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<th>Sentinel Event Policy</th>
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<td>Policy Number:</td>
<td>MR-005</td>
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<tr>
<td>Joseph S. Gordy, CEO</td>
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<td>Flagler Hospital</td>
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<tr>
<td>Originator:</td>
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<td>National Quality Forum – List of Serious Reportable Events</td>
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<td>CMS – 482.13</td>
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POLICY: SENTINEL EVENT POLICY

OBJECTIVE: It is a policy of this hospital to establish mechanisms for identifying, responding to, and reporting sentinel events that occur in the organization.

SCOPE AND APPLICABILITY
This is an organization-wide policy. As such it applies to all care settings.

DEFINITIONS
1. Sentinel Event - A sentinel event is defined as 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.

2. Severe Temporary Harm - 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, or additional major surgery.

3. Major Permanent Loss of Function
Means sensory, motor, physiological, or intellectual impairment, not present upon entry into the care setting, which requires continued and ongoing treatment or life-style change. When major permanent loss of function cannot be immediately determined, applicability of the policy is not established until either the patient is discharged with continued major loss of function or two weeks have elapsed with persistent major loss of function, whichever is the longer period.

EXAMPLES OF SENTINEL EVENTS

Surgical or Invasive Procedure Events:
• Surgery or other invasive procedures performed on the wrong patient, wrong side of the body, or wrong site, or wrong (unintended) procedure.
• Unintended retention of a foreign body in a patient after surgery or other invasive procedure. (If a foreign object (e.g. needle tip or screw) is left in because clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, then this is not considered a sentinel event; however, disclosure to the patient of the unintended retention must be made.)
• Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient.

Product or Device Events:
• Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting.
• Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended.
• Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting.
**Patient Protection Events:**
- Discharge or release of a patient of any age, who is unable to make decisions, to other than an authorized person.
- Elopement, i.e., unauthorized departure, of a patient from a staffed around-the-clock care setting (including ED) leading to death, permanent harm or severe temporary harm to the patient.
- 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).
- Attempted suicide, or self-harm that results in serious injury while being cared for in a healthcare setting.
- Infant or child abduction or discharge to the wrong family.

**Care Management Events:**
- A patient death, paralysis, coma, or other major permanent loss of function associated with a medication error (e.g. errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration).
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups).
- Patient death or serious injury associated with unsafe administration of blood products.
- Any intrapartum (related to the birth process) maternal death.
- Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting.
- Any perinatal death unrelated to a congenital condition in an infant having a birth weight greater than 2500 grams.
- Unanticipated death of a full-term infant.
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy.
- Severe maternal morbidity when it (not primarily related to the natural course of the patient’s illness or underlying condition) reaches a patient and results in any of the following: permanent harm or severe temporary harm.
- Severe neonatal hyperbilirubinemia (bilirubin > 30 milligrams/deciliter).
- A patient fall that results in death or major permanent loss of function as a direct result of the injuries sustained in the fall.
- Any Stage 3, Stage 4 and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting.
- Artificial insemination with the wrong donor sperm or wrong egg.
- Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen.
- Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.
- Unanticipated death or major permanent loss of function associated with a health care-acquired infection.
- An unexpected patient death or major permanent loss of function, not related to the patient’s underlying physical condition or disease process.
- A patient death or major permanent loss of function associated with a delay in treatment.

**Environmental Events**
- Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting.
- Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances.
- 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 healthcare setting.
- Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting.
- Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care.
Radiologic Events
• Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area.
• 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.

Potential Criminal Events
• Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.
• Abduction of any patient receiving care, treatment, and services.
• 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.
• 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.
• Death or serious injury of a patient or staff member resulting from a physical assault (i.e. battery) that occurs within or on the grounds of a healthcare setting.

4. Root Cause Analysis
A root cause analysis is defined as a process for identifying the basic and causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes.

A root cause analysis is considered **THOROUGH** if it includes the following:
• A determination of the human and other factors most directly associated with the sentinel event, and the process(es) and systems related to its occurrence;

• Analysis of the underlying systems and processes through a series of “Why?” questions to determine where redesign might reduce risk;

• Identification of risk points and their potential contributions to this type of event;

• A determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities existed; and

• Addresses the minimum scope of analysis required for specific types of sentinel events as outlined in ATTACHMENT A.

A root cause analysis is considered **CREDIBLE** if the following can be demonstrated:
• It includes participation by leadership of the organization and by the individuals most closely involved in the processes and systems under review.

• It is internally consistent, that is, it does not contradict itself or leave obvious questions unanswered.

• Provides an explanation or rationale for a finding in which “no problem” was identified, or investigation into a process or system was deemed to be “non-applicable” to the analysis.

• It includes consideration of any relevant literature.
5. **Action Plan**

The product of the root cause analysis which identifies the strategies that an organization intends to implement to reduce the risk of similar events occurring in the future. An appropriate action plan should demonstrate the following:

- Identification of changes that can be implemented to reduce risk, or formulates a rationale for not undertaking such changes.

- The plan should address who is responsible for implementation, oversight, pilot testing as appropriate, time-lines, and strategies for measuring the effectiveness of the actions.

**POLICY**

1. **Identification of a Sentinel Event**

   Any potential sentinel event is to be reported immediately to the Risk Manager or - if not available - to the senior administrative representative in the house. Upon notification, this individual (in consultation with the Chief Medical Officer) will undertake or direct an initial investigation to determine if the occurrence is indeed a sentinel event as defined by this policy.

   If the event is determined not to be sentinel in nature, it will be addressed in accordance with established incident management policy and procedure. If the event is determined to be sentinel in nature, then the organization shall respond as noted in this policy.

2. **Notification / Communication of Sentinel Events**

   Upon determination that a sentinel event has occurred, the Chief Medical Officer shall convene a Sentinel Event Review meeting and shall serve as the Chairperson. The Risk Manager will notify all appropriate parties of a date/time/location of the “Sentinel Event Review” meeting.

3. **Formation of a Sentinel Event Response Team**

   As per the hospital’s Performance Improvement Plan, the Sentinel Event Response Team shall include the following:
   
   - Chief Medical Officer (to serve as Chairman)
   - Chief of the Medical Staff Department (most closely associated with the patient’s care)
   - Risk Manager
   - Involved staff/physicians
   - Quality Management staff
   - Chief Learning Officer

   - It is noted that the team should have appropriate representatives of administration, medical staff, nursing, risk management, and quality management. (The Marketing/Strategic Planning Department will be advised as necessary.)

   - In addition, the team should have those individuals directly involved in the event. Staff members involved in a sentinel event occurrence will receive support from the Sentinel Event Committee regarding the staff member's professional and emotional reconciliation of the sentinel event. The Sentinel Event Committee encourages the staff member's involvement in the root cause analysis and action plan processes, to allow the staff member an active role in process resolution.

   - The purpose of the team will be to coordinate an investigation into the incident, conduct a root cause analysis, and determine corrective actions to undertake in response to findings and/or identified opportunities for improvement.
4. **Protection from Discovery**
   All activities undertaken by the team should be done under the auspices of the medical staff quality assurance / peer review process. Other legal protections are to be implemented as determined by legal counsel.

5. **Immediate Remediation**
   The team will undertake those actions necessary to remediate any immediate threat or likelihood of the sentinel event recurring.

6. **Investigation of Event / Conducting a Root Cause Analysis**
   The team is to undertake a thorough and credible root cause analysis (RCA) of the sentinel event. The RCA should be completed within 45 days of the event or the organization becoming aware of the event.

7. **Failure to Conduct a Root Cause Analysis Within JCAHO Time Frames**
   If the JCAHO becomes aware of the sentinel event, the JCAHO must then determine if the RCA is acceptable. The hospital will be allowed 15 calendar days for its response. If the organization fails to submit an acceptable RCA within the 45 calendar days (or within 15 calendar days, if the 45 calendar days have already elapsed), its accreditation decision may be impacted.

8. **Developing and Implementing an Action Plan**
   Once the RCA has been completed, the team is to develop and implement a corrective action plan that will address both direct and root causes as well as – when appropriate -- special and common cause variation.

9. **Measures of Success Monitoring**
   One or more sentinel event measures of success will be monitored as part of follow up activity of the action plan. If the RCA and action plan were reviewed by the JCAHO, these MOS are due in 4 months and will be assigned by the JCAHO. If the planned action can be associated with a standard or National Patient Safety Goal requirement, it will have a level of compliance expectation based on the type of element of performance (EP) for the associated standard of NPSG requirement. Ex: EP A = 100%; EP C = 90% If the action cannot be associated with an existing standard or NPSG requirement, the level of compliance must be at least 85%, subject to approval by the Joint Commission.

   The number of cases to sample for a “Measure of Success” are as follows:
   - Population less than 30 – sample 100%
   - Up to 100 – sample 30 cases
   - Population 101 – 500 – sample 50 cases
   - Population over 500 – 70 cases

10. **Reporting Within the Organization**
    A summary (blinded) of the sentinel event, the root cause(s) identified, and the corrective actions taken will be reported to the Governing Body through the Board Quality Committee. The corrective action plan will also be communicated to other appropriate parties within the organization.

11. **Disclosure to Patient**
    Disclosure of the adverse event should be made to the affected patient or patient’s substitute decision maker if patient is deceased or deemed incapable of understanding a discussion of this nature. This disclosure generally rests with the most responsible clinician, but in certain cases the disclosure may be made by staff who have the most thorough knowledge of the adverse event. An apology or an expression of sorrow will be offered to the patient and/or family affected by the never event. (For more detailed information on disclosure, please refer to policy P&P - DISCLOSURE OF MEDICAL ERRORS JAN 2015 MR-001 ).
12. **Waiving of Costs**
Any potential “Sentinel Event” will be evaluated. A system will be maintained in order to waive costs as deemed directly related to the sentinel event.

13. **Reporting of Sentinel Events to the Joint Commission (JCAHO)**
No sentinel event is to be self-reported to the Joint Commission until an appropriate risk/benefit analysis has been conducted by Administration. If the decision of the team is to self-report, then the report shall be made by the Chief Executive Officer, or designee, following consultation and guidance from legal counsel.

14. **Reporting of Sentinel Events During Joint Commission Accreditation Survey**
The organization will report the occurrence of a sentinel event, documentation of the subsequent RCA, and the corrective action plan to the JCAHO during the next scheduled accreditation survey. Joint Commission personnel may then conduct an on-site review during the survey. No document should be transmitted to the Joint Commission without prior approval from legal counsel.

15. **Reporting of Sentinel Event to Patient Safety Organization**
The Risk Management Office will report any sentinel event to the hospital’s “Patient Safety Organization” within 10 days of becoming aware of the sentinel event.

16. **Reporting of Restraint/Seclusion Related Death to C.M.S.**
In keeping with federal law “Conditions of Participation”, the hospital must report deaths associated with the use of restraints. (This includes *both* med-surg restraints and behavioral management restraints.) The death shall be reported to the CMS Regional Office IV by the next business day following the patient’s death. This report shall be made by the Risk Manager. (See Restraint Policy for further guidelines).

17. **Record Keeping**
A record of the investigation into the sentinel event, the subsequent RCA, and any performance improvement activities undertaken is to be maintained by the Risk Management Office and should be constructed in such a way as to be afforded statutory protection from discovery.

18. **Availability of Policy**
The hospital shall make a copy of this policy available to patients, patients’ family members, and payers upon request.
ATTACHMENT A
Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events

<table>
<thead>
<tr>
<th>Process</th>
<th>Suicide/24h Care</th>
<th>Medication Error</th>
<th>Procedure/Compartment</th>
<th>Wrong Site Surgery</th>
<th>Treatment Delay</th>
<th>Restrict. Death</th>
<th>Elopement Death</th>
<th>Assault/Rape/Homicide</th>
<th>Transfusion Death</th>
<th>Infant Abduction</th>
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(1) Includes the process for assessing patient’s risk to self (and to others, in cases of assault, rape, or homicide where patient is the assailant)
(2) Includes search for contraband
(3) Includes supervision of physicians-in-training
(4) Includes furnishings; hardware (e.g. bars, hooks, rods); lighting; distractions, etc.
(5) Includes selection & procurement; storage; ordering & transcribing; preparing and dispensing; administration; monitoring

Reviewed: 1/5/11
Flagler Hospital, Inc.
St. Augustine, Florida

SENTINEL EVENT SUMMARY

Chart #: ___________________ Admit Date: _______________ Attending MD: _______________ Consultants: ___________________
Meeting Date: _______________ Discharge Date: _______________ Surgeon: _______________ ___________________
Occurrence Date: _______________
Disciplines Present: 

Individual Performance Issue? [ ] Yes [ ] No
[ ] Referred to dept chairman: ___________________
[ ] Referred to dept director: ___________________

System's Issue? [ ] Yes [ ] No

PROBLEM:
Significant Event: (state summary of case and problem encountered)
ROOT CAUSES/CONTRIBUTING FACTORS
(Include analysis of human factors, equipment factors, controllable & non-controllable environmental factors, information management issues, leadership issues, communication issues, human resource issues.)

Care of the Patient Processes:
---Assessment Processes
---Patient Identification Processes
---Patient Observation Procedures
---Continuum of Care
---Care Planning Processes
---Control of Medications - storage/access/labeling

Human Resource Issues:
---Staffing Levels
---Orientation & Training of Staff
---Competency Assessment/Credentialing
---Supervision of Staff

Communication Issues:
---Communication with Patient/Family
---Communication Among Staff Members

Information Management Issues:
---Availability of Information
---Adequacy of Technological Support

Equipment Factors:
---Equipment maintenance/management

Environmental Factors:
---Physical Environment
---Security Systems & Processes

Leadership Issues
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<th>Changes to reduce risk of a future occurrence</th>
<th>Who will implement changes?</th>
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<th>Monitoring the Effectiveness: What is to be monitored?</th>
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