I. STATEMENT OF PURPOSE
To establish guidelines for managing a serious clinical adverse event.

II. POLICY
It is the policy of [name of organization] to identify and effectively manage the risks associated with a serious clinical adverse event. The organization will conduct an investigation and implement an improvement plan.

III. RESPONSIBILITY/SCOPE
All organization services and staff members

IV. DEFINITIONS
- **Serious Clinical Adverse Event** – A serious clinical adverse event is a serious adverse health event, including, but not limited to, the actual or potential loss of life, limb or function, or an event that required significant and prolonged medical intervention or treatment. When attempting to determine if an event is serious, severity should be utilized as a determining factor (e.g., impact on the patient, potential impact on the patient and impact on operations, financial loss control, media exposure, market share, environment, and/or regulatory implications). There is recognition that at times, an event without harm to the patient will meet criteria for a serious clinical adverse event response due to the high potential for harm.

Examples of events that are considered serious clinical adverse events include the following:
- Sentinel events as defined by The Joint Commission
- Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital’s emergency department (ED)
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment and services
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- Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting) including the ED, leading to death, permanent harm, or severe temporary harm to the patient
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
- Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on-site at the hospital
  - Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual sexual contact involving a patient and another patient, staff member or other perpetrator while being treated or on the premises of the hospital, including oral, vaginal, or anal penetration or fondling of the patient’s sex organ(s) by another individual’s hand, sex organ, or object. 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 hospital to support allegations of unconsented sexual contact
- Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
  - If a foreign object (for example, a needle tip or screw) is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a sentinel event to be reviewed
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- Prolonged fluoroscopy with cumulative doses >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose
- Fire, flame, or unanticipated smoke, heat or flashes occurring during an episode of patient care
  - Fire is defined as a rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities. A combustion process that results in smoldering condition (no flame) is still classified as fire.4
- Any intrapartum (related to the birth process) maternal death or severe maternal morbidity

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- **Severe maternal morbidity** is defined by the American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society of Maternal and Fetal Medicine as a patient safety event that occurs intrapartum through the immediate postpartum period (24 hours), that requires the transfusions of 4 or more units of blood products (fresh frozen plasma, packed red blood cells, whole blood, platelets) and/or admission to the intensive care unit (ICU). Admission to the ICU is defined as admissions to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support.

- Events that require reporting to the state or other regulatory body
- CMS hospital-acquired conditions that were not present on admission
- Workplace violence
- Serious Safety Events as defined by The American Society for Healthcare Risk Management (ASHRM)
  - Failure to follow standard procedures such as with medication administration and patient identification
  - Failure to assess a patient for the risk of falling
  - Failure to implement standard fall prevention methods for high-risk patients.
  - Failure to monitor and assess patient condition
  - Delays in care
  - Wrong method or process for care delivery
  - Wrong procedure or a procedure done on a wrong patient.
  - Lack of a backup generator for surgical cases
  - Implantation after a product has been recalled
  - Failure to upgrade substandard fire pumps

V. GOALS OF SERIOUS CLINICAL ADVERSE EVENT RESPONSE

- To respond to the needs of any persons affected by the event
- To confirm the safety of involved persons and secure the interests of the organization
- To disseminate appropriate information to interested parties (e.g., staff members, administrators, legal counsel, physicians, patients, patient family members, community, state health department, accreditation organizations, patient safety organizations, Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA))
- To take action to prevent a recurrence

VI. PROCEDURE

A. Internal Reporting and Investigation

The following actions may be taken by the risk/quality manager in response to a serious clinical adverse event. The actions do not need to be taken sequentially; the order in which the actions are taken will depend upon the situation. The Serious Clinical Adverse...
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Event Response Checklist form may be used to document actions taken in response to the event.

1. Focus on the immediate situation. Assess the situation to confirm that no one is in any “immediate” danger or exposed to practices not supported by professional standards. Determine if staff members, physicians or the patient's family members require immediate support.

2. Determine the severity of the event. Consider the impact on the patient and on organizational operations (e.g., financial loss, media exposure, regulatory implications).

3. Notify the appropriate managers, leaders, and medical staff members.

4. Initiate a serious clinical adverse event response team if criteria for doing so are met. The serious clinical adverse event response team may include the involved managers, the organization’s leaders and medical staff leaders. The purpose of the serious clinical adverse event response team is to conduct an immediate review of the facts known about the event, determine the course of action, and ensure that needed resources are available to implement the actions.

5. Secure the area and gather and sequester evidence. Evidence includes, but is not limited to, medical records, equipment (retain the internal settings), supplies, (including disposables and vials, etc.), packaging and the communications (e.g., email) of involved employees.

6. Begin the process of disclosing the event to the patient and the patient’s family members. Refer to the organization’s disclosure policy.

7. Determine if there are external reporting requirements. Determine the timeframe and information needed for external reporting.

8. Notify the insurance company.

9. Determine which additional disciplines were involved in the event. Include them in the investigation, analysis and action planning.

10. Develop a plan for conducting an investigation.

11. Conduct the investigation under the quality/professional review process, attorney/client privilege or as Patient Safety Work Product for this organizations who participate in a Patient Safety Organization.

12. Determine and communicate the roles of the involved managers for investigation, corrective action planning, and implementation.

13. Determine if a focused review or a root cause analysis will be conducted.

14. Conduct a focused review or a root cause analysis
   i. Interview involved individuals. Conduct interviews surrounding the event in a supportive and non-punitive fashion. Staff members may be asked to document the event on an event report. Staff members must not create personal notes because the notes could become discoverable. The purpose of the interview (i.e., performance improvement versus accountability versus claims management) should be clearly communicated to staff members.
   ii. Prepare a timeline of the event. The timeline will be based on information gathered from the medical record and interviews.
   iii. Map the event. Tools for mapping the event include flowcharts, time/person grids, tabular timeline, and a chronological timeline.
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iv. Conduct a literature search. Identify evidence-based best practices for the process under review.
v. Brainstorm to identify root and contributing causes of the event.

15. Analyze the information gathered in the investigation. Identify contributing and root causes.

16. Develop a corrective action plan. Clearly define the following:
   i. Action items or risk reduction measures
   ii. Person responsible for implementing each action item
   iii. Timeline for implementing each action item
   iv. Measurement method and target
   v. Person responsible for measurement
   vi. Timeline for measurement

17. Monitor the effectiveness of the actions taken.

18. Consider making a referral to human resource and/or peer review as appropriate.

19. Prepare for the media. Assign a “point person” and prepare a statement.

20. Assess the need for involving an accrediting or licensing body and anticipate a survey.

21. Consider whether it is appropriate to notify law enforcement, the medical examiner and/or other officials.

B. Communication

Disclosure of adverse events – It is appropriate to disclose adverse events, errors and/or unanticipated outcomes that could affect a patient’s emotional or physical health. The framework for discussing unanticipated outcomes should be premised on strong communication processes, both before and after treatment or procedures. The roles and responsibilities for communication should be well-defined prior to the point of the actual disclosure. Refer to the organization’s disclosure policy.