DISCLOSURE OF UNANTICIPATED OUTCOMES

I. Purpose

To define the policy and procedure for communicating with patients and their families following an unanticipated outcome.

II. Policy

Aurora Health Care, Inc. (“Aurora”) recognizes the importance of effectively communicating with patients and their families to foster better decision-making and transparency. A factual summary of the outcomes of a patient’s care, treatment and services, including unanticipated outcomes, shall be disclosed to the patient, or, if appropriate, his or her surrogate decision maker.

III. Definitions

A. An “unanticipated outcome” is an outcome, whether positive or negative, and whether from error or not, that significantly differs from what was the desired outcome of care. An unanticipated outcome is an outcome that may be within the realm of possibilities (as may have been discussed in the Informed Consent process), but is not expected in light of, for example, the patient’s medical condition and/or nature of the procedure or treatment.

B. A “factual summary” is a brief depiction of known facts regarding the patient care outcome, which is not speculative and does not assume that fault or error caused the unanticipated outcome.

C. A “Licensed Independent Practitioner (LIP)” is a physician, oral and maxillofacial surgeon, dentist, podiatrist and some advanced practice registered nurses. (Reference: JCAHO Standard MS.2.10).

D. The following examples demonstrate disclosure opportunities, all meriting disclosure to patients:

1. Outcome was unanticipated, but the patient was not harmed.
2. Outcome was unanticipated and there was a need for increased patient assessments, but no change in vital signs and no patient harm.
3. Outcome was unanticipated and there was temporary patient harm, as well as a need for treatment or intervention or prolonged hospitalization.
4. Outcome was unanticipated and resulted in permanent patient harm or near death, such as anaphylaxis
5. Outcome was unanticipated and resulted in death.

IV. Procedure

A. Accountable Person to Disclose
1. The LIP, and/or other appropriate staff should determine if the outcome differs significantly from the expected. Timely, voluntary reporting of unanticipated events is essential to ensure timely intervention and help rectify unanticipated patient harms. In some cases, an unanticipated outcome may be a sentinel or significant event; please refer to the Aurora Incident Reporting/Sentinel Event policy.

2. The responsibility of disclosing unanticipated outcomes to the patient and family generally is the responsibility of the LIP most closely associated with the outcome unless the entity determines there is a more appropriate individual (e.g., Visiting Nurse Association will not typically utilize LIP for actual disclosure, or the particular situation, as determined by site and system leadership, indicates that another individual or group of individuals should disclose). The process of disclosure often requires utmost empathy and tact, and support by other staff shall be available when requested and/or appropriate. If the event results in patient harm or increased monitoring, entity leadership will determine whether a representative from Administration needs to be present at the time of disclosure.

3. The procedure outlined below is to be followed when a clinical staff member is involved with or discovers an unanticipated outcome. (E.g., a nurse draws up the wrong amount of medication and gives it to the patient which results in an unanticipated outcome.)

   a. Upon discovery of an unanticipated outcome in a non-emergent situation, or after the emergent situation has been addressed, personnel shall report the unanticipated outcome to their immediate supervisor or the head of their department.

   b. The supervisor or department head shall report the unanticipated outcome to facility Administration, including risk management, and the LIP most closely associated with the outcome and to the patient’s attending physician. If the unanticipated outcome is a potential significant or sentinel event, notification occurs per the Aurora Health Care Incident Reporting/Sentinel Event Policy, #166.

   c. Unless otherwise directed, clinical staff members shall not disclose the unanticipated outcome to the patient or his or her surrogate decision maker; however, such personnel may be present for the disclosure if Administration and the LIP deems it appropriate.

   d. Unless otherwise directed, clinical staff members shall direct questions from the patient or his or her surrogate decision maker about the unanticipated outcome to the LIP most closely associated with the outcome or to the attending physician.

      i. Each Aurora entity shall have a designated team for responding to and evaluating unanticipated outcomes that may require disclosure. The entity team shall communicate with system risk management, legal counsel, patient safety officer, chief medical officer, chief clinical officer, compliance, media relations, and any other department or service as needed. This team shall work in conjunction with the site or system team reviewing the event. Please refer to the Sentinel Event Policy, #166.

B. To Whom the Outcome Is Disclosed

1. The unanticipated outcome shall be disclosed to the patient if he or she has decision-making capacity, unless the patient expresses a preference that the disclosure be made to his or her surrogate decision maker.
2. The unanticipated outcome shall be disclosed to the patient’s surrogate decision-maker if the patient either lacks decision-making capacity or expresses a preference that the disclosure be made to the surrogate decision-maker. The order of priority of surrogate decision-maker is:
   a. the power of attorney for health care agent; (if activated);
   b. the patient’s guardian;
   c. the patient’s surrogate designated for the spell of illness or hospital stay; or
   d. the patient’s family member or close friend.

C. When to Disclose
   The disclosure shall be made as soon as practicable and in the best interest of the patient, as determined by the designated team as described in section A, 4 above.

D. Dispute Resolution as to Whether an Outcome Is Unanticipated
   If there is some question as to whether an outcome is unanticipated, the site shall consult with the system patient safety officer and the system director of clinical risk management.

E. What Information Shall Be Disclosed
   1. A truthful, factual, and compassionate account of the unanticipated outcome;
   2. Any short or long-term effects expected as a result of the unanticipated outcome;
   3. Any medical care or treatment available to the patient required as a result of the unanticipated outcome, including but not limited to, the risks, benefits and alternatives of such care and treatment;
   4. An expression of regret that the unanticipated outcome occurred;
   5. Assurance that the unanticipated outcome will be evaluated so steps may be taken to reduce the likelihood of similar risk to other patients;
   6. Time for the patient and/or family to ask questions or raise concerns; and
   7. Name of the individual(s) responsible for managing ongoing communications with the patient and the patient’s family members’ regarding additional questions, complaints and follow-up.

F. The Person Making the Disclosure:
   1. Shall not blame or criticize other providers leadership, or the Aurora Facility, the Aurora System, or the policies and practices of the Aurora Facility, System, or Leadership.
   2. Shall not speculate as to how event occurred.
   3. Shall not make any statement of fault or liability for causing the unanticipated outcome.
   4. Shall not make any statements that could be construed as promises or guarantees regarding future medical services or bills.
5. Shall not discuss financial issues with the patient. Such financial issues or questions shall be directed to the Site and system risk management staff.

G. Documentation

1. The LIP or designee who makes the disclosure shall note the circumstances of the disclosure in the progress notes section of the patient’s medical records. The note shall include:
   a. a factual summary of what was disclosed;
   b. the persons present during the disclosure and their relationships to the patient; and
   c. the time, date, and place of the discussion.

2. The note shall not include suspicions, opinions and other non-clinical information regarding the unanticipated outcome. Any follow-up discussions shall be noted in the same manner.
   a. Licensed Independent Practitioner (LIP) and care provider support

3. There is acknowledgment of the effect that an unanticipated outcome may have on the LIP and clinical staff. The Employee Assistance Program (EAP), or the entity’s designated program, can be accessed to facilitate the debriefing process.

H. Education

1. Upon hire, all employees shall receive training on this policy at orientation.

2. Specific department orientation shall include ongoing education on the procedures related to the reporting, and disclosure, of unanticipated outcomes.

3. The Medical Staff will be advised and notified by the entity regarding the procedure to disclose unanticipated outcomes in accordance with this policy.

Cross References: Sentinel/Significant Event Policy, #166

Owner: Director, Clinical Risk management