US DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Institutional Disclosure Policy Requirements Should Be Clarified

Management Advisory Memorandum	23-02386-91	March 13, 2024

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DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20001

December 12, 2023[1]

MANAGEMENT ADVISORY MEMORANDUM

TO: Dr. Shereef Elnahal, Under Secretary for Health
Veterans Health Administration (10)

FROM: Dr. John D. Daigh, Jr., Assistant Inspector General
VA Office of Inspector General, Office of Healthcare Inspections (54)

SUBJECT: Institutional Disclosure Policy Requirements Should Be Clarified

The purpose of this memorandum is to highlight concerns with facility-level expectations described in the Veterans Health Administration (VHA) policy for conducting institutional disclosures of adverse events to patients or the patients' personal representatives. The Office of Inspector General's (OIG's) oversight function includes interpretation of VHA policies in practice. Unclear policies create challenges for oversight and may impact the services veterans receive. The OIG identified unclear language in VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*.[2] The OIG also identified inconsistent application of the institutional disclosure policy during various healthcare inspections that took place during fiscal years 2022 and 2023.

Institutional Disclosure

"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."[3] VHA policy requires, "an unwavering ethical obligation to disclose to patients harmful adverse events that have been sustained in the course of their Department of Veterans

[1] This memorandum was sent to the Veterans Health Administration on December 12, 2023, to provide the opportunity for review and comment.

[2] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The directive applies to clinical, institutional, and large-scale disclosures; however, the focus of this Management Advisory Memorandum is on institutional disclosure.

[3] VHA Directive 1004.08. Adverse events are defined as "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."

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."[4]

According to VHA policy, "disclosure" is required for "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, or that are sentinel events as defined by The Joint Commission [TJC]." VHA policy does not specify these adverse events require "institutional disclosure." VHA policy specifies that 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, including, for example, sentinel events as defined by The Joint Commission. . . Such adverse events require institutional disclosure regardless of whether they resulted from an error."[5]

VHA policy requires that institutional disclosure "must be initiated as soon as reasonably possible and generally within 72 hours. This time frame does not apply to adverse events that are only recognized after the associated episode of care, for example, through investigation of a sentinel event, a routine quality review, or a look-back."[6]

VHA requires institutional disclosure to include

- "an expression of concern and an apology, including an explanation of the facts to the extent that they are known;"
- "an outline of treatment options, if appropriate;"
- "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;"
- "contact information regarding designated staff who are to respond to questions regarding the disclosed information or clinical sequelae associated with the adverse event;"
- "notification that the patient or personal representative has the option of obtaining outside medical or legal advice for further guidance;" and
- "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."

[4] VHA Directive 1004.08.

[5] VHA Directive 1004.08.

[6] VHA Directive 1004.08.

- "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."[7]

Sentinel Events

VHA policy adopts The Joint Commission's (TJC's) definition of a sentinel event, which has changed over time. At its inception in 1996, TJC's sentinel event policy applied only to events that occurred to patients. In 2013, sentinel events were expanded to include harmful events to hospital staff, visitors, and vendors on a hospital's premises that do not necessarily occur during the course of patient care. In July 2021, TJC added criminal events occurring on hospital premises or while individuals are under the supervision of hospital employees, including the sexual abuse of a patient, staff, visitor, or vendor, and physical assault of any of these individuals if the physical assault results in death, permanent harm, or severe temporary harm. However, VHA policy addressing institutional disclosures provides a sentinel event as an example of an adverse event requiring disclosure but also poses the requirement that the adverse event take place "during the patient's care." This inconsistency is unclear as related to sentinel events because TJC has expanded the definition beyond those instances that occur during patient care.

Effective January 2022, TJC defines a sentinel event as "a patient safety event (not primarily related to the natural course of an illness or underlying condition of an individual served) that reaches an individual served and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm)." TJC considers the following (non-comprehensive) list of patient safety events to meet the definition of reportable sentinel events:[8]

- "Suicide of any individual served receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the health care organization's emergency department (ED)"
- "Surgery or other invasive procedure performed at the wrong site, on the wrong patient, or that is the wrong (unintended) procedure for a patient regardless of the type of procedure or the magnitude of the outcome"[9]

[7] VHA Directive 1004.08.

[8] The Joint Commission, "Sentinel Event Policy (SE)," Comprehensive Accreditation Manual for Hospitals, July 2023.

[9] An invasive procedure is defined as, "A medical procedure that invades (enters) the body, usually by cutting or puncturing the skin or by inserting instruments into the body," National Cancer Institute, *NCI Dictionary of Cancer Terms,* "invasive procedure," accessed July 13, 2023, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/invasive-procedure.

- "Fall in a staffed-around-the-clock care setting or fall in a care setting not staffed around the clock during a time when staff are present resulting in any of the following:
    - Any fracture
    - Surgery, casting, or traction
    - Required consult/management or comfort care for a neurological (for example, skull fracture, subdural or intracranial hemorrhage) or internal (for example, rib fracture, small liver laceration) injury
    - A patient with coagulopathy who receives blood products as a result of the fall
    - Death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall)"

In its Comprehensive Accreditation Manual for Hospitals, TJC offers to review patient safety event information when healthcare organizations request a determination by TJC as to whether an adverse event is considered a sentinel event.

Unclear Requirements Regarding Sentinel Events and Institutional Disclosure

The OIG determined that VHA policy language is unclear as to whether a sentinel event automatically triggers the need for institutional disclosure, in part because of the evolving TJC definition of a sentinel event, which now includes non-patient-care events. Although VHA policy requires "disclosure" for sentinel events "as defined by The Joint Commission," the definition for "institutional disclosure" states that the death or serious injury occur "during the patient's care," providing some ambiguity.

Based on a fiscal year 2023 hotline inspection involving a sentinel event, the OIG also discovered unclear criteria regarding the definition of suicide as a sentinel event, and whether all sentinel events require institutional disclosure.[10]

TJC defines two instances when suicide constitutes a sentinel event: (1) occurring in an around-the-clock setting, or (2) within 72 hours of discharge. However, VA guidance in the form of a checklist to guide facilities in their response to suicides that occur on VA property includes a broader definition than that of TJC. This VA guidance defines "a death by suicide on a VA campus" as a sentinel event.[11] Although this particular definition involving suicide is not

[10] VA OIG, Deficiencies in Quality of Care at the VA Maine Healthcare System in Augusta, Report No. 23-00528-92, March 12, 2024.

[11] VA, "Guidance for Action Following a Suicide on a VA Campus."

specifically included in VHA Directive 1004.08, the guidance could be construed as an expansion of VHA policy.[12] Read in combination, the VA guidance and VHA policy would require institutional disclosure of suicides occurring on VA property. VHA's Office of Medical-Legal Risk Management is aware of ambiguous language involving sentinel events and institutional disclosures and reported to the OIG the intent to clarify the language in VHA policy.[13]

Discrepancies in Facility Decisions to Conduct Institutional Disclosures

During comprehensive healthcare inspections of VA medical facilities in fiscal year 2022, the OIG noted discrepancies in facility decisions related to conducting institutional disclosures.[14] The OIG noted the following adverse events during healthcare inspections of VA medical facilities in fiscal year 2022 lacked institutional disclosures when disclosure appeared to be required by VHA policy:

- Wrong site surgery. A patient was scheduled for the extraction of second molar tooth and second bicuspid tooth under local anesthesia. However, the resident physician performing the procedure incorrectly, extracted the patient's third molar tooth (a wisdom tooth).[15]
- Falls with serious injury. Multiple patients experienced falls within the healthcare setting, many of which resulted in serious injury (e.g., hip fracture and subdural hematomas requiring surgical intervention).

The OIG found that these incidents required institutional disclosures because the events resulted in serious harm and occurred during the patients' care.

The OIG also reviewed the following events, identified as sentinel events by VHA medical facility staff, during healthcare inspections of VA medical facilities in fiscal year 2022 with completed institutional disclosure when it may not have been indicated according to VHA policy:

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[12] The United States Department of Justice, 1-19.000 – *Principles for Issuance and Use of Guidance Documents*, updated April 2022, https://www.justice.gov/jm/1-19000-limitation-issuance-guidance-documents-1. "A guidance document is a statement of general applicability issued by an agency to inform the public of its policies or legal interpretations."

[13] In June 2023, VHA's Office of Medical-Legal Risk Management (VHA OMLRM) notified the OIG that the directive was undergoing revision to reduce confusion as to whether all sentinel events mandated an institutional disclosure be conducted.

[14] The OIG's Comprehensive Healthcare Inspection Program conducts routine oversight of VA medical facilities that provide healthcare services to veterans. One element of the Comprehensive Healthcare Inspection Program is to assess factors related to possible lapses in standards of care and leaders' responses, including the incidence of serious adverse events, specifically sentinel events, that warrant institutional disclosure.

[15] Event documentation provided by facility staff.

- Injury outside the healthcare setting, unrelated to direct care, and not meeting the definition of a sentinel event. A patient was walking down the stairs to the facility parking lot, began to hurry, and started to stumble. The patient jumped the last four to five steps then felt heel pain upon landing.
- Postmortem injury. While staff were moving a deceased patient in the morgue from one level to another, the patient dropped approximately two feet and sustained a one-inch laceration to the head.

The OIG found that these incidents did not require institutional disclosures because the events did not occur during episodes of patient care and result in, or reasonably expect to result in, death or serious injury. It is important to note, however, that although VHA policy does not require an institutional disclosure of a postmortem injury, the OIG would expect the event to be discussed with the patient's family, next-of-kin, or personal representative.

During comprehensive healthcare inspections of VHA medical facilities in fiscal year 2022, the OIG found that staff and leaders failed to conduct institutional disclosures for some sentinel events based on a belief that conducting institutional disclosures was at the discretion of facility leadership. Facility leaders also reported exercising discretion to not conduct an institutional disclosure to next-of-kin regarding distant sentinel events in order to avoid dredging up painful memories without any meaningful benefit. However, VHA policy states that institutional disclosure is required when an adverse event causes death or serious injury, regardless of when discovered, and does not allow for discretion. The OIG did not find in its review of the VHA policy that leaders have discretion to not conduct an institutional disclosure based on a delay in discovering a reportable event.[16]

Conclusion

Unclear requirements may have resulted in VHA medical facility leaders' confusion about when to make institutional disclosures. Additionally, the OIG found that VHA Directive 1004.08 does not provide leaders with discretion on whether to make an institutional disclosure of an event based on a delay in discovery of a serious adverse incident when, according to 1004.08, an institutional disclosure, would otherwise be implemented.

Requested Action

The OIG requests the Under Secretary for Health to (1) more clearly specify in an amended or updated policy when a sentinel event as defined by The Joint Commission should trigger an institutional disclosure; (2) reinforce to VHA staff the indications for institutional disclosure; and

[16] VHA Directive 1004.08.

(3) reinforce to staff that the present policy requires institutional disclosure for specific events regardless of timeliness of discovery.

VHA Response

The Under Secretary for Health reported that the Office of Medical Legal Risk Management has completed draft revisions to update VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, which addresses the areas of concern highlighted in the management advisory memorandum. Once the updated directive is finalized, the Office of Medical Legal Risk Management will publicize the content to key VHA stakeholders. The full text of the Under Secretary for Health's response is included in appendix A.

OIG Response

Unclear policies create challenges for oversight and may impact the services veterans receive. To ensure VHA provides attention to the publication of the updated VHA Directive 1004.08, the OIG will continue to follow up periodically with VHA for the status of completion.

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General
for Healthcare Inspections

Appendix A: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: January 9, 2024

From: Under Secretary for Health (10)

Subj: OIG Management Advisory Memorandum, Institutional Disclosure Policy Requirements Should Be Clarified (VIEWS 11201395)

To: Director, Office of Healthcare Information (54HI00)

1. Thank you for the opportunity to review and comment on the draft management advisory memorandum regarding the Veterans Health Administration (VHA) institutional disclosure policy requirements.

2. The Office of Medical Legal Risk Management (MLRM) completed draft revisions to update VHA Directive 1004.08 Disclosure of Adverse Events to Patients, which addresses the areas of concern highlighted in the management advisory memorandum. The draft directive has undergone initial review by the Office of Regulations, Appeals, and Policy. The Office of MLRM will consult with other Department of Veterans Affairs and VHA program offices, for example, the Office of General Counsel, and the National Center for Ethics in Healthcare, which have relevant contributions to the policy content. The directive will also clarify if and when facility leadership can exercise discretion in the disclosure decision-making process.

3. Once the updated directive is finalized, the Office of MLRM will publicize the content to key VHA stakeholders. The Office of MLRM will reach out to groups on national calls, such as Veterans Integrated Service Network Chief Medical Officers/Quality Management Officers/Patient Safety Officers, VHA Chiefs of Staff, VHA Risk Managers, and the Office of General Counsel Torts Law Group to review the new policy and answer questions. This information will also be included in Risk Management Boot Camp training programs where Disclosure of Adverse Events to Patients, including Institutional Disclosure, is part of the training curriculum.

4. I want to also highlight that the Office of MLRM participated in the Office of Quality Management Falls with Fractures Workgroup. The Office of MLRM was tasked with clarifying responsibilities associated with sentinel events related to falls with fractures where an Institutional Disclosure may be indicated. A presentation was developed and will be publicized to VHA stakeholders.

5. Comments regarding this memorandum may be directed to the GAO OIG Accountability Liaison Office at VACOVHA10BGOALOIG@va.gov.

(Original signed by:)
Shereef Elnahal, M.D., MBA

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