 CHRISTUS SANTA ROSA Health Care	PRIMARY FUNCTION: MEDICAL STAFF	POLICY#:CO-AD-02-10
	EFFECTIVE DATE: 10/01	PAGE 1 OF 3
LAST REVIEW DATE: 3/07		REVISION DATE: 3/07
SUBJECT: DISCLOSURE OF MEDICAL ERRORS		

PURPOSE:

To define policies and procedures related to disclosure of medical errors to patients and, when appropriate, their families.

POLICY:


1. Patients and, when appropriate, their families have a right to be informed about outcomes of care including unanticipated outcomes related to a Significant Medical Error.
2. The patient's attending practitioner or designee (another practitioner) has the responsibility to clearly explain the outcomes of any treatment or procedure to the patient and/or family whenever those outcomes differ from the anticipated outcome secondary to a Significant Medical Error.

DEFINITIONS:

1. Medical Error – An unintentional act either of omission or commission. An error occurs when either a correct action is not executed properly or an incorrect action is executed.
2. Significant Medical Error – A significant medical error is a Medical Error which causes a clinically significant, unanticipated adverse outcome resulting in a substantive change or modification of the patient's orders or treatment plan.
3. Examples of clinically significant, unanticipated adverse outcomes include but are not limited to:
 - a. Death
 - b. Permanent disability or permanent functional impairment
 - c. Second-degree burns
 - d. Loss of consciousness
 - e. Falls resulting in injury
 - f. State III or Stage IV decubitus
 - g. Pulmonary edema
 - h. Surgery on the wrong body part
 - i. Need for unanticipated surgical procedure
 - j. Hemolytic reaction to blood

PROCEDURE:

1. If a Significant Medical Error is suspected by the Attending Practitioner, another practitioner, or an associate, the identifying person shall contact the hospital Risk Manager who will arrange a meeting as soon as possible with the Attending Practitioner, the appropriate department chairperson or designee, and the appropriate Vice President or designee.
2. In coordination the Attending Practitioner, the department chair-person or designee, and Chief Executive Officer or designee will discuss the event with the Risk Manager and determine if a Significant Medical Error has occurred.
 - a. If it has been determined that a Significant Medical Error has occurred, it will be the responsibility of the Attending Physician to discuss the Significant Medical Error with the patient and/or the patient's family.
 - b. If it has been determined that a Significant Medical Error has occurred, the Attending Practitioner, department chairperson or designee, and the Chief Executive Officer or designee will determine what other hospital personnel shall be involved in the Significant


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Medical Error disclosure discussions with the patient and the patient's family. For example, the patient's nurse or pharmacist could also be present to help answer questions and reassure the patient. The hospital representative chosen would depend on the nature of the Significant Medical Error and the unanticipated outcome and may include other Medical Staff members or administrative personnel.

- c. If the Significant Medical Error is associated with an event meeting the organization's definition of a sentinel event, then the Sentinel Event Policy shall also be followed.
3. When a Significant Medical Error is disclosed to and discussed with the patient and/or patient's family, the Attending Practitioner shall:
 - a. Be prepared to answer all reasonable questions the patient and/or family may have about the error.
 - b. Involve at least one other hospital representative, as appropriate, and as identified above in the Significant Medical Error disclosure.
 - c. Schedule additional follow-up meetings, discussions, or clinical evaluation of the patient as indicated by the nature of the Significant Medical Error.
4. At a minimum, the error disclosure discussion should include information regarding:
 - a. The nature of the error which occurred.
 - b. Any implications the error has or will have on the patient's care and on the patient's short- and long-term health status.
 - c. Point of contact for further questions and/or any necessary follow-up.
5. After notification, the Attending Practitioner must:
 - a. Make an entry in the medical record regarding the specific error disclosure and notification which was given to the patient and/or family. The entry in the medical record will also list any family members and/or hospital representatives who were present for the discussion. The entry in the medical record must be dated.
 - b. Notify the hospital Risk Manager that the Significant Medical Error disclosure has occurred.
6. The patient and/or family members should not be asked to sign or attest to any document that purports to limit their rights to pursue further action up to and including legal grievance.
7. Notification of a Significant Medical Error should be performed with empathy and compassion and should provide full disclosure and assumption of appropriate responsibility. Care should be taken to ensure that the hospital staff members involved with the event and/or notification do not intimidate the patient and/or family member.
8. If a potential Significant Medical Error has been identified by a hospital staff member and the patient's Attending Practitioner does not agree that a Significant Medical Error has occurred or does not want the patient and/or family to be notified of the potential Significant Medical Error which has occurred, the hospital staff member identifying the potential Significant Medical Error should follow the hospital "chain of command" policy regarding reporting of the event.

RESPONSIBLE POSITION

Regional Vice President/Chief Administrative Officer
Chief Nursing Officer


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APPROVAL:

Don Beeler, CEO

Cary Fox, CAO

Katherine Bullard, RN, MSHSA - CNO

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APPROVED BY:	LAST REVIEW DATE: 6/02	
SUBJECT: Disclosure of Unanticipated Outcomes	REVISION DATE: 6/02	

PURPOSE

The purpose of this policy is to establish the written guidelines and procedures for informing patients about unanticipated outcomes.

POLICY

Patients and, when appropriate their families, have a right to be informed about the outcomes of care including unanticipated outcomes. The attending practitioner or designee has an obligation to clearly explain the outcome of any treatment or procedure to the patient and, when appropriate, the family whenever the outcome differs significantly from the anticipated outcome.


DEFINITIONS

UNANTICIPATED OUTCOMES – A negative unexpected result stemming from a diagnostic test, medical treatment, or surgical intervention. For purposes of this policy, unanticipated outcomes include death, serious physical or psychological injury, or any outcome, which results in an increased length of stay or a substantive change or modification in the patient’s orders or treatment plan

COMMON CAUSE EFFECT – An event which is a known possible outcome related to the diagnostic procedure, medical treatment, or surgical intervention the patient is undergoing. Although common cause events may be undesirable and not expected to occur they are know to occur with the diagnostic procedure, medical treatment, or surgical intervention even if the diagnostic procedure, medical treatment, or surgical intervention is performed in accordance with acceptable standards of practice and no medical error has occurred.

PROCEDURE

1. An Unanticipated Outcome may or may not be related to a medical error.
2. If an Unanticipated Outcome occurs and the attending practitioner or designee feels that the Unanticipated Outcome is related to a medical error, disclosure of the Unanticipated Outcome and medical error to the patient and patient’s family must occur pursuant to the Medical Staff Policy on Disclosure of Medical Errors.
3. If an Unanticipated Outcome occurs and the attending practitioner feels the Unanticipated Outcome represents a Common Cause Event or is otherwise related to the natural course of the patient’s disease and is not related to a medical error, the Unanticipated Outcome should be discussed by the attending practitioner with the patient and, when appropriate, the patient’s family pursuant to this policy.
4. When disclosing an Unanticipated outcome pursuant to the policy, the attending practitioner must:
 - a) Communicate the exact nature of the Unanticipated Outcome to the patient and, when appropriate, to the patient’s family
 - b) Document his or her discussion with the patient and patient’s family in the medical record.
 - c) Complete and variance report describing the Unanticipated Outcome and a summary of discussions with the patient and patient’s family.

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5. If the Unanticipated outcome is associated with an event meeting the organization's definition of a sentinel event, then the Sentinel Event Policy shall also be followed.

REFERENCE:

1. JCAHO Hospital Accreditation Standards, Revision 2001