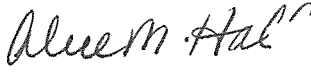
 <p><b>HAWAII HEALTH SYSTEMS</b> CORPORATION <i>"Quality Healthcare for All"</i></p> <p><b>PROCEDURE</b></p>	<p>Department: Office of General Counsel</p>	<p>Procedure No.: <b>PAT 0012B</b></p>
	<p>Issued by: General Counsel</p>	<p>Revision No.: 1</p>
<p>Subject:</p> <p><b>Disclosure of Unanticipated Outcomes</b></p>	<p>Approved by:</p>  <p>Alice M. Hall, Esq. Acting President &amp; CEO</p>	<p>Effective Date: January 16, 2014</p>
		<p>Supersedes Policy: August 1, 2002</p>
		<p>Page: 1 of 3</p>

Reviewed January 2, 2014; Next Review January 2, 2017.

I. **PURPOSE:** The purpose of this policy is to identify the process for discussing a disclosure of an unanticipated outcome with a patient, the family or legal guardian/surrogate, making a statement of sympathy, commiseration, or condolence, and proper documentation of these events.

II. **POLICY STATEMENT:** The responsible hospital representative, a 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 patient/family will be informed about adverse events, medical errors, sentinel events and some near misses. The goal of the disclosure process is to provide accurate factual information after an investigation and evaluation, and improve patient and staff safety.

III. **POLICY:**

A. **Definitions:**

1. Adverse Event – An unintended injury or complication caused by healthcare management and not the patient's underlying disease. Adverse events are not necessarily markers of substandard care.
2. Apology – When occurring in a conversation with a patient or family member following an adverse event or medical error or sentinel event, Hawaii law defines an apology as a statement that acknowledges or implies fault or admits liability for the injury or damages. **IF THE PROVIDER IS NOT INTENDING TO ACKNOWLEDGE FAULT, S/HE SHOULD NOT ISSUE AN APOLOGY.**
3. Disclosure- Communication of information to the patient or a delegate regarding an adverse event, near miss, medical error, or sentinel event.
4. Medical Error – An unintended event in the provision of care with actual negative consequences to the patient.

5. Near Miss – A medical error that occurred but the consequences of the error (injury, damage) did not reach the patient due to a fortuitous break in the chain-of-events. A near miss event is not disclosed to the patient in most cases.
  - a. Sentinel Event- as defined by the Joint Commission on Accreditation of Healthcare Organizations (TJC), a sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. 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.
6. 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 (such as a nursing or technician error, patient fall en route to 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 disclosed as well as the date, time and everyone who participated in the meeting are documented in the medical record. Incident/occurrence reports are filled out but are not made part of the medical record. If it is a sentinel event, 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 will speak with the patient/family, and make the appropriate chart notation. It is the physician’s decision whether or not any one else is to be involved in the disclosure. If the physician fails or refuses to make the disclosure, the CMO will be notified immediately and arrangements will be made for a hospital representative to make the disclosure. The physician is encouraged to notify his/her insurance carrier for advice as appropriate, and will be 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 sec. B.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 as of the time the conversation takes place. As the investigation proceeds and additional information becomes available, updated information should be provided to the patient and family.

2. The communication should include:
  - a. If you are not apologizing and admitting fault, it is always good to clarify that fact. **All statements must be made without suggesting blame or fault on the part of any other 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.
3. Apologies. Apologies and admissions of fault are admissible in court. There are instances when an apology is appropriate. An apology or admission of fault should ONLY be made after the facts are certain and legal counsel has been consulted. NEVER blame someone else.
4. Offers of Assistance. There may be instances when the provider wishes to offer some sort of assistance (waive a bill, offer to pay for extra expenses, etc.). This may be appropriate in certain circumstances. Employees MUST work with the risk manager before making ANY representations that the hospital will provide monetary assistance or anything else of value to the patient or family.

**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. Whether the discussion included an apology or a statement of sympathy, commiseration, or condolence.
5. Documentation of an offer of support or assistance and the response.
6. Consultations with those providing psychiatric or ethics evaluations should be recorded in accordance with facility policy.
7. Any follow up discussions should be documented including time, date, place, names, and relationships of those present.

8. 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 Affairs 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 TJC, 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.

**IV. APPLICABILITY:**

This policy applies to all HHSC facilities.

**V. AUTHORITY:**

TJC Manual Intent Statement RI 1.2.2  
Rule 409.5, Hawaii Rules of Civil Procedure