TITLE: SENTINEL EVENT

PURPOSE: To provide a mechanism for identifying, reporting and responding to the occurrence of a sentinel event or medical error as defined by Texas law within University Health System (Health System) facilities and to provide a process for conducting a thorough review such as a root-cause analysis (RCA) of any such events. This is a revised policy and supersedes the policy dated 09/07/04. [Key Words: Sentinel Event, Root-cause Analysis, Medical Error]

POLICY STATEMENT:

The Health System is committed to providing quality care to all patients seen within its facilities. Commensurate with this commitment, the Health System, through its Quality Risk Management Committee and subcommittees, will take the appropriate steps to prevent the occurrence of sentinel events or medical errors, as defined within this policy, and will conduct thorough reviews and/or root-cause analyses of such events. Based upon the findings of the review, the Health System will undertake the necessary steps to eliminate or substantially reduce the risk of similar events reoccurring.

POLICY ELABORATION:

I. DEFINITIONS

A. Sentinel Event – as defined by The Joint Commission, an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof. The phrase “or risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious outcome.

1. Sentinel events subject to the review of the Joint Commission includes any occurrence that meets any of the following criteria:
a. An event that has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient’s illness or underlying condition. (This includes death or major permanent loss of function related to health care – associated infection.)

b. Suicide of a patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 hours of discharge.

c. Discharge of an infant to the wrong family.

d. Abduction of any individual receiving care, treatment, and services.

e. Rape (See Endnote 1).

f. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

g. Surgery on the wrong patient or wrong body part

h. Unanticipated death of a full-term infant.

i. Unintended retention of a foreign object in a patient after surgery or other procedure.

j. Severe neonatal hyperbilirubinemia (bilirubin > 30 milligrams/deciliter).

k. 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.
B. **Medical Error** – as defined by the Texas Department of State Health Services (TDSHS), the failure of a planned action to be completed as intended, the use of a wrong plan to achieve an aim, or the failure of an unplanned action that should have been completed, that results in an adverse event.

1. A medical error or adverse event or occurrence that requires an RCA includes the following:

   a. A medication error resulting in a patient’s unanticipated death or major permanent loss of bodily function in circumstances unrelated to the natural course of the illness or underlying condition of the patient.

   b. A perinatal death unrelated to a congenital condition in an infant with a birth weight greater than 2,500 grams.

   c. The suicide of a patient in a setting in which the patient received care 24 hours a day.

   d. The abduction of a newborn infant patient from the hospital or the discharge of a newborn infant patient from the hospital into the custody of an individual in circumstances in which the hospital knew, or in the exercise of ordinary care should have known, that the individual did not have legal custody of the infant.

   e. The sexual assault of a patient during treatment or while the patient was on the premises of the Health System.

   f. A hemolytic transfusion reaction in a patient resulting from the administration of blood or blood
products with major blood group incompatibilities.

g. A foreign object accidentally left in a patient during a procedure.

h. A patient death or serious disability associated with the use or function of a device designed for patient care that is used for functions other than as intended.

C. **Serious Physical Injury** – includes the loss of limb or function.

D. **Major Permanent Loss of Function** – sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or life-style change. If it cannot be determined at the time of the event whether or not major permanent loss of function has occurred, then applicability of this policy will be established when either the patient is discharged with continued major loss of function or two weeks have elapsed and the loss of function has persisted, whichever occurs first.

E. **Root-cause analysis (RCA)** – a process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event or medical error. An RCA focuses primarily on systems and processes, not on individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and systems and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future or determine, after analysis that no such improvement opportunities exist.
F. **Action Plan** – the product of the RCA that identifies the strategies that the Health System intends to implement in order to reduce the risk of similar events occurring in the future. The plan, as appropriate, addresses responsibility for implementation, oversight, time lines, and strategies for measuring the effectiveness of the actions.

G. **Designated Administrator**: The Health System senior leadership member with responsibility for the facility and/or the service area in which the sentinel event or medical error has occurred.

II. **PROCEDURE**

A. **Initial Reporting**

1. Any Health System employee, contractor, volunteer, member of the Medical-Dental staff or House Staff that witnesses or has knowledge of a sentinel event or medical error as defined herein shall immediately report the event to:

   a. His/her supervisor

   b. The supervisor will then report the event to the Designated Administrator.

   c. If the witness or person with knowledge of the event is a Health System contractor, the report is to be made to the person within the Health System to whom the contractor reports with regard to the contracted services.

2. The Designated Administrator to whom the report is made shall immediately notify the Director, Risk Management
(RM). If the Director is unavailable, the Attorney on Call should be notified. While the initial report may be made either in person or by telephone, it must be immediately followed by submission of an electronic Risk Assessment Form (eRAF), to the Risk Management Department.

3. The Director, RM, Executive Vice President/Chief Medical Officer (CMO) and the Vice President, Legal Services, with consultation from the person reporting the sentinel event or medical error and any other appropriate staff, will determine whether or not the event constitutes a sentinel event or medical error as defined within this policy.

4. If it is determined that the event is a sentinel event or medical error the following actions will be taken:

   a. The President and Chief Executive Officer (CEO) of the Health System will be notified by the CMO and advised of the event and any immediate action taken to ensure patient, staff, and/or visitor safety. If the CMO is unavailable, the Chief Operating Officer (COO) will notify the President and CEO.

   b. The President and CEO, in consultation with staff, will make a determination regarding the reporting of the event to any regulatory or accrediting agency as may be required. If such reporting is required, it will be done on behalf of the CEO and the Health System by the Director, Risk Management.

5. If it is determined that the event is not a sentinel event or medical error, the event will be handled in accordance with established Health System policies and additional follow up measures will be taken as may be appropriate.
B. Conducting a Root-Cause Analysis

1. All events determined to be a sentinel event or medical error must undergo a root-cause analysis. The Quality/Risk Management Committee may follow the same root cause analysis process or other appropriate alternatives for any other occurrence. The determination of the appropriate alternative analysis process will be made by the Director, Risk Management in concert with the Chief Medical Officer.

2. Under the auspices of the Quality/Risk Management Committee, the Director, RM, shall assemble an ad hoc Sentinel Event Review Committee (SERC) to review and evaluate the event. The SERC will be responsible for performing a root-cause analysis of the event. Each root cause analysis (RCA) will be conducted to be thorough and credible and follow an approved format.

3. The SERC will consist of the following members:
   
a. Designated Administrator of facility where incident occurred or designee (Chair)

   b. Designated Legal Counsel

   c. Associate Administrator/Chief Nursing Officer or designee, if the event involves patient care issues

   d. Medical Director of the service area or designee, if the event involves patient care issues

   e. Director, RM or designee

   f. Administrative Director, Quality and Process
Improvement or designee

g. Other members as may be deemed appropriate and necessary.

4. The SERC shall expeditiously undertake a review and analysis of the event. The review and analysis may include, but need not be limited to, the following:

a. interviewing all individuals, including but not limited to Medical-Dental staff and House staff members, that may have knowledge relevant to the event

b. interviewing all health care providers with involvement in the event

c. reviewing the medical record

d. inspecting the area where an event occurred and/or any equipment, materials or devices involved in the event (if necessary, such items should be secured)

e. reviewing staffing schedules

f. reviewing relevant Health System policies and procedures

g. reviewing relevant publications, protocols, standards and/or guidelines

h. any documents or information related to equipment, services or contractual relationships involved in the event.
5. Any Health System employee, member of the Medical-Dental staff or member of the House Staff that is either appointed to the SERC or is requested to attend a SERC meeting must attend, unless otherwise excused by the Chair.

6. The SERC should focus its review and analysis primarily on systems and processes and not on individual performance. It should consider factors such as staffing, communication, orientation and training, equipment, medication management, patient assessment, and information management.

7. The RCA must include a review of relevant literature.

8. The RCA process must be conducted within 45 days of the known occurrence of the event.

9. Upon completion of its review and analysis, the SERC shall prepare a final written report of its findings, recommendations and action plan that will be forwarded to the Quality/Risk Management Committee through the Director, Risk Management. The report will also include a determination and recommendation of whether or not there are opportunities to improve processes or systems that would tend to decrease the likelihood of such events. The report shall not identify any patient or individual involved in the sentinel event or medical error.

10. The SERC’s report must include risk reduction strategies and a corrective action plan that includes appropriate measurement strategies. It shall also include recommendations for ongoing monitoring and identify persons charged with implementing and monitoring the corrective action plan.
11. All documents created as a result of the sentinel event or medical error, including but not limited to those created at the direction of the SERC, shall be maintained in a strictly confidential manner. All documents should be clearly marked “Confidential” and shall not be disseminated outside the membership of the SERC.

12. The SERC may determine, at any time during the process, that the conduct of a member of the Medical-Dental Staff, House staff or Health System employee warrants professional review. If such a determination is made, the Department of RM will ensure that this is undertaken.

C. Confidentiality of Information and Documentation

All reports, information and communication related to a sentinel event or medical error shall be treated as confidential and shall be maintained in a confidential manner by the Director, RM on behalf of the Quality/Risk Management Committee. All documents shall be marked as follows: “All proceedings and records of the Quality Risk Management Committee are confidential and all professional review actions and communications made to the Quality Risk Management Committee are privileged under Texas and federal law.

D. Support for Staff Involved in an Event

Services are available to support staff involved in a sentinel event or medical error through the Health System’s Employee Assistance Program.
REFERENCES/BIBLIOGRAPHY:

The Joint Commission 2011 Hospital Accreditation Standards and Sentinel Event Policy and Procedure

TEX.OCC.CODE ANN. Chps. 151 and 160 (Vernon Supp. 2002)

TEX. HEALTH and SAFETY CODE Chp. 161, Subchapter D (Vernon 2001)
42 USC § 11101 et seq.

Tex. Administrative Code, Title 25, Part 1, Chp 133, Subchapter C, Rule 133.48

OFFICE OF PRIMARY RESPONSIBILITY:

Executive Vice President/Chief Medical Officer

ENDNOTE:

“Rape” as used in this policy and has been defined by the JCAHO means: non-consented sexual contact involving a patient and another patient, staff member, or unknown perpetrator while being treated in or while on the premises of any Health System facility, 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:

1. Staff witnessed the conduct
2. Presence of sufficient clinical evidence to support an allegation of non-consensual sexual contact
3. Admission of the conduct by the individual(s) involved