Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

Amended

September 22, 2026

VHA DIRECTIVE 1004.08(1)
Transmittal Sheet
October 31, 2018

DISCLOSURE OF ADVERSE EVENTS TO PATIENTS

1. REASONS FOR ISSUE: This Veterans Health Administration (VHA) directive establishes the policy to ensure consistent practice in disclosing to patients or to the patient's personal representative the occurrence of adverse events related to the patient's clinical care.

2. SUMMARY OF MAJOR CHANGES:

a. Amendment dated September 22, 2026, removes reference to sentinel events as defined by the Joint Commission. The decision to conduct an institutional disclosure is based on the level of harm or potential harm, regardless of whether the event meets the definition of a sentinel event as defined by the Joint Commission or other external organization, or in any other VA policy or guiding document.

b. On October 31, 2018, this directive:

(1) Added responsibilities for the Deputy Under Secretary for Health for Community Care.

(2) Removed the requirement that VA medical facility leaders must confer with District Chief Counsel prior to initiating an institutional disclosure. Consultation with District Chief Counsel is now at the discretion of VA medical facility leadership.

(3) Provided an updated graphical user interface (GUI) Text Template required for documenting institutional disclosure of adverse events to patients (see Appendix A).

(4) Provided a link to an updated flow chart depicting the process for assessment of adverse events that might require large-scale disclosure (see Appendix B).

3. RELATED ISSUES: VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009; VHA Handbook 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated November 12, 2014; VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 17, 2015; VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

4. RESPONSIBLE OFFICES: The National Center for Ethics in Health Care (10E1E) is responsible for the management of this directive. Questions about policy interpretation pertaining to clinical disclosure or institutional disclosure should be directed to the National Center for Ethics in Health Care at 202-632-8457 or vhaethics@va.gov. Questions about quarterly reporting of institutional disclosures should be directed to VHAMedicalLegalRiskM@va.gov. Questions about large-scale disclosure decisions should be directed to VHACERTActions@va.gov.

5. RESCISSION: VHA Handbook 1004.08, Disclosure of Adverse Events to Patients, dated October 2, 2012, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of October, 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

/s/ Richard A. Stone, M.D.
Executive in Charge

DISTRIBUTION: Emailed to the VHA Publications Distribution List on November 1, 2018.

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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DISCLOSURE OF ADVERSE EVENTS TO PATIENTS

2. PURPOSE

This Veterans Health Administration (VHA) directive provides the policy for the disclosure of adverse events to patients or their personal representatives related to clinical care. **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b). ***NOTE:*** *Information pertaining to adverse events in research can be found in VHA Handbook 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated November 12, 2014, and VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 17, 2015.*

3. BACKGROUND

a. VHA believes that there is an unwavering ethical obligation to disclose to patients harmful adverse events that have been sustained in the course of their Department of Veterans Affairs (VA) care, including cases where the harm may not be obvious, or where there is a potential for harm to occur in the future (see paragraphs 13.k.–13.z.).

b. The commitment to disclose the occurrence of harmful adverse events to patients is consistent with the VA core values of integrity, commitment, advocacy, respect, and excellence; it demonstrates professionalism, and respect for the patient; and is foundational to providing care. While any such disclosure must be in keeping with applicable law, the explicit intent is to inform patients about substantive issues related to their care, and not to manage the institution's risk.

c. This directive is consistent with The Joint Commission standards that patients, and when appropriate, their families be told of unanticipated outcomes of care (see paragraphs 13.q.–13.r.).

d. Disclosure of adverse events to patients and the reporting of adverse events to regulatory agencies are separate requirements. Actions taken to disclose adverse events to patients in no way remove the need to report adverse events and close calls as required under VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011; VHA DIR 1070, Adverse Drug Event Reporting and Monitoring, dated September 12, 2014, and VHA Handbook 1100.17, National Practitioner Data Bank (NPDB) Reports, dated December 28, 2009.

e. Despite the ethical obligation to disclose adverse events to patients, there are legal requirements that establish limits on the information that may be shared and with whom it may be shared. Release of protected health information (verbally or in record form) must always be done according to law and VA standards. Assistance regarding information that may be released is available through the facility's Privacy and Freedom of Information Act (FOIA) Officer(s), or designee. The following paragraphs describe the most common standards regarding the release of information:

(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 paragraph and in paragraph 2.e.(2) (see VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016, and VA Handbook 6300.4, Procedures for Processing Requests for Records Subject to the Privacy Act, dated August 19, 2013).*

(2) Under 38 U.S.C. 7332 (b)(2)(F), VHA may disclose information related to the patient's treatment for substance abuse, including alcohol, sickle cell anemia, or infection with the Human Immunodeficiency Virus (HIV) to the patient's surrogate if the patient lacks decision-making capacity and the practitioner deems the information necessary for the surrogate to make an informed decision regarding the patient's treatment. Otherwise such information may not be disclosed, 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 VA medical facility's Privacy Officer. ***NOTE:*** *Consultation with VHA's Privacy Officer may also be necessary (see VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016).*

(3) Under 38 U.S.C. 5705, VHA may not communicate to patients or their personal representative's information that is obtained from quality management activities. Quality management or quality assurance (QA) activities are those that are conducted by or for VA in the process of conducting systematic health care reviews for the purpose of improving the quality of health care or improving the utilization of health care resources in VA medical facilities. Examples of QA activities include Root Cause Analyses (RCA) or peer reviews for quality management.

f. Disclosure of an adverse event or close calls, as discussed in paragraph 2.c. is a separate action from QA review, analysis, or investigation of an adverse event. The purpose of a QA activity is to allow for effective self-evaluation in the interest of improving the quality of care. When a disclosure of information is made, the information that is being disclosed must not originate with a QA document; in other words, any information that is shared with the patient regarding the adverse event must come from a source other than a QA document. QA documents may contain information protected under other confidentiality statutes, such as the Privacy Act (see paragraph 1.e(1) for limitations related to those statutes). Assistance regarding the release of information that also might be the product of a QA activity is available through the facility's FOIA Officer(s), or designee. Other specific questions regarding information that may not be disclosed to the patient or representative may be found in VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

4. DEFINITIONS

a. **Adverse Event.** Adverse events are untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers. ***NOTE:*** *To determine*

which incidents need to be considered for root cause analysis, consult VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.

b. **Clinical Review Board.** The Clinical Review Board (CRB) is a multi-disciplinary board convened at the request of the Principal Deputy Under Secretary for Health in response to adverse events that may pose a clinically significant risk of harm to multiple patients or members of patients' families, but the probability of harm and/or the severity of the potential harm cannot be determined. The CRB uses a transparent and systematic process to consider whether disclosure is ethically warranted in light of the indeterminate risk.

c. **Close Call.** A close call is an event or situation that could have resulted in an adverse event but did not, either by chance or through timely intervention. Such events have also been referred to as near miss incidents.

d. **Disclosure of Adverse Events.** For purposes of this directive, disclosure of adverse events refers to the forthright and empathetic discussion of clinically-significant facts between providers or other VHA personnel and patients or their personal representatives about the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future. ***NOTE:*** *Depending on the nature of the adverse event, the disclosure process may involve any or all of the three types of disclosure defined in (1) through (3) below. See paragraphs 7–10 for additional information on the three types of disclosure, including what must be disclosed, by whom, when, and how*

(1) **Clinical Disclosure of Adverse Events.** Clinical disclosure of adverse events is a process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the patient's care (see paragraph 8). ***NOTE:*** *Clinicians may also be involved in communicating information as part of an institutional disclosure or a large-scale disclosure, but this is not considered a clinical disclosure.*

(2) **Institutional Disclosure of Adverse Events.** Institutional disclosure of adverse events, sometimes referred to as administrative disclosure, is a formal process by which VA medical facility leader(s), together with clinicians and others as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse (see paragraph 9). ***NOTE:*** *VA medical facility leaders may also be involved in communicating information as part of a large-scale disclosure, but this is not considered an institutional disclosure*.

(3) **Large-scale Disclosure of Adverse Events.** Large-scale disclosure of adverse events, sometimes referred to as notification, is a formal process by which VHA officials assist with coordinating the notification to multiple patients, or their personal representatives, that they may have been affected by an adverse event resulting from a systems issue (that is, a problem that might require system improvement at one or more

facilities). This process also generally includes public notification and direct communication to key stakeholders (see paragraph 10).

e. **Epidemiologic Investigation.** An epidemiologic investigation is a study of potentially affected populations to ascertain whether there is a linkage between health effects, for example, an infection, and a cause, for example, an exposure.

f. **Exposure.** Exposure is the proximity to, or contact with, an environmental condition, for example, an infectious pathogen, a toxic chemical, or radiation, in such a manner that transmission of harmful effects may occur.

g. **Look-back.** A look-back is an organized process for identifying patients or staff with exposure to potential risk incurred through past clinical activities, with the explicit intent to notify them and offer care and recourse, as appropriate.

h. **Personal Representative.** A personal representative is a person who, under applicable law, has legal authority to act on behalf of an individual. This authority may include power of attorney, legal guardianship of an individual, the appointment as the executor of the estate of a deceased individual, or the authority granted to someone under Federal, state, local, or tribal law, such as the parent of a minor. The personal representative generally is the patient's surrogate for the informed consent process (see Title 38 Code of Federal Regulations (CFR) 17.32(e) for authorized surrogates for informed consent. For information on the disclosure of a patient's health information to a personal representative, see VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

i. **Subject Matter Expert Review Panel.** The Subject Matter Expert (SME) Review Panel is a panel convened to conduct fact-finding, including, as needed, site visits, literature reviews, and risk assessment regarding events that have the potential to require a large-scale disclosure.

j. **Surrogate Decision Maker.** A surrogate decision maker, also referred to as surrogate, refers to an individual authorized under VHA policy to make health care decisions on behalf of a patient who lacks decision-making capacity (see VHA Handbook 1004.01, Informed Consent for Clinical Treatment and Procedures, dated August 14, 2009, for information about surrogate selection, priority, and the surrogate's role in health care decision-making).

5. POLICY

It is VHA policy to disclose harmful or potentially harmful adverse events to patients or their personal representatives in order to maintain trust between patients and VA health care professionals, and to ensure uniform practice across all VA medical facilities.

6. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health, or designee is responsible for ensuring overall VHA compliance with this directive.

b. **Principal Deputy Under Secretary for Health.** The Principal Deputy Under Secretary for Health, or designee is responsible for oversight of the large-scale disclosure process, including:

(1) Appointing the Chairperson of the CRB from the Deputy Under Secretary-level, for example, Deputy Under Secretary for Health for Policy and Services or Deputy Under Secretary for Health for Operations and Management.

(2) Concurring or non-concurring with the recommendation of the Deputy Under Secretary for Health for Operations and Management's coordinated triage process or SME Review Panel to disclose, not disclose, or to convene a CRB, and providing a written record of this decision to the Deputy Under Secretary for Health for Operations and Management.

(3) If a decision is made to convene the CRB, communicating the charge to the CRB Chairperson and simultaneously notifying the Deputy Under Secretary for Health for Operations and Management and other relevant VA Central Office programs, for example, the Office of the General Counsel (OGC), Office of Public and Intergovernmental Affairs (OPIA), and Office of Congressional and Legislative Affairs (OCLA), to begin preparations for a possible disclosure.

(4) Concurring or non-concurring with the CRB recommendations, and communicating that decision to the Deputy Under Secretary for Health for Operations and Management and the CRB Chairperson.

(5) Requesting further information or guidance from the CRB, as needed, prior to making a final decision.

(6) Ensuring that Veterans Benefits Administration (VBA) Central Office is notified when Veterans' benefits may be affected by a decision to make a large-scale disclosure.

(7) Ensuring that VA medical facility and VISN leadership is notified that an epidemiologic investigation is going to take place, and the establishment of a clear line of authority, access, and accountability.

(8) Ensuring a mechanism for maintaining CRB-related documents relating to large-scale disclosure of adverse events.

(9) Assigning responsibility for leading, organizing, and conducting any required VHA look-back program and epidemiologic investigation as part of, or following, a large-scale disclosure to patients.

c. **Deputy Under Secretary for Health for Community Care.** As VA continues to provide Veterans with access to community care, the agency is committed to ensuring that eligible Veterans receive the same high quality of care no matter where it is provided. VA Community Care providers, like all health care professionals, have an ethical obligation to disclose to patients, harmful adverse events that have occurred in the course of their care. This obligation is specified in all codes of professional ethics for health care professionals, and exists independent of any contractual obligation with VA. This obligation is also reflected in the Joint Commission's standards related to patient safety and patient rights (see paragraph 13.r.). To promote and support these standards of professionalism, the Deputy Under Secretary for Health for Community Care is responsible for coordinating contracts, tools, technologies, and processes to detect, report, and investigate adverse events and other patient safety events, and improve patient safety for Veterans who receive care in the community.

d. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management, or designee is responsible for:

(1) Ensuring a coordinated triage process for a review of each potential adverse event that may require large-scale disclosure (see Appendix B). The triage process must include designated staff from the offices of: the Deputy Under Secretary for Health for Operations and Management; the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; the Deputy Under Secretary for Health for Policy and Services; and other offices and field-based SMEs, as needed, to recommend, based on preliminary information, that the adverse event:

(a) Involves a negligible or clinically-insignificant risk of harm and, therefore, requires no large scale-disclosure so the issue can be closed; or

(b) Requires large scale-disclosure or referral to an appropriately constituted CRB or SME Review Panel (see paragraphs 1.e.–1.h.) for a more detailed review;

(2) Ensuring that potential cases are referred to the SME Review Panel or CRB for more detailed review;

(3) Providing oversight to the SME Review Panel, summarizing the SME Review Panel findings regarding risk, and submitting a written report and recommendation to the Principal Deputy Under Secretary for Health concerning whether there is a negligible risk of harm and no disclosure is required; or there is a clinically-significant risk of harm and disclosure is required; or there is an indeterminate risk of harm and a CRB needs to be convened to consider whether disclosure is ethically warranted based on factors other than risk alone;

(4) Developing, maintaining, and implementing standard operating procedures for the implementation of large-scale disclosures;

(5) Implementing a decision by the Principal Deputy Under Secretary for Health to conduct a large-scale disclosure with coordination among appropriate field and Central

Office programs including OGC, OPIA, OCLA, and others. Implementation includes notification of field sites, activation of a site visit team, a review of written materials and statements by OGC, and other appropriate offices (see Appendix B);

(6) Designating and facilitating any required look-back activities and epidemiologic investigations;

(7) Conducting an After Action Review of the event with appropriate SME participation and submitting a report to the Under Secretary for Health; and

(8) Ensuring a mechanism for maintaining documents related to large-scale disclosure of adverse events.

(9) Leading the Subject Matter Expert Review panel (see paragraph 1.h.)

e. **Chairperson of the Clinical Review Board.** The Chairperson of the CRB is appointed by the Principal Deputy Under Secretary for Health, and is responsible for:

(1) Convening and chairing the CRB;

(2) Ensuring that CRB deliberations and recommendations follow the process outlined in paragraph 1.f–1.g, and Appendices B and C;

(3) Providing, on behalf of the CRB, written recommendations and justifications to the Principal Deputy Under Secretary for Health that disclosure is recommended or that no disclosure is recommended. If the CRB concludes that there is insufficient information to make a recommendation, the Chairperson is responsible for providing the Principal Deputy Under Secretary for Health with a plan and timeline for a definitive CRB recommendation;

(4) Providing a written statement to the Principal Deputy Under Secretary for Health regarding whether the CRB recommendation regarding disclosure was unanimous and, if not, the number of assenting and dissenting votes and the related rationales;

(5) Ensuring that a CRB recommendation in favor of large-scale disclosure addresses:

(a) Notification to potentially-affected patients, patients' personal representatives, patients' next-of-kin, and other involved parties consistent with information disclosure policies (see paragraph 2.e., and VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016);

(b) Notification to involved facilities for required clinical follow up with potentially-affected patients, and other involved parties; and

(c) The need for inquiry into similar processes at other facilities; and

(6) Ensuring a mechanism for maintaining CRB-related documents relating to large-scale disclosure of adverse events.

f. **CRB Membership.**

(1) The CRB is made up of appropriate representatives from the following member offices: Office of the Deputy Under Secretary for Health for Operations and Management; National Center for Ethics in Health Care; Office of Nursing Services; National Center for Patient Safety; Office of Patient Care Services; Office of Specialty Care Services; Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; and OGC. The SME Review Panel Chairperson also serves as a member.

(2) The CRB Chairperson and each member office, with the exception of OGC, has one vote in the CRB decision. When the Chair of the SME Review Panel represents one of the member offices, the member office still only has one vote in the CRB decision.

(3) The CRB may include non-voting members (for example, SMEs from VHA programs, the relevant field facility or facilities, program offices, and VHA experts), as needed. The CRB may solicit input from outside experts for example, equipment manufacturers, as appropriate.

g. **Clinical Review Board.** The CRB is responsible for:

(1) Considering those adverse events where it is unclear whether there is a clinically-significant harm or potential harm to patients as determined by the Principal Deputy Under Secretary for Health following the SME Review Panel's findings.

(2) Reviewing the information and risk assessment provided by the SME Review Panel, seeking clarifications as necessary.

(3) Considering all available clinical, scientific, and epidemiologic information and discussing additional non-clinical factors (as described in Appendix C) to determine whether a recommendation for disclosure of the adverse event to patients and families is appropriate.

(a) Determining if an epidemiologic investigation is recommended.

(b) Ensuring that all documents relevant to the CRB's deliberations are provided to the CRB Chairperson.

h. **Subject Matter Expert Review Panel.**

(1) The SME Review Panel is a standing panel that meets as necessary to review and make recommendations on cases referred by the Principal Deputy Under Secretary for Health concerning adverse events that potentially warrant large-scale disclosure.

(2) The SME Review Panel is led by the Deputy Under Secretary for Health for Operations and Management, or designee, and is made up of appropriate SMEs from the office of the Assistant Deputy Under Secretary for Clinical Operations; Assistant Deputy Under Secretary for Health for Quality, Safety, and Value; the National Center for Patient Safety; the Office of Patient Care Services; the Office of Nursing Services, and other program offices (for example, Sterile Processing Service, National Infectious Disease Service, Office of Informatics and Analytics, Office of Specialty Care Services), as needed.

(3) The SME Review Panel is responsible for:

(a) Conducting fact-finding, including site visits if needed, literature reviews, risk assessments, and summarizing findings regarding risk to patients, and if relevant, members of patients' families.

(b) Submitting a written report to the Principal Deputy Under Secretary for Health with one of the following three findings and corresponding recommendations:

1. There is a negligible risk of harm, considering both the probability of harm and the severity of potential harm; therefore, no disclosure is required and the issue should be closed.

2. There is a clinically-significant risk of harm, considering both the probability of harm and the severity of potential harm; therefore, disclosure is required and there is no need to convene a CRB.

3. There is an indeterminate risk of harm, considering both the probability of harm and the severity of potential harm; therefore, a CRB should be convened to consider whether disclosure is ethically warranted based on factors other than risk alone.

(c) Ensuring that all documents relevant to the SME Review Panel's deliberations are provided to the SME Review Panel Chairperson.

i. **Assistant Deputy Under Secretary for Health for Patient Care Services.** The Assistant Deputy Under Secretary for Patient Care Services is responsible for providing appropriate expertise regarding large-scale disclosure recommendations to the Deputy Under Secretary for Health for Operations and Management coordinated triage process, SME Review Panel, and CRB, and support to VAMCs and VISNs as required or requested.

j. **Assistant Deputy Under Secretary for Health for Quality, Safety, and Value.** The Assistant Deputy Under Secretary for Health for Quality, Safety, and Value, or designee is responsible for:

(1) Participating in the CRB and the SME Review Panel processes.

(2) Providing a representative from the National Center for Patient Safety to participate in the CRB and SME Review Panel processes.

(3) Interpreting and updating the risk management content of this directive, as requested by the National Center for Ethics and Health Care.

(4) Completing a quarterly review and analysis of institutional disclosures reported by each VISN office and providing recommendations to appropriate program offices based on analysis of the quarterly review.

k. **Chief Officer for Specialty Care Services.** The Chief Officer for Specialty Care Services is responsible for providing appropriate expertise regarding large-scale disclosure recommendations to the Deputy Under Secretary for Health for Operations and Management coordinated triage process, SME Review Panel, and CRB, and support to VAMCs and VISNs as required or requested.

l. **Executive Director, National Center for Ethics in Health Care.** The Executive Director, National Center for Ethics in Health Care, or designee is responsible for:

(1) Participating in the CRB process.

(2) Participating in the Deputy Under Secretary for Health for Operations and Management triage process and SME Review Panel process, as requested.

(3) Interpreting policy questions pertaining to disclosure of adverse events.

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

(1) Submitting an Issue Brief to the Deputy Under Secretary for Health for Operations and Management immediately upon receiving communication from a VA medical facility Director or from appropriate reports that an adverse event has been discovered that is not an isolated case but rather a systems issue affecting multiple patients and thus that may require large-scale disclosure (see Appendix B).

(2) Participating in the Field-VA Central Office process for determining the need for and implementation of large-scale disclosure decisions, as requested (see Appendix B).

(3) Ensuring a mechanism for maintaining all VISN-related documents relating to large-scale disclosure of adverse events.

(4) Providing a report quarterly, and as requested, to the Assistant Deputy Under Secretary for Health for Quality, Safety, and Value, on the number and types of institutional disclosures provided by facilities within the VISN. The report must include the date of the adverse event, date of institutional disclosure, number of unique patients, whether there was a patient death, department(s) involved, and a brief description of the triggering event for each institutional disclosure.

n. **VA Medical Facility Director.** The VA medical facility Director, or designee is responsible for:

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

(2) Ensuring that clinical and institutional disclosures of adverse events are performed openly and promptly with patients or their personal representatives.

(3) Ensuring that relevant staff are aware of this directive.

(4) Ensuring that the patient (or the patient's personal representative if the patient is deceased, incapacitated, or otherwise unable to take part in the disclosure process) is provided (e.g., by the Risk Manager or other assigned staff member) with contact information for designated VA health care staff, as needed, to respond to questions regarding the disclosed information or clinical events associated with an adverse event.

(5) Ensuring that the patient or patient representative is referred (e.g., by the Risk Manager or other assigned staff member) to the VACO National Torts Group for coordination of document requests, if it is known that a tort claim has been filed.

(6) Ensuring that adverse events that may require institutional disclosure are communicated immediately to District Chief Counsel.

(7) Submitting an Issue Brief to the VISN Director and District Chief Counsel immediately following the discovery at the facility of an adverse event that is not an isolated case, but rather a systems issue affecting multiple patients which might require a large-scale disclosure (see Appendix B).

(8) Participating in the VA Central Office fact-finding process, CRB process, large-scale disclosure implementation, look-back, and epidemiologic investigations, as requested. This includes ensuring that sufficient resources are available to perform these processes in a proper and timely manner. For example, a case manager may be needed to coordinate clinical, laboratory, communications, and other aspects of the investigations (see Appendices B and C).

(9) Ensuring that institutional disclosures are correctly documented in CPRS, to include:

(a) Ensuring that the updated graphical user interface (GUI) Text Template (Institutional Disclosure of Adverse Event) (Appendix A) is associated with the progress note title, Institutional Disclosure of Adverse Event.

(b) Ensuring that the progress note title, Institutional Disclosure of Adverse Event is mapped to the national standard title of Communication of Adverse Event.

(c) Ensuring that a User Class and Business Rules are created to restrict the entering of the GUI Template/Progress Note, Institutional Disclosure of Adverse Event to specific users (for example, Risk Manager, Patient Safety Manager, Quality Manager, Chief of Staff). Business rules for initial progress note creation must also be applied to

the creation and signature of any addenda attached to this progress note. Access restrictions are only to be placed on entering, not on viewing.

(d) Ensuring that the updated Institutional Disclosure of Adverse Event Note template (Appendix A) is used only to document institutional disclosure of adverse events.

(10) Ensuring that information about potential compensation through the Veterans Benefits Administration and the Federal Tort Claims Act is provided to patients or patient representatives as part of the institutional disclosure process.

(11) Ensuring a mechanism for maintaining documents relating to large-scale disclosure of adverse events.

(12) Providing a report quarterly, and as requested, to the VISN Director, regarding the number and types of institutional disclosures that have been provided by the facility.

o. **VA Medical Center Chief of Staff and Associate Director of Patient Care Services.** The VA Medical Center Chief of Staff and Associate Director of Patient Care Services are responsible for:

(1) Immediately notifying the VA medical facility Director regarding the discovery of any significant adverse event that is brought to their attention.

(2) Participating in discussions and institutional disclosures with others, for example, clinicians, facility senior management team, District Chief Counsel, VISN staff, patients, or personal representatives, as appropriate, concerning the adverse event.

(3) Participating in any look-back or epidemiologic investigations required.

p. **VA Medical Facility Risk Manager.** The VA medical facility Risk Manager, or designee is responsible for:

(1) Immediately notifying the Associate Director for Patient Care Services, Chief of Staff, or VA medical facility Director about the discovery of a significant adverse event that is brought to the attention of the Risk Manager; especially those that may require institutional disclosure or a decision regarding a large-scale disclosure of adverse events.

(2) Referring providers who have questions about the legal dimensions of disclosure of adverse events to District Chief Counsel.

(3) Establishing a dialogue with District Chief Counsel and requesting that District Chief Counsel educate providers, as needed, regarding legal dimensions of institutional disclosure of adverse events, its documentation, and its relationship to the Federal Tort Claims Act.

(4) Participating in any look-back or epidemiologic investigations required.

(5) Establishing a process for collection, tracking, and analysis of relevant information related to institutional disclosures conducted at the facility for submission to the VISN Director in a quarterly report.

q. **Health Care Providers Responsible for the Patient's Care.** Health care providers responsible for the patient's care, or designee are responsible for:

(1) Providing clinical disclosure to patients as specified in this directive.

(2) Participating in institutional disclosures, if appropriate, as requested by facility leadership.

7. ADVERSE EVENTS THAT WARRANT DISCLOSURE

Disclosure is warranted for harmful or potentially-harmful adverse events, defined broadly to include:

a. Adverse events that cause death or disability, lead to prolonged hospitalization, require life-sustaining intervention or intervention to prevent impairment or damage, or that are reasonably expected to result in death or serious or permanent disability.

b. Adverse events that have had, or are reasonably expected to have, an 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 a diuretic, a medication that dramatically increases urine output, disclosure is required because a perceptible effect has, or is anticipated to occur.

c. Adverse events that precipitate a change in the patient's care, for example, a medication error that necessitates extra blood tests, extra hospital days, follow-up visits that would otherwise not be required, or a surgical error that necessitates further corrective surgery.

d. Adverse events with a clinically-significant risk of serious future health consequences to patients, even if the likelihood of that risk is small, for example, an 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, for example, 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, the disclosure decision needs to be based on the risks and benefits of disclosure relative to the probability of serious future health consequences. If, after disclosure in such cases, it is later determined through the look-back process or subsequent investigation that harm did not occur, or that the risk of harm is actually negligible, disclosure of the new risk information must be made to the patient. Caution must be exercised in differentiating clinically significant risk of harm from harm that is only plausible or hypothetical.

e. Any event that requires an unexpected treatment or procedure to be initiated without the patient's consent, for example, if an event occurs while a patient is under anesthesia, necessitating a deviation from the procedure the patient expected. Patients have a fundamental right to be informed about what is done to them and why.

(1) Where adverse events occur that have a potential to affect, or may have already affected multiple patients at one or more VA medical facilities, the process for large-scale disclosure must be followed (see the process providing the ethical and clinical considerations outlined in Appendices B and C).

(2) Disclosure of adverse events other than those that fall under the previous descriptions is optional and at the discretion of the providers involved. Cases must be considered individually and in relation to the specific circumstances.

(3) Disclosure of close calls to patients is discretionary, but is advisable at times, such as when the patient or family become aware that something out of the ordinary has occurred.

(a) For example, a nurse sets up a patient for a blood transfusion and, discovering that the patient is about to receive the wrong unit of blood, then abruptly stops the transfusion just before the blood enters the patient's vein. The patient deserves an explanation, even if this is not considered a clinical disclosure of an adverse event.

(b) Although the disclosure of a close call to the patient is optional, reporting close calls is required under VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.

(4) There may be times when a complication that was anticipated and discussed in the informed consent process occurs. Such complications need to be discussed with the patient or patient's personal representative as part of ongoing clinical care. A serious complication may also require investigation or focused review as described in VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011. If the complication is deemed to be untoward or preventable, then an appropriate disclosure is required under this directive.

8. COMMUNICATING ADVERSE EVENTS

a. The process for disclosing an adverse event depends on the nature and circumstances of the event. VA recognizes three types of adverse event disclosure: clinical, institutional, and large-scale (see paragraphs 8, 9, and 10).

b. The process of adverse event disclosure is not necessarily a singular event, but may involve a series of conversations. For example, as more information is learned in a particular case, a clinical disclosure may need to be followed by an institutional disclosure, which itself may involve multiple conversations. In some cases, the disclosure process may ultimately involve all three types of disclosures.

c. Whenever a potential harm is disclosed to a patient, it may be necessary, after an investigation has been conducted, to follow up with the patient to inform the patient whether the potential harm that was initially disclosed did or did not, in fact, occur (for example, a patient who is initially told that the patient may have been exposed to a blood-borne virus as a result of improperly sterilized equipment, must be informed of investigation results that would have a significant impact on the patient's health or wellbeing).

d. For the patient who is deceased, incapacitated, or otherwise unable to participate in the process of adverse event disclosure, any clinical or institutional disclosure must be communicated to the patient's personal representative and may involve others, as designated by the personal representative in accordance with VHA Directive 1605.01.

e. Any release of information regarding a deceased Veteran whose clinical records are covered by 38 U.S.C. 7332, must be made in accordance with applicable law. ***NOTE:*** *For additional guidance, refer to VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016, and confer with the facility Privacy Officer, as necessary.*

f. In some cases, it may be apparent that an adverse event has occurred, but its cause is not clear. In those situations, the Veteran or the Veteran's personal representative needs to be told what has occurred and what is known about the problem. They need to be informed as to whether the problem is being investigated and if additional information will be provided to them once a review is completed.

9. CLINICAL DISCLOSURE OF ADVERSE EVENTS

Clinical disclosure is a process by which the patient's clinician informs the patient or the patient's personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the course of care. A clinical disclosure is appropriate for all adverse events that cause only minor harm to the patient, except those minor harms that are discovered after the patient has completed the associated episode of care and that have no implications for the patient's future health. A clinical disclosure is also appropriate for more serious adverse events as the appropriate first step in a process that may ultimately require an institutional or large-scale disclosure. While clinical disclosure of adverse events is considered a routine part of clinical care, clinicians must be sensitive to any limitations on sharing information from the Veteran's health record (see paragraph 2.e.). In general, clinical disclosure of an adverse event proceeds as follows:

a. Clinical disclosure of adverse events that cause minor harm may be performed by any member of the clinical team involved in the patient's care. However, clinical disclosures relating to events where the harm is more than minor must be performed by the responsible practitioner, in other words, the licensed independent practitioner who has primary responsibility for the patient during the current episode of care, or that practitioner's designee. If a harm is significant enough to require an incident report or local equivalent, it should be considered more than minor. Trainees may be present for

clinical disclosures, but the disclosure itself is the responsibility of the supervising clinician or designated clinical team member.

b. During the clinical disclosure process, one or more members of the clinical team.

(1) Provides preliminary factual information, to the extent it is known, to the patient or the patient's personal representative.

(2) Expresses concern for the patient's welfare.

(3) Reassures the patient or personal representative that steps are being taken to investigate the situation, remedy any injury, and prevent further harm. ***NOTE:*** *A general statement to this effect is recommended. Statements should not be made regarding specific actions VA may undertake because those steps may not be possible to implement, or may be subject to change.*

c. Additional staff members, such as a registered nurse, social worker, chaplain, clinical ethicist, or patient advocate, may be present to help the patient or personal representative cope with the news and to offer support.

d. The patient or patient's personal representative must be provided with contact information of the designated VA health care staff to respond to questions regarding the disclosed information or clinical sequelae associated with the adverse event.

e. Clinical disclosures need to be made face-to-face with the patient or the patient's personal representative whenever possible and practical. Disclosure needs to take place in a suitable environment to ensure privacy, and without interruption, in order to provide adequate time to ensure that the patient's questions and concerns can be addressed.

f. Clinicians are expected to conduct clinical disclosures as a routine part of care. Clinical disclosures are not the occasion to discuss rights or compensation under 38 U.S.C. 1151 or the Federal Tort Claims Act.

g. Clinical disclosure must be initiated as soon as reasonably possible and generally within 24 hours of occurrence. Clinical disclosure is not required for minor harms that are discovered after the patient has completed the associated episode of care when there are no implications for the patient's future health. Under such circumstances, the benefits associated with respecting the patient's right to information about their health care are generally outweighed by the burdens associated with unnecessarily worrying or confusing patients with inconsequential information.

h. Documentation of Clinical Disclosures.

(1) Specific documentation in the Computerized Patient Record System (CPRS) is not required for all clinical disclosures. Requiring documentation of clinical disclosure for all minor events would create a barrier to making such disclosures a part of routine practice. However, as a rule, documentation of a clinical disclosure is required when

harm is more than minor. This documentation can be in a progress note for the encounter.

(2) Clinical disclosures must not be documented using the CPRS note template for institutional disclosure.

10. INSTITUTIONAL DISCLOSURE OF ADVERSE EVENTS

a. Institutional disclosure of adverse events, sometimes referred to as administrative disclosure, is a formal process by which facility leaders, together with clinicians and other appropriate individuals, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in or is reasonably expected to result in death or serious injury. Serious injury may include significant or permanent disability, injury that leads to prolonged hospitalization, injury requiring life-sustaining intervention, or intervention to prevent impairment or damage. Such adverse events require institutional disclosure regardless of whether they resulted from an error.

(1) When an adverse event has resulted in or is reasonably expected to result in death or serious injury, an institutional disclosure must be performed regardless of when the event is discovered. This disclosure is required even if clinical disclosure has already occurred. If an initial clinical disclosure has been made, it is important to determine what role, if any, the treating clinician(s) will play in the institutional disclosure process, as well as in the ongoing care of the patient.

(2) Institutional disclosure must be initiated as soon as reasonably possible and generally within 72 hours. This timeframe does not apply to adverse events that are only recognized after the associated episode of care, for example, through investigation of an event, a routine quality review, or a look-back. Under such circumstances, if the adverse event has resulted in or is reasonably expected to result in death or serious injury, institutional disclosure is required, but disclosure may be delayed allowing for a thorough investigation of the facts provided.

b. Prior to conducting an institutional disclosure, organizational leaders, for example, the VA medical facility Director, Chief of Staff, Associate Director for Patient Care Services, members of the treatment team, or others as appropriate, may confer with District Chief Counsel for assistance in deciding what is to be communicated, by whom, and how.

c. When initiating an institutional disclosure, institutional leaders invite the patient or personal representative to meet. ***NOTE:*** *The facility Risk Manager or Patient Safety Manager, treating practitioner, a mental health professional, or other VHA personnel deemed appropriate, may be included in this conference at the discretion of facility leadership.*

d. Institutional disclosure ideally needs to be made face-to-face with the patient or the patient's personal representative, unless it is neither possible nor practical. In the

rare instances when an institutional disclosure must be conveyed by other modalities, for example, telephone contact or letter, documentation of the communication must include the reason it was not done in person. Disclosure needs to take place in a suitable environment, to ensure privacy and without interruption, in order to provide adequate time to ensure that the patient's questions and concerns can be addressed.

e. If the patient is not capable of understanding either the situation or the information provided in a disclosure, and does not have a personal representative as defined in VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016, the facility must make the institutional disclosure to a family member involved in the patient's care, if available. ***NOTE:*** *The facility's or VHA's Privacy Office or District Chief Counsel need to be consulted for additional guidance regarding necessary authorizations and any limitations on what information may be provided as part of the institutional disclosure.*

f. A request made in advance of the discussion by a patient or personal representative to bring an attorney must be honored, but may influence the choice of participants on behalf of the institution.

g. Institutional disclosure of adverse events must include:

(1) An expression of concern and an apology, including an explanation of the facts to the extent that they are known.

(2) An outline of treatment options, if appropriate.

(3) Arrangements for a second opinion, additional monitoring, expediting clinical consultations, bereavement support, or whatever might be appropriate depending on the circumstances and within the constraints of VA's statutory and regulatory authority.

(4) Contact information regarding designated staff who are to respond to questions regarding the disclosed information or clinical sequelae associated with the adverse event.

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

(6) Offering information about potential compensation from the Veterans Benefits Administration and under the Federal Tort Claims Act if the patient is a Veteran, or only under the Federal Tort Claims Act if the patient is not a Veteran. This information needs to include information about the procedures available to request compensation and where and how to obtain assistance in filing forms. Such information must be provided, even when not considered relevant, if requested by the patient or personal representative. There must be no assurance that compensation will be granted, as the adverse event may not give rise to and meet legal criteria for compensation.

(7) Ongoing communication whereby the Risk Manager or organizational leaders engage the patient or personal representative to keep them apprised, as appropriate, of information that emerges from investigation of the facts related to the adverse event.

h. Documentation, such as reports of contact or incident reports may be kept in a separate file at the facility's discretion and titled, Adverse Event and Close Call Report. This information must not be retrieved by a 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. 5705.*

i. A patient or the patient's personal representative may ask whether an investigation will be conducted and if the patient or the patient's personal representative will be told of the results of an investigation. In these cases, the patient or personal representative is to be informed that the information is being reviewed or investigated, as applicable. If indicated, the individual providing the information may state that depending on the type of review conducted, information may be available under Freedom of Information Act (FOIA). In addition, the patient or personal representative may also be advised that information documented in the course of a QA activity under 38 U.S.C. 5705 is not releasable. The patient or patient representative must be referred to VACO National Torts Group for coordination of document requests, if a tort claim has been filed.

j. As noted previously, documents created in the course of 38 U.S.C. 5705–protected activities, such as RCA, local incident reports that meet the threshold QA criteria, and peer reviews for quality management, may be released only with specific authority and must not be released to patients, their attorneys, or personal representatives. The facts discovered during quality management activities, however, may reveal adverse event information that requires disclosure. Documenting information in records protected under 38 U.S.C. 5705 must never be done to shield information to which a patient or personal representative is entitled. In order to be able to reveal such information to the patient or personal representative, the information must be retrieved from a non-QA document, such as one documented in CPRS.

k. Documentation of Institutional Disclosures. Documentation of institutional disclosures must be done using the CPRS Institutional Disclosure of Adverse Event Note Template (see Appendix A). Subsequent communications with the patient or personal representative that relate to the event must be documented in an addendum to the original note.

11. LARGE-SCALE DISCLOSURE OF ADVERSE EVENTS

a. Large-scale disclosure of adverse events, sometimes referred to as notification, is a formal process by which VHA officials assist with coordinating the notification to multiple patients (or their personal representatives) that they have been or may have been affected by an adverse event involving actual or potential harm to multiple patients.

b. Events having potential for large-scale disclosure require coordination with VA Central Office for the purposes of assessment and planning. To initiate this coordination process, the VA medical facility Director, VISN Director, or Program Officer, as appropriate, must submit an Issue Brief within 24 hours of discovery of the event (see Appendix B).

c. At the time an adverse event is discovered, or near the time an adverse event occurs, clinical or institutional disclosure must proceed as usual if the potential harm to the individual patient is clear.

d. If the adverse event is only recognized after the associated episode of care (for example, through investigation of an event, a routine quality review, or a look-back), it is appropriate to wait until the required VA Central Office coordination process for large-scale disclosure is completed before making either a large-scale or institutional disclosure to an individual patient, but only if it is determined that the delay will not negatively affect the patient's health or wellbeing. The coordination process is designed to ensure that all required disclosures are based on a thorough investigation of the facts, a careful assessment of the risks involved, and the development of a plan for the best way to perform the disclosure.

e. Decisions regarding large-scale disclosure of adverse events are made by the Principal Deputy Under Secretary for Health, or designee, following a multi-step VA Central Office process that begins with the Deputy Under Secretary for Health for Operations and Management's coordinated triage process and may involve a SME Review Panel and/or the CRB. ***NOTE:*** *There are legal limitations regarding the type of information that can be released and to whom, particularly with regard to information protected under 38 U.S.C. 7332 (see paragraph 2.e.(2)). Additional guidance on large-scale disclosure is provided in Appendices B and C.*

f. A large-scale disclosure may entail any or all of the following:

(1) An offer to provide follow-up treatment, and testing when it is medically indicated based on the clinical circumstances. ***NOTE:*** *In addressing the subject of whether family members or personal contacts of patients may also be tested, the facility needs to indicate that testing, either directly or through fee-basis, of non-Veterans is limited to those otherwise eligible for VA care (see 38 U.S.C. 1781). The facility needs to be prepared to advise non-Veterans of local resources for testing and treatment if they do not have an established primary care provider.*

(2) Coordination with VA medical facilities to ensure that required clinical follow-up is provided for potentially-affected patients.

(3) Notification by VA Central Office to the Veterans Benefits Administration (VBA) Central Office component when Veterans' benefits may be implicated.

(4) Development of appropriate and effective communications strategies. This communication includes public affairs strategies such as an announcement through the media, for example, telephone, mail, newspapers, and electronic media; clear and

coherent information to patients, providers, and stakeholders; action plans for facilities and clinical providers; briefings for the Secretary of Veterans Affairs and Congress; and establishment of call centers, internet sites or social media. Large-scale disclosure communications may be delivered by clinicians, VA medical facility leaders, and/or other VA officials in person, by telephone, or in writing.

(5) Notification by VA Central Office to VA medical facility and VISN leadership if an epidemiologic investigation is going to take place, and the establishment of a clear line of authority, access, and accountability.

12. TRAINING REQUIREMENTS

There are no formal training requirements associated with this directive.

13. RECORDS MANAGEMENT

All Federal records regardless of format (paper, electronic, electronic systems) created by this directive will be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management may be directed to the facility Records Manager or Records Liaison.

14. REFERENCES

a. 5 U.S.C. 552.

b. 28 U.S.C. 2671–2680.

c. 38 U.S.C. 1151.

d. 38 U.S.C. 1781.

e. 38 U.S.C. 5705.

f. 38 U.S.C. 7332.

g. VA Handbook 6300.4, Procedures for Processing Requests for Records Subject to the Privacy Act, dated August 19, 2013.

h. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009.

i. VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011.

j. VHA Handbook 1058.01, Research Compliance Reporting Requirements, dated June 17, 2015.

k. VHA Handbook 1100.17, National Practitioner Data Bank (NPDB) Reports, dated December 28, 2009.

l. VHA Handbook 1200.05(2), Requirements for the Protection of Human Subjects in Research, dated November 12, 2014.

m. VHA Directive 1605.01, Privacy And Release Of Information, dated August 31, 2016.

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aa. Wu AW, Boyle DJ, Wallace G, Mazor KM. Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement. Journal of Public Health Research. 2013 Dec;2(3):e32.

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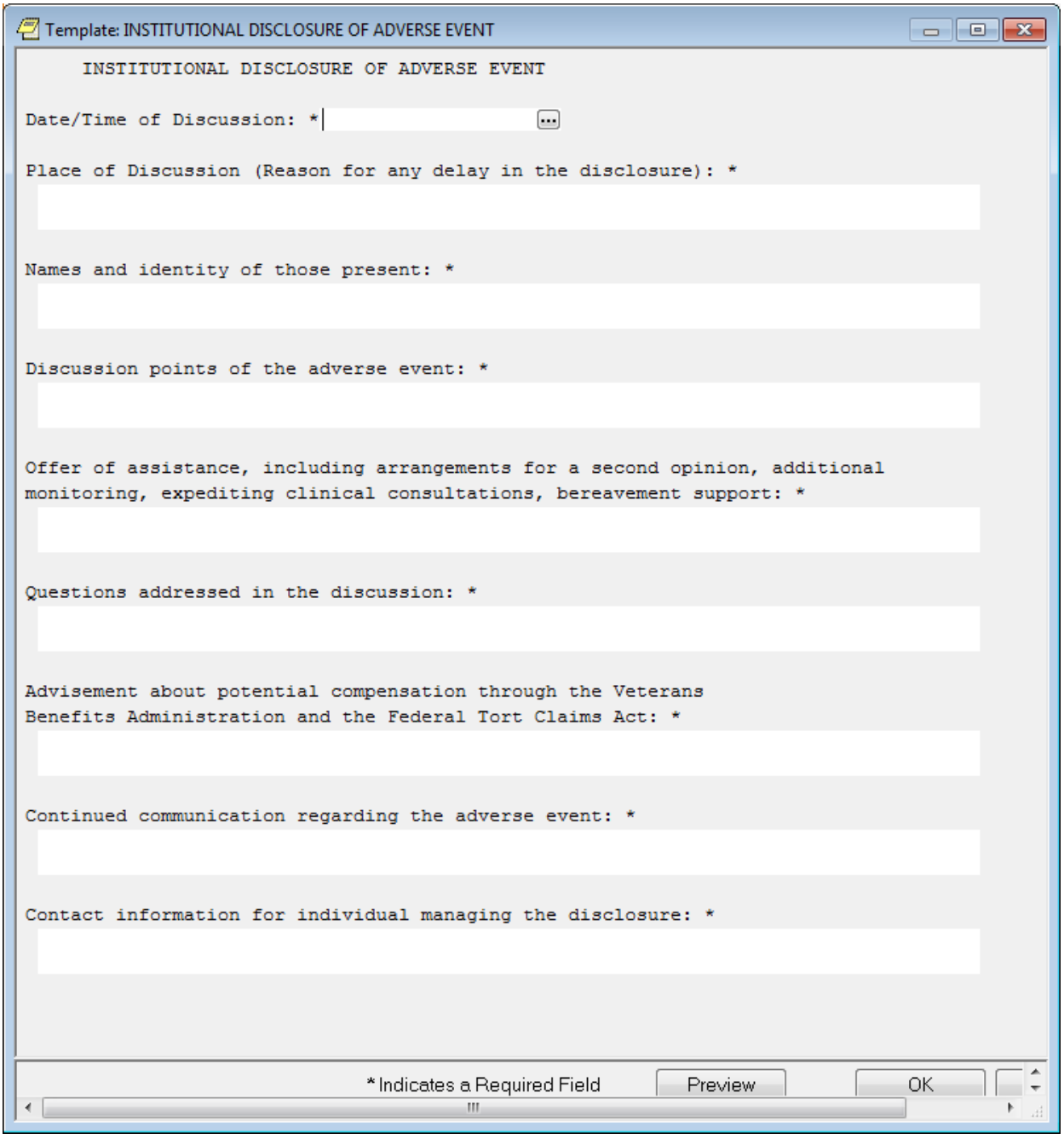
INSTITUTIONAL DISCLOSURE OF ADVERSE EVENT NOTE TEMPLATE



1. Facilities must update the Institutional Disclosure of Adverse Event Template with the following fields:

   a. Date and Time of Discussion-Drop-down calendar: *

   b. Place of Discussion (Reason for any delay in the disclosure): *

c. Names and identity of those present: *

d. Discussion points of the adverse event: *

e. Offer of assistance, including arrangements for a second opinion, additional monitoring, expediting clinical consultations, bereavement support: *

f. Questions addressed in the discussion: *

g. Advisement about potential compensation through the Veterans Benefits Administration and the Federal Tort Claims Act: *

h. Continued Communication regarding the adverse event: *

i. Contact information for individual managing the disclosure: *

2. All elements within the graphical user interface (GUI) template have a free text box for documenting the information.

3. Each of the elements within the GUI template is a required field (* *indicates a required field*) that must be completed before the note can be signed by the author.

4. The screenshot of this note template is available at: http://vaww.ethics.va.gov/docs/policy/Note_Template_Institutional_Disclosure_of_Adverse_Event.pdf. ***NOTE:*** *This is an internal VHA web site and can only be accessed by authorized users.*

FLOWCHART: PROCESS FOR ASSESSMENT OF ADVERSE EVENTS THAT MIGHT REQUIRE LARGE-SCALE DISCLOSURE

1. The Clinical Episode Review Team (CERT) is the name of the team that serves as the Deputy Under Secretary for Health for Operations and Management's coordinated triage process for review of each potential adverse event that may require large-scale disclosure (see paragraph 5.d.(1)).

2. The Process for Assessment of Adverse Events That Might Require Large-scale Disclosure flowchart is available at: http://vaww.ethics.va.gov/docs/policy/Large_Scale_Disclosure_Assessment_Flowchart.pdf. ***NOTE:*** *This is an internal VHA web site and can only be accessed by authorized users.*

ETHICAL LEADERSHIP DECISION PROCESS FOR LARGE-SCALE DISCLOSURE OF ADVERSE EVENTS FOR USE BY THE CLINICAL REVIEW BOARD (CRB)

Within the Veterans Health Administration (VHA), there is a presumptive obligation to disclose adverse events that cause harm or potential harms 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 severity 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 patients and potentially-affected third parties; benefit and burden of disclosure to patients, including medical, psychological, social, or economic; impact on the institution's perceived integrity and its capacity to provide care and treatment for all patients; as well as applicable policy and relevant precedent. In providing a recommendation about large-scale disclosure to the Principal Deputy Under Secretary for Health, the Clinical Review Board (CRB) needs to include the following considerations in its decision process:

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

a. What is the probability that a given patient was exposed to the adverse event?

b. What is the probability that the adverse event will cause a particular patient harm?

c. What is the nature of the potential harm?

d. What is the expected severity of the harm?

e. What is the expected duration of the harm?

f. Is there treatment available to prevent or ameliorate the harm?

g. 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?

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

In addition to the standing members of the CRB, individuals and groups need to be included on a case-by-case basis to ensure that the perspectives of all relevant Department of Veterans Affairs (VA) subject matter experts and stakeholders affected by the decision have an opportunity for input.

3. DOES THIS DECISION REFLECT ORGANIZATIONAL, PROFESSIONAL, AND SOCIAL VALUES?

a. Does the decision reflect VHA core values, such as excellence, integrity and accountability? For example, would the decision inspire a high degree of confidence in

VHA's honesty, reliability, and sincere good intent? Would the decision demonstrate an understanding of, sensitivity to, and concern for, each person's individuality and importance? Would the decision indicate that VHA is taking responsibility for collective action, is preserving the organization's reputation, and exercising appropriate stewardship of public resources?

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 VHA's patients?

c. Does the decision reflect values central to public health practice? For example, does the decision reflect and make use of the best epidemiological evidence to improve population health? ***NOTE:*** *On a case-by-case basis, additional values may be relevant.*

4. DO THE LIKELY BENEFITS OF THE DECISION OUTWEIGH ANY LIKELY HARMS?

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 patients, 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 patients?

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. DOES THIS DECISION ESTABLISH A GOOD MODEL FOR FUTURE DECISION MAKING?

a. Is this a good model for how similar questions need to 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?

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

b. Will the decision be understood and accepted by patients and 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.