**ADVERSE EVENT REPORTING AND DECISION TREE**

A Level 1 adverse event is defined in COMAR 10.07.06 as any event that causes death or serious disability. Serious disability is defined in COMAR 10.07.06.02B(11) as a physical or mental impairment that substantially limits one or more major life activities of an individual lasting more than seven days or is present at the time of discharge.

OHCQ’s Patient Safety Program continues to classify the types of Level 1 adverse events in our database using the National Quality Forum’s “Serious Reportable Events”[[1]](#footnote-1) taxonomy.This is a nationally known classification schema used by several state reporting systems as their criteria for reporting. Given that the National Quality Forum (NQF) system is nationally recognized, it enables the OHCQ to compare its data with other state reporting systems. Because the Maryland Patient Safety Program is focused on patient outcomes and does not define or limit the types of events reported by hospitals, we have supplemented the NQF list with other types of frequently reported events.

These additional classifications include:

* death or serious disability related to the use of anticoagulants;
* death or serious disability resulting from an unanticipated complication;
* death or serious disability related to a delay in treatment;
* death or serious disability associated with airway management;
* death or serious disability related to a healthcare-associated infection;
* unanticipated fetal or neonatal death or injury; and
* Misdiagnosis causing death or serious disability.

A hospital shall report any level 1 adverse event to the Department within 5 days of the hospital’s knowledge that the event occurred (Date of discovery).

When in doubt about whether to do a RCA for Level 3 and near misses, remember that a lot of valuable information can be gained in the process. Asking these questions may help you decide if a RCA is needed:

1. Does this event or hazard represent a substantial risk to patient safety?
2. Is the event due to faulty processes or system failures that are likely to cause a similar, perhaps more harmful event if not corrected?
3. If the hazardous condition is not corrected, is there a high probability that a sentinel or adverse event will occur?
4. Will the organization receive significant negative publicity if the cause of the event is not corrected?
5. Will failure to conduct a RCA result in deterioration of staff or physician morale and/or trust in the leadership’s commitment to patient safety?

If an event is a criminal or deliberate unsafe act, consider other reporting requirements and Risk management review.

Hospital acquired pressure injuries (HAPI) are reportable if Stage III, IV, or unstageable pressure ulcers acquired after admission. Excludes progression from wounds acquired pre-admission as long as they were recognized at admission. Excludes DTIs unless these evolve into or are debrided into St. III or IV. Excludes so-called Kennedy Ulcers arising in the 24-48 hour period prior to death. Excludes dry necrotic areas on feet from arterial insufficiency.

*2 An event would be considered to be part of a patient’s normal disease course if the untoward event arose from the patient’s intrinsic condition, rather than from the exogenous medical treatment. For instance, a patient goes into DIC and dies. If the patient has an underlying coagulopathy or sepsis, or any other condition that caused the DIC, this would not be considered a reportable event. However, if the patient has a hemolytic transfusion reaction because of incorrect typing and goes into DIC and dies- that is a reportable level 1 event. Another example is if a patient falls and develops a subdural hematoma and dies, this is a reportable level 1 event, even if the development of the SDH was the result of an underlying coagulopathy. The patient would not have developed the SDH that killed him had he not fallen. The event is the fall, not the development of the SDH. 3 Serious disability is defined in 10.07.06 as a physical or mental impairment that substantially limits one or more major life activities of an individual lasting more than seven days or still present at the time of discharge.*

**ADVERSE EVENT DECISION TREE**

*Physical or Sexual Assualt*

Criminal or deliberate unsafe act? Consider other reporting requirement and risk management review. If physical or sexual assault follow YES pathway

Event considered JC Sentinel Event or NQF Never1 Event

No

Yes

Level 2

RCA REQUIRED

No Submission Required

Level 3

RCA optional

No Submission Required

Yes

Yes

No

Yes

Medical Intervention required to prevent death or serious disability3

Yes

Yes

No

No

No

No

Not reportable

Near Miss

(Consider RCA)

Level 1

RCA REQUIRED

RCA Submission Required

Event resulted in Death or serious disability

Event r/t medical tx, Omission or delay

Event r/t normal disease course2/tx

Unexpected event or situation

Event reached the patient

1. <http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx#sre4> [↑](#footnote-ref-1)