Adventist Health

☐ **Facility:**

☐ **System-wide Corporate Policy**
  ☐ **Standard Policy**
  ☒ **Model Policy**

Policy No.

Department:
Category/Section:
Manual:

POLICY: Disclosure of Unanticipated Outcomes

POLICY SUMMARY/INTENT:

Diagnostic tests or treatment sometimes results in unplanned or unwelcome outcomes. That these outcomes occur is not necessarily the result of substandard practice, error, or medical malpractice. Unwelcome outcomes may occur even when treatment is excellent. The purpose of this policy is to provide a communication framework for discussing unanticipated outcomes with patients and their families.

This facility believes that patients are entitled to information related to unanticipated outcomes, whether positive or negative, and that the disclosure of this information is part of the communication process that forms the context for a trusting caregiver-patient relationship. Full disclosure can make a difference in how a patient or the patient's family responds to the incident. Leaving patients with the wrong impression and then having to correct it may cast doubt about the reliability of the information provided and the credibility of those furnishing it. Additionally, withholding information that the patient needs to know is equally wrong, leaving the patient and family to speculate, raising questions about the integrity and reliability of the caregiver-patient relationship. A clear, understandable explanation of the outcome, free of conjecture or innuendo, is necessary to maintain the integrity of this relationship. Such a dialogue can be reassuring, diffusing the possibility of misunderstanding or distrust.

This institution firmly believes that we have an ethical responsibility to communicate with the patient and a legal duty to notify the patient of any unanticipated outcome, whether or not it is related to a medical error.

DEFINITIONS:

1. **Disclosure:** Communication of information regarding the results of a diagnostic test, medical treatment or surgical intervention.

2. **Unanticipated Outcome:** A result that differs significantly from what was intended to be the result of a treatment or procedure.

3. **Medical Error:** Failure of a planned action to be completed as intended or the use of a wrong plan to achieve this aim.

AFFECTED DEPARTMENTS/SERVICES:

All clinical departments.

POLICY: COMPLIANCE – KEY ELEMENTS

A. Consent Process

1. What might be characterized as an "unanticipated outcome" may actually be a known remote risk that could have been discussed by the physician in the informed consent

process. In other instances, the exchange of information that takes place during the informed consent process may actually reveal important details that lead a physician to change the plan of care. In such circumstances, the informed consent process is a true patient safety tool helpful in avoiding risk-prone treatment.

2. When a patient is informed in advance about risk potential, the fact that it has come to fruition no longer renders the outcome unexpected. Patients are entitled to an explanation of the intended outcome of a diagnostic test, medical treatment or surgical intervention. However, there is a major difference for all concerned discussing what is categorized as an “unanticipated” risk as compared to what was known as a potential outcome.

   Having the framework of the pre-diagnostic or treatment consent dialogue, and the benefit of good communication, the physician can better discuss the results of less than desired diagnostic or treatment outcomes.

B. Communication of Unanticipated Outcome

1. Responsibility

   a. Because of the need to consider the effect the unanticipated outcome has on the patient’s medical condition, further treatment, and current hospitalization, the attending physician, or consulting physician in certain situations, is the most appropriate responsible party for discussing unanticipated outcomes with the patient, family or legally authorized representative. Even in situations in which a hospital employee may have committed an error, the physician is better suited to respond to questions from the patient and family.

      To avoid injury and prevent further harm and in accordance with SB 1339 (California hospitals only), when a medication-related error occurs resulting in an unanticipated outcome, the Pharmacist will be included in the communication process.

   b. When an unanticipated outcome has occurred, the physician should be notified immediately. A thorough investigation as to the cause(s) of the unanticipated outcome will be conducted per hospital policy. The event will be reported to Risk Management and state or federal agencies as required for mandatory reporting.

   c. Administrative, social services, chaplain services, or clinical management staff should be available to the physician as deemed necessary prior to, during, and after the discussion with the patient/family. It is absolutely essential that each situation be considered unique, and as such, situations may be handled differently on a case-by-case basis depending on interventions that best meet the needs of the individual patient and other staff or family members who may be involved.

   d. Support staff should offer to meet with the physician in advance of patient/family conference and “role play” the conversation. The physician should be encouraged, if he/she desires, to contact his/her own professional liability insurer for assistance with difficult questions the patient might ask.

   e. Empathetic support is necessary for the patient/family and the physician should listen carefully to their concerns and fears. It may be necessary to tell the patient/family that the cause or causes of the result may not be known for some

time. If this is the case, the physician should discuss what the outcome means in terms of additional tests or treatment. As further details are learned about the unanticipated outcome, this information should be provided to the patient or family. Recommended next steps should be discussed where appropriate.

f. In the event the physician refuses to inform the patient/family about the situation, a request should be made, via the medical staff chain of command or administration, that the physician contact his/her professional liability carrier or personal attorney for guidance. In most, if not all, cases, the physician will receive counsel to proceed with disclosing the unanticipated outcome and how to communicate and document such.
If the physician continues to refuse to discuss the unanticipated outcome with the patient/family, the medical staff chain of command should be activated and local and corporate risk management should be notified.

2. Communication Strategies and Patients with Special Needs

a. The physician should provide an explanation of the circumstances surrounding the unanticipated outcome and, if appropriate, a treatment plan designed to correct or mitigate any medical injury. To avoid the appearance of contradictory information, the explanation should be in a context that allows for further elaboration as details become available.

It is important to remember that the opportunity to perform a detailed analysis can lead to a better understanding of what transpired and a more in-depth explanation which may differ from an earlier discussion of the test or treatment outcome. This approach can dispel the prospect of patients perceiving “mixed signals” and uncertainty as to whose explanation is credible.

b. Qualified interpreters or social services personnel may be required in cases where patients or family members demonstrate limited English proficiency or where there are dramatically different cultural needs. Additionally, special support services will be necessary to communicate with patients with language, auditory or visual challenges and those with cognitive impairment. Empathetic support is required when working with the patient/family to address their immediate needs (e.g., housing/accommodations, long distance telephone call services, contacting relatives, etc.)

c. Steps taken to provide empathetic support do not signify an admission of liability or of error on the part of the caregiver or the facility. Rather, it is a genuine effort to provide needed support to the patient and family. Those who are enlisted to assist the physician must understand their role and responsibility. Thus they should refrain from offering an opinion or speculating about the unanticipated outcome or attempting to answer any questions about it. To ensure that accurate, consistent explanations come from the same source, such queries should be directed back to the physician.

d. Additional follow-up discussions with patient, family, or legally authorized representative regarding findings linked to the unanticipated outcome may be necessary and the method used for such communication should be clearly explained to patient/family, i.e., in-person, by telephone, or in writing. Any patient grievance related to an unanticipated outcome will be managed according to hospital policy.

e. The confidentiality of the patient's care will be protected and the results of specific tests or treatment will not be disclosed to the public.

f. Healthcare professionals involved in an unanticipated outcome require understanding and support. Empathetic support should be provided to assist employees involved in the situation. That assistance and support is available does not negate the need, in appropriate circumstances, for corrective action or discipline. Such steps should be taken when considered necessary by hospital leadership.

C. Withholding Information: Exceptions to Disclosure

1. Circumstances may occur in which more harm can be done than prevented with disclosure of unanticipated outcome information. Sometimes the outcome information can put a patient at risk of harm either due to psychological trauma or exposure to physical harm. These kinds of situations may include suspected or known abuse or neglect, police or compliance investigations, and psychological and emotional concerns for the patient. In such situations, professional judgement is in order and the reason for withholding the information should be documented.

2. When the possibility of psychological trauma is the concern, it may be appropriate to have a mental health caregiver conduct an assessment. Such an individual should not be associated with the regular care of the patient or a member of the attending physician's practice. The information that is revealed to the patient should be documented. If at a later time the patient is able to participate in a discussion with the physician, disclosure should proceed regarding the unanticipated outcome. The fact that this has occurred should be documented, along with the date, time, and names of those present during the discussion.

3. Withholding information has both legal and ethical connotations. Having the input of a neutral, objective resource can be helpful in determining the most appropriate course of action. Consultations with the Ethics Committee or an individual bioethics consultant may be necessary. When such a resource is used, it must be done in concert with applicable hospital policy. The fact that this has been done should be documented to demonstrate the framework for the decision process used in delicate cases.

4. There are situations in which the explanation provided to a patient or family may be inconsistent with information disseminated to a governmental body or agency under mandatory reporting obligation, i.e., abuse or neglect. The safety or well being of the patient may necessitate a different explanation. The same response may be the result of requests by law enforcement authorities that fear that complete explanation could harm on-going criminal investigation or cause a suspect to flee.

   Safeguarding the patient is of paramount importance. If providing for the welfare and safety of the patient necessitates a different explanation than that made under mandatory reporting, provision can be made for a subsequent dialogue to provide additional details to the patient when it is prudent to do so.

5. Individual state laws relating to withholding information and abuse reporting must be followed.

D. Documentation

1. Documentation of Care Delivered

a. Legally, the patient care delivered, treatments and procedures administered, and all professional interventions must be documented.

b. Documentation of this care must not misrepresent or be false in any way.

c. If a medical error has occurred, each clinician is legally bound to factually document the care he/she provided and the outcome of that care in the patient's medical record.

2. Documentation of Disclosure

Details of the disclosure related to an unanticipated outcome should be documented as soon as possible. The fact that the disclosure process has been used is documented to substantiate communication with the patient and family and to provide for presentation of consistent information during subsequent discussions. This documentation should include:

a. Date, time, and place of the discussion.

b. Name and relationship(s) of those present.

c. Documentation that there was discussion of the unanticipated outcome. Emphasis should be on medical consequences and follow-up care and not on causes of medical error.

d. In appropriate cases, documentation that as further information becomes available, this information will be shared with patient, family, or legally authorized representative.

e. An offer of assistance and the response to the offer.

f. Documentation of any questions posed by the patient, family, or legally authorized representative, and that the physician provided answers.

g. In specific cases in which a decision is made to withhold some or all information, appropriate documentation is made of the reason(s) for this decision. These cases may include instances where in the physician's professional judgement, disclosure may not be therapeutic for an individual patient's care. It is acknowledged that in some cases the documentation may be separate from the medical record to protect the safety or welfare of the patient. Separate documentation is best done by way of an Occurrence/Incident Report Form.

h. Consultations with those providing psychiatric or ethics evaluations should be recorded in accordance with hospital policy.

i. Any follow-up discussions should be documented, including date, time, place, and the names and relationships of those present.

APPLICABLE STANDARDS OR REGULATORY REQUIREMENTS: JCAHO Patient Safety Standards
REFERENCES: AMA Position: Ethical Duty of Physician to Disclose Medical Error; American Society for Healthcare Risk Management: "Perspective on Disclosure of Unanticipated Outcome Information", April 2001; "Communicating Medical Error", Risk Management Opinion, Peggy Nakamura, AH, Number 01-004, May 17, 2001; "Management of Sentinel Events", Legal Opinion, Peggy Nakamura, AH, January 23, 2001.
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