DISCLOSURE OF UNANTICIPATED OUTCOMES

Purpose:

To define the role of the healthcare provider in communicating the outcome of any treatment, procedure, or diagnostic test, to the patient, and/or the family/legally authorized representative, whenever the outcome differs significantly from that which was anticipated.

Definitions:

1. Adverse Event – any event which is not consistent with routine patient care or the routine operation of the facility, and which adversely affects or has the potential to affect the health, life or comfort of the patient and is not caused by the patient’s underlying disease.

2. Disclosure – communication of information regarding the results of a diagnostic test, medical, surgical or other interventional treatment.

3. Unanticipated Outcome – a result that differs significantly from what was anticipated to be the result of a diagnostic test, medical treatment or surgical/invasive procedure. A known complication or side effect is not an unanticipated outcome, but information about such outcomes should also be disclosed to patients as a routine course of their treatment and care.

4. Medical Error – an act or omission with potential or actual negative consequences for a patient that, based on standards of care, is considered to be an incorrect course of action.

5. Sentinel Event—an unexpected event as defined by the Joint Commission on Accreditation of Healthcare Organizations and/or regulatory agencies as an adverse event or unexpected occurrence involving death or serious physical or psychological injury or the risk thereof.

Procedure:

A. Notification

1. An unanticipated outcome shall be reported immediately upon recognition to the Hospital Administrator/Administrator on Call. The Administrator/designee shall contact the Senior Associate Dean for Clinical Affairs/Medical Director and any other appropriate parties relative to the nature of the occurrence.
Some unanticipated outcomes arise from events (such as medication variances, patient safety issues, falls, or sentinel events) that are reported under other policies; those reports shall be filed as required. In all cases a Variance Report shall be completed (see hospital policy #2.22, Variance Reporting/Sentinel Events).

2. The Senior Associate Dean of Clinical Affairs/Medical Director is responsible to assure that the process of disclosure occurs in a timely and appropriate manner.

3. The disclosure process shall not be initiated until the Senior Associate Dean of Clinical Affairs/Medical Director and Administrator/designee has been contacted.

B. Disclosure Process

1. The attending physician (faculty) responsible for the patient’s care or his designee appointed by the Senior Associate Dean of Clinical Affairs/Medical Director shall serve as the primary communicator of an unanticipated outcome to the patient and/or family/legal guardian.

2. The intent of disclosure is to provide necessary medical information, not to provide the basis for legal liability. The act/documentation of disclosure is not to place blame or discuss fault.

3. Subjects to be communicated:
   Generally the physician managing the communications should presume that all information, which describes the specific event affecting a patient, can and should be disclosed, with the exception of identifying the specific staff members involved in the adverse event if unknown to the family. During discussions, the following subjects may be discussed, although discussion of each item is not required nor is discussion limited to these topics:
   - That LSUHSC and its staff regret and apologize that an unanticipated outcome has occurred
   - The nature of the adverse event
   - The time, place and circumstances of the occurrence
   - The proximal cause, if known
   - The known, definite consequences for the patient and potential or anticipated consequences
   - Actions taken to treat or ameliorate the consequences or outcome
   - Who will manage ongoing care of the patient
   - Planned analysis or review of the occurrence
   - Who else has been informed of the occurrence (internal hospital departments, review agencies, etc)
• Actions taken, if any, to identify system issues which may have contributed to the occurrence and to prevent the same or similar occurrences from occurring
• Who will manage ongoing communications with the family; names and phone numbers of individuals in the hospital to whom complaints or concerns may be addressed

C. Documentation

1. The person designated as the primary communicator with the patient/family shall document in the progress notes of the patient’s medical record what was communicated to the patient/family and any response or other discussion.

2. Confidentiality of peer processes shall be maintained. Patients/families shall not be given official reports of those processes.

3. The Hospital Administrator shall be responsible for completion and filing of any mandatory reports to outside regulatory agencies, such as the Centers for Medicare and Medicaid (CMS), Joint Commission on Accreditation of Healthcare Organizations (TJC), etc.

[Administrator's signature]

Administrator

3/15/11

Date

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