NOTICES

PATIENT SAFETY AUTHORITY AND DEPARTMENT OF HEALTH

Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements under the Medical Care Availability and Reduction of Error (MCARE) Law

[citation] [date]

Purpose

This document outlines final guidance to Pennsylvania acute healthcare facilities in making determinations about whether specific occurrences meet the statutory definitions of Serious Events, Incidents, and Infrastructure Failures as defined in Chapter 3 of the Medical Care Availability and Reduction of Error Act of 2002. This guidance was developed by a multidisciplinary work group consisting of staff from the Patient Safety Authority (Authority), two physician members of the Authority’s Board of Directors, and the Department of Health (the Department), as well as representatives of the Hospital and HealthSystem Association of Pennsylvania (HAP), the Hospital Council of Western Pennsylvania (HCWP), and the Pennsylvania Ambulatory Surgery Association (PASA). The work group included individuals with backgrounds in medicine, nursing, administration and facility operations, regulation, and patient safety and healthcare quality. Draft guidance was issued for public comment on January 4, 2014, and this document includes the agencies’ response to the 53 letters received.

This guidance was developed to provide consistent and clear standards for MCARE’s reporting requirements so that the Authority, the Department, and healthcare facility staff have a shared understanding of the requirements. The subjects of these requirements were identified based on frequently asked questions, controversies, and inconsistencies that are evident in the data collected by the Authority and the Department. They include many subjects identified in a 2009 draft guidance document the Authority issued for public comment which was never subsequently issued as final guidance from the Authority and the Department.
Implementation

The principles below have been approved by the Patient Safety Authority and the Department of Health. The agencies are in the process of modifying PA-PSRS to support implementation of these standards and developing an education program to inform Patient Safety Officers and other stakeholders of these changes. Education will be made available prior to changes taking effect in PA-PSRS. Current plans are to have the new standards go into effect on April 1, 2015.

Statutory Definitions of Reportable Events

Serious Event: 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 health care services to the patient.

Incident: An event, occurrence, or situation involving the clinical care of a patient in a medical facility, which could have injured the patient, but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient.

Infrastructure Failure: An undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.

Final Guidance on Reporting Standards

The final guidance on reporting standards appears below. Some of these standards have been revised in response to feedback we received during the public comment period. Descriptions of all comments received and our responses to those comments appear in the subsequent section.

Interpretations of Serious Event Definition & Component Terms

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.
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.
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.

5. A Serious Event that is within statistical norms or within benchmarks available in the clinical literature must still be reported. There is nothing in the law that allows for reporting Serious Events only when they exceed a statistical norm or benchmark.

6. A Serious Event can include an unanticipated event, occurrence or situation that: a) hastens death (as in a terminally ill patient); or b) exacerbates a preexisting condition requiring additional health care services.

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.

8. Any unnecessary invasive procedure or invasive procedure performed in error that carries risk for the patient constitutes an injury, and performance of the correct or intended procedure then constitutes additional healthcare services. These occurrences are Serious Events.

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.

Exclusions

10. Deaths or injuries resulting from the patient's disease, in the absence of a contributing event, occurrence or situation, are not Serious Events.

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.

12. A mid-procedure change in the plan of care in response to new information discovered during the procedure does not constitute an injury.

13. Additional healthcare services:
   a. Healthcare services provided to prevent an injury from occurring are excluded from this term for the purpose of Serious Event determinations.
   b. 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.
c. Non-invasive diagnostic services provided to rule out an injury (e.g., x-ray following a fall) do not constitute additional healthcare services for purposes of the Serious Event determination.

**Reporting of Specific Types of Events**

14. Restraints and seclusion
   a. 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.
   b. 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).
   c. Any death in restraints or in which restraints were used within 24 hours of death (other than soft wrist restraints) in which the restraints are not suspected of playing a role are reportable as “Other.”

15. Suicide and Other Forms of Patient Self-Harm
   a. Suicide attempts that result in death or injury requiring additional healthcare services are reportable as Serious Events. Suicide attempts not resulting in injury requiring additional healthcare services are reportable as Infrastructure Failures.
   b. Other forms of intentional self-harm that result in injury requiring additional healthcare services are reportable as Serious Events. Other forms of intentional self-harm not resulting in injury requiring additional healthcare services may be reportable as Incidents.

16. Inter- and Intra-Hospital Patient Transfers
   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—in the absence of a precipitating event that would meet the definition of a Serious Event, Incident, or Infrastructure Failure—are not reportable.
   b. Routine intra-hospital transfers between nearby buildings for specialized testing or other services in the normal course of treatment are not reportable.
   c. Unanticipated intra-hospital transfers to higher levels of care due to an error or unanticipated complication of care are reportable as a Serious Event.
   d. 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.

17. Transfers and Cancellations from Ambulatory Surgery Facilities
   a. 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.
      i. ASF admissions includes patients who have completed registration upon entry into the facility.
ii. Cancellations prior to completing registration are not reportable.

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

iv. ASF discharge occurs when the patient leaves the confines of the ASF.

b. Intra-operative transfer from an ASF to a hospital is reportable as a Serious Event.

c. The ASF’s reporting obligation ends after discharge.

18. Patients leaving the Emergency Department 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.

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.

22. Boarding patients in the Emergency Department or Post-Anesthesia Care Unit more than six hours after the ED or PACU physician has written the discharge order is reportable as an Infrastructure Failure.

23. Patient falls

a. Patient falls are to be reported as either Serious Events or Incidents.

b. A fall is defined as any unplanned descent to the floor (or other horizontal surface such as a chair or table), with or without injury to the patient. The definition of falls includes: 1) assisted falls in which a caregiver sees a patient about to fall and intervenes, lowering them to a bed or floor, 2) falls during physical or occupational therapy, in which a caregiver is present specifically to catch the patient in case of fall, 3) physiologic falls in which a patient falls as a result of seizure or syncope.

c. The definition excludes failures to rise, in which a patient attempts but fails to rise from a sitting or reclining position.

d. Falls with harm: Any fall that requires more than first aid care. Treatment beyond first aid care includes a laceration that requires medical intervention (e.g., sutures), more serious injury (e.g., fracture), or death.

e. Note: We believe the criteria for falls as outlined here are consistent with the definitions and criteria used by the National Database of Nursing Quality Indicators (NDNQI). One notable exception is that NDNQI only counts falls occurring on nursing units and excludes other care settings (e.g., physical therapy). MCARE reporting requirements apply to the entire facility.

24. Fires/Patient burns

a. Any fire of any kind is reportable as an Infrastructure Failure.

b. 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.

c. Any fire alarm or sprinkler system that is out of service for 4 hours or more in a 24-hour period is reportable as an Infrastructure Failure.

d. Patient burns requiring additional healthcare services are reportable as Serious Events, even if the associated fire is reported as an IF.

e. Patient burns from sources other than fires (e.g., chemical burns, cautery burns) may be reportable as Serious Events depending on the severity of the injury.

25. Health Information Technology (IT)

a. 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.

b. Safety concerns with Health IT cut across multiple event types and should continue being reported as Serious Events or Incidents.

26. Healthcare-Associated Infections that meet CDC definitions/criteria and which a hospital reports into NHSN should not also be reported into PA-PSRS.

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

Reporting of Incidents

28. Incidents must be reported within the healthcare organization by healthcare workers immediately or as soon thereafter as reasonably practicable, but in no event later than 24 hours after the occurrence or discovery of an incident. Healthcare organizations should report them to the Authority in a timely manner. It is not the Authority's expectation that healthcare facilities report Incidents within 24 hours. Most if not all Incidents should be reported within 90 days of occurrence.

Response to Comments on Draft Guidance on Reporting Standards

Interpretations of Serious Event Definition & Component Terms

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.

We received seven letters disagreeing with this principle, stating that medical error and preventability were fundamental concepts in MCARE and citing as evidence the name of the Medical Care Availability and Reduction of Error Act, and the declaration of legislative purpose which includes: “a person who has sustained injury or death as a result of medical negligence by a health care provider must be afforded a prompt determination and fair compensation”, and “every effort must be made to reduce and eliminate medical errors by identifying problems and implementing solutions that promote patient safety.” [MCARE, Section 102 (4), (5)] One letter stated that this principle “may have the unintended consequence of discouraging reporting due to
concern that reporting and the associated written disclosure of events in which there is no error and/or were not preventable will prompt litigation.”

Response: While we agree that MCARE includes the concept of medical errors, many events commonly treated as genuine patient safety concerns and perceived as harmful by patients do not necessarily involve errors by caregivers, such as behavioral choices by the patient that can lead to patient falls, pressure ulcers, adverse drug reactions, and healthcare associated infections (HAIs). Whether such occurrences are preventable is subjective, and perceptions of preventability change over time. For example, central line-related infections are an order of magnitude lower than they once were, and rates that were once considered a cost of doing business would now be considered in most cases preventable. We disagree with the notion that including in the Serious Event definition events that do not involve errors will increase providers’ liability. On the contrary, we believe the opposite is true. If every Serious Event necessarily involves an error, this interpretation could lead people to assume any Serious Event disclosure is an admission of negligence.

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.

We received seven comments in response to this principle. Four comments mentioned the concept of the reasonably prudent patient; two supported the idea, and two opposed it. Those opposing argued that this would “cast too wide a net,” leading providers to report complications in which there was no precipitating event involving an error, and they question the statutory basis for an interpretation that adopts the perspective of the patient.

Three comments referred to an algorithm the Authority previously published as being helpful to facilities and suggested this be updated.

One comment stated that “medical standards” be relied upon when determining the meaning of unanticipated injury.

One comment noted that the proposed clarification also uses subjective language (e.g., “rarely”) and would also be subject to varying interpretations.

Response:

In applying the definition of Serious Event, the phrase “unanticipated injury” begs the question, “Unanticipated by whom?” We believe there are only two potentially relevant perspectives: that of the patient or their representative and that of the provider(s) involved in the care. Whether there is a statutory basis for choosing one or both of these as the relevant perspective(s), applying
the definition requires this. Even if one leaves it implicit, then each person implicitly considers one or both of these perspectives when judging a particular case.

We believe the patient perspective is the most appropriate one. While it would be reasonable to suggest that an injury is anticipated if both the provider and the patient anticipate it, the patient’s perspective would still be the pivotal one. If a patient anticipates an injury from a medical procedure (i.e., they consider it likely) and they still choose to undergo the procedure anyway for the chance of benefiting from the procedure, it is most likely because the provider conveyed the risk of injury to the patient. To put this another way, can we conceive of a patient anticipating an injury that the provider doesn’t anticipate? So, only if one is willing to argue that the patient’s perspective is irrelevant here, will the provider’s perspective alone be determinative.

The algorithm referred to above is mentioned in relation to other principles as well, and we may develop this as part of the education program that will help implement these principles. Some comments seemed to propose the algorithm as an alternative to defining the principles as we have done here. However, if we do not define our terms or make explicit our interpretations of the language in the authorizing legislation, an algorithm that limits itself to the statutory definitions would do little to reduce the variation in reporting standards.

The language in this principle that seems subjective is by design, as explained directly below.

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.

5. A Serious Event that is within statistical norms or within benchmarks available in the clinical literature must still be reported. There is nothing in the law that allows for reporting Serious Events only when they exceed a statistical norm or benchmark.

Principles 3-5 are addressed together because they work together to clarify the margins of people’s interpretations of the phrase “unanticipated injury.”

We received 11 comments on the importance of the informed consent process, taking the position that a potential complication that was discussed with the patient before the procedure and for which consent was obtained should not qualify as a Serious Event. In essence, the patient’s acceptance of the risk of that complication constitutes the patient’s anticipation of the complication.

We received 7 comments suggesting that principle number 5 be deleted, arguing that statistical norms and benchmarks are often relayed to the patient as part of the informed consent process and that if such complications occur within expected ranges, they are anticipated and therefore
could not be Serious Events. One comment suggested eliminating principle 3 for the same reason. Another suggested this alternative language: “A known and consented for complication, timely recognized and treated, for which there was informed consent is not a Serious Event.”

Response: Little consensus exists about the meaning of “unanticipated injury” in the Serious Event definition, particularly with respect to known complications of medical procedures. The dictionary definitions of “anticipate” support a multitude of interpretations ranging from “to conceive of something as possible” to “to consider something likely or probable.”

Arguments that complications discussed during the informed consent process are anticipated are only viable if one interprets “anticipate” to mean “to conceive of something as possible.” While there was not consensus among the committee members about the meaning of “anticipate,” there was a clear majority that believed the meaning was closer to “likely or probable” than to “possible or conceivable.”

An example of a complication one might regard as probable is urinary incontinence after radical prostatectomy, which occurs in 50% of cases. An example at the opposite end of the continuum, a complication one would regard as conceivable but not likely, would be intraoperative death from a reaction to anesthesia, which occurs in 1 of 100,000 surgeries (or 0.001%). There was consensus among the committee members that the first example was sufficiently frequent that its occurrence should be considered anticipated and therefore not qualify as a Serious Event. There was also consensus that the latter example was sufficiently infrequent that its occurrence should be considered unanticipated and therefore should qualify as a Serious Event.

There our consensus ended. We could not establish a frequency or rate of incidence that would make a complication transition from unanticipated to anticipated. Therefore, we attempted to craft a set of principles that would bring in the margins on outlier interpretations that complications are always or never anticipated. This leaves facilities with broad discretion to adopt their own thresholds and heuristics.

Regarding statistical norms and benchmarks, we agree that these are relevant to the determination of whether certain complications occur with sufficient frequency that they are or should be anticipated by a reasonable patient making an informed choice to undergo a related procedure. What this frequency is, we have left to facilities’ discretion. Note, however, that many healthcare associated infections (HAIs) would be discussed in informed consent processes in relation to most procedures; yet, the Legislature has clearly determined that these are consistent with the Serious Event definition. Therefore, the position that any complication consented for cannot be a Serious Event is unsupportable.

6. An event, occurrence, or situation that: a) hastens death (as in a terminally ill patient), or b) exacerbates a pre-existing condition requiring additional healthcare services, is a Serious Event.

We received two comments about this principle, one recommending deletion of the word “situation” and incorporating the idea that Serious Events must always involve errors or be preventable. The second proposed alternative language as follows: “A Serious Event can include
an unanticipated event, occurrence or situation that: a) hastens death (as in a terminally ill patient); or b) exacerbates a preexisting condition requiring additional health care services.” This commenter continued: “There are situations when an intervention is done with the full knowledge that there is a reasonable likelihood it may hasten death, but the patient chooses to proceed notwithstanding this risk. For example, at the end of life a patient may choose to receive certain pain medications to alleviate suffering which can reasonably be anticipated to slow respiration and possibly hasten death. If the hastening of death is fully anticipated but is accepted as a risk in the face of the alternatives, that event is anticipated and should not be reported as a Serious Event. Facility acknowledges that there are other situations, where death is hastened or preexisting conditions are exacerbated and additional health care services are offered, which would meet the definition of a Serious Event and are required to be reported as such, which is why the recommended modification allows for either alternative.”

Response: We agree with the commenter’s interpretation of the end-of-life care example. This should not be considered a Serious Event because the potential for respiratory depression is anticipated in a patient receiving palliative care. (While it doesn’t bear on this principle, we would contrast this scenario with respiratory depression in a patient on a PCA pump after a knee replacement, which would be unanticipated.)

Our intent with this principle was to establish only that an occurrence that would otherwise qualify as a Serious Event would not be exempt by virtue of the fact that the patient was dying anyway or that they already had a related injury prior to the occurrence being reported. The suggested language cited above better reflects this intent and will be adopted in the final guidance.

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.

We received three comments suggesting that this principle be deleted on grounds that: a) facilities have existing processes in place to review unexpected deaths such as peer review and morbidity and mortality conferences, and b) if the event causing the death or injury is unknown or undetermined one cannot report it.

Response: The precise cause(s) of many events facilities currently report is unknown, e.g., pressure ulcers, infections. Certain things are, on their face, unanticipated iatrogenic injuries. Death of a healthy patient during an elective surgery is surely one of them.

8. Any unnecessary invasive procedure or invasive procedure performed in error that carries risk for the patient constitutes an injury, and performance of the correct or intended procedure then constitutes additional healthcare services. These occurrences are Serious Events.

We received 8 comments about this principle, all advocating that it be limited to invasive procedures. The committee agrees with this revision and has incorporated it.
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.

We received no comments about this principle.

Exclusions

10. Deaths or injuries resulting from the patient's disease, in the absence of a contributing event, occurrence or situation, are not Serious Events.

We received one comment recommending deletion of this principle as unnecessary. It was originally drafted to clarify issues raised by some facilities claiming they had been instructed to report all deaths, or all deaths from the operating room. This principle makes clear that these are not categorically reportable.

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.

We received two comments supporting this 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, so long as this potential change was discussed with the patient or the patient’s representative at the time of consent.

We received comments from 10 individuals in response to this principle. Many recommended removing the phrase “so long as this potential change was discussed with the patient or the patient’s representative at the time of consent” but otherwise agreed with the principle.

The concern raised in most comments was that while every effort is made to anticipate mid-procedure occurrences, 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 constitute an injury. Moreover, if the new information was not expected, the health care provider will not have had the opportunity to discuss the change to the plan of care in advance. Health care facilities have processes in place to address such circumstances and endeavor to inform the patient's representative to obtain consent.
Response: We agree, and the intent of mentioning the patient’s representative was to allow for situations where the family must be consulted to obtain additional consent mid-surgery while the patient is under anesthesia. We have revised the text as suggested.

13. Additional healthcare services:
   a. Healthcare services provided to prevent an injury from occurring are excluded from this term for the purpose of Serious Event determinations.
   b. 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.
   c. Non-invasive diagnostic services provided to rule out an injury (e.g., x-ray following a fall) do not constitute additional healthcare services for purposes of the Serious Event determination.

We received two comments about this principle: one supporting it, the other asking for clarification or an example for 13.a.

Response: An example for 13.a would be that following cataract surgery there is sometimes a rise in the patient’s intraocular pressure, and a vitrectomy may be performed to prevent subsequent injury from the rise in intraocular pressure.

Reporting of Specific Types of Events

14. Restraints and seclusion
   a. 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.
   b. 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 MD order, finding patients in unsafe position while in restraints).
   c. Any death in restraints or in which restraints were used within 24 hours of death (other than soft wrist restraints) in which the restraints are not suspected of playing a role are reportable as Infrastructure Failures.

Two comments addressed 14.b. One recommended changing “MD” to “physician” and suggested we define “timely.”

Five individuals commented on 14.c, four stating that it was outside the statutory definition of infrastructure failure and recommending it be deleted. The fifth individual felt the guidance was unclear and asked whether for every death in the hospital one would have to review the medical record to look for use of restraints in the previous 24 hours.

Response: In 14.b, we have replaced MD with physician. The word “timely” was used only in an example illustrating that there may be events involving restraints that meet the definition of Incident. We are not adopting standards for the timeliness of executing physicians’ orders.
Principle 14.c is consistent with CMS reporting requirements. We maintain the requirement to also report in PA-PSRS because CMS data are not available to the Department of Health. A facility’s quality assurance monitoring procedures should involve medical record review of every death. PSA will modify PA-PSRS to facilitate reporting these events under an “Other” category so they are not construed as Infrastructure Failures.

15. Suicide and Other Forms of Patient Self-Harm
   c. Suicide attempts that result in death or injury requiring additional healthcare services are reportable as Serious Events. Suicide attempts not resulting in injury requiring additional healthcare services are reportable as Infrastructure Failures.
   d. Other forms of intentional self-harm that result in injury requiring additional healthcare services are reportable as Serious Events. Other forms of intentional self-harm not resulting in injury requiring additional healthcare services may be reportable as Incidents.

We received comments from 9 individuals on these principles. Eight stated that suicide attempts or other forms of self-harm in which the patient is not injured do not meet the statutory definition of Infrastructure Failure and should be reported as Incidents. Several of these suggested the following revised wording: “Suicide attempts that result in death or injury requiring additional healthcare services are reportable as Serious Events. Suicide attempts not resulting in injury requiring additional healthcare services are reportable as Serious Events.”

Three comments stated that healthcare providers should not be held responsible for patients’ intentional self-harmful behavior or that these events do not involve patients’ clinical care.

One comment questioned the need for 15.b asking what it was meant to address that was not covered in 15.a.

Response: Suicide attempt without injury and other forms of intentional self-harm should be reported as an Infrastructure Failure to allow for monitoring of patient protection procedures. We agree that in some instances patients harm themselves despite the presence of effective preventive measures and the facility’s full compliance with those measures.

16. Inter- and Intra-Hospital Patient Transfers
   e. 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.
   f. Routine intra-hospital transfers between nearby buildings for specialized testing or other services in the normal course of treatment are not reportable.
   g. Unanticipated intra-hospital transfers to higher levels of care due to an error or unanticipated complication of care are reportable as a Serious Event.
h. 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.

We received comments from 11 individuals about these principles.

Two comments addressed 16.a. One asked whether this meant that two reports would be required: one for the underlying event and one for the transfer. The other asked whether an Infrastructure Failure report is required when a specialized unit (e.g., mental health, but it could be ANY specialized unit) is at capacity, and a patient (who has arrived in the ED) needs to be transferred to another facility after the medical screening and disposition is determined?

Response: Only one report would be required. Transfer of a patient is not reportable as an Infrastructure Failure when 1) a patient has been evaluated and the medical diagnosis or treatment plan requires specialized treatment or service and 2) the required treatment or service is outside the facility’s scope or is provided by the facility but is not available due to full capacity.

One comment addressed 16.b, asking when a unit reaches bed capacity is the number of patients transferred during that time period required to be reported?

Response: See above response to item 16.a.

Regarding 16.c, 8 comments suggested excluding transfers as a result of complications, 7 suggested including only transfers that were the result of an error, and 6 suggested revising “unexpected” to read “unanticipated.” Alternative language suggested by several individuals reads: “Unanticipated intra-hospital transfers to higher levels of care due to an error are reportable as a Serious Event.”

Response: For reasons cited earlier, complications (unless it can be argued the patient expected them to occur) that result in additional healthcare services are within the scope of the Serious Event definition.

17. Transfers and Cancellations from Ambulatory Surgery Facilities
   d. 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 at least as Incidents unless criteria for Serious Event are present.
      v. ASF admissions includes patients who have completed registration upon entry into the facility.
      vi. Cancellations prior to completing registration are not reportable.
      vii. Hospital Transfer/Admission: Any transfer/admission from an ASF directly to an acute care hospital, including hospital emergency room.
      viii. ASF discharge occurs when the patient leaves the confines of the ASF.
e. Intra-operative transfer from an ASF to a hospital due to an error or unanticipated complication of care is reportable as a Serious Event.
f. Complications or other events associated with a surgical procedure that require hospital admission, even if after discharge, are reportable as Serious Events by the ASF, assuming they become aware of it.

We received comments from 11 individuals about this principle.

Six comments related to 17.a. Two recommended removing the phrase “at least” before Incidents. Two noted that they had previously believed these were required to be reported as Infrastructure Failures and noted the reporting system must be changed to accommodate this. Two comments noted that transferring patients in need of hospital treatment represented appropriate care, and one of these stated “If a patient arrives for a scheduled procedure and is found to have a condition requiring immediate hospital attention, a transfer is common sense and should not be reportable at all because the ASF did not contribute to the condition, only discovered it.” Two individuals proposed the following alternative language: “When a patient admitted to an Ambulatory Surgery Facility (ASF) requires transfer to a hospital, these events may be reportable as Incidents.”

Response: We have removed the phase “at least” as suggested. The PA-PSRS reporting system will be modified to be consistent with the adopted principles.

The rationale for monitoring these events carefully is explained in the rationale for the NQF-endorsed measure referenced in the principle: “The need for transfer/admission is an unanticipated outcome and could be the result of insufficient rigor in patient or procedure selection. Hospital transfers/admissions can result in unplanned cost and time burdens that must be borne by patients and payors. Selected states have expressed an interest in the public reporting of such events. While hospital transfers and admissions undoubtedly represent good patient care when necessary, high rates may be an indicator that practice patterns or patient selection guidelines are in need of review.” (Accessed via the National Quality Measures Clearinghouse: http://www.qualitymeasures.ahrq.gov/content.aspx?id=35278, February 13, 2014).

Transfers to acute care are also among the top three kinds of events reported to PSA by ASFs. The Authority has also recently completed a collaborative program on reducing these events. Transfers to acute care accounted for one-third of all Serious Events submitted to PSA by ASFs. If we were to standardize reporting of any event in this care setting, this would be an obvious choice for these reasons. We also understand that the Centers for Medicare and Medicaid Services (CMS) are considering adopting this measure and reporting it publicly on a “HospitalCompare” like web site for ASFs. We believe it will benefit Pennsylvania ASFs to get an early start on addressing this patient safety challenge.

With respect to 17.b, three comments stated that complications resulting in transfer should not be reported, and one comment stated that using the word error was confusing since other principles stated that Serious Events did not have to involve errors.

Response: The phrase “due to an error or complication” was intended to convey that intra-operative transfers from an ASF to a hospital were reportable as Serious Events regardless whether they resulted from errors or complications. To clarify, we have deleted this phrase.
With respect to 17.c, three comments noted that the timeframe post-discharge is not specified, and one stated that the ASFs reporting obligation should end at the time of patient discharge. Three comments recommended deleting this principle stating that transfers did not meet the statutory definitions for reportable events. To make this case, one individual used the example of a patient who is transferred to a hospital for monitoring because they have not yet fully recovered from anesthesia and the ASF is closing for the night. Two individuals stated that it should be the event that resulted in transfer that should be evaluated as reportable or not, as opposed to the transfer itself.

Another comment stated that hospital admissions after ASF discharge should be related to the care provided by the ASF in order to be reportable. Another cited principle number 4, which states that if complications that occur frequently are considered anticipated, they do not meet the Serious Event definition, presumably arguing that transfers are sufficiently frequent that they should be considered anticipated.

Response: Please refer to the discussion above for the rationale for including these events.

The Committee believes it should maintain consistency with the NQF quality measure cited above, which does not evaluate the cause(s) of the transfer. The NQF measure as currently defined would have the facility’s monitoring obligation end at discharge; this will be incorporated into the final guidance.

18. Patients leaving the Emergency Department without being seen/treated:
   c. Patients leaving the ED waiting room or treatment area without being seen are not reportable unless they are in the 302 process.
   d. 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.

We received 9 letters that commented on this principle. Six letters commented that the timeframe following elopement is undefined; four of these agreed that patients involuntarily committed should be reported as Infrastructure Failures, but they disagreed that injuries during an elopement episode should be reported as Serious Events because such injuries are beyond the facility’s control and do not involve “the clinical care of the patient,” a component of the Serious Event definition.

Two letters asked that we define “left without being seen” and “ED treatment area.” One letter asked that we clarify that nothing in our interpretive guidance should be taken to expand EMTALA requirements.

Response: ED treatment area is defined by each facility.

A patient who leaves without being seen is one who has registered in the ED but who leaves before being evaluated by a licensed practitioner. These are only reportable if the patient is being involuntarily committed. This principle does not affect a facility’s obligations with respect to EMTALA compliance.
19. Inpatient elopements are reportable as Infrastructure Failures. If an eloped patient is injured during an elopement, this is reportable as a Serious Event.

Seven letters commented on this principle. Four reiterated the issues related to principle 19, in which they felt hospitals should not be held responsible for injuries occurring when the patient is not in their care, and three noted the lack of a defined timeframe. Three letters concurred that inpatient elopements should be considered Infrastructure Failures. Two questioned whether this applied to all inpatients or only mental health patients.

Response: This applies to all elopements.

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

One letter commented on this principle, concurring that patients leaving AMA should not be reportable. It also stated that this principle was inconsistent with 19.

Response: An elopement is when the facility was not aware that the patient left the facility. AMA is when the facility is aware of the patient’s desire to leave and informs the patient of the risks of leaving, whether or not the patient signs the AMA form.

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.

Ten letters commented on this principle, all of which stated that this principle should be limited to inpatient care and should exclude the ED and other outpatient areas. Three specifically mentioned that the use of hall beds in the ED while waiting for an inpatient bed to be cleaned should not be reported. Seven letters expressed a desire to submit only one report per occurrence rather than a separate report for each patient, since such events often involve multiple patients.

Response: The reporting requirement pertains to use of unlicensed beds for patient care and treatment. We agree that use of the hallway for a patient who has a physician’s order for transfer from the ED to an inpatient unit does not constitute an Infrastructure Failure if the hallway is used only during the period of time while waiting for the assigned inpatient bed to be cleaned. We require a report that identifies all occurrences of patients receiving care or treatment in an area not designated for patient care. A single report may be submitted to cover multiple patients.

22. Boarding patients in the Emergency Department or Post-Anesthesia Care Unit more than two hours after the ED or PACU physician has determined they meet discharge criteria is reportable as an Infrastructure Failure.

Thirteen letters commented on this principle. Five letters stated that this requirement poses an undue burden on facilities and that boarding patients doesn’t meet the statutory definition of Infrastructure Failure because it doesn’t compromise patient safety or involve an interruption in services. Nine letters proposed a variety of longer timeframes before boarding a patient would
become reportable, but the most commonly suggested timeframe was six hours, which was cited as consistent with recently issued Joint Commission ED-related standards. Six letters stated that the timeframe should be based on the physician's discharge or transfer order. Five letters each recommended that hospitals be able to submit a single report covering multiple patients and that special consideration be made for natural disasters and other large-scale uncontrollable events. Four letters questioned the patients to whom this standard applies, questioning whether this applies to patients who are discharged to home.

The following was proposed in multiple letters (with some variations) as alternative language for this principle: “Boarding patients in the Emergency Department or Post-Anesthesia Care Unit more than 6 hours after the ED or PACU physician has written the discharge order is reportable as an Infrastructure Failure.”

Response: We agree with the proposed alternative language and will revise the principle accordingly.

23. Patient falls
   a. Patient falls are to be reported as either Serious Events or Incidents.
   b. A fall is defined as any unplanned descent to the floor (or other horizontal surface such as a chair or table), with or without injury to the patient. The definition of falls includes: 1) assisted falls in which a caregiver sees a patient about to fall and intervenes, lowering them to a bed or floor, 2) therapeutic falls, in which a patient falls during a physical therapy session with a caregiver present specifically to catch the patient in case of fall, 3) physiologic falls in which a patient falls as a result of seizure or syncope.
   c. The definition excludes failures to rise, in which a patient attempts but fails to rise from a sitting or reclining position.
   d. Falls with harm: Any fall that requires more than first aid care. Treatment beyond first aid care includes a laceration that requires physician intervention (e.g., sutures), more serious injury (e.g., fracture), or death.
   e. Note: We believe the criteria for falls as outlined here are consistent with the definitions and criteria used by the National Database of Nursing Quality Indicators (NDNQI). One notable exception is that NDNQI only counts falls occurring on nursing units and excludes other care settings (e.g., physical therapy). MCARE reporting requirements apply to the entire facility.

We received eight letters commenting on this principle. There was general support for the basic definition of falls, though some modifications were suggested. Four letters suggested renaming “therapeutic falls” as “falls during physical therapy,” and three of the four agreed with including these within the definition; one suggested reporting these as falls only when they involve falling to the floor. Four letters supported including assisted falls. Three letters suggested excluding physiologic falls, while two supported including them. One suggested excluding falls into chairs.

Two letters stated that the definition of falls with harm was over-broad because we identified physician intervention as the level of treatment indicating that harm requiring additional healthcare services has occurred. One letter suggested truncating that phrase about physician
intervention in the definition, presumably leaving each facility to construct its own definition of first aid care.

One letter suggested that 23.a be reworded to state that falls *may be* [italics added] reported as either Serious Events or Incidents.

One letter stated that NDNQI was a voluntary program and should not serve as the basis for the mandatory reporting requirements.

Response: We have modified the clause about “therapeutic falls” as suggested. While some facilities argue that falls resulting from an unexpected change in the patient’s physiologic state should be excluded, in our conversations with Patient Safety Officers we have found this to be a minority view. Seizures, syncope, and other changes in physiologic status are often the result of reactions to medications, poor management of diet or insulin, and other causes at least potentially within the hospital’s control.

24. Fires/Patient burns
   a. Any fire of any kind is reportable as an Infrastructure Failure.
   b. 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.
   c. Any fire alarm or sprinkler system that is out of service for 4 hours or more in a 24 hour period is reportable as an Infrastructure Failure.
   d. Patient burns requiring additional healthcare services are reportable as Serious Events, even if the associated fire is reported as an IF.
   e. Patient burns from sources other than fires (e.g., chemical burns, cautery burns) may be reportable as Serious Events depending on the severity of the injury.

We received nine letters in response to this principle. One letter suggested adding the word “unplanned” before the word fire in 24.a, to exclude planned fires such as those in the kitchen.

Regarding 24.b, five letters suggested excluding false alarms, and four stated that activation of the facility’s response plan after an alarm was appropriate and that if it did not result in an interruption of service and/or require patients to be moved, it would not meet the statutory definition of Infrastructure Failure.

Regarding 24.c, eight letters recommended that only unplanned alarm/sprinkler outages should be reportable, because during construction and other planned outages contingency plans are activated. Four suggested increasing the timeframe for reportability from 4 hours to 10, which two letters cited as being consistent with NFPA 101 (ed. 2000) Life Safety Code 9.7.6.2, which provides, “Sprinkler impairment procedures shall comply with NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems.” NFPA 25 (e. 2014) Life Safety code 15.5.2 (4) speaks to actions and notifications to be made “Where a fire protection system is out of service for more than 10 hours in a 24-hour period.”
Response: This requirement remains unchanged. The Department of Health reviews all fires for compliance with the facility’s policies and procedures.

25. Health Information Technology (IT)
   a. 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.
   b. Safety concerns with Health IT cut across multiple event types and should continue being reported as Serious Events or Incidents.

We received four letters commenting on this principle, two stating that it did little to clarify existing reporting practices, and two requesting that a single report be able to address multiple patients affected by the same event.

Response: The Patient Safety Authority has seen a marked increase of HIT-related events since the American Recovery and Reinvestment Act provided financial incentives for providers to adopt electronic health records. This is also increasingly becoming a focus of Patient Safety Organizations nationally. While many HIT-related events are reported under Serious Event and Incident categories, Patient Safety Officers have stated that they sometimes report these events as Infrastructure Failures. This guidance clarifies that they should be reported as Serious Events or Incidents. The Authority may modify PA-PSRS to more accurately identify HIT-related events.

26. Healthcare-Associated Infections (HAIs)
   a. Any HAI that meets CDC definitions/criteria and which a hospital reports into NHSN should not also be reported into PA-PSRS.
   b. Any HAI that is clearly healthcare-acquired but which falls outside the CDC definitions/criteria should be reported as an Infrastructure Failure.
   c. This is a temporary measure that may be revisited in the future as CDC’s surveillance criteria evolve and deal with changing healthcare delivery patterns (e.g., shortening length of stay).

We received 42 letters addressing this principle. We received no comments regarding 26.a.

Regarding 26.b. and 26.c, 11 letters recommended deleting one or both of these principles. Thirty-one letters cited confusion and conflict with existing CDC guidance on HAI surveillance and referencing the already overlapping communicable disease reporting requirements with the National Electronic Disease Surveillance System (NEDSS), and 12 expressed a generalized burden with reporting or confusion about reporting requirements.

Forty-three letters requested that case definitions and surveillance criteria be provided in order for reporting of these infections to be consistent. Related to this, three letters asked whether HAIs treated empirically by physicians would meet the test in 26.b; if so, this would involve a significant expansion of reporting requirements and a loss of data quality.

Twenty-four letters asked whether HAIs reported as IFs would trigger the written disclosure requirement associated with Serious Events. Three letters stated that HAIs not defined by CDC
surveillance criteria were outside the scope of the IF statutory definition. Three letters stated that if non-CDC-defined infections were to be reported they should be reported as Serious Events or Incidents. One letter asked whether the Commonwealth’s HAI Advisory Panel was consulted about this change.

Response: The Department is concerned with identification of HAI that manifest symptoms after hospital discharge. Due to difficulty in structuring a reporting requirement that gathers this data through a clear and effective process that does not burden or confuse facilities, we agree to withdraw 26 b. and 26.c.

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

We received nine letters in response to this principle, all of which argued that unplanned power failures in which the backup generator deploys and there is no interruption in service does not meet the statutory definition of Infrastructure Failure because the backup system worked as designed. Most of the letters recommended removing the word “or” from the principle as drafted. Suggested language proposed in one letter reads: “Unplanned power failures involving backup generator deployment in which the backup generator fails to deploy, are reportable as Infrastructure Failures. Planned power failures where there is no interruption of service should not be reported.”

Response: This requirement remains unchanged. The Department of Health reviews all power failures for compliance with the facility’s policies and procedures.

Reporting of Incidents

28. Incidents must be reported within the healthcare organization by healthcare workers within 24 hours. Healthcare organizations should report them to the Patient Safety Authority in a timely manner. It is not the Authority’s expectation that healthcare facilities report Incidents within 24 hours. Most if not all Incidents should be reported within 90 days of occurrence.

We received 11 letters addressing this principle. Six of these concurred that Incidents should be reported to the Authority in a timely manner; four of these six endorsed the 90-day timeframe.

Five letters recommended deleting the last sentence of the principle as drafted, stating that establishing a specific timeframe by which Incidents must be submitted exceeded the legislative authority granted by MCARE.

Proposed language, from one of the letters that endorsed the 90-day timeframe, softened the language to make it more of a suggestion than a requirement: “Incidents must be reported within the healthcare organization by healthcare workers immediately or as soon thereafter as reasonably practicable, but in no event later than 24 hours after the occurrence or discovery of an incident. Healthcare organizations should report them to the Authority in a timely manner. It is
not the Authority's expectation that healthcare facilities report Incidents within 24 hours. Most if not all Incidents should be reported within 90 days of occurrence.”

Response: While there is no specific timeframe for reporting of Incidents by the healthcare facility to the Authority, MCARE clearly requires that these reports be submitted, and no comments received dispute this. Even those letters disputing whether the agencies have the statutory authority to prescribe a timeframe supported that reports should be submitted “timely.”

The purpose of establishing a timeframe is to set boundaries beyond which a facility may be determined out of compliance with the requirement to report Incidents. Currently, this is at the discretion of DOH surveyors, and the lack of a standard has resulted in variation. Healthcare facilities have complained about this inconsistency. Is a hospital that goes six months without reporting any Incidents complying with this provision of MCARE? What if they go five years? At some point, further delay must be taken to indicate non-compliance.

We deliberately chose a timeframe that would impose a minimal burden on the facilities. In reviewing the elapsed time between Incident occurrence and submission, we found that 93% of all Incident reports are submitted within 90 days. Therefore, this standard imposes little change on most facilities’ current practices and conveys a uniform standard to DOH surveyors for evaluating facilities’ compliance. In the absence of a standard established here, multiple inconsistent standards will be established by each DOH surveyor.

We have modified the text of this principle in accordance with the suggested language from one of the public comments above.