

**DISCLOSURE OF ADVERSE EVENTS**

**1. PURPOSE:** The purpose of this policy is to provide guidance in the disclosure of adverse events related to clinical care to patients and/or their personal representatives at the South Texas Veterans Health Care System (STVHCS).

**2. POLICY:**

a. STVHCS facilities and its individual providers have an ethical and legal obligation to disclose to patients adverse events that have been sustained in the course of their care, including cases where the adverse event may not be obvious or severe, or where the harm may only be evident in the future.

(1) The patient is free to involve family members in the disclosure process.

(2) 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 personal representative and anyone who is designated by the personal representative.

b. Disclosure of adverse events to patients or their personal representatives is consistent with STVHCS 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.

d. Disclosure of adverse events and the reporting of adverse events to regulatory agencies are separate requirements. Actions taken to disclose adverse events to patients according to this policy 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 patient safety activities records, may not be subsequently used as the source of information communicated in the disclosure of an adverse event.

***Note: This policy is consistent with The Joint Commission requirement that patients and, when appropriate, their families be told of "unanticipated outcomes of care, treatment, and services that relate to sentinel events". (Standard-Ethics, Rights and Responsibilities of the Individual RI.01.02.01.21).***

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e. Despite the general obligation to disclose adverse events to patients, there are legal restrictions on the information that can be shared. The information communicated must come from those involved in the adverse event and from factual information in the patient's medical record.

(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)(see VHA Handbook 1605.1).

(2) Under 38 U.S.C. Section 7332. STVHCS 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, STVHCS may not communicate to patients, or their personal representatives, information that is obtained from documentation of certain quality management activities, such as root cause analyses or patient's safety registry records. 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 STVHCS's Privacy Officer.

f. **Definitions:**

(1) **Adverse Event.** Adverse events are untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of the Audie L. Murphy Memorial Hospital, an outpatient clinic, or other STVHCS facility. Note: To determine which incidents need to be considered for Root Cause Analysis, refer to VHA Handbook 1050.1.

(2) **Disclosure of an Adverse Event.** The phrase 'disclosure of adverse events' refers to the forthright and empathetic discussion of clinically significant facts between providers and/or other STVHCS personnel and patients or their personal representatives about the occurrence of a harmful adverse event that resulted in patient harm, or could result in harm in the foreseeable future. VA recognizes three types of disclosure of adverse events:

(a) **Clinical Disclosure of Adverse Events.** An informal process for informing patients or their personal 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 personal representative that steps are being taken to investigate the situation, remedy any injury, and prevent further harm. The clinical disclosure of adverse events is considered a routine part of clinical care, and needs to be made by the attending or senior practitioner, or designee. The

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clinical disclosure is documented in a progress note. Additional guidance on what must be disclosed, when, and how is provided in Attachment A.

(b) **Institutional Disclosure of Adverse Events.** In cases resulting in serious injury or death, or those involving reasonably expected serious injury, or potential legal liability, a formal process is needed; this process is called institutional disclosure of adverse events. Institutional disclosure of adverse events should not take place until organizational leaders, including, as appropriate, the Center Director, the Chief of Staff, Nurse Executive, or Risk Manager, and members of the treatment team have conferred with a Regional Counsel staff attorney and addressed what is to be communicated, by whom and how. The patient or personal representative and any family member(s) designated by the patient or personal representative are invited to meet with institutional leaders or 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 (Attachment B).

(c) **Large Scale Disclosure of Adverse Events.** “Large-scale” is defined as involving a large number of patients, even if at a single facility. For large scale disclosures of adverse events, collaboration with Department of Veterans Affairs (VA) Central Office is required for evaluation and planning. Decisions regarding large scale disclosure of adverse events will be made by the Principal Deputy Under Secretary for Health and may include consultation with the Clinical Risk Assessment Advisory Board (CRAAB). Note: Additional Guidance on large scale disclosure is provided in Attachment A.

(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.

(4) **Clinical Risk Assessment Advisory Board (CRAAB).** The CRAAB is a VA Central Office board which will be convened at the request of the Deputy Under Secretary for Health for Operations and Management (10N) in response to actual or potential adverse events which may not be limited to a small number of patients, especially “large scale” disclosures as defined in subparagraph 2f(2)(c). Notification of VA regarding the potential need for large scale disclosure does not eliminate the requirement for adverse event reporting and follow-up as described in VHA Handbook 1050.1.

**3. ACTION:**

a. **Center Director.** The Center Director is responsible for:

(1) Ensuring that STVHCS health care providers communicate, as appropriate, harmful adverse events openly and promptly with patients and/or patients’ personal representatives and that when necessary the process for large scale adverse event disclosure is appropriately initiated.

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

(3) Ensuring that clinical staff are aware of the Directive and this policy and are implementing them. NOTE: Practitioners are encouraged to confer with the local ethics consultation service, their Service Chief, Chief of Staff, Nurse Executive, 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 adverse events are appropriately disclosed in collaboration with the Chief of Staff, Risk Manager, Nurse Executive and the treatment team. Appropriate disclosure includes:

(a) Ensuring that as part of the disclosure process, patients or their personal 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 veteran patients or their personal representatives are made aware of their rights under 38 U.S.C. Section 1151, of the Tort Claim process, and provided information concerning the necessary forms.

(c) Ensuring that adverse events that may require large scale patient disclosures are thoroughly documented and communicated to the VISN Director.

(6) Ensuring that 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 (Attachment B). Clinical disclosure is considered a part of routine care and should be documented in a progress note. It is appropriate to document the clinical disclosure of significant and unexpected adverse events in a “Disclosure of Adverse Event Note”.

(7) Ensuring the VISN Director and the Deputy Under Secretary for Health for Operations and Management are informed of significant, critical, or urgent adverse events.

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

(1) Immediately notifying the Center Director or designee, about the discovery of a significant adverse event, especially those that may require institutional disclosure or a decision regarding a large scale disclosure of adverse events.

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(2) Establishing a regular dialogue with a Regional Counsel staff attorney to request the education of providers as needed about the legal dimensions of institutional disclosure of adverse events, its documentation, and its relationship to the Federal Tort Claims Act.

(3) Coordinating the institutional disclosure conference to include the patient or patient representative, the attending, and bereavement support or social worker if needed.

c. **Chief of Staff and Nurse Executive.** The Chief of Staff and Nurse Executive or designee are responsible for:

(1) Immediately notifying the Center Director about the discovery of a significant adverse event.

(2) Participating in discussions with others, e.g., clinicians, facility top management team, Regional Counsel, VISN staff, patients or personal representatives, as appropriate, concerning the adverse event.

d. **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 a Regional Counsel staff attorney and STVHCS staff is established to ensure appropriate and timely disclosure of adverse events to patients.

(3) Ensuring that adverse events that may require large scale patient disclosures are thoroughly documented and communicated to the Office of the Deputy Under Secretary for Health for Operations and Management.

e. **Deputy Under Secretary for Health for Operations and Management (10N).** The Deputy Under Secretary for Health for Operations and Management is responsible for reviewing those adverse events that may require large scale adverse event disclosures to determine if the adverse event needs to be sent to the CRAAB for its review and recommendations. If there are clinical issues, consultation with the Chief Consultant, Medical-Surgical Service of Patient Care Services and other senior officials may be necessary to assist in the decision making process.

f. **The Clinical Risk Assessment Advisory Board (CRAAB).** The CRAAB is responsible for:

(1) Conducting, for each request by the Deputy Under Secretary for Health for Operations and Management, a decision process based on organization, ethical, and clinical risk considerations outlined in Attachment C.

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(2) Establishing and communicating the evaluation factors to be used to determine population risk. Note: One example for the Clinical Risk Assessment Advisory Board to use as a starting point is provided in the Matrix and Flow Chart in Attachment D.

(3) Providing recommendations and documentation to the Principal Deputy Under Secretary for Health regarding the necessity of a large scale disclosure.

(4) Providing recommendations and documentation to the Principal Deputy Under Secretary for Health, if a large scale disclosure is approved, on how it should be conducted and serve in an advisory role to the individual or group assigned to conduct the actual disclosure.

**g. The Principal Deputy Under Secretary for Health.** The Principal Deputy Under Secretary for Health makes the decision concerning large scale adverse event disclosures and communicates that decision to the Deputy Under Secretary for Health for Operations and Management with a copy to the Chair, CRAAB.

**4. REFERENCES:**

- a. VHA Directive 2008-002, Disclosure of Adverse Events to Patients, January 18, 2008.
- b. STVHCS Policy Memorandum 002-07-05, Disclosure of Adverse Events May 2, 2007.
- c. STVHCS Policy Memorandum 002-07-08, Patient Safety Improvement (Risk Management) Program, July 13, 2007.

**5. RESPONSIBILITY:** Chief, Quality Management (002)

**6. RESCISSION:** Disclosure of Adverse Events Policy Memorandum 002-07-05, dated May 2, 2007.

**7. RECERTIFICATION:** December 2014

MARIE L. WELDON, FACHE  
Director

Attachment (4)

DISTRIBUTION: B

**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. For an adverse event that has the apparent potential to affect, or may have already affected patients at more than one STVHCS facility, or affects a significant number of patients, or involves significant actual or potential severity the process for large scale disclosure must be followed. The process will be based on ethical and clinical considerations as outlined in Attachment C.

b. For all other adverse events, patients or their personal representatives must be informed of the occurrence of any adverse event that has resulted in, or can be 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 anticipated to occur.

(2) Adverse events that necessitate a change in the patient's care. For example, a medication error that necessitates extra blood tests, extra hospital days, or follow-up visits that would otherwise not be required, or a surgical procedure, such as a retained foreign object, 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, a known, accidental exposure of a patient to ionizing radiation, a toxin, an organism, or infectious entity associated with a rare, but recognized serious short-term or long-term effect (e.g., blood borne pathogen infection or increased incidence of cancer). In some cases, however, no definite exposure of this type can be determined. Only an increased risk of exposure is known or thought to exist. In such cases, disclosure should be decided on a case by case basis considering the best interests of the patient, weighing the risks and benefits of disclosure relative to the probability of serious future health consequences.

(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 what is done to them and why.

a. Disclosure of other adverse events is optional and at the discretion of the

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providers involved. Cases need to be considered individually and in relation to the specific circumstances.

b. 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. NOTE: Although the disclosure of a close call to the patient is optional, it is required under VHA Handbook 1050.1.

**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 time to collect preliminary information and plan the best way to disclose. For patients who are aware of, or suspect, an adverse event, more time prior to disclosure may increase the chance for patients to have anxiety and suspicion, and decrease the patient’s trust of STVHCS health care providers and management.

a. Clinical disclosure of adverse events needs to occur within 24 hours of a practitioner’s discovery of the adverse event if adequate information is available.

b. Institutional disclosure of adverse events, must take place as soon as possible (Generally within 24 hours, but no more than 72 hours if adequate information is available) after a practitioner’s discovery of the adverse event.

c. For large scale adverse event disclosure, adequate time is necessary for evaluation and planning in collaboration with the Principal Deputy Under Secretary for Health, Deputy Under Secretary for Health for Operations and Management, and the CRAAB. In these cases, the disclosure process should start within 30 days after the Chair person of CRAAB has accepted the adverse event(s) for review, unless extension is granted by the Principal Deputy Under Secretary for Health.

**3. HOW SHOULD ADVERSE EVENTS BE COMMUNICATED?**

**a. Clinical Disclosure of Adverse Events:** In general, communication about an adverse event done as a clinical disclosure of adverse events proceeds as follows:

(1) 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 personal representative that steps are being taken to investigate the situation, remedy any injury, and prevent further harm.

(2) A chaplain, social worker, or other staff may be present to support the patient or personal representative in coping with the disclosed information.



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(3) The patient's attending or senior practitioner or designee is responsible for determining who shall communicate this information. Such disclosure needs to occur in a quiet private setting and be done face-to-face. Adequate time needs to be set aside, with no interruptions.

b. **Institutional Disclosure of Adverse Events:** Sometimes, given the nature, likelihood, 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, a clinical disclosure. Like clinical disclosure, institutional disclosure 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. This size of this VA system may impact the possibility of the patient or personal representative from traveling, a distance of 30 to more than 200 miles, to the main facility for a disclosure conference. In this instance, a telephone conference will take place with permission from the patient or personal representative.

Institutional disclosure includes the following elements:

(1) The Risk Manager or designee will invite the patient or personal representative to meet for an Institutional Disclosure Conference. Institutional leaders may only invite the personal representative if he or she is involved in the patient's care (and the patient does not object), or is acting as a personal representative as outlined in VHA Handbook 1605.1.

(2) An institutional disclosure should not take place until organizational leaders, including, as appropriate, the Chief of Staff, Nurse Executive, Center Director, Risk Manager, and members of the treatment team, have conferred with Regional Counsel staff attorney 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 related to the adverse event. Documents such as Root Cause Analyses and Peer Reviews cannot be disclosed to attorneys, patients, or personal representative and may only be used for patient safety and quality improvement.

(5) If the patient is not capable of understanding the disclosure of an 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 STVHCS facility's or VHA's Privacy Office for additional guidance.

(6) Institutional disclosure must be documented using the template in Attachment B.

(7) Institutional disclosure of adverse events must include:

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(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 what may 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.

(8) After complete investigation of the facts, the patient or personal 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.

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

**c. Large Scale Disclosure of Adverse Events.**

(1) Large scale disclosure will be done in alignment with the plan for disclosure as developed by the VA CRAAB with adequate time for evaluation and planning at the VACO level. Depending on the nature of the event, disclosure to veterans may entail any or all of the following:

(a) Institutional disclosure to affected veterans.

(b) Notification by mail or telephone to potentially affected veterans.

(c) Notification to facilities for required follow up with potentially affected veterans.

(2) In addition, the disclosure plan may include public affairs strategies such as announcement through the media, information and support to clinical providers, and/or establishment of call centers or web sites.



**ATTACHMENT C**

**LEADERSHIP DECISION PROCESS FOR  
LARGE SCALE DISCLOSURE OF ADVERSE EVENTS**

**NOTE: This guidance is based on the Veterans Health Administration (VHA), VHA National Center for Ethics Report on Ethical Leadership: Fostering an Ethical Environment and Culture. 2007, page 34.**

I. Within the Veterans Health Administration (VHA), there is a presumptive obligation to disclose adverse events that cause harm to patients. However, in the case of an adverse event that has the potential to affect dozens or even thousands of patients, a public health response also requires a determination of the probability and magnitude of harm resulting from the adverse event as well as a weighing of additional factors, including, but not limited to salient ethical principles; risk of harm to veterans and identifiable third parties; benefit and burden of disclosure to veterans including medical, psychological, social or economic, impact on the institution's perceived integrity and its capacity to provide care and treatment for all veterans; as well as applicable policy and relevant precedent. The Clinical Risk Assessment Advisory Board (CRAAB) needs to include the following considerations in its decision process:

**1. DO WE HAVE ALL THE IMPORTANT FACTS RELEVANT TO THE DECISION?**

- a. How many veterans exposed or potentially exposed?
- b. What is the probability that a given veteran was exposed to the adverse event?
- c. What is the probability that the adverse event will cause a particular veteran harm?
- d. What is the nature of the potential harm?
- e. What is the expected magnitude of the harm?
- f. What is the expected duration of the harm?
- g. Is there treatment available to prevent or ameliorate the harm?
- h. Does the harm have the potential to extend beyond the identified patient, to third parties and what is the probability that the extension of harm would occur?

**NOTE: On a case-by-case basis, additional questions may be relevant. Consult the matrix and flow chart in this Attachment D to analyze relevant facts.**

**2. HAVE WE INVOLVED EVERYONE WHO SHOULD BE PART OF THIS DECISION?**

a. Membership in the CRAAB includes the following offices:

(1) Deputy Under Secretary for Health for Operations and Management;

(2) Office of Patient Care Services (e.g., Infectious Diseases Program Office and/or Primary Care or Pharmacy Benefits Management, as appropriate to the event);

(3) National Center for Ethics in Health Care;

(4) National Center for Patient Safety;

(5) Office of Public Health and Environmental Hazards;

(6) Office of Nursing Services; and

(7) Office of Quality and Performance.

NOTE: Consideration is to be given on a case-by-case basis to including other individuals or groups to ensure that the perspectives of all relevant subject matter experts and stakeholders affected by the decision have an opportunity for input.

**3. DOES THIS DECISION REFLECT ORGANIZATIONAL, PROFESSIONAL, AND SOCIAL VALUES?** The following questions may be considered:

a. Does the decision reflect STVHCS core values such as trust, respect, excellence and commitment?

b. Does the decision reflect values central to health care provider professionalism? For example, does the decision hold in high regard the dignity and worth of our patients?

c. Does the decision reflect values central to public health practice?

**4. DO THE LIKELY BENEFITS OF THE DECISION OUTWEIGH ANY POTENTIAL HARM?**

Although it is difficult to weigh all benefits and harms, situations prompting a decision whether to conduct large scale disclosure of adverse events likely involves the following considerations:

a. Are there medical, social, psychological, or economic benefits or burdens to the veterans, resulting from the disclosure itself?

b. What is the burden of disclosure to the institution, focusing principally on the institution's capacity to provide health care to other veterans?

c. What is the potential harm to the institution of both disclosure and non-disclosure in the level of trust that veterans and Congress would have in STVHCS?

NOTE: On a case-by-case basis, additional questions may be relevant.

**5. WILL THIS DECISION KEEP THE PROBLEM FROM RECURRING OR ESTABLISH A GOOD PRECEDENT?** The following questions may be considered:

a. Is this a good model for how similar questions should be handled in the future?

b. Has the decision process been followed and documented in a way that can be easily referenced for any similar future cases?

**6. HOW WOULD THIS DECISION LOOK TO SOMEONE OUTSIDE THE ORGANIZATION?** The following questions may be considered:

a. Does this decision reflect similar decisions by other large health care systems?

b. Will the decision be understood and accepted by veterans, the public?

c. Was the process used to make the decision systematic, examining the question from all angles?

d. Was the process used to make the decision transparent, that is, was the reasoning made clear to all involved?

II. In any particular large scale case, the answers to these questions should assist in the assessment of the benefits and burdens of disclosure. After these issues are considered, the Matrix and Flow Chart in Attachment D is an example of aids for the Clinical Risk Assessment Advisory Board to use as a starting point for making disclosure decisions for large scale adverse events. Based on the nature of the adverse event, the Clinical Risk Assessment Advisory Board may also seek other sources or develop additional aids to assist with this patient centered decision making.

ATTACHMENT D

**FLOW CHART TO AID IN ADVERSE EVENT DISCLOSURE DECISIONS  
FOR LARGE SCALE EVENTS**

The following Flow Chart is an example of an aid for the Clinical Risk Assessment Advisory Board to use as a starting point for making disclosure decisions for large scale adverse events. Based on the nature of the adverse event, the Clinical Risk Assessment Advisory Board may also seek out other sources and/or develop additional aids to assist with this patient-centered decision making.

**\*Clinically Significant:** This is a condition that causes harm or illness and/or requires testing, monitoring or short-term or long-term treatment.

**+Not Clinically Significant:** This is a condition that causes no perceptible harm or illness and requires no testing, monitoring, or short-term or long-term treatment.

**†Probability:** The probability is determined based on a review of the literature, or, if inadequate literature, by the expert opinion of the VA Central Office Clinical Risk Assessment Advisory Board. Previous VA and non-VA experience with similar adverse events or exposure may be appropriate for consideration, even if not available in the published literature.

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