Department of Veterans Affairs Veterans Health Administration Washington, DC 20420 VHA DIRECTIVE 1099 Transmittal Sheet April 22, 2020

VHA MEDICAL ADVISORY OPINION REQUESTS BY GENERAL COUNSEL

- 1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive states policy for requiring Veterans Integrated Service Networks (VISN) and VHA health care providers to provide medical advisory opinions when such opinions are requested by the Office of General Counsel (OGC) through the Office of Medical-Legal Affairs (OMLA).
- **2. SUMMARY OF MAJOR CHANGES:** Major changes include updating procedures for the mandatory reporting of advisory opinions
- 3. RELATED ISSUES: None.
- **4. RESPONSIBLE OFFICE:** The Office of Medical-Legal Affairs (10E2E) is responsible for the contents of this directive. Questions may be directed to Director, OMLA at 716-862-8521 or 716-862-8519.
- **5. RESCISSIONS:** VHA Directive 2007-028, VHA Medical Advisory Opinion Requests by Regional Counsel, dated September 17, 2007, is rescinded.
- **6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of April 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

/s/ Gerard R. Cox, MD, MHA
Deputy Under Secretary for Health for
Organizational Excellence

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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VHA MEDICAL ADVISORY OPINION REQUESTS BY GENERAL COUNSEL

1. PURPOSE

This Veterans Health Administration (VHA) directive requires all VHA health care providers, to include full-time, part-time, and contract health care providers, to provide medical advisory opinions (MAO) regarding the care provided to VHA patients for whom a tort claim alleging medical malpractice has been filed, when requested by an Office of General Counsel (OGC) attorney or paralegal through the Office of Medical-Legal Affairs (OMLA). **AUTHORITY:** Title 38 Code of Federal Regulations (CFR) 14.605(b). **NOTE:** Contracts for provision of patient care by contract personnel must include the requirement to participate in the MAO process per this directive.

2. BACKGROUND

- a. Every year, more than 1,500 tort claims are submitted under the Federal Tort Claims Act alleging medical malpractice by VHA health care providers; almost all of these claims require at least one MAO. MAOs are an essential component of the Department of Veterans Affairs (VA) OGC's decision to settle or deny these claims.
- b. VA regulation 38 CFR 14.601(b) provides that OGC is guided by the views of the Under Secretary for Health as to the standard of medical care and treatment, the nature and extent of the injuries, the degree of the Veteran's temporary or permanent disability, the prognosis, the necessity for future treatment or physical rehabilitation, and any other pertinent medical aspects of a claim.
- c. MAOs are exempt from disclosure under the Freedom of Information Act, Title 5 United States Code (U.S.C.) 552(b)(5) and are generally protected from discovery in litigation under the attorney work-product doctrine codified in Rule 26(b)(3) of the Federal Rules of Civil Procedure. They are not, however, considered confidential and privileged quality assurance records under 38 U.S.C. Section 5705. No disclosure should be made of such opinions without the approval of OGC. The MAO should address in detail all the questions raised by the OGC. Medical issues not identified by the OGC, but which the reviewer believes may be relevant to a decision on the claim should also be addressed.

3. DEFINITIONS

- a. <u>Individually-Identifiable Health Information</u>. Individually-Identifiable Health Information (IIHI) is a subset of health information, including demographic information collected from an individual, which:
- (1) Is created or received by a health care provider, health plan, or health care clearinghouse;
- (2) Is related to the past, present, or future condition of an individual and provision of, or payment for health care; and

(3) Identifies the individual or a reasonable basis exists to believe the information can be used to identify the individual.

NOTE: IIHI does not have to be retrieved by name or other unique identifier to be covered by this directive.

- b. <u>Medical Advisory Opinion</u>. For the purpose of this directive, MAO are reviews of the episode of care, by the profession, specialty or sub-specialty requested by OGC and in response to questions provided by OGC. MAOs provide substantive information regarding the standard of medical care and treatment in place at the time of the event, the nature and extent of the injuries, the degree of the Veteran's temporary or permanent disability, the prognosis, the necessity for future treatment or physical rehabilitation, and any other pertinent medical aspects of a claim. Medical issues not identified by OGC, but which the reviewer believes may be relevant to a decision on the claim should also be addressed.
- c. <u>Protected Health Information.</u> Protected Health Information (PHI) is IIHI maintained in any form or medium. *NOTE:* PHI excludes employment records held by a Covered Entity in its role as an employer.
- d. <u>Tort Claim.</u> For the purpose of this directive, a tort claim is a claim under the Federal Tort Claims Act against VA arising out of an alleged wrongful act or omission of a health care employee while furnishing medical care in or for VHA.
- e. <u>Work-Product Doctrine.</u> Written or oral materials prepared by or for an attorney in the course of legal representation, especially in preparation for litigation. Generally, an opposing party may not discover or compel disclosure of work product.

4. POLICY

It is VHA policy that all Veterans Integrated Service Networks (VISNs) and VA health care providers will provide thorough medical advisory reviews when requested by OGC through OMLA.

5. RESPONSIBILITIES

- a. <u>Under Secretary for Health.</u> The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.
- b. <u>Deputy Under Secretary for Health for Operations and Management.</u> The Deputy Under Secretary for Health for Operations and Management is responsible for:
 - (1) Communicating the contents of this directive to each of the VISNs.
- (2) Ensuring that each VISN Director has the sufficient resources to fulfill the terms of this directive in all the VA medical facilities within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.

- (4) When VISN Directors report issues of inability to complete MAOs from specific specialties, even with re-assignment, partner with OMLA to identify or develop suitable alternative sources for MAOs.
- c. <u>Director, Office of Medical-Legal Affairs.</u> The Director, OMLA, is responsible for:
- (1) Receiving and coordinating the receipt of requests from OGC for MAOs and the assignment of these MAOs across VISNs. MAO assignments are as follows:
- (a) First, MAO assignments are evenly distributed across the VISNs. **NOTE:** To reduce any potential for bias, a VISN associated with the claim is ineligible for that assignment.
- (b) Then, the VISN's MAO workload is evenly assigned across their VA medical facilities, on a rotating basis by means of a distribution list provided, maintained, and updated by the CMOs. **NOTE:** This does not prohibit VA medical facility staff reviews of episodes of care which led to the claim when requested by OGC, the VISN Director, or VA medical facility leadership.
- (2) Notifying OGC and the assigned VA medical facility's Senior Clinical Executive (SCE) of the assignment. The notice to the VA medical facility SCE must include the name of the requesting attorney or paralegal. This assignment information is communicated in a manner that minimizes unnecessary delay and repeated transmission of PHI.
 - (3) Receiving completed MAOs from the assigned VA medical facility.
- (4) Receiving notifications from VISN CMO's of an inability to complete an assigned MAO, even using the reassignment process outlined in paragraph 5.g.(4). In this case, OMLA will notify OGC of the need to use an alternative resource for that MAO (e.g., the ORM contractor or other solutions identified). The VISN will be then be available for a new MAO assignment of a different specialty per schedule.
- (5) If notified by Deputy Under Secretary for Health for Operations and Management of a persistent problem in completing MAOs of a specific specialty, partner with the Deputy Under Secretary for Health for Operations and Management to identify suitable alternative sources for those MAOs.
 - (6) Tracking the completion of the MAOs for timeliness.
- (7) Annually, providing VISN Chief Medical Officers (CMOs), the Office of the Deputy Under Secretary for Health for Operations and Management, the ADUSH for Quality, Safety, and Value, and OGC a report of the types, amount and time to completion of MAOs assigned during the prior fiscal year.

(8) Providing, when requested by OGC or VISN CMOs, a VISN-level report of the types and amounts of MAOs for the current fiscal year.

- d. **General Counsel.** OGC assumes responsibility for:
- (1) Initiating requests for MAOs by providing OMLA the Veteran's name, involved VISN(s), and required specialty.
- (2) Upon notification by OMLA of the VA medical facility to which the preparation of the requested MAO has been assigned, providing to the assigned SCE the Veteran's name and last four digits of the Social Security number (if known), as well as clearly and concisely-stated medical questions pertinent to the review.
- (3) Clarifying questions for the assigned VA medical facility SCE, VISN CMO, and reviewer(s).
- (4) Notifying the VISN CMO of any issues which may affect a timely completion of the assigned review. The VISN CMO coordinates with VA medical facility SCE to ensure completion or reassignment of the requested review.
- (5) Upon completion, ensuring OMLA is provided the questions that were submitted by OGC and a copy of the completed MAO(s).
- (6) Soliciting input from Risk Management Program Office to assist in identifying specialty review requests via external contractor. See Appendix A.
- e. <u>Risk Management Program Office.</u> The Risk Management Program Office is responsible for responding to OGC requests for an MAO through the VACO Risk Management Program's external contractors. See Appendix A.
- f. <u>Veterans Integrated Service Network Director</u>. The VISN Director is responsible for:
 - (1) Supporting CMOs in their duties as described below.
- (2) In the rare event that the VISN CMO is not able to accommodate the VA medical facility's SCE's request to reassign a requested review through designated reassignment process outlined in paragraph 5.g.(4), the VISN Director will notify the Deputy Under Secretary for Health for Operations and Management of the inability to meet the need for MAO review of care by the requested specialty with current resources.
 - g. **VISN Chief Medical Officer.** The VISN CMO is responsible for:
- (1) Providing and maintaining a listing of available professions, specialties, and subspecialties available for MAOs at each of the VA medical facilities within its VISN, ensuring coverage for all professions, specialties, and subspecialties by at least one VA medical facility within its VISN. **NOTE:** CMOs can access this listing located at

https://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/10NC/Medical%20Advisory%20Opinion%20Spreadsheet/Forms/AllItems.aspx This is an internal VA Web site that is not available to the public. If a CMO does not have access to this SharePoint, the CMO should contact the ADUSH for Clinical Operations (10NC). VA medical facilities are to manage this listing through their CMOs.

- (2) Assuming overall responsibility for the request when OMLA assigns a MAO request to a VA medical facility SCE by means of the distribution list.
- (3) Ensuring, in cooperation with the VA medical facility SCE, that the review is provided to the requesting OGC attorney or paralegal within 30 days of the assignment to the VA medical facility, or otherwise in a timely manner consistent with the complexity of the review.
- (4) When notified by the SCE of the assigned VA medical facility that they no longer have the capability to complete the review as scheduled, contacting other VA medical facility SCEs within the VISN, or other VISN CMOs to arrange for reassignment of the requested review, and then notifying the requesting OGC attorney or paralegal and the VHA Health Information Access Program of the change in assignment.
- (5) If the VISN CMO is not able to accommodate the VA medical facility's SCE's request to reassign a requested review through designated re-assignment process outlined in paragraph 5.g.(4) (above), the CMO will notify OMLA and VISN Director of inability to meet need for MAO review of care by that requested specialty.
 - h. **VA Medical Facility Director.** The VA medical facility Director is responsible for:
- (1) Ensuring the SCE has sufficient resources to support the OMLA notification of MAO assignment to the VA medical facility and timely re-assignment to the reviewing provider.
- (2) Ensuring the assigned reviewing provider is allotted time to complete the review per schedule.
- (3) When unable to complete the assignment process per 5.g.(4) (above), report to the Deputy Under Secretary for Health for Operations and Management the inability to complete MAOs from specific specialties.
- i. <u>VA Medical Facility Senior Clinical Executive</u>. The SCE refers to the Chief of Staff for oversight of practitioner professions and other specialties under COS supervision and includes the Associate Director for Patient Care Services (ADPCS) for oversight of practitioner professions and specialties under ADPCS supervision. Both COS and ADPCS will be notified of need for MAO assignments for their VA medical facility. The VA medical facility SCE is responsible for:
- (1) Contacting the requesting OGC attorney or paralegal for clarification of medical questions pertinent to the review within 2 business days if possible, but not to exceed 5 business days.

- (2) Assigning the case to the appropriate specialty or subspecialty reviewer and providing the attorney contact information to reviewer to permit further clarification of medical questions pertinent to the review.
- (3) Providing the assigned reviewer contact information to the requesting OGC attorney or paralegal and the VHA Health Information Access Program.
- (4) Contacting the VISN CMO, if unable to assign a case for review or if unable to complete the review per schedule.
- (5) When needed, arranging for the reviewer(s) to have access to the electronic medical records of the involved Veteran, in accordance with processes established by the VHA Privacy Officer and VHA Office of Information.
- (6) Ensuring, in cooperation with the VISN CMO, that the review is provided to the requesting OGC attorney or paralegal within 30 days of the assignment to the VA medical facility, or otherwise in a timely manner consistent with the complexity of the review.
- j. <u>VHA Health Care Provider.</u> The VHA health care provider, including full-time, part-time, and contract personnel, assigned to provide a MAO is responsible for or has assumed responsibility for conducting a review within 30 days of assignment to the VA medical facility, or otherwise in a timely manner consistent with the complexity of the review.

6. TRAINING

There are no formal training requirements associated with this directive, however the VHA health care provider assigned to review the case is encouraged to complete the TMS Course, Completing a Medical Advisory Opinion for the VA Office of General Counsel, TMS Number: VA 3863525 (https://www.tms.va.gov/SecureAuth35/ NOTE: This is an internal VA Web site that is not available to the public.).

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created in this directive shall 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 should be addressed to the appropriate Records Manager or Records Liaison.

8. REFERENCES

- a. 5 U.S.C. 552(b)(5).
- b. 38 U.S.C. Section 5705.
- c. 38 C.F.R. 14.601(b).

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d. 38 C.F.R. 14.605 (b)(3).

REQUEST TO PROCESS MEDICAL ADVISORY OPINIONS AS MANAGEMENT REVIEW UNDER EXTERNAL PEER REVIEW CONTRACT THROUGH THE VACO RISK MANAGEMENT PROGRAM

- **1.** Review process for obtaining a Medical Advisory Opinion (MAO) using the Veterans Affairs (VA) Central Office Risk Management Program Office is as follows:
- a. OGC will continue to contact the Office of Medical Legal Affairs (OMLA) and request a VA medical facility assignment for a MAO.
- b. OMLA will notify the Veterans Integrated Service Network (VISN), VA medical facility and OGC attorney of the VA medical facility assignment. Additional parties, e.g. VACO Risk Management Office, Risk Manager, may be included in this notification.
 - c. OGC attorney determines the credential and specialty to be reviewed.
- d. Assigned VA medical facility verifies specialty requested and notifies the VISN if they cannot provide a clinician to conduct the MAO.
- e. VISN Chief Medical Officer (CMO) (or designee) determines if MAO can be assigned elsewhere within the VISN.
- f. If reassignment options are not available within the VISN, the VISN CMO (or designee) contacts VACO Risk Management Program (VACO Risk Management Mail Group, VHA10E2ERiskManagementStaff@va.gov) to determine if the case can be forwarded to the external contractor.
- **2.** The following factors impact whether VACO Risk Management can accept a case:
- a. The contractor must have a reviewer that is a specialty peer match and is qualified to evaluate the specific care concerns identified by OGC.
- b. The involved VA medical facility must have the capacity to create secure CDs of images OGC determines are required to complete the review.
- c. The MAO start date will begin 30-days from the date at which all documentation, including images, are in the possession of the contractor.
- **3.** VACO Risk Management staff will determine if the MAO can be conducted using the external contract, based on prevailing contract requirements.
- a. If Risk Management Program accepts the case, the VISN CMO (or designee) will notify the requesting OGC attorney or paralegal that the case is being handed off to VACO Risk Management to be processed by the external contractor.
- b. If the VACO Risk Management Program cannot accept the case, the VISN will retain the case and attempt to locate another provider elsewhere within VHA.

EXTERNAL CONTRACTOR REVIEW WORKSHEET

The Office of General Counsel (OGC) attorney or paralegal requesting to send the case to the external contractor will contact the Department of Veterans Affairs (VA) Central Office Risk Management Program staff directly with the following information.

NOTE: Risk Management Program staff can assist.

- **1.** Questions to be answered by the reviewer in a word document, drafted with enough specificity that the VA Central Office Risk Management staff and the external reviewer can address:
- a. The name of the involved Veterans Integrated Service Network (VISN) and VA medical facility.
 - b. Patient demographics, first and last name, DOB and full Social Security Number.
 - c. Specific allegation(s) being made by the claimant.
 - d. Date (or date range) that the alleged substandard care occurred.
- e. Clinical specialty such as a generalist (e.g., Internal Medicine, Primary Care) versus a specialist (e.g., cardiologist, orthopedic surgeon) being requested to complete the review.
- f. Involved provider names, if known, to assist with locating the appropriate clinical information; notes, orders, etc. Include names of residents/fellows, if known.
- g. Specific standard of care parameters to be assessed in the review (e.g., Were the medications administered to treat the heart condition appropriate?).
- h. A note regarding any specific images, scanned documents or other items in the VA medical record needed for the review, but not visible in the Community Viewer system used by the reviewers.
- **2.** VA Central Office Risk Management will transmit the completed review to the OGC attorney or paralegal.
- **3.** If there are questions that will require further clarification (or discussion with the Medical Advisory Opinion (MAO) reviewer), OGC attorney or paralegal is requested to contact VA Central Office Risk Management Program staff to coordinate at (VHA10E2ERiskManagementStaff@va.gov).