



- a. Discharge or release of a patient /resident of any age, who is unable to make decisions, to other than an authorized person\*\*
  - b. Patient death or serious disability associated with patient elopement (disappearance)\*
  - c. Patient suicide, attempted suicide, or self-harm resulting in serious disability, while being cared for in a health care facility\*\*
4. Care management events
- a. Patient death or serious injury associate with a medication error
  - b. Patient death or serious injury associated with unsafe administration of blood products\*
  - c. Maternal death or serious injury associate with labor or deliver in a low-risk pregnancy while being care for in a health care setting\*
  - d. Death or serious injury of a neonate associate with labor or deliver in a low-risk pregnancy\*
  - e. Artificial insemination with the wrong donor sperm or wrong egg
  - f. Patient death or serious injury associated with a fall while being cared for in a health care setting
  - g. Any stage 3, stage 4, or unstageable pressure ulcers acquired after admission/presentation to a health care facility
  - h. Patient death or serious disability resulting from the irretrievable loss of an irreplaceable biological specimen
  - i. Patient death or serious injury resulting from failure to follow or communicate laboratory, pathology, or radiology test results
5. Environmental events
- a. Patient or staff death or serious disability associated with an electric shock in the course of a patient care process in a healthcare setting
  - b. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances
  - c. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a health care setting
  - d. Patient death or serious injury associated with use of restraints or bedrails while being cared for in a health care setting
6. Radiologic events
- a. Death or serious injury of a patient or staff associated with introduction of a metallic object into the MRI area
7. Criminal events
- a. Any instance of care order by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
  - b. Abduction of a patient/resident of any age\*
  - c. Sexual abuse/assault on a patient within or on the grounds of a health care setting\*
  - d. Death or significant injury of a patient or staff member resulting from physical assault that occurs within or on the grounds of a health care setting\*\*

A Sentinel Event is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, permanent harm, or severe temporary harm.

1. Death
2. Permanent harm
3. Severe temporary harm: defined as a critical, potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition.

These events are called "sentinel" because they signal the need for immediate full investigation and response. Events subject to review include any events that meet the following criteria:

1. Suicide of any individual receiving care, treatment or services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital Emergency Department.
2. Unanticipated death of a full-term infant.
3. Discharge of an infant to the wrong family.
4. Abduction of any individual receiving care, treatment or services.
5. Any elopement (that is, unauthorized departure) of a patient from a staffed around the clock care setting (including the Emergency Department ), leading to death, permanent harm, or severe temporary harm to the patient.

6. Sexual abuse/physical assault and homicide\*Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual sexual contact, including oral, vaginal, or anal penetration or fondling of the individual's sex organ(s) by another individual. One or more of the following must be present to determine that it is a sentinel event:
  - Any staff-witnessed sexual contact as described above.
  - Admission by the perpetrator that sexual contact, as described above, occurred on the premises.
  - Sufficient clinical evidence obtained by the health care organization to support allegations of unconsented sexual contact.
- a. Sexual abuse/assault of any [patient/client] while receiving care, treatment, and services while on site at the organization/facility or while under the supervision/care of the organization.\*
- b. Sexual abuse/assault of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization/facility or while providing care/supervision to [patients/clients].\*
- c. Physical assault of any [patient/client] (leading to death, permanent harm, or severe temporary harm) while receiving care, treatment, and services while on site at the organization/facility or while under the supervision/care of the organization.
- d. Physical assault (leading to death, permanent harm, or severe temporary harm) of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization/facility or while providing care/supervision to [patients/clients].
- e. Homicide of any [patient/client] while receiving care, treatment, and services while on site at the organization/facility or while under the supervision/care of the organization.
- f. Homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the organization/facility or while providing care/supervision to [patients/clients].
7. Administration of blood or blood products having unintended ABO and non-ABO (Rh, Duffy, Kell, Lewis, and other clinically important blood groups) incompatibilities, hemolytic transfusion reactions, or transfusions resulting in severe temporary harm, permanent harm, or death
8. Surgery or other Invasive procedure performed on the wrong patient, at the wrong site or wrong (unintended) procedure for that patient.
9. Unintended retention of a foreign object in a patient after an invasive procedure, including surgery.
10. Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong body region, or >25% above the planned radiotherapy dose.
11. Fire, flame, or unanticipated smoke, heat, or flashes Occurring during direct patient care caused by equipment operated and used by the hospital. To be considered a sentinel event, equipment must be in use at the time of the event; staff do not need to be present
12. Any intrapartum (related to the birth process) maternal death
13. Severe maternal morbidity (not primarily related to the natural course of the patient's illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm
14. Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
15. Fall event – Fall resulting in any of the following: any fracture; surgery, casting, or traction; required consult/management or comfort care for a neurological (for example, skull fracture, subdural or intracranial hemorrhage) or internal (for example, rib fracture, small liver laceration) injury; or a patient with coagulopathy who receives blood products as a result of the fall; death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall).

#### **D: Procedures**

1. Any employee, resident, student, physician, administrator or persons performing work for UTMC who is aware of an incident that may be an Adverse Event, Never Event or a Sentinel Event is responsible for contacting the primary physician and the House Supervisor and for entering an Incident Report into the Patient Safety Net in accordance with the Patient Safety Event Reporting Policy, 3364-100-50-39.

- Appropriate standards of care will occur to stabilize the patient. An Incident Report will also be entered into the Patient Safety Net for an incident that is considered a Near Miss.
2. The House Supervisor will immediately compare the events reported against the Sentinel and Never Event criteria. If the incident has the potential to meet the established Sentinel Event criteria, then the House Supervisor will notify the Administrator On-Call and the Chief Medical Officer (CMO), or person in lieu of CMO if CMO is not available.
    - a. The CMO will work with the primary physician, nursing staff, and administrator On-Call to assure stabilization of the patient has occurred.
    - b. The Administrator On-Call and the CMO will notify the individuals as outlined in the attached Communication Flow Chart and determine, within 24 hours of notification of the incident, whether the incident is a Sentinel Event. If applicable, the I'm Sorry protocol will be initiated as per the I'm Sorry policy 3364-100-60-10. The CMO may convene a Committee to assist in his or her analysis in determining whether the incident is a Sentinel Event and any immediate actions required which may include the Administrative overseeing, Quality, hospital administrator, Chief of Staff, legal counsel or others as may be helpful. Physicians who were involved in the patient care of a potential Sentinel Event will not be involved in the final determination of whether an event is a Sentinel Event, but they may provide input.
    - c. If the CMO is not physically present for determination of whether an incident is a Sentinel Event, the next physician on the list for call rotation will step in to make the determination.
    - d. Medical Staff physicians may ask the CMO or Administrator for Quality to review whether certain events should be considered Sentinel Events.
    - e. Once it is determined that a Sentinel or Never Event is present, a comprehensive systematic analysis will be completed no more than 45 days after the incident, or after the incident was discovered.
    - f. A Comprehensive Systematic Analysis is used for identifying the causal and contributory factors that underlie variation in systems and processes and may have contributed to the event. A Root Cause Analysis is the most commonly used form of a comprehensive systematic analysis used to identify the factors that underlie a Sentinel Event. A Root Cause Analysis focuses on systems and processes, not individual performance.
    - g. An Intense Analysis, is a performance improvement process that may be applied to Near Misses or an Adverse Event, and which trends and analyzes data and focuses primarily on systems and processes.
    - h. In accordance with the I'm Sorry Protocol, the CMO may meet with the patient, or the patient's family if appropriate, after discussing with the attending physician to answer any questions that the patient or family may have.
  3. The Quality department will begin the investigation immediately. The investigation will include at a minimum the following:
    - a. Review of medical record;
    - b. Review of relevant policies, procedures and standards of care;
    - c. Interview applicable personnel, including but not limited to medical staff members, outside employees and hospital employees, who witnessed or have any knowledge or information regarding the Sentinel Event;
      - i. Inspect or review all relevant material, equipment and devices and secure the same;
      - ii. Meet with and interview the patient or family of the affected patient, as appropriate
      - iii. Document findings, conclusions, actions.
  4. The Quality department will convene a team to conduct a Comprehensive Systematic Analysis in the form of a Root Cause Analysis. This team may be comprised of a person from the Quality Department, Hospital Administration, Office of Legal Affairs, pertinent staff members, and physicians as necessary.
    - a. Within 45 days of the event or of becoming aware of the event, the team will develop an action plan. The action plan will identify strategies that will be taken to reduce the risk of similar events occurring in the future. The action plan will include recommendations for assigning responsibility for the implementation of these actions, ongoing monitoring and specific time frames. In addition, strategies for measuring effectiveness and sustaining the change will be included. Ongoing compliance for implementation of the action plan will be tracked by the Quality department
  5. The Quality Department will present the findings and recommendations to the Quality and Patient Safety Council (QPSC). The QPSC will either accept or decline the findings and action plan.
    - a. If accepted, it must be implemented and the QPSC will assist with action plan compliance.
    - b. If declined, the Root Cause Analysis Team will reconvene and gather more information or modify the action plan as requested by the QPSC.
    - c. Matters involving physician activity will be referred to the Peer Review Committee as appropriate.

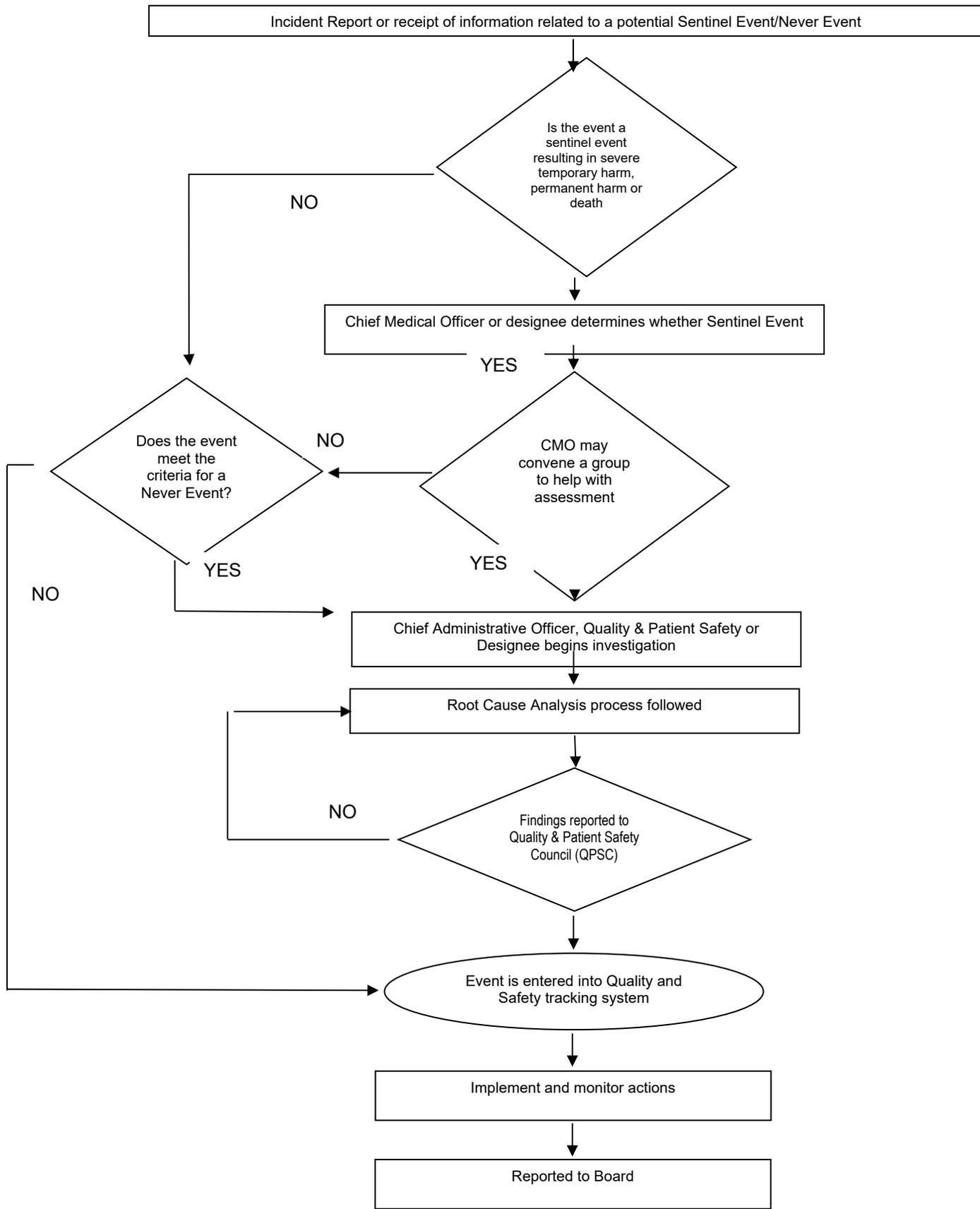
- d. The QPSC will be periodically updated and will help facilitate compliance as necessary.
6. The CMO, or designee, will report Never Event and Sentinel Event activities to the Clinical Affairs Committee of the Board of Trustees.
  7. The University of Toledo Medical Center will report all Never and Sentinel Events through the process of their Patient Safety Organization (PSO). In addition appropriate Events will be reported by UTMC administration to external agencies to the extent required in accordance with applicable laws, regulations and the rules of accrediting agencies. ( For example: Events related to renal transplants will be reported to OPTN and ESRD Network as applicable, Reports to IRB if related to human subject research; Report to FDA if related to a medical device; Report to CDC if related to transmission of a communicable disease; Report to OPO if related to an infectious disease present in a recovered organ from a deceased donor that could be transmitted to other recipients.)
  8. All documents generated as a result of a Sentinel Event, Never Event, an Adverse Event or a Near Miss, including but not limited to the initial report, the findings and the Root Cause Analysis forms will be maintained in a strictly confidential manner by all parties who receive the documentation. These documents are considered to be confidential reports and are part of the peer review and quality assessment process of the Hospitals. They are protected from disclosure pursuant to the provisions of ORC 2305.25 and ORC 2305.25.3. Unauthorized disclosure or duplication is absolutely prohibited.
  9. Administration will work with finance to determine appropriate waiving of cost on a case by case scenario with the thresholds being incremental costs associated with the Event to the entire bill for that episode of care.

**References:**

1. The Joint Commission CAMH Update 2: January 2020: Sentinel Events
2. National Quality Forum: Serious Reportable Events in Healthcare-2011 Update
3. Agency for Healthcare Research and Quality: U.S. Department of Health and Human Services: Patient Safety Primer September 2019: Never Events accessed 6/30/2020  
<https://psnet.ahrq.gov/primer/never-events>

<p><b>Approved by:</b></p> <p><u>/s/</u> <u>03/12/2021</u>        Richard Swaine        Chief Executive Officer - UTMC        Date</p> <p><u>/s/</u> <u>03/13/2021</u>        Andrew Casabianca, MD        Chief of Staff        Date</p> <p><i>Review/Revision Completed By:</i>        HAS        Quality Management        Chief of Staff        Office of Legal Affairs - HSC</p>	<p><b>Review/Revision Date:</b>        10/15/98        03/01/99        03/02/01        11/01/03        03/10/05        06/30/05        7/13/05        3/8/06        2/27/08        2/23/2011        8/27/13        1/2/2014        7/1/2015        11/1/2016        10/23/2019        8/1/2020        1/1/2021</p> <hr/> <p><b>Next Review Date:</b> 1/1/2024</p>
<p><b>Policies Superseded by This Policy:</b> 7-50-38 Sentinel Events/Adverse Events</p>	

## Adverse//Never/Sentinel Event Flow Process



## Communication Flow Chart

