**Policy:** PATIENT SAFETY EVENTS

**PURPOSE:**
To define the process of managing patient safety events.

**SKILL LEVEL:** All employees

**GUIDELINES:**
To improve the quality and safety of patient care at Southeast Health through the following: 1) identification and evaluation of errors, near misses or hazardous/unsafe conditions that are a threat to patient safety or have the potential to result in patient harm; 2) to improve systems and processes; and 3) to foster a culture of safety and learning across the organization by openly discussing patient safety at all levels.

Within a culture of safety, there is continuous reporting of patient safety events, near misses and hazardous conditions so these occurrences can be analyzed and processes can be changed or systems improved.

Reporting is essential to the identification and evaluation of errors for the purpose of identifying root causes and trends which leads to improving processes which is essential to reduce risk and prevent patient harm. All employees are required to participate in the detection and reporting of any error, medication error, near miss, hazardous/unsafe condition, process failures, injuries involving patients, visitors and staff or a sentinel event.

**PROCEDURE-Definitions**

1. **Patient Safety Event** – an event, incident or condition that could have resulted or did result in harm to a patient and can be but is not necessarily the result of a defective system or process design, a system breakdown, equipment failure or human error. They can also include adverse events, no-harm events, near misses and hazardous conditions.

2. **Adverse event** – a patient safety event that resulted in harm to a patient.
3. **No-harm event** – a patient safety event that reaches the patient but does not cause harm.

4. **Near miss event** (or “great catch”) – a patient safety event that did not reach the patient.

5. **Hazardous condition** (or unsafe condition) – a circumstance, other than the patient’s own disease process or condition, that increases the probability of an adverse event.

6. **Sentinel Event** – 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:
   a. Death
   b. Permanent Harm
   c. Severe temporary harm

An event is also considered sentinel if it is one of the following:

   d. Any intrapartum (related to the birth process) maternal death or maternal morbidity
   e. Unanticipated death of a full-term infant
   f. 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.
   g. Discharge of an infant to the wrong family.
   h. Suicide of any patient receiving care, treatment and services in a staffed around the clock care setting or within 72 hours of discharge from Southeast Hospital, including from the hospital’s emergency department.
   i. Abduction of any patient receiving care, treatment or services.
   j. 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.
   k. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities – ABO, Rh, other blood groups. (Transfusion reaction involving administration of wrong blood type.)
   l. Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure.
   m. Unintended retention of a foreign object in a patient after an invasive procedure, including surgery.
   n. Severe neonatal hyperbilirubinemia (Bilirubin >30 milligrams/deciliter)
   o. Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery or radiotherapy to the wrong body region or >25% above the planned radiotherapy
   p. 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 health care organization.
   q. Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care.

7. **Never Events** - Serious events as defined by the National Quality forum that should never
8. **Disclosure**: for the purpose of this policy, disclosure is the sharing of a patient’s health information to individuals, or their personal representatives, specifically when they request access to, or an accounting of disclosures of, their protected health information; and to Health and Human Services (HHS) when it is undertaking a compliance investigation or review or enforcement action.

9. **Root Cause Analysis (RCA)** - a process for identifying basic or casual factor(s) underlying variation in performance, including the occurrence or possible occurrence of a sentinel event. The RCA will include assessment of the problem, identification of an opportunity for improvement, planning and implementation of improvement strategies and long-term effectiveness evaluation for sustained improvement.

10. **Patient Safety Organization (PSO)** – for the purpose of this policy, the PSO is the Center for Patient Safety (formerly Missouri Center for Patient Safety), a federally-designated PSO, positioned to assist new and current participants to obtain valuable protections available within the 2005 Patient Safety and Quality Improvement Act and to prevent patient harm. PSO shall have the same meaning as defined at 42 CFR §3.20. See *Patient Safety Organization (PSO) Policy for additional detailed information.*

**PROCEDURE – Frontline Staff:**

1. **Ensure patient safety** – after the event has occurred or hazardous condition has been identified, first and foremost staff should ensure the safety of the patient and notify physician as appropriate.

2. **Secure involved equipment** – if any device or equipment was involved in the event, remove it from service, tag it and report it to Biomed through the work order system. Include information about the device or equipment in the event report.

3. **Reporting** – When a patient safety event or hazardous condition has been identified, the event should immediately be reported. The preferred method of reporting is through the online event reporting system, providing a brief, objective, factual narrative description of the occurrence. At minimum the event should be reported to the manager or immediate supervisor.

   a. If a serious or sentinel event has occurred or is suspected to have occurred, the event will also be reported to at least one of the following individuals:
      1) Department Director or House Supervisor
      2) Executive Director of Quality
      3) Patient Advocate
      4) Patient Safety Manager
      5) Compliance Officer
      6) Hospital Administrators
      7) Compliance Hotline 1-888-394-2291 (anonymously)

   b. Under no circumstances will the reporting of any such event serve as a basis for retaliatory actions to be taken against any patient, staff or other person making the report. Reporting patient safety events is mandatory and persons failing to report such events may be subject to disciplinary action.
4. Participation in investigation – Staff will participate in any follow-up investigation as necessary including:
   a. Follow-up discussions with managers or other persons assigned to conduct an investigation
   b. Participation in an RCA if requested and hold all conversations regarding the event as confidential.

PROCEDURE – Department Director/Manager:

1. Reporting – If, upon receiving a report regarding a patient safety event the department director/manager determines the event to be a potential or actual sentinel event, they will immediately notify the administrator on call, Executive Director of Quality and/or Patient Safety manager.
2. Investigation – Once an event has been reported, the department director/manager will complete an initial investigation of the event as soon as possible and document findings in the event follow-up in the electronic event reporting system.
3. Staff follow-up – Staff involved in patient safety events, specifically serious events, will be offered opportunities for debriefing and support services consisting of pastoral care, social services, and/or referral to the Employee Assistance Program, as appropriate. The Ethics Committee may also be consulted for patient or staff issues involving ethical matters.
4. Risk Mitigation – Should an event occur that meets the definition of sentinel event, the administrative chain of command will be implemented to determine the need for immediate mitigating steps that should be instituted. Immediate mitigating steps may include but are not limited to:
   a. Notification of IT to add verbiage alerting staff on the intranet crawl
   b. Dissemination of temporary steps to all direct care leaders about the findings and temporary solutions
   c. Huddle/Lessons Learned information on SharePoint via the intranet crawl
   d. The use of printed material and sign-in sheets for staff as they come on shift after the event
   e. The use of the Learning Management System to educate/inform and track completion

5. Organizational learning – Department directors/managers will share pertinent lessons learned from patient safety events with other staff during staff huddles to raise awareness of patient safety and promote transparency. Should an event occur that meets the definition of a sentinel event, necessary staff will be educated immediately on the actions to be implemented to mitigate the risk of patient harm. For staff currently not on duty, the education will occur prior to staff members performing direct patient care.

PROCEDURE – Sentinel and Never Events:
1. Physicians and/or staff will immediately report information that suggests a sentinel event has occurred as outlined above to at least one of the following:
   • Department Director or House Supervisor
   • Executive Director of Quality
   • Patient Advocate
   • Patient Safety Manager
   • Compliance Officer
   • Hospital Administrators
   • Compliance Hotline 1-888-394-2291 (anonymously)

When there is uncertainty as to whether the event meets the above definition of a sentinel event, it will be presumed to be a sentinel event and should be treated as such until the investigation proves otherwise.

2. When a serious event occurs, investigation will begin immediately and the serious event RCA will be conducted within the patient safety evaluation system within 72 hours of the reporting of the event or as soon as the investigation is complete. Frontline staff involved in or having knowledge of the event are required to participate in the RCA; the RCA facilitator and Department Manager will collaborate on choosing appropriate staff and level of participation. Frontline staff are key in affecting patient safety improvement activities.

3. The RCA will include completion of a systematic analysis for identifying factors that contributed to or caused the event to occur, corrective actions to be taken and a timeline for completion of corrective actions.

4. Department leaders are required to participate in serious event RCA for events involving or occurring in their department(s). Leaders are expected to arrange schedules so frontline staff can attend the RCA. Interviews and/or group meetings with staff and physician(s) involved in the event are conducted to determine the chronological order of the event findings and each participant’s role perspective in the event. The Vice President /Chief Nursing Officer or designee participates in RCA meetings. Other hospital administrators may participate as it pertains to departments under their leadership. All investigation measures, interviews, and meetings are documented and maintained as patient safety work product (PSWP) in the patient safety evaluation system (PSES).

5. Necessary staff will be educated immediately on the actions to be implemented, to mitigate the risk of patient harm. For staff currently not on duty, the education will occur prior to staff members performing direct patient care.

6. If a never event occurs Southeast will (See Addendum A for list of never events.):
   a. Apologize to the patient/patient representative.
   b. Report the event in the hospital event reporting system.
   c. Perform a root cause analysis.
   d. Waive costs directly related to the event.
   e. Provide a copy of the hospital’s policy on never events to patients and payers upon request.

7. The Quality Management Department will notify the hospital’s legal counsel of the sentinel event and pending investigation. The hospital legal counsel will work with the
hospital’s liability carrier to coordinate any investigation and defense of the event as a potential litigation matter. Any risk management work product is developed outside the patient safety evaluation system and is not considered patient safety work product as outlined in the Patient Safety Organization policy.

8. When applicable, the Executive Director of Quality or designee notifies the Chief Medical Officer and/or the Chair of the Physician Excellence Committee of any serious events involving physician quality of care concerns.

9. Department leaders, in collaboration with their staff, with the assistance of the RCA facilitator, complete the RCA report detailing the serious event, causal factors that may have led to the variation in performance, any corrective actions taken to reduce the potential for future events, and the evaluation on the success of the corrective actions. The serious event investigation process focuses primarily on systems and processes, not individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future, or determines, after analysis that no such improvement opportunities exist. An action plan is the product of the investigation. It identifies the strategies implemented to reduce the risk of similar events occurring in the future. The plan will address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions. Lessons learned from the investigation and RCA will be shared throughout the organization by distributing the “lessons learned document” to the organization’s leaders to be communicated to their respective staff as appropriate.

10. The Executive Director of Quality/Patient Safety Manager report all serious events, investigation analysis, and corrective action plans to the Quality Council of Southeast Hospital’s governing body. In addition, the Executive Director of Quality/Patient Safety Manager report serious event RCA findings to the Patient Safety Committee for educational and improvement purposes and to the Serious Event Review Team (SERT) for appropriate communication to Senior Management (Vice President/CNO, Vice President/CMO, and Executive Director of Quality).

11. Patients and staff involved in a serious event are offered opportunities for debriefing and support services consisting of pastoral care, social services, and/or referral to the Employee Assistance Program as appropriate. The Ethics Committee may also be consulted for patient or staff issues involving ethical matters.

12. Serious or Never Event Charging Practice:

1) The hospital will not charge patients or payers for care that resulted in or was made necessary by a serious event as defined by the NQF list of never events.

2) A root cause analysis should determine that an event meets the following criteria:
   a. The event is preventable
   b. Within control of the hospital
   c. The result of an error
   d. Results in harm

3) This applies to hospital services, but may include other services. Physician and or
other provider’s billing decisions will be made on a case-by-case basis.

4) The Patient Safety Manager, or Executive Director of Quality will notify Billing when this practice needs to be applied.

5) Billing will utilize a code for waived charges for NQF Serious Event. (Example: “Quality and Safety-No Charge”).

DISCLOSURE:

Attending physicians, having primary responsibility for patient care, are responsible for initiating disclosure and maintaining all communications with the patient, or surrogate decision maker, about any unanticipated outcomes of care including but not limited to those defined as serious events. Such disclosure will occur timely - within 24 hours, or as soon as the patient or surrogate decision maker is physically and mentally able to comprehend the information provided. Disclosure should occur in accordance with the hospital’s Disclosure of Events Policy.

REFERENCES:

- http://www.mocps.org/patient-safety-organization-ps/ (PSO definition)
- The Joint Commission (sentinel event definition)
- National Quality Forum (serious reportable events definition and listing)
- (42 USC: 299b-21)

Attachments: Appendix A
Appendix A: National Quality Forum’s Never Events

1. Surgery performed on the wrong site
2. Surgery performed on the wrong patient
3. Wrong surgical or other invasive procedure performed on a patient
4. Unintended retention of a foreign object in a patient after surgery or other invasive procedure
5. Intraoperative or immediately postoperative/post-procedure death in an ASA Class 1 patient
6. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics
7. 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
8. Patient death or serious injury associated with intravascular air embolism
9. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
10. Patient death or serious injury associated with patient elopement
11. Patient suicide, attempted suicide, or self-harm that results in serious injury
12. Patient death or serious injury 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)
13. Patient death or serious injury associated with unsafe administration of blood products
14. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy
15. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
16. Patient death or serious injury associated with a fall
17. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation
18. Artificial insemination with the wrong donor sperm or wrong egg
19. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
20. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results
21. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process
22. 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
23. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process
24. Patient death or serious injury associated with the use of physical restraints or bedrails
25. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area
26. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
27. Abduction of a patient/resident of any age
28. Sexual abuse/assault on a patient or staff member within or on the grounds
29. 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