TITLE: COMMUNICATION OF ADVERSE EVENTS

PURPOSE: To delineate the University Health System's (Health System) philosophy and approach for patient communication regarding outcomes of care, including adverse events. This is a revised policy and supersedes policy dated June 29, 2010. [Key Words: Adverse Event, Disclosure, Hospital Acquired Condition, Medical Error, Unanticipated Outcomes].

POLICY STATEMENT:

Patients have the right to receive timely, accurate, and understandable information to make informed health care decisions. Health System patients and, when appropriate, their families or authorized representatives, must be informed about the outcomes of their care, including adverse events.

POLICY ELABORATION:

The Health System is firmly committed to encouraging timely reporting of actual, potential or suspected unanticipated patient outcomes and prohibits any retribution, retaliation or harassment directed against a staff member for making a good faith effort to report such events.

I. DEFINITIONS

A. Adverse Event – an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.

B. Event Disclosure – the process of the forthright and empathetic discussion of the known clinical facts between the patient or patient representative and the provider and/or provider care team of the harmful or potentially harmful adverse event that has occurred.

C. 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. Sentinel events subject to the review of the Joint Commission includes any occurrence that meets any of the following criteria:

1. 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.)

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

3. Discharge of an infant to the wrong family.

4. Abduction of **any** individual receiving care, treatment, and services.

5. Rape

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

7. Surgery on the wrong patient or wrong body part

8. Unanticipated death of a full-term infant.

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

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

11. 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.

II. DISCLOSURE

A. The discovery of an adverse event must be communicated to the supervising attending physician and primary health care team responsible for the patient's care.

B. The disclosure of an adverse event can be made to the patient or patient representative by a resident of the patient's primary health care team, after dialogue with the supervising attending physician. Attachment I offers communication guidelines.

C. In instance of a major permanent loss of function, sentinel event, serious physical injury or potential for permanent harm, the attending is responsible for disclosure to the patient or patient's representative.

D. All adverse events will be communicated in a timely and appropriate manner, as soon as reasonably possible, taking into consideration the patient's condition. Acknowledgment of the adverse event between the patient or patient representative and provider should occur as soon as possible. In all instances, absent extraordinary circumstances, the communication should occur no later than 24 hours after becoming aware that the adverse event has occurred.

E. The Administrator on Call or other senior Health System leadership may wish to be present during the disclosure of an adverse event that constitutes a sentinel event.

F. In rare instances where the attending physician believes that the patient or appropriate representative may be harmed by the disclosure, the discussion may be postponed until the benefits of disclosure are greater than the potential harm. Documentation

regarding these circumstances should be made in the patient's medical record.

III. DOCUMENTATION

A. Medical record documentation is the same as for all other medical care and should include the following:

1. a factual explanation of the outcome
2. any treatment plan changes or recommendations
3. level of understanding exhibited by the patient or representative
4. the names of persons present for the conversation to include their relationship to the patient
5. assistance provided by an interpreter, other interpreter services, or communication assistance if provided

B. Follow-up plans and action must be documented in the established risk management adverse event reporting system.

REFERENCES/BIBLIOGRAPHY:

The Joint Commission (2014) Hospital Accreditation Standards; Participation in care decisions, Standard R1:01.02.01 A20

Health System Policy No. 2.13, Reporting Errors and Incidents of Misconduct

Health System Policy No. 5.015, Occurrence Reporting

Health System Policy No. 5.08, Sentinel Events

Doing Right by Our Patients When Things Go Wrong in the Ambulatory Setting, The Joint Commission Journal on Quality and Patient Safety, February 2014, Volume 40 Number 2

National Quality Forum, NQF Patient Safety Terms and Definitions, American Society for Health care Risk Management series on Disclosures: Part I, II, III. 2014

OFFICE OF PRIMARY RESPONSIBILITY:

Executive Vice President/Chief Medical Officer

ENDNOTES:

I. CONFIDENTIALITY

A. Disclosure of an unanticipated outcome abides by the confidentiality statutes and regulations, including the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule as outlined in Corporate Policy 2.1401 Uses and Disclosures of Protected Health Information.

B. All reports, information and communication related to an unanticipated outcome must be treated as confidential and will be maintained in a confidential manner by the Director, Risk Management 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. TX. OCC. CODE ANN. Chps. 151and 160; Tex Health and Safety Code § 161.032; and 42 USC § 11101 et seq."

II. RELATED DEFINITIONS

A. Hospital Acquired Condition – an event that could reasonably have been prevented through the application of evidence-based guidelines.

B. 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.

C. **Medical Error –** defined by the Texas Department of State Health Services (TDSHS), as 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.

D. **Near Miss –** an event or a situation that did not produce patient harm, but only because of intervening factors, such as patient health, timely intervention, or system technological alert or safety check. Near misses are not disclosed to the patient or family, but will be reported internally to identify trends and to educate staff.

E. **Second Victim –** a member of the health care team who is involved in an unanticipated or stressful event and is traumatized by the event.

F. **Serious Event** – the term to describe an event that results in death or loss of a body part, disability, or loss of bodily function lasting more than seven days or is still present at the time of discharge from an inpatient health care facility or, when referring to other than an adverse event, a non-trivial event.

G. **A Serious Physical Injury –** the loss of limb or function.

H. **Unanticipated Outcome –** a result that differs significantly from what is anticipated to be the result of the performance of care or omission of care provided to a patient, including both adverse outcomes and near misses. Unanticipated Outcomes should be reported in accordance with Health System Policy No. 5.01.05, Occurrence Reporting.

I. **Usually Preventable Event** – a recognized event that may not always be preventable, given the complexity of health care and patient.