POLICY

Policy Name:	**Disclosure Guideline**					
Policy #:	**8316.1184**	**Policy Dept.:**	**Administrative**			
Approval Authority:	MEC		**Effective:**	12/2015	**Reviewed:**	1/4/2016, 7/30/2019
Responsible Executive:	C.M.O.		**Revised:**	7/30/2019, 11/18/2019		
Responsible Office:	Medical Executive Committee		**Contact:**	Jackie Bishop 423-778-2055		

Policy statement:
This policy outlines the process for disclosing unanticipated events and outcomes to patients and their family members or authorized representatives, when appropriate. This guideline should not prevent or delay communication with families, but provide support for the Disclosure process[1].

Scope: Erlanger Health System (EHS)

I. DEFINITIONS:

1. Adverse Drug Reactions (ADR) - Any response to a drug which is noxious and unintended and which occurs at doses used in human beings for prophylaxis, diagnosis or treatment (World Health Organization). Report ADRs to pharmacy and the patient's Attending Physician.
2. Attending Physician- The physician primarily responsible for the care and treatment of a patient. Ordinarily this is the admitting physician or the covering attending physician on call.
3. Communication Plan- The plan established by the Responding Physician, Risk Management, other caregivers and administration to disclose an unintended outcome or Event to the family and patient.
4. Disclosure- Letting a patient/family/authorized representative know an unintended outcome of treatment or event occurred.
5. Adverse Event- Any unexpected incident, occurrence or circumstance that is not consistent with the routine patient care or operations of the facility that either did or could directly result in injury or has potential to cause harm or injury.
6. Disclosable Event- An Adverse Event reaching the patient.

[1] Please see attached flow charts as quick reference visual aids broadly outlining the Disclosure process.

7. Occurrence- Any unplanned instance or event that has caused, or has the potential to cause, harm or loss.
8. Responding Physician- The physician covering care of the patient at the time of identification of the Disclosable Event.
9. Disclosing Physician – The physician who discloses the Adverse Event to the patient/patient representative/family.
10. eSafe- Erlanger's electronic safety event reporting system.

II. WHEN TO DISCLOSE ADVERSE EVENT:

Based upon Level of Harm per Safety Event Reporting Policy 8316.074

1. **Levels A, B -** *The event has not reached the patient*. **No requirement to disclose**. The Attending Physician decides whether to disclose; however there is no requirement to do so. Patient's Nurse and the Disclosing Physician should collaborate prior to Disclosure.

2. **Levels C, D** – *An event occurred that reached the patient but did not cause harm*. **Disclosure is required**. The Attending Physician decides when to disclose. Nurse and the Disclosing Physician should collaborate prior to Disclosure.

3. **Level E –** *An event occurred that resulted in temporary harm and required treatment and/or intervention*. **Disclosure is required.**

4. **Levels F-I –** *An event occurred that resulted in initial or prolonged hospitalization causing temporary patient harm, permanent patient harm, or a near death event requiring intervention to sustain life*. **Disclosure is required.**

III. IMMEDIATE RESPONSE TO ADVERSE EVENT

These recommended actions should occur in an order most appropriate to the circumstances:

1. Ensure immediate patient care needs are met.
2. EHS Patient Flow Manager or designee ("PFM") will immediately act to ensure the protection of patient, staff and other patients from imminent harm.
3. PFM will assess situation and involved caregiver(s). If necessary, he/she will remove the caregiver(s) from the situation.
4. If Responding Physician is a Resident or Fellow, the Supervising Attending or Attending On-Call Physician should be notified.
5. PFM will call Risk Management and/or the Administrator on Call, if necessary.
6. PFM will ensure reporting of event in Erlanger's electronic incident reporting system (eSafe).
7. If needed, PFM will assist with the Disclosure process.

IV. TIMING OF DISCLOSURE

The optimal timing for disclosing Adverse Events varies with the specific circumstances of the event.

1. If patient needs urgent treatment to minimize injuries resulting from an Adverse Event, clinical Disclosure must occur quickly and as soon as possible.
2. If immediate corrective action is not required, Disclosure may be delayed, but only long enough to give staff members' time to collect preliminary information and plan the best way to disclose.
3. Disclosure of an Adverse Event should occur as soon as reasonably possible and within 24-48 hours of a practitioner's discovery of the Adverse Event if adequate information is available. When patients who are aware of or suspect an Adverse Event, more time before Disclosure may increase the patient's anxiety and decrease their trust in the Erlanger providers and management.

V. WHERE TO DISCLOSE

When possible meetings should be:

- In person
- At a location and time of the patient's preference
- In a private area to maintain confidentiality, and
- In a space free from interruptions.

VI. HOW TO DISCLOSE AN ADVERSE EVENT

Disclosure Process:

It is essential during any Disclosure discussion that speculation, opinion, or attributing blame does not occur.

Initial Disclosure:

1. Nurse Manager/ Designee notifies the Responding Physician of the Adverse Event (if the physician is not aware of the Adverse Event).

2. Responding Physician notifies the Attending Physician as soon as possible. If the Attending Physician is not available, the Responding Physician should notify the most senior physician available.
    - If notification to the Attending Physician occurs prior to Disclosure, the Attending Physician will be involved in determining who should make the Disclosure.

3. *If the family is aware of the event* (i.e. they discover the event) the involved staff person should:
    - Acknowledge the event and
    - Assure the family the appropriate Physician is being notified and will discuss the event with them.

4. Patient Representatives, Patient Flow Managers, Supervisors or Patient Family Support resources may support the family while awaiting arrival of the Responding Physician.

5. *If the family is not aware of the Adverse Event*, the Disclosing Physician uses his/her judgment about the timing of Disclosure and coordinates timing of Disclosure with the care team.
    - The Disclosing Physician may also involve the administrator on-call or patient flow manager.
    - If the Disclosing Physician, patient flow manager or other employee needs help deciding the proper course of action, they should call Risk Management for guidance and support.

6. The Responding or Attending Physician discloses the event to the family. He/she answers questions and addressees the family's concerns. Refer to "Stage 1—Initial Disclosure Section" AND REMEMBER
    - Disclosure <u>will not include</u> *speculation on cause or blame or discussions/opinions regarding liability*.

7. If the Event or unanticipated outcome is a known complication of the procedure or treatment, a mention of the patient informed consent process may be included in the discussion.

8. **The physician(s) participating in the Disclosure will document the Disclosure in the patient's health record, as described below**.

<u>Post Analysis Disclosure</u>:

1. If the Adverse Event review reveals additional pertinent facts, or results in process improvement, or if the Patient/Family requests follow-up discussion, a subsequent meeting is scheduled by someone in leadership/administration.

2. The meeting may include providers, depending on the circumstances.

3. Refer to "Stage 2—Post Analysis Disclosure Section".

<u>Stages of Disclosure</u>:

Disclosure is often a dialogue over time; generally occurring in two broad stages:

1. <u>Stage 1 -- Initial Disclosure</u>
    - Initial discussion with the patient should occur *as soon as reasonably possible* after the event.
    - The Disclosing Physician leads the discussion except when the Disclosing Physician and an EHS representative decide that it is more appropriate for an administrative designee to disclose.
    - Focuses on the patient's current medical condition.
    - It is primarily the responsibility of the providers, although Erlanger administration may provide advice or assistance as needed.
    - The minimum number of EHS participants will attend. Who to include will be decided on a case-by-case basis. The patient and/or family may have input regarding who attends the meeting.

- Risk Management and Legal Services will not be included in the Disclosure meeting.
- Tape recording of the meeting is not permitted.

a. Explain the *facts* of the event and/or harm known at the time.
b. Explain the steps taken and the recommended options and decisions in the ongoing care of the patient (e.g. changes to care plan as applicable).
c. Apologize by expressing sympathy or regret for what occurred ("I am sorry this happened").
d. Give a brief overview of the investigative process that follows
e. An offer of future meetings, including key contact information.
f. Time for questions and answers
g. Avoid speculation, opinion, or attributing blame.
h. Provide emotional/ practical support for the patient.

2. Stage 2 – Post Analysis Disclosure – Ensure event is entered into Erlanger's electronic incident reporting system (eSafe) so event is analyzed through proper channels.

- The eSafe report generated results in a quality review and analysis of the Occurrence. The analysis may identify additional facts and reasons for the event.
- Erlanger administration, in consultation with providers, determines what additional information to disclose to the patient/patient representative.
- Legal/Risk provides advice on how much additional information to provide the patient/patient representative, considering applicable law.

a. Continue providing practical/emotional support, if needed.
b. Reinforce or correct information provided in previous discussions.
c. Provide additional facts are they are available.
d. If applicable, and when all facts are established, a further expression of regret that may include an apology, as appropriate.
e. Describe system improvements made due to internal analysis of the Adverse Event, if applicable.
f. Avoid speculation, opinion, or attributing blame

VII. Communication Plan:

1. When indicated, Case Management will work with Risk Management to coordinate a Communication Plan meeting.
2. The Disclosing Physician, administrator on-call, Patient Flow Manager, administrative physician on-call, Risk Management and, if necessary, legal counsel will discuss and create the appropriate Communication Plan ("Plan") to be used with the patient and/or family member(s).
3. The Plan should contain the following key points:
   - an objective statement of the medically relevant facts currently known about the outcome, results, or event
   - the patient's current condition

- the physician's recommendations for treatment, follow-up testing, and/or procedures and any other facts the patient/family may need in order to make informed decisions both in the near future and long term
- what is known about the anticipated long-term prognosis
- that EHS will fully investigate the processes surrounding the outcome or event
- that the patient/family will be provided with additional information if and when it becomes available
- an offer of a specifically designated individual to be available for further questions

4. All members of the group creating the Communication Plan will agree that the information is confidential, and will not discuss it outside of the Disclosure to the family or other related peer review protected meetings.

VIII. Documentation:

1. The Disclosing Physician(s) will document each discussion including Disclosure of an unanticipated outcome or Event.

2. Documentation in the medical record should include:
   - Time, place and date of the meetings
   - Identity of all attendees
   - The medically significant facts disclosed
   - Next steps or changes in treatment that were discussed

Committee	Approval/Date
Quality Oversight Committee	12/03/15
Medical Executive Committee	01/04/16

Medical Director	Approval/Date

References:
Occurrence Reporting Policy 8316.074