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DISCLOSURE OF ADVERSE EVENTS TO PATIENTS

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy pertaining exclusively to the disclosure of adverse events related to clinical care to patients or their representatives. *NOTE: Information pertaining to adverse events in research can be found in [VHA Handbook 1200.5](#) and [VHA Handbook 1058.1](#).*

2. BACKGROUND

a. VHA facilities and individual VHA providers have an obligation to disclose adverse events to patients who have been harmed in the course of their care, including cases where the harm may not be obvious or severe, or where the harm may only be evident in the future. The patient is free to involve family members in the disclosure process. *NOTE: If the patient is deceased, incapacitated, or otherwise unable to take part in a process of adverse event disclosure, the process needs to involve the patient's representative and anyone who is designated by the representative.*

b. Disclosure of adverse events to patients or their representatives is consistent with VHA core values of trust, respect, excellence, commitment, and compassion. Providers have an ethical obligation to be honest with their patients. Honestly discussing the difficult truth that an adverse event has occurred demonstrates respect for the patient, professionalism, and a commitment to improving care.

c. Clinicians and organizational leaders must work together to ensure that appropriate disclosure to patients or their representatives is a routine part of the response to a harmful or potentially harmful adverse event. Telling patients or their representatives about harmful or potentially harmful adverse events is never easy, and it must be done with skill and tact.

d. Disclosure of adverse events and the reporting of adverse events are separate requirements. Actions taken to disclose adverse events to patients according to this Directive in no way obviate the need to report adverse events (and close calls) as required under [VHA Handbook 1050.1](#). Internal reporting through the adverse event and close call reports are protected from disclosure under Title 38 United States Code (U.S.C.) Section 5705. Records protected under 38 U.S.C. Section 5705, that is, quality management and safety activities records, may not be subsequently used as the source of information communicated in the disclosure of an adverse event. The information communicated must come from those involved in the adverse event and from factual information in the patient's medical record.

NOTE: This Directive is consistent with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requirement that hospitalized patients and their families be told of "unanticipated outcomes" of care (Standard - Ethics, Rights, and Responsibilities (RI) 2.90,

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2005). JCAHO requires that clinicians and health care organizations inform patients and families of adverse events.

e. Despite the general obligation to disclose adverse events to patients, there are some legal restrictions on the information that can be shared:

(1) Confidentiality statutes and regulations, such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, limit disclosure of any record containing a patient's personal information to others without the patient's authorization or other legal authority. **NOTE:** *The patient's personal representative is authorized to have access to the patient's protected health information except as noted in this subparagraph and subparagraph 2e(2).*

(2) Under 38 U.S.C. Section 7332, VHA may not disclose information related to the patient's treatment for substance abuse (including alcohol), sickle cell anemia disease, or infection with the Human Immunodeficiency Virus (HIV) to others even after a patient's death without a "special authorization" or other exception. Questions about release of such information in the case of an adverse event are to be referred to the facility's Privacy Officer. **NOTE:** *Consultation with VHA's Privacy Officer may also be necessary.*

(3) Under 38 U.S.C. Section 5705, VHA may not communicate to patients, or their representatives, information that is obtained from documentation of certain quality management activities, such as root cause analyses or patient safety registry records. Rather, the information communicated must come from those involved in the adverse event and from factual information in the patient's medical record. **NOTE:** *Specific questions regarding sources of information that may not be disclosed or released to the patient or representative may be found in VHA Handbook 1605.1. Other guidance is available from VHA's Privacy Officer.*

f. Definitions

(1) **Adverse Event.** An adverse event is any untoward incident, therapeutic misadventure, iatrogenic injury, or other undesirable occurrence directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic, or other VHA facility.

(2) **Disclosure of Adverse Events.** For the purpose of this Directive, the phrase "disclosure of adverse events" refers to the forthright and empathetic discussion of clinically significant facts between providers and/or other VHA personnel and patients or their representatives about the occurrence of an adverse event that resulted in patient harm, or could result in harm in the foreseeable future. VA recognizes two types of disclosure of adverse events:

(a) Clinical Disclosure of Adverse Events. An informal process for informing patients or their representatives of harmful adverse events related to the patient's care. In a clinical disclosure, one or more members of the clinical team provides factual information to the extent it is known, expresses concern for the patient's welfare, and reassures the patient or representative that steps are being taken to investigate the situation, remedy any injury, and prevent further

harm. The clinical disclosure of adverse events needs to be considered a routine part of clinical care, and needs to be made by the attending or senior practitioner, or designee.

(b) Institutional Disclosure of Adverse Events. In cases resulting in serious injury or death, or those involving potential legal liability, a more formal process is needed. This process is called institutional disclosure of adverse events. In an institutional disclosure the patient or representative and any family members designated by the patient or representative are invited to meet with institutional leaders and others, as appropriate. An apology is made, and information about compensation and procedures available to request compensation is provided, when appropriate. Additional guidance on what must be disclosed, when and how is provided in Attachment A. Documentation of institutional disclosure using the Computerized Patient Record System (CPRS) template is mandatory (see Att. B).

(3) **Patient's Personal Representative**. Representatives of the individual are any person(s) who, under applicable law, has authority to act on behalf of the individual when making decisions related to health care or to act on behalf of a deceased individual. The personal representative of an individual has the ability to exercise the individual's rights. A personal representative for the purposes of this handbook does not necessarily equate to a surrogate for the informed consent process (see Title 38 Code of Federal Regulations (CFR) §17.32(e) for authorized surrogates for informed consent; see VHA Handbook 1605.1 for details on personal representatives).

3. POLICY: It is VHA Policy that each medical center develop and establish a policy, by April 1, 2006, to ensure health care providers communicate adverse events openly and promptly with their patients, and/or the patients' representatives.

4. ACTION

a. **The Veterans Integrated Service Network (VISN) Director**. The VISN Director, or designee, is responsible for:

(1) Promoting an ethical health care environment in which appropriate disclosure of adverse events becomes routine practice.

(2) Ensuring that a collaborative relationship between Regional Counsel and VA medical center staff is established to ensure appropriate and timely disclosure of adverse events to patients.

b. **Facility Director**. The facility Director is responsible for:

(1) Promoting an ethical health care environment in which appropriate disclosure of adverse events becomes routine practice.

(2) Ensuring that a local facility policy, based on this national policy, is developed by April 1, 2006.

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(3) Ensuring that clinical staff are aware of this Directive and are implementing it. **NOTE:** *Practitioners are encouraged to confer with the local ethics consultation service, their Service Chief, Regional Counsel, or Risk Manager to clarify any concerns about how best to communicate this information and what adverse events are applicable to the disclosure of adverse event process.*

(4) Ensuring that staff members involved in adverse events and subsequent disclosure processes are provided with adequate support systems and for ensuring that staff members are aware of them.

(5) Ensuring that harmful adverse events are appropriately disclosed in collaboration with the Chief of Staff, Risk Manager, and the treatment team. Appropriate disclosure includes:

(a) Ensuring that as part of the disclosure process, patients or their representatives are offered appropriate options, such as arrangements for a second opinion, additional monitoring, expediting clinical consultations, bereavement support, or whatever might be appropriate depending on the adverse event.

(b) Ensuring that patients or their representatives are made aware of their rights under 38 U.S.C. Section 1151, made aware of the Tort Claim process, and provided information concerning where to obtain assistance in filling out the necessary forms.

(6) Ensuring that harmful adverse events are documented in CPRS.

(a) Institutional disclosure of adverse events must be documented in CPRS utilizing the "Disclosure of Adverse Event Note" template (see Att. B). Specific documentation in CPRS is not required for all clinical disclosures, as clinical disclosure is considered a part of routine care; however, for significant adverse events, it is appropriate to document the clinical disclosure of the adverse event in the template or a progress note.

(b) In cases requiring reporting, documentation such as the report of contact or incident report may be kept in some other file at the facility's discretion and entitled "Adverse Event and Close Call Report." This information must not be retrieved by patient identifier and must be identified by a case number. **NOTE:** *The Adverse Event and Close Call Report is protected under 38 U.S.C. Section 5705.*

(c) Documenting information in records protected under 38 U.S.C. Section 5705 should never be done to shield information to which a patient is entitled. Likewise, the fact that information may be documented in records protected under 38 U.S.C. Section 5705 does not mean that the identical information, documented in CPRS, cannot be retrieved by patients.

c. **Risk Manager.** The Risk Manager is responsible for:

(1) Immediately notifying the Chief of Staff about the discovery of a significant adverse event.

(2) Establishing a regular dialogue with Regional Counsel and requesting that Regional Counsel educate providers about the legal dimensions of institutional disclosure of adverse events, its documentation, and its relationship to the Federal Tort Claims Act.

5. REFERENCES

- a. American Society for Healthcare Risk Management of the American Hospital Association. "Perspective on Disclosure of Unanticipated Outcome Information," April 2001.
- b. American Society for Healthcare Risk Management of the American Hospital Association. "Disclosure of Unanticipated Events: The Next Step In Better Communication With Patients," May 2003.
- c. American Society for Healthcare Risk Management of the American Hospital Association. "Disclosure of Unanticipated Events: Creating An Effective Patient Communication Policy," November 2003.
- d. American Society for Healthcare Risk Management of the American Hospital Association. "Communication: What Works Now and What Can Work Even Better," February 2004.
- e. JCAHO Accreditation Manual for Hospitals, Ethics, Rights and Responsibilities, RI 2.90, 2005.
- f. JCAHO Accreditation Manual for Hospitals, Leadership Standards, LD 4.40, 2005.
- g. VA Handbook 6300.4, Procedures for Processing Requests for Records Subject to the Privacy Act.
- h. VHA Handbook 1050.1, VHA National Patient Safety Improvement Handbook.
- i. VHA Handbook 1004.1, VHA Informed Consent for Clinical Treatments and Procedures.
- j. VHA Handbook 1605.1 Privacy and Release of Information.
- k. VHA National Ethics Committee, Disclosing Adverse Events to Patients, March 2003. <http://vaww1.va.gov/vhaethics/download/AdverseEventsReport.doc>
- l. Andrews, Lori B., Carol Stocking, Thomas Krizek, et al, "An alternative strategy for studying adverse events in medical care." The Lancet. Volume 349:313-7, February 1, 1997.
- m. Kraman, Steve S. and Ginny Hamm, "Risk Management: Extreme Honesty May Be the Best Policy," Annals of Internal Medicine. Volume 131:963-7, December 1, 1999.

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n. Levinson, Wendy, Debra L. Roter, John P. Mullooly, et al., "Physician-Patient Communication: The Relationship With Malpractice Claims Among Primary Care Physicians and Surgeons," Journal of American Medical Association. Volume 277:553-9, February 19, 1997.

o. Wu, Albert W., "Handling Hospital Errors: Is Disclosure the Best Defense?" Annals of Internal Medicine. Volume 131:970-2, December 21, 1999.

p. Wu, Albert W., et al., "To Tell the Truth: Ethical and Practical Issues in Disclosing Medical Mistakes to Patients," The Journal of General Internal Medicine. Volume 12:770-5, December 1997.

6. FOLLOW-UP RESPONSIBILITY: The Deputy Under Secretary for Health for Operations and Management (10N) and the National Center for Ethics in Health Care (10E) are jointly responsible for this Directive. Questions about operational issues may be addressed to (202) 273-5852. Questions about the ethical content may be addressed to (202) 501-0364.

7. RESCISSION: None. This VHA Directive expires October 31, 2010.

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Under Secretary for Health

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ATTACHMENT A

**WHAT ADVERSE EVENTS WARRANT DISCLOSURE?
WHEN SHOULD DISCLOSURE OF AN ADVERSE EVENT OCCUR?
HOW SHOULD ADVERSE EVENTS BE COMMUNICATED?**

1. WHAT ADVERSE EVENTS WARRANT DISCLOSURE?

a. Patients and/or their representatives must be informed of the probable or definite occurrence of any adverse event that has resulted in, or is expected to result in, harm to the patient, including the following:

(1) Adverse events that have had or are expected to have a clinical effect on the patient that is perceptible to either the patient or the health care team. For example, if a patient is mistakenly given a dose of furosemide (a diuretic that dramatically increases urine output), disclosure is required because a perceptible effect is expected to occur.

(2) Adverse events that necessitate a change in the patient's care. For example, a medication error that necessitates close observation, extra blood tests, extra hospital days, or follow-up visits that would otherwise not be required, or a surgical procedure that necessitates further (corrective) surgery.

(3) Adverse events with a known risk of serious future health consequences, even if the likelihood of that risk is extremely small. For example, accidental exposure of a patient to a toxin associated with a rare, but recognized serious long-term effect (e.g., HIV infection or increased incidence of cancer).

(4) Adverse events that require providing a treatment or procedure without the patient's consent. For example, if an adverse event occurs while a patient is under anesthesia, necessitating a deviation from the procedure the patient expected, the adverse event needs to be disclosed. Patients have a fundamental right to be informed about what is done to them and why.

b. Disclosure of other adverse events is optional and at the discretion of the providers involved. Cases need to be considered individually and in relation to the specific circumstances.

c. Disclosure of "close calls" to patients is also discretionary, but is advisable at times, such as when the patient or family becomes aware that something out of the ordinary has occurred. For example, a nurse sets a patient up for a blood transfusion and, discovering that the patient is about to receive the wrong unit of blood, abruptly stops the transfusion just before the blood enters the patient's vein. The patient deserves an explanation, even if this would not be considered a clinical disclosure of adverse events. **NOTE:** *Although the disclosure of a close call to the patient is optional, its reporting under [VHA Handbook 1050.1](#) is required.*

2. WHEN SHOULD DISCLOSURE OF AN ADVERSE EVENT OCCUR?

Optimal timing of disclosure of adverse events varies with the specific circumstances of the case. If a patient needs urgent treatment to minimize injuries resulting from an adverse event, clinical disclosure must occur quickly. 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. Clinical disclosure of adverse events needs to occur within 24 hours of a practitioner's discovery of the adverse event. Institutional disclosure of adverse events, when necessary, needs to take place as soon as possible (generally within 24 hours, but no more than 72 hours) after a practitioner's discovery of the event. For patients who are aware of, or suspect, an adverse event, more time prior to disclosure increases the chance that patients will think information is being deliberately withheld.

3. HOW SHOULD ADVERSE EVENTS BE COMMUNICATED?

a. Disclosure of an adverse event needs to occur in an appropriate setting and be done face-to-face. The location needs to be a quiet, private place and adequate time needs to be set aside, with no interruptions.

b. In general, communication about the adverse event needs to be done through a clinical disclosure of adverse events, when one or more members of the clinical team provides preliminary factual information to the extent it is known, expresses concern for the patient's welfare, and reassures the patient or representative that steps are being taken to investigate the situation, remedy any injury, and prevent further harm. Social workers, chaplains, patient advocate, or other staff may be present to help the patient or representative cope with the news and to offer support, if needed. The patient's treating practitioner is responsible for determining who shall communicate this information.

c. Sometimes, given the nature, likelihood, and severity of injury, and the degree of risk for legal liability, there will be a need for institutional disclosure of adverse events either instead of, or in addition to, clinical disclosure. Institutional disclosure includes the following elements:

(1) Institutional Leaders (e.g., the Chief of Staff or facility Director) invite the patient or personal representative to meet for an Institutional Disclosure of Adverse Event Conference. Institutional leaders may only invite the representative if he or she is involved in the patient's care (and the patient does not object), or the representative is the personal representative as outlined in VHA Handbook 1605.1. *NOTE: The facility Risk Manager, treating physician, or other VHA personnel deemed appropriate, may be included in this conference at the discretion of facility leadership.*

(2) Institutional disclosure of adverse events should not take place until organizational leaders, including, as appropriate, the facility Director, Chief of Staff, and members of the treatment team, have conferred with Regional Counsel and addressed what is to be communicated, by whom and how.

(3) Any request by a patient or personal representative to bring an attorney must be honored, but may influence whether providers will participate.

(4) The Risk Manager or organizational leaders need to engage in ongoing communication with the patient or personal representative to keep them apprised, as appropriate, of information that emerges from the investigation of the facts.

NOTE: If the patient is not capable of understanding the disclosure of adverse event, and the patient does not have a personal representative as defined in VHA Handbook 1605.1, the facility may make the institutional disclosure to a family member involved in the patient's care. Consult the facility's or VHA's Privacy Office for additional guidance.

(5) Institutional disclosure of adverse events must include:

(a) An apology including a complete explanation of the facts.

(b) An outline of treatment options.

(c) Arrangements for a second opinion, additional monitoring, expediting clinical consultations, bereavement support, or whatever might be appropriate depending on the adverse event.

(d) Notification that the patient or representative has the option of obtaining outside legal advice for further guidance.

(e) After complete investigation of the facts, the patient or representative is to be given information about compensation under Title 38 United States Code (U.S.C.) Section 1151 and the Federal Tort Claims Act claims processes, including information about procedures available to request compensation and where and how to obtain assistance in filing forms. In the event that the investigation is not complete, information about compensation may be given based on the current understanding of the facts or information may be deferred until the investigation is completed. There should be no assurance that compensation will be granted, as the adverse event may not give rise to and meet legal criteria for compensation under 38 U.S.C. Section 1151 and the Federal Tort Claims Act.

(f) If a patient or personal representative asks whether an investigation will be conducted and whether the patient or representative will be told of the results of an investigation, the patient or representative is to be informed that only the results of an administrative board of investigation (AIB) may be released.

ATTACHMENT B

DISCLOSURE OF ADVERSE EVENT TEMPLATE

The screenshot shows the VistA CPRS interface. At the top, the window title is "VistA CPRS in use by:". Below the title bar is a menu bar with "File", "Edit", "View", "Action", "Options", "Tools", and "Help". The main interface is divided into several sections:

- Patient Information:** "CPRSPATIENT_01E" (000-00-0001, Jan 01, 1945 (60)), "2ASM 102-1" (Provider), and "Primary Care Team Unassigned" (Attending).
- Administrative:** "Adm: 08/02/05 DISCLOSURE OF ADVERSE EVENT NOTE, 2ASM, (Aug 17,05@05:47)".
- Notes List:** "Last 100 Signed Notes" with a tree view showing "All unsigned notes for" and "All signed notes". A specific note is selected: "Aug 17,05 DISCLOSURE OF ADVERSE EVENT NOTE, 2ASM, ANDREW J BAKKE".
- Form Fields:** A large text area containing the following fields:
 - TITLE: DISCLOSURE OF ADVERSE EVENT NOTE
 - DATE OF NOTE: AUG 17, 2005@05:47 ENTRY DATE: AUG 17, 2005@05:47:10
 - AUTHOR: EXP COSIGNER:
 - URGENCY: STATUS: UNSIGNED
 - DATE, TIME, AND PLACE OF DISCUSSION:
 - NAMES OF THOSE PRESENT:
 - DISCUSSION POINTS OF THE ADVERSE EVENT:
 - OFFER OF ASSISTANCE INCLUDING BEREAVEMENT SUPPORT:
 - QUESTIONS ADDRESSED IN THE DISCUSSION:
 - ADVISEMENT OF 1151 CLAIMS PROCESS AND RIGHT TO FILE ADMINISTRATIVE TORT CLAIM:
 - CONTINUED COMMUNICATIONS REGARDING THE ADVERSE EVENT:
- Navigation:** Buttons for "Templates", "Encounter", and "New Note".
- Footer:** A menu bar with "Cover Sheet", "Problems", "Meds", "Orders", "Notes", "Consults", "Surgery", "D/C Summ", "Labs", and "Reports".