28 standardized reporting Principles for acute healthcare reporting facilities.

You can access Program Memorandum No. 2015-01: Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements under the Medical Care Availability and Reduction of Error (MCARE) Act.

You can access the Program Memorandum No. 2015-02: Interpretation of the Definition of Serious Events Used by the Pennsylvania Patient Safety Reporting System Analysts—Updated
since the Release of the Authority’s Final Guidance for Acute Healthcare Facilities Determination of Reporting Requirements Under the Medical Care and Reduction of Error (MCARE) Act 13 (September 27, 2014.)

Infrastructure Failure change in reporting re: Incident involving zero or multiple clients

**QUESTION**

Recently I noticed a change to the infrastructure report in the PA-PSRS system: "Incident involving zero or multiple clients." Soon after I started to use this check box, I was called by the state staff member assigned to reviewing my PA-PSRS reports; she said that several of my reports were showing with no birthdates. I explained that I am unable to enter a report without a birthdate. I believe by clicking this box, the reports are showing up without ages.

I have two questions related to this item:

- Should I be using this check box?
- If I use the check box, should I then be entering the encounter for both patients in the same PA-PSRS report? I had previously been entering them in separate reports.

**RESPONSE**

That check box is for events such as activation of the emergency plan, EMR downtime, and so on. These are things that affect an entire department or institution. The check box was not intended to cover more than one patient for other types of events—for example, patient-to-patient abuse. The other example would be boarding a patient or caring for patients in areas not designated for patient care (but this is more for the ED).
PA Bulletin list of preventable serious adverse events

QUESTIONS

In August 2009 (separate from the draft guidance at that time) Feb 2009, The Pennsylvania Bulletin 939 PaB.4955) Saturday August 15, 2009, published Notice of List of Preventable Serious Adverse Events. This list is also under reportable serious events by the National Quality Forum, as noted in the Bulletin. Question: Are all of these listed in effect? If so, are they reportable as Serious Events regardless if there was harm/injury to the patient?

If the list is applicable regardless of harm, what falls under the unintended retention of a foreign object in a patient after surgery or other procedure? Specific example: needle breaks off in a patient during surgery, unable to retrieve, risk of harm for retrieval is greater than leaving it in. Is this reportable as a Serious Event? If so, does the size of the needle make any difference?

RESPONSES

Facilities are required to follow the Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements under the MCARE Act. Of note, the events on the NQF list (from both 2009 and currently) are likely to also meet the definitions set forth in MCARE and should be reported as such.

The additional diagnosis of a retained foreign body is generally considered a Serious Event. In addition, the fact that the risk outweighs the harm of removal does not change the consideration of whether it is a Serious Event. Please see principle 9. Additional care services b. “If a patient sustains an unanticipated injury and additional healthcare services are possible but the risk of those services outweighs the negative consequences of the injury, this is considered a Serious Event.”

While the guidelines do not specifically address an example such as this, if the facility is unsure of whether an event actually occurred (in this case, a potential retained foreign body), the facility should consider reporting this event as a Serious Event, along with full disclosure to the patient. A reasonably prudent patient would expect that the potential of a retained foreign body is disclosed to him/her.