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 registry records. Note: Specific questions regarding sources of information that may not be disclosed or released to patient or representative may be found in VHA Handbook 1605.1. Other guidance is available from STVHCS's Privacy Officer.

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 number of patients, even if at a single facility. For large scale disclosure 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) **.** 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 nu
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 atives and that when necessary the process for large scale adverse event disclosure is appropriately initiated.

(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 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

a part of routine care and should be documented in a progress note, as appropriate to

of Adverse Event

(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.

(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 as 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.

(3)

(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 detailed 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:

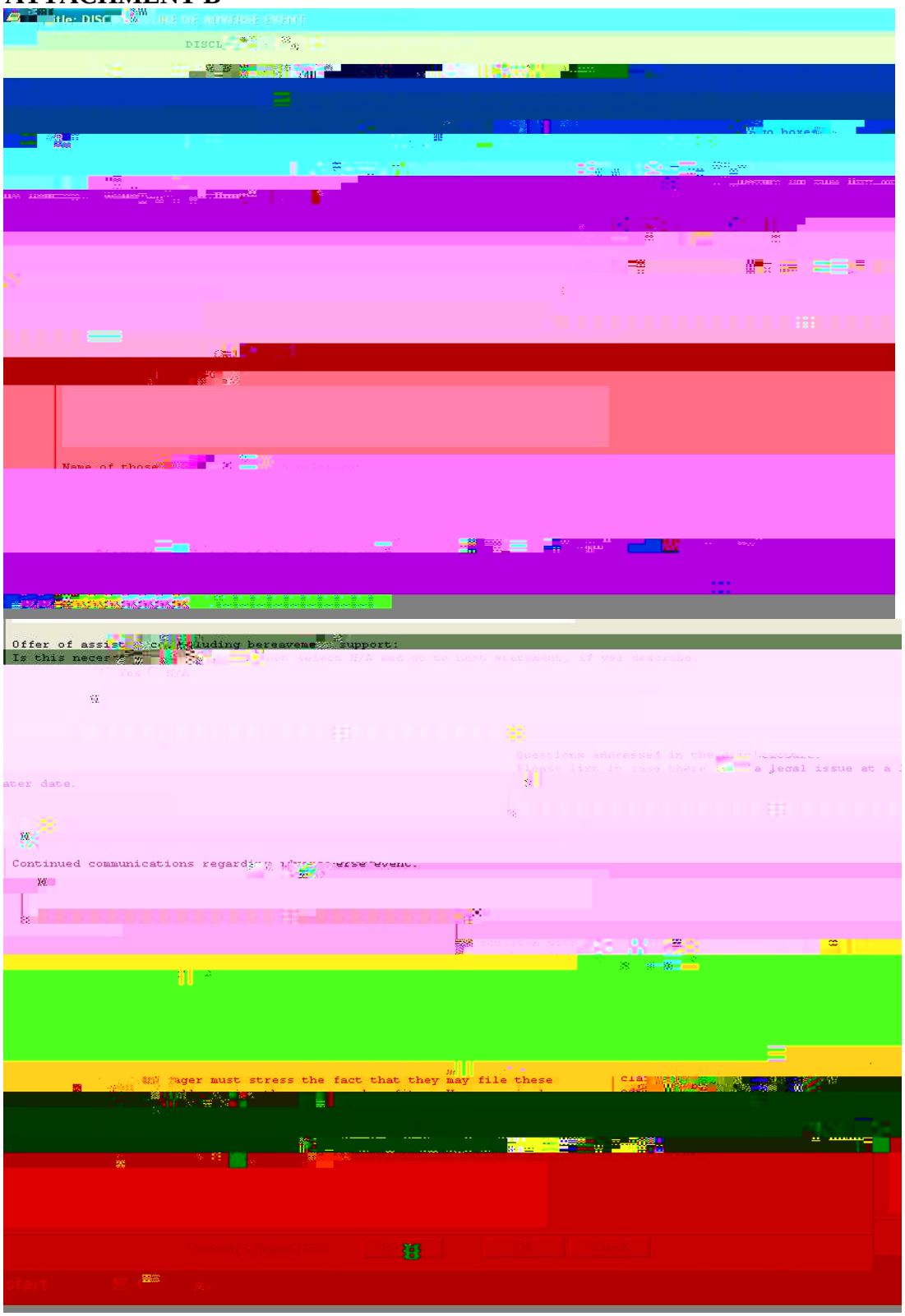
(a) Institutional disclosure to affected veterans.

(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 establishment of call centers or websites.

ATTACHMENT B



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2.

b. What is the burden of disclosure to the institution, focusing principally on the 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 VHA?

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:

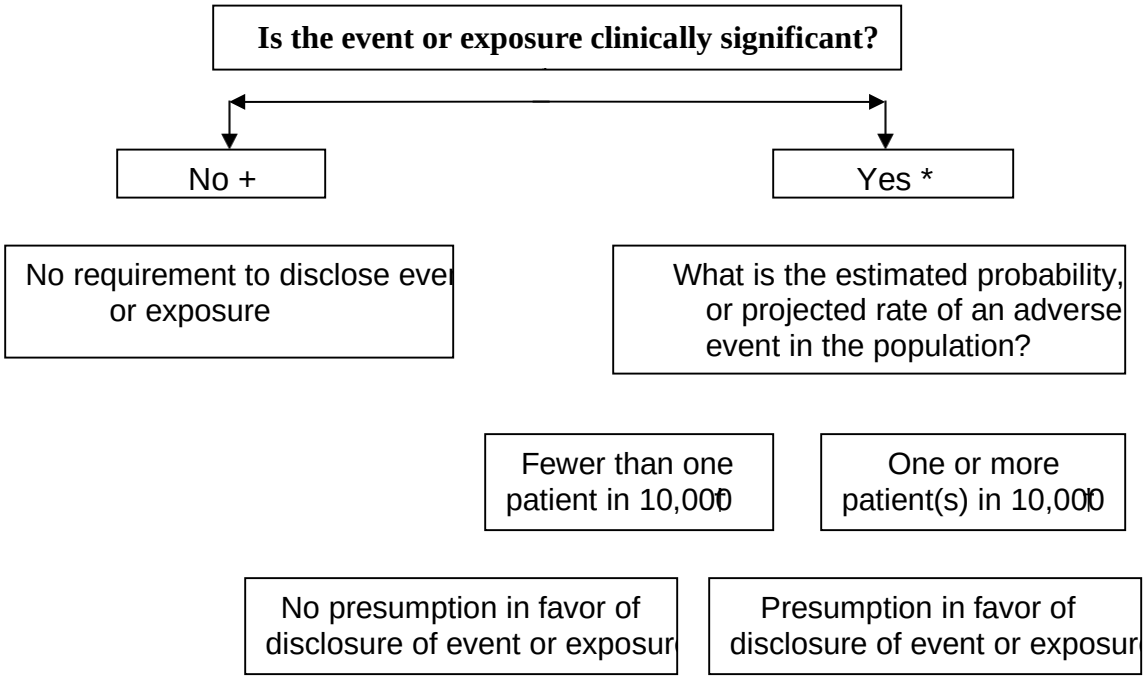
a. Does this decision reflect similar decisions by other large health systems?

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