Serious Adverse Event Reporting, Investigation and Conducting a Root Cause Analysis (RCA) – SAMPLE

Subject: Serious Adverse Event Reporting, Investigation and Conducting a Root Cause Analysis (RCA)

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(Signature) Date

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I. STATEMENT OF PURPOSE:

To establish guidelines for identifying, reporting and internally investigating each event that meets the definition of a serious adverse event or near miss, while maintaining confidentiality of the investigative process and protecting hospital documents under state peer review statutes, including but not limited to [*reference state statutes*] and any other applicable state and federal laws.

II. POLICY:

It is the policy of [*Facility Name*] to identify, analyze, evaluate and eliminate or reduce risks to patients and deliver safe, quality healthcare. As such, the organization will identify, investigate and respond to serious adverse events or near misses for the purpose of improving care and reducing morbidity and mortality.

III. RESPONSIBILITY/SCOPE:

All hospital services; all hospital staff members.

IV. DEFINITIONS:

- Serious Adverse Event: The significance of unanticipated events is determined by severity and probability of reoccurrence. Key factors for severity are the extent of any injury, length of stay, level of care required for remedy, and actual or estimated physical plant costs. Probability can at times be determined by data; it is often a conclusion based on experience and judgement. A risk-based prioritization system based on severity and probability of recurrence, whether actual or potential, provides a credible and efficient means of determining what hazards constitute a "serious event" that warrants the use of organizational resources to analyze and remediate.

  Serious adverse events are also specifically defined by both regulatory agencies and state mandates, as below.

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- Sentinel Event (From The Joint Commission): 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 any of the following:
    - Death.
    - Permanent harm.
    - Severe temporary harm and intervention necessary to sustain life.[a]

- An event is also considered sentinel if it is one of the following:
    - 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.
    - 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.[b]
    - Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital.
    - Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure.[c]
    - Unintended retention of a foreign object in a patient after an invasive procedure, including surgery.[d]
    - Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter).
    - Prolonged fluoroscopy with cumulative dose >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.[e]
    - Any intrapartum (related to the birth process) maternal death.
    - 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 any of the following:
        - Permanent harm or severe temporary harm.[f]

[Footnotes]

a. *Severe temporary harm* is 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.

b. 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.

c. Invasive procedures, including surgery, on the wrong patient, or at the wrong site, or that is the wrong procedure are reviewable under the policy, regardless of the type of the procedure or the magnitude of the outcome.

d. 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. However, in such cases, the organization shall (1) disclose to the patient the unintended retention, and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.

e. *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. Source: National Fire Protection Association.

f. *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 patient safety event that occurs intrapartum through the immediate postpartum period (24 hrs), that requires the transfusion 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). Facilities are strongly encouraged to review all cases of severe maternal morbidity for learning and improvement. *Admission to the ICU* is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support.[1]

State Reportable Event: (Enter state reportable events, as applicable.)

FDA Serious Adverse Event:
An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious and may be voluntarily reported to FDA when the patient outcome is:

- Death.
- Life-threatening.
- Requires initial or prolonged hospitalization.
- Disability or permanent damage.
- Congenital anomaly or birth defect.
- Requires intervention to prevent permanent impairment or damage (devices).
- Any event that may jeopardize the patient.[2]

Root Cause Analysis (RCA):
A process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event - The goal of an RCA is to reduce morbidity and mortality, focusing primarily on systems and processes, not individual performance. An RCA progresses from special causes in clinical processes to common causes in organizational processes. It further identifies improvements in processes or systems that decrease the likelihood of such events recurring in the future or determines, after analysis that no such improvement opportunities exist.

1. For detailed guidance on conducting a RCA, please refer to "RCA²: Improving Root Cause Analyses and Actions to Prevent Harm" http://www.ihi.org/resources/Pages/Tools/RCA2-Improving-Root-Cause-Analyses-and-Actions-to-Prevent-Harm.aspx.

V. PROCEDURES:

A. Internal Reporting and Investigation of Serious Adverse Events

1. Staff members will take the following actions:
   - Ensure the safety of the patient/family and staff members.
   - Immediately notify their manager/supervisor, risk management (during business hours) or designated administrative leader (after hours, weekends and holidays).
   - Follow the procedure for completing an unanticipated event report.
   - Sequester all equipment and products involved in the event (including bottles, syringes and wrappers), labeling them with the patient's name and event date.

     ***NOTE**: Manufacturers may be contacted to replace equipment, but equipment or devices involved in an event are not to be released to the manufacturer for evaluation or repair, except as authorized by risk management.*

2. The risk manager or designee will take the following actions:
   - Consult with administrative leaders (CEO, CNO, Vice President of Quality) to determine whether the event meets any of the definitions of a serious event. Consult with legal counsel if necessary.

- Use the organization's criteria to assess whether the event or near miss warrants a RCA. This determination should be made within 72 hours of the event.
- Initiate an investigation of the event, which may include the following:
  - Reviewing all equipment involved in the event.
  - Interviewing staff members, in accordance with peer/professional review functions.
  - Sequestering physical and/or documentary evidence.
  - Securing the site.
  - Reviewing related policies and procedures.
  - Reviewing pertinent literature.
  - Reviewing "best practices".
- In conjunction with the CEO, CNO and/or Vice President of Quality will determine and fulfill reporting requirements of the event to their accrediting agency, state or patient safety organization (PSO).

  ***NOTE**: All sentinel event and state reportable event investigation and monitoring documents shall be included in the risk management/quality file. All documents shall be labeled with a statement of confidentiality which cites the appropriate statutes.*

B. Under the direction of the clinical quality oversight committee, the director of risk/quality or designee will assemble a root cause analysis team consisting of 4-6 members with an appointed team leader and recorder. Members can fulfill more than one role. Members should typically **NOT** be individuals involved in the actual event. The members should include:
   - A subject matter expert.
   - Someone familiar with the RCA process but not the event being reviewed.
   - Managers and supervisors only if the event did not occur in their area of responsibility and their subordinates are not team members.
   - A physician for clinical events.
   - Consider a patient or family member not involved in the event.

1. The RCA team will perform the following:
   - As soon as possible, conduct a thorough and credible RCA, focusing on process and system factors. Ideally, the RCA process should be completed within 30-45 days.
   - Utilize analytical tools to determine the "root causes" (e.g., flowcharts, brainstorming, barrier analysis).
   - Ask "why?" repeatedly.
   - Identify performance improvement and/or risk reduction measures.
   - Develop a corrective action plan that will:
     - Identify performance improvement and/or risk reduction strategies to be taken, including pilot testing, if appropriate.
     - Assign individual(s) to implement performance improvement action(s).
     - Assign completion date(s) for performance improvement action(s).

NOTE: *Confidential records, data and meeting minutes generated by or on behalf of the RCA team will be labeled as professional/peer/quality review documents, will only be distributed at team meetings, and will be collected and destroyed at the end of each meeting, with one copy retained for the risk management/quality file. If the documents are considered Patient Safety Work Product, there may also be federal confidentiality protection.*

2. Ongoing monitoring of the effectiveness of corrective action(s) and process/system improvements will be conducted by risk management/quality. The RCA team will reconvene if ongoing monitoring reveals the need for revisions to the corrective action plan.
3. A summary of the RCA and action plan will be reported to the clinical quality oversight committee and the governing body.
4. The event, root cause analysis and action plan may be reported to a PSO, as directed by leaders.

References:

1. The Joint Commission, "Sentinel Events (SE)," *CAMH Update 1*, July 2017, pp. SE-1 to SE-3.
2. U.S. Food and Drug Administration (FDA), "What is a Serious Adverse Event?" Page last updated February 1, 2016, http://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm, 06/02/2016.