

NOTICES

PATIENT SAFETY AUTHORITY AND DEPARTMENT OF HEALTH

Draft Guidance for Acute Healthcare Facility Determinations of Reporting Requirements under the Medical Care Availability and Reduction of Error (MCARE) Law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This document outlines draft guidance to Pennsylvania acute healthcare facilities in making determinations about whether specific occurrences meet the statutory definitions of Serious Events,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 This draft guidance was developed by a multi-disciplinary work group consisting of staff from the Patient Safety Authority (Authority), [two physician members of the Authority's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 (~~DOH~~[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.

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 They include many subjects identified in a 2009 draft guidance document the Authority issued for public comment which was never subsequently issued as final guidance from the Authority and the Department.

Please see the instructions for submitting comments at the end of this document.

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.

Draft 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 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 injury complication was disclosed to the patient in the informed consent discussion and documented on the consent form.
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. An event, occurrence, or situation that: a) hastens death (as in a terminally ill patient), or b) exacerbates a pre-existing injury condition requiring additional healthcare services, is a Serious Event.
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 procedure or 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.

Comment [MB1]: From me, after Bob's comment, to avoid conflicting with #3 above

Comment [MB2]: From Fran

Comment [MB3]: From Bob Yonash

Comment [MB4]: From Fran

Comment [MB5]: From me

- 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, so long as this potential change was discussed with the patient or the patient's representative at the time of consent.
- 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.

Comment [MB6]: From me, to clarify that we don't want SEs to include tumors discovered during surgery where the surgeon gets the family's consent to remove them to avoid another surgery.

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.
- 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

Comment [MB7]: From Fran

self-harm not resulting in injury requiring additional healthcare services may be reportable as Incidents.

16. Inter- and Intra-Hospital Patient Transfers

~~a.~~ 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.

~~a-b.~~ a-b. Routine intra-hospital transfers between nearby buildings for specialized testing or other services in the normal course of treatment are not reportable.

~~b-c.~~ b-c. Unexpected intra-hospital transfers to higher levels of care due to an error or complication of care ~~is-are~~ reportable as a Serious Event.

~~e-d.~~ e-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 ~~is-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 at least as Incidents.

i. ASF admissions includes patients who have completed registration upon entry into the facility.

~~i-ii.~~ i-ii. Cancellations prior to completing registration are not reportable.

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

~~iii-iv.~~ iii-iv. ASF discharge occurs when the patient leaves the confines of the ASF.

b. Intra-operative transfer from an ASF to a hospital due to an error or complication of care is reportable as a Serious Event.

c. 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.

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 ~~inpatient care~~ or patients receiving ~~inpatient~~ treatment in an area not designated for patient care (e.g., hallways, atrium, quiet room, tent on grounds) is reportable as an Infrastructure Failure.

Comment [MB8]: Recommended by Bob Yonash. I remember that we discussed this and felt like there was consensus. I think the wording above in 16.a was meant to address this, but this makes it explicit.

Comment [MB9]: Recommended by Regina Hoffman. I think this is the same issue as above; I intended the text in 17.a to exclude this type of case, but this makes it explicit.

Comment [MB10]: From Anna Marie

Comment [MB11]: I struggled with this part of it, as I don't think we want to establish formal post-discharge surveillance standards, but we also don't want to imply they don't need to do any post-d/c surveillance.

Comment [MB12]: Clarified by Ed Woods

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

Comment [MB13]: From Arlene

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.

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. Activation of a fire alarm (including false alarms) is reportable as an Infrastructure Failure.~~
- ~~b-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.
- ~~e-d.~~ Patient burns requiring additional healthcare services are reportable as Serious Events, even if the associated fire is reported as an IF.
- ~~d-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.

Comment [MB14]: From DOH. Addresses concerns raised by facilities at HAP meeting.

Comment [MB15]: Based on DOH consultation w/ life safety code

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 (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).

27. Unplanned power failures involving backup generator deployment or in which the backup generator fails to deploy, are reportable as Infrastructure Failures, even if the backup generator functions properly and there is no disruption in patient care.

Miscellaneous 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.

Instructions for Submitting Comments

Comments will be accepted for 30 days following the publication of this document. Comments may be submitted in the following manner.

By email to: patientsafetyauthority@state.pa.us

By fax to: Attention Bulletin Response (717) 346-1090

By regular mail to: Patient Safety Authority
Attention Bulletin Response
P. O. Box 8410
Harrisburg, PA 17105-8410

Both the Authority and the Department and the other members of the work group have a common goal of reviewing the public comments to this document, making selected changes in response to those comments, and issuing a final guidance document to guide interpretations of the MCARE statutory definitions.

We expect that final guidance will be published jointly by the Authority and ~~DOH~~ the Department in the *Pennsylvania Bulletin*. Healthcare facilities may rely upon the final guidance as a standard to which they will be held by their ~~DOH~~ Department surveyors. Final guidance will require approval from the Authority Board of Directors and the Secretary of the ~~DOH~~ Department.

Assuming both agencies approve the final guidance document, implementation will include education for staff of both agencies as well as affected healthcare facilities. Some standards will require changes to PA-PSRS and hospital electronic interfaces to PA-PSRS. The final guidance document resulting from this process will include a timeline that accounts for these steps in implementation.

Comment [MB16]: Revised to address feedback from DOH: "It takes 10 seconds of a power outage to deploy the generator. Additionally according to Charlie, no generator powers the entire facility, therefore, there will always be some disruption of services. This is information that is needed, especially during a crisis. It is one of most important questions QA needs to answer to the Governors' office and aids into the deployment of supplementary services, such as getting gas to facilities that have been on generator service for a while or providing a supplementary generator.... We did this during Hurricane Sandy. This is an issue that the whole bureau feels strongly about."

| [SIGNED BY PSA EXEC DIR AND DOH SECRETARY]