I. PURPOSE: The purpose of this policy is to identify the process for discussing and documenting disclosure of an unanticipated outcome to a patient, the family or legal guardian/surrogate.

II. POLICY STATEMENT: The responsible licensed independent practitioner or his or her designee will clearly explain the outcome of any treatments or procedures to the patient, and when appropriate the family or legal guardian/surrogate whenever an outcome differs significantly from the anticipated outcome. The goal of the disclosure process is to provide accurate factual information about the event, evaluate and improve patient and staff safety.

III. POLICY:

A. Definitions.

1. Adverse Event – a negative or untoward result stemming from a diagnostic test, medical treatment or surgical intervention.

2. Disclosure- communication of information regarding the results of a diagnostic test, medical treatment or surgical intervention.

3. Near Miss Event – any unintended event in the provision of care which would have constituted a medical accident but which was intercepted before it actually reached the patient. A near miss event is not disclosed to the patient in most cases.

4. Medical Accident – an unintended event in the provision of care with actual negative consequences to the patient.

5. Patient Safety Event - Any near miss event, medical accident, sentinel event, significant procedural variance, or other possible threat to safety.

6. Sentinel Event- a reportable event defined by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as:

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1 JCAHO Manual Intent Statement RI 1.2.2
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.
b. Suicide of a patient in a setting where a patient receives around-the-clock care.
c. Infant abduction or discharge to the wrong family.
d. Rape.
e. Surgery on the wrong body part.

7. Unanticipated Outcome- a result that differs significantly from what was anticipated to be the result of a treatment or procedure.

B. Disclosures may fall into three categories.

1. Hospital only event - If it is a hospital only event (nursing judgment, medical error, lab error, fall in X-Ray, etc.), the hospital representative will notify the attending physician and advise him/her that the representative will disclose this event to the family/patient and ask if he/she will participate. Facts of the event are documented in the medical record as well as the meeting with the family. Incidence/occurrence reports are filled out. If it is a sentinel event, then that process is initiated and the insurance carrier and legal counsel is notified.

2. Physician only event - If it is a physician only event, the physician is notified and it is the physician’s decision whether or not any one else is to be involved in the disclosure. The physician is encouraged to notify his/her insurance carrier for advice as appropriate, and is offered assistance when meeting with family.

3. Hospital and physician event - If the event involves both the hospital and the physician, then the hospital representative and physician or physicians involved, act as a team and meet with the family and/or patient for disclosure. All other steps in #1 are followed as well.

C. Information to be Communicated.

1. The individual managing the disclosure of information should communicate the facts, as they are understood, at the time the conversation takes place. To avoid the prospect of contradictory information, it is important to provide “unanticipated outcome” information with the understanding that as information becomes available from the investigation process, it may help to shed light on the unexpected event.

2. Guidelines for communication may include:
   a. An apology that the event occurred should always be offered. This should be done without suggesting blame or fault on the part of any member of the health care team.
   b. The nature of the event or accident as understood it at the time of the conversation.
   c. The time, place and circumstances of the event or accident as understood at the time of conversation.
d. The known, definite consequences of the accident to the patient and potential or anticipated consequences.

e. Actions taken to treat or ameliorate the consequences of the accident or event.

f. Who will manage the ongoing care of the patient.

g. Who else has been informed of the accident (in the hospital, regulatory agencies, etc.).

h. The actions that have been or will be taken to identify process issues which may have contributed to the accident or event and to prevent the same or similar situations from occurring.

i. Who will manage ongoing communication with the family

j. The names and phone numbers of individuals in the hospital to whom the patient, family or legal guardian/surrogate may address complaints or concerns.

k. Information on how to obtain support and counseling regarding the event and its consequences, both within the facility and from outside resources as appropriate.

l. Offer of support and availability to answer additional questions.

D. **Documentation of Disclosures.** The following information should be documented in the medical record:

1. Time, date, and place of the discussion.

2. Name and relationship of all persons present during the discussion.

3. Nature of the event and discussion of the unanticipated outcome.

4. Documentation of an offer of support or assistance and the response.

5. Consultations with those providing psychiatric or ethics evaluations should be recorded in accordance with facility policy.

6. Any follow up discussions should be documented including time, date, place, names and relationships of those present.

7. Additional information as appropriate to the situation.

E. **Exceptions to Disclosure.** If the physician believes in his/her professional judgment that the patient will be harmed if the disclosure occurs, this assessment which may include psychological evaluation of the patient, should be explained and documented in the medical record.

F. **Public Relations.** Depending on the medical accident or event, administration may notify the Director of Public Relations or the Corporate Communications and Public Relations Director to facilitate any external communications, including contact with the media or requests for public information.

G. **Regulatory Reporting.** Administration, with input from the Director of Quality Management and the Risk Manager, determines if the event is reportable to JCAHO, CMS, State regulatory agencies, or law enforcement agencies. Reporting to regulatory bodies or agencies does not relieve responsibility for disclosure to patients and/or family/legal guardians/surrogates as outlined in this policy.