Disclosure Policy - SAMPLE

Subject: Disclosure Policy: Adverse Events, Errors, and Unanticipated Outcomes
Number: _____
Effective Date: _____
Supersedes SPP#: _____
Dated:
Approved by: _____
(signature) Dated:
Distribution: _____

I. STATEMENT OF POLICY:

It is the policy of [*insert name of facility*] to maintain transparency and integrity in all of the organization's functions. Consistent with this policy, it is appropriate to disclose adverse events, errors and/or unanticipated outcomes that could affect a patient's emotional or physical health. Our framework for discussing unanticipated outcomes is premised on strong communication processes, both before and after treatment or procedures.

II. Definitions

A. **Adverse event** is an unintended or negative result or complication stemming from a diagnostic test, medical/surgical treatment or medical error.

B. **Errors** are preventable adverse events.

C. **Disclosure** involves communicating information regarding the results of a diagnostic test, medical treatment, or surgical intervention.

D. **Unanticipated outcomes** are results that differ significantly from what was anticipated to be the result of a treatment or procedure.

Note: An outcome may be negative and/or unanticipated, but not necessarily be the result of an error. The informed consent process should address possible risks, complications and adverse outcomes. A discussion about an unanticipated outcome that was addressed as part of the informed consent process is a much different discussion than disclosing an error.

III. General Principles

A. **Events to be disclosed** — This includes adverse events, unanticipated outcomes, and occurrences in which patients are significantly harmed or have the potential to be significantly harmed.

B. **To whom disclosure will be made** — Make disclosure to the patient and, only when appropriate, to the patient's family, significant other or patient advocate.

C. **Timing of disclosure** — Disclose adverse events as soon as possible after the identification that an adverse event has occurred. If event analysis is incomplete within the first 24 hours, then sharing only partial factual information is more important than waiting until all details of the event have been factually ascertained. If the patient is not able to comprehend the information, it should be disclosed to the patient advocate, depending on the severity of the occurrence and his/her need to know the information.

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D. **Honest disclosure** — Tell the patient the facts as known, and assure the patient that you are committed to obtaining and providing all available information as it becomes known. Consider the use of support services (e.g., social worker, chaplain services, patient relations specialist, mental health therapist), as appropriate.

E. **Cultural sensitivity** — Demonstrate respect for individual cultures and provide interpreters for non-English speaking or cognitively impaired patients.

F. **Who will disclose events** — Disclosing adverse events is primarily the attending physician's responsibility. When it is impractical or unreasonable for the physician to do so, a designee may be used. If the physician is uncertain regarding the event and/or the obligation to disclose or finds it difficult (is unable) to disclose the event to the patient, the physician will consult with the practice administrator and/or the office manager to determine who will disclose the events. The practice administrator and/or office manager, in consultation with the physician, may disclose the adverse event to a patient, if a physician cannot or does not inform the patient in a timely manner.

G. **Events for which disclosure may be discretionary** — Disclosure of certain events is a matter of clinical judgment. Errors that do not harm a patient and do not have the potential to do so may not require disclosure to patients.

H. **Mechanism to assist with the disclosure process** – The physician practice administrator and/or office manager may provide assistance to physicians regarding disclosure. These individuals have the authority to help clinicians make decisions about which adverse events need to be reported and disclosed and to help make decisions about disclosure when the most responsible clinician fails to do so or is unable.

I. **Beneficial consequences of disclosures (and error reporting)** –

1. Patients receive prompt care for injuries suffered and are fully informed to assist in further decision-making and treatment planning.
2. Errors are opportunities to learn how to improve patient safety.
3. Lessons learned from error reporting will serve to correct system problems.

IV. Procedure

A. Staff Member and Physician Actions

1. Take immediate actions to safeguard the patient, as needed.
2. If the adverse event is of a serious nature, notify the office manager and/or the physician as soon as possible. Complete an occurrence report and inform the patient's attending physician.
3. Document the event in an objective and factual manner in the patient's record as soon as possible after the event.
4. In consultation with risk management, discuss the factual details and sequence of what occurred with the healthcare team and attempt to reconcile any differing perceptions of what occurred.
5. Determine how the details of the event, the outcome and the treatment plan will be explained to the patient and his/her family members. Decide which member of the healthcare team (generally the physician) will discuss the event and with whom (patient and/or family member). Designate a family contact person.
6. Be accessible for questions. Repeated requests for an explanation of the event are a common reaction when patients and family members are informed of an adverse event or medical error.

7. If the event involved a medical device or piece of equipment, preserve these materials for investigation. Do not clean or alter the device or equipment in any way and contact the office manager and/or the physician. Do not return defective devices or equipment to a manufacturer.
8. Notify your malpractice insurance carrier of the event in a timely manner and obtain guidance, as applicable.
9. Defer to the office manager and/or the physician to determine when and if patient billing should occur. Follow compliance policies.

B. Communication Framework for Disclosure

1. Have the attending physician and/or a leadership staff member meet with the patient (and family members as appropriate) as promptly as other duties permit. Delays should be avoided.
2. Present the nature, severity and contributing cause (if known) of the adverse event in a straightforward and nonjudgmental manner.
3. Avoid attributing blame to yourself or to specific individuals or to the organization as a whole. Serious adverse events are rarely due to the sole action or inaction of one person. Do not criticize the care or response of another provider.
4. Disclosure is a process; be sure the disclosing medical providers avoid speculation and focus on what is known at the time of the discussion, what happened, what led to the event, and the recommended course of action.
5. To avoid the appearance of contradicting information, provide a caveat that as information becomes available, further discussion will take place.
6. If further treatment is necessary as a result of the adverse event, describe what can be done, if anything, to correct the consequences of the adverse event.
7. Identify someone (staff member or physician) to have ongoing communication with the patient and/or family members.
8. Convey empathy and use language that is understandable to the patient. Make eye contact and concentrate on presenting your body language in an open and caring manner.
9. Apologizing for the observed occurrence of the adverse event is appropriate. This aspect of communication is separate from discussing ascertained causes of the event. A sincere show of concern can increase the rapport between the patient and provider.

C. Withholding of Information

1. Sometimes the outcome information can put a patient at risk of harm either due to psychological trauma or exposure to physical harm. In such situations, clinical judgment regarding disclosure should be exercised.
2. If information is withheld, document the reasons for such. It may be appropriate to have a mental health provider conduct an assessment to determine concurrence.

D. Reporting and Accountability

Prompt and thorough reporting and disclosure of adverse events by the physician and staff members will be managed from the perspective of the organization's systems as well as individual provider accountability. The practice will address patient safety concerns through the medical staff peer review process and/or human resource procedures when the investigation reveals a serious lack of provider knowledge, skill deficit(ds), unawareness of the hazard, oversight, or negligent or reckless disregard for patient safety.

E. Documentation

1. Document facts objectively, completely and contemporaneously, including that a discussion of the unanticipated event took place.
2. Ensure that the documentation is dated, timed and signed at the time of the entry.
3. Avoid writing any information unrelated to the care of the patient (e.g., incident report filed or legal office notified) in the medical record.
4. Do not alter any prior documentation or insert backdated information.
5. Record the name and relationship of those present.
6. Include documentation of any questions posed by the patient/family members and indicate that answers were provided by the caregiver.
7. While an addendum to the record may be made, consider carefully whether this information is relevant to the patient's clinical management. Accepted reasons for an addendum are for the correction of facts (i.e., persons involved, time of event, sequence of events) and for the addition of facts or clarifying information. If you participated in the care, but were unable to access the record until a later date, you may provide added information. Do not use an addendum to state your opinions, perceptions or defenses.
8. Assign the most involved and knowledgeable staff member(s) to record the factual statement of the event in the patient's record, as well as any follow-up needed or done as a result of the event.

The following references were utilized in creating this sample policy. When developing your disclosure policy, check your state's laws and regulations concerning disclosure to ensure compliance.

- Geri Amori, *Disclosure of Unanticipated Events in 2013 – Prologue to the Re-Release of the Three ASHRM Disclosure Monographs*, 2013, http://www.ashrm.org/ashrm/education/development/monographs/Disclosure-of-Unanticipated-Events-in-2013_Prologue.pdf, 01/16/2015.
- ASHRM Monograph, *Disclosure of Unanticipated Events: The Next Step in Better Communication with Patients*, 2003, http://www.ashrm.org/ashrm/education/development/monographs/Disclosure-of-Unanticipated-Events-in-2013_Prologue.pdf, 01/16/2015.
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- Minnesota Hospital Association, *Communicating Outcomes to Patients*, 2002.
- Martha Kerr, "Medical Error Disclosure: Easier Said Than Done," *Caring for the Ages*, Vol. 4, No. 5, May 2003, http://www.amda.com/publications/caring/may2003/mederrors.cfm, 01/16/2015.
- The Joint Commission, *Health Care at the Cross Road: Strategies for Improving the Medical Liability System and Preventing Patient Injury*, 2005.