Preliminary Workgroup Recommendations Regarding Standardization of MCARE Reporting Requirements 11-11-13						
No.	**Short Description**	**Discussion/Examples**	**Notes**	**Options**	**Recommendation**	**Status**
1	SE definition: event, occurrence, or situation	Deaths or injuries resulting from the patient's disease, in the absence of a contributing event, occurrence or situation, are not Serious Events	Principle 1, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 5/23/13
2	SE definition: error, preventability	The concepts of error and preventability do not appear in the SE 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 SE.	Principle 3, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 5/23/13
3	SE definition: results in death…injury	If the event, occurrence, or situation hastens death (as in a terminally ill patient) or exacerbates a pre-existing injury, this is a Serious Event.	Principle 6, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 6/6/13
4	SE definition: involving the clinical care of the patient	The clinical care of the patient includes time in which the patient is in your custody, not only the moments during which care is actively delivered. It also includes a timeframe during which the patient's condition can be affected by care provided by your facility. For patients undergoing	Principle 4, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	remain silent	Closed 6/6/13

		surgery, the clinical care of the patient includes the standard post-operative period.				
5	SE definition: event, occurrence, or situation where cause is unknown	The event, occurrence, or situation that caused the death or unanticipated injury may be unknown but may still be 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.	Principle 2, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 6/6/13
6	Reporting events that occur in other facilities	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.	Principle 19, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 7/11/13

7	Restraints/seclusion	1. 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. 2. 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 patient in unsafe position while in restraints). 3. 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.			Adopt principle	Closed 8/1/13

8	Transfers/cancellations from ASFs	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. ii. Hospital Transfer/Admission: Any transfer/admission from an ASF directly to an acute care hospital, including hospital emergency room. iii. 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		Create explicit event type on one side or other; do nothing	Adopt principle	Closed 9/12/13

		that require hospital admission, even if after discharge, are reportable as Serious Events.				
9	Clarify what is a reportable patient transfer.	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.				Closed 9/12/13

		Unexpected intra-hospital transfers to higher levels of care due to an error or complication of care is reportable as a Serious Event. 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 not reportable.				
10	Suicides/suicide attempts	Some are reported as SE/I; others as IFs. Proposed principles: 1. 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. 2. Other forms of patient self-harm that result in injury requiring additional healthcare services are reportable as Serious Events. Other forms of attempted self-harm not resulting in injury requiring additional healthcare	Suicide attempt and self harm event types already exist on IF side	Clarify in published guidance; address in training; do nothing	Adopt principle	Closed 8/15/13

		services may be reportable as Incidents.				
11	IFs involving patient harm avoid SE notification requirement	If an event results in patient harm (e.g., inpatient suicide) and the facility has a rationale for classifying the event as an IF rather than a SE, this may get around the requirement for a Serious Event notice to the patient/family.		Adopt principle that events involving patient harm (and otherwise being reportable) must be SE's rather than IF's; do nothing	Addressed in #10	Closed 8/15/13
12	SE definition: additional healthcare services	Healthcare services provided to prevent an injury from occurring are excluded from this term for the purpose of Serious Event determinations.	Principle 13, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Remain silent, but address as part of the "unanticipated" issue	Closed 8/15/13
13	SE definition: additional healthcare services	Any unnecessary procedure or procedure performed in error constitutes an injury, and performance of the correct or intended procedure then constitutes the additional healthcare services.	Principle 14, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 8/15/13

14	SE definition: additional healthcare services	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 15, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 8/15/13
15	SE definition: additional healthcare services	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.			Adopt principle	Closed 8/15/13
16	Clarify what is a reportable for a patient leaving the ER AMA / Unnoticed / Untreated	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. c. Inpatient elopements are reportable as Infrastructure Failures. If an eloped patient is injured during an			Adopt principle	Closed 9/12/13

		elopement, this is reportable as a Serious Event. d. Events in which a patient leaves against medical advice (AMA), whether or not they sign a waiver, are not reportable.				
17	Handling reporting of patient elopement				Addressed above	Closed 9/12/13
18	Unlicensed beds used for inpatient care	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. PSA will add event types to PSRS to categorize these events, and DOH will determine whether they can be reported in the aggregate rather than per patient.				Closed 9/26/13
19	Patients boarded in the ED or kept in hallways, patients stuck in PACU	Patients being held in the PACU or boarded in the ED because inpatient beds are unavailable are reportable as Infrastructure Failures. The trigger for reportability is				Closed 9/26/13

		when the patient meets PACU or ED discharge criteria and there is no clean inpatient bed available. PSA will add event types to PSRS to categorize these events, and DOH agrees they can be reported in the aggregate rather than per patient.				
20	Reports under IF related to surge/overflow capacity	Of the 1162 entries in the *Other* category, a significant number of entries (494) were related to Surge/Overflow, Increased Census Issues or Divert.			Addressed above	Closed 10/10/13
21	Infections in ASFs	Agencies have not provided clear guidance on whether ASFs are required to report infections, and if so, where		Clarify whether ASFs are to report, and if so, where and when; do nothing	Do nothing	Closed 9/26/13
22	Timeframe for reporting Incidents	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		Clarify in published guidance; address in training; do nothing	Adopt principle	Closed 10/10/13

		days of occurrence.				
23	Facilities report being instructed by their surveyor to report falls as IFs	Patient falls are to be reported as either Incidents or Serious Events.			Adopt principle	Closed 9/26/13
24	Add "other" categories to IF subtypes	Add *Other* categories to each of the subcategories in the *Infrastructure Failure* section and consider eliminating the general *Other* category all together. This is what has already done in *Serious Event* and *Incident* sections.			PSA to modify PSRS	Closed 10/10/13
25	Fires/burns	Any fire of any kind is reportable as an Infrastructure Failure. Activation of a fire alarm (including false alarms) is reportable as an Infrastructure Failure. Patient burns requiring additional healthcare services are reportable as Serious Events, even if the associated fire is reported as an IF. Patient burns from sources other than fires (e.g., chemical burns, Bovie burns) may be reportable as Serious Events		Create explicit event type on one side or other; do nothing	Adopt principle. PSA to add event types to IF taxonomy.	Closed 10/10/13

		depending on the severity of the injury.				
26	Health IT related events	Already reported for the most part under SE/I categories of medication errors, lab errors, radiology errors. HIT cuts across multiple event types and should remain on SE/I side.		Create explicit event type on one side or other; do nothing	Adopt principle. PSA to add HIT data elements to PSRS taxonomy.	Closed 10/10/13
27	SE definition: additional healthcare services	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.	Principle 16, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 10/10/13
28	SE definition: additional healthcare services	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.	Principle 17, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 10/10/13

29	SE definition: additional healthcare services	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 18, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 10/10/13
30	Med Safety/IF	DOH wants to eliminate the Medication Safety category from IFs, move narcotics discrepancy to the criminal activity category, and discontinue the code for ADC cabinets.			PSA to modify PSRS	Closed 10/10/13
31	Standardize definitions of falls and falls with harm for all facilities, i.e., make the standards mandatory	Fall: 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			Obtain input during HAP meeting Nov 15	Closed 10/10/13

		falls in which a patient falls as a result of seizure or syncope. The definition excludes failures to rise, in which a patient attempts but fails to rise from a sitting or reclining position. 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.				
32	Infections in hospitals	Any infection that meets CDC definitions and which a hospital reports into NHSN should not also be reported into PA-PSRS. PSA should deactivate HAI-related event types in PSRS for hospitals. PSA should add event type to IF: "Failure of Infection Control Plan." DOH may ask for several event sub-type categories under this. DOH may have some follow up questions to add to the IF report forms related to these events. This is a temporary measure that may be revisited	Hospitals must report thru NHSN per Act 52	Clarify in published guidance; address in training; do nothing	Adopt principle. PSA to modify PSRS	Closed 10/24/13

		in the future as CDC's surveillance criteria evolve and deal with changing healthcare delivery patterns (e.g., shortening LOS).				
33	Reporting equipment failures	Serious Event/incident or Infrastructure Failure			Address in education	Closed 10/24/13
34	SE definition: results in death…injury	An incorrect or missed diagnosis resulting in a delay in care that materially affects the patient's condition once the correct diagnosis is made constitutes an injury.	Principle 7, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Do nothing	Closed 10/24/13
35	SE definition: unanticipated injury	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 at the time of consent.	Principle 10, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 10/24/13
36	SE definition: compromises patient safety	This phrase in the law is redundant. An event that results in an unanticipated injury requiring additional healthcare services presumes compromise of patient safety, and the absence of such	Principle 8, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Do nothing	Closed 10/24/13

		an event presumes patient safety is not compromised. Therefore, this clause in the definition is redundant and not necessary for making Serious Event determinations.				
37	Facilities report conflicting guidance from DOH surveyors on event reportability and on SE vs IF determinations	Examples of things facilities report surveyors have instructed them to report as IFs: all patient falls, all transfers to higher level care, all deaths, all deaths in the OR, all returns to OR, events that occur in other facilities		Address by clarifying in published guidance; provide training; do nothing	Mostly addressed in earlier principles. Clarify in education.	Closed 10/24/13
38	SE definition: unanticipated injury	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	Principle 11, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 11/7/13

		anticipated, complications that occur rarely would be unanticipated by most patients.				
39	SE definition: unanticipated injury, complications	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.	Principle 9, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 11/7/13
40	SE definition: unanticipated injury	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 probability of this injury was disclosed to the patient in the informed consent discussion.		Remain silent; define cutoff/interpretation, and address consequnces for complications	Adopt principle	Closed 11/7/13

41	SE definition: unanticipated injury	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.	Principle 12, 2009 PA Bull notice	Remain silent; adopt principle; modify principle	Adopt principle	Closed 11/7/13
42	SE definition: unanticipated injury	When are known complications of care considered unanticipated injuries? The answer should be consisent with how we define "anticipate" and whose perspective we adopt, and whether including a complication in the consent process makes it anticipated. Note that the legislature defined infections as SEs, and they would fall into the category of rare complications that would be on most consent forms.		Remain silent; develop principle	Addressed above	Closed 11/7/13

43	Consider clarifying those entries in the *Infrastructure Failure* reporting so that it be related to <u>systematic structural issues</u> and not related to harm to an individual patient which may or may not be related to the systematic structural issues.	Include a section for a specific statement description of how the entry is related to systematic structural issues. An exception to this rule, would made be for the use of restrains, unspecified deaths, criminal or possibly criminal activity as currently listed in the infrastructure categories.				Open
44	SE definition: results in death…injury	The event, occurrence, or situation need not be the exclusive cause of the death or unanticipated injury in order to be a Serious Event.	Principle 5, 2009 PA Bull notice	Remain silent; adopt principle; modify principle		Open
45	28 PA Code §51.3 reportables	Add a section for a situation or the occurrence of a systemic situation at the facility which could seriously compromise quality assurance or patient safety. Include subsection for the reason of occurrence and steps taken to clarify it. This would allow system issues that are not reported elsewhere to be captured, but need to be reported according to 28 PA Code §51.3. Examples of an acceptable entry in the *Infrastructure Failure* section:				Open

		Exposure of Nutritional staff to infectious diseases because of improper disposal of food items in an isolation room, Improper cleaning of radioactive urine for a patient undergoing a nuclear test.				
46	Power failure with immediate generator deployment but no interruption in patient care: is this reportable?					Open
47	Unplanned EMR downtime with no interruption in patient care: is this reportable?					Open