DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

VETERANS HEALTH ADMINISTRATION

Manipulation of Radiology Reports and Leadership Failures in the Medical Imaging Service at the Clement J. Zablocki VA Medical Center Milwaukee, Wisconsin

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to review (a) allegations from an anonymous complainant that a radiologist (subject radiologist) made gross errors that resulted in treatment delays, placed misleading addenda in two patients electronic health records (EHRs), and that leadership was tolerant of this practice; and (b) the adequacy of facility leaders' response to the OIG's query (OIG Hotline case referral) related to the allegations at the Clement J. Zablocki VA Medical Center (facility) in Milwaukee, Wisconsin.[1]

During the inspection, the OIG identified concerns with manipulation and vulnerability of the EHR and management of the Medical Imaging Service. Given the importance of the integrity of health care records for patient safety and quality of care, this report first describes the inspection findings related to the integrity of the radiology reports in the EHR and management of the Medical Imaging Service. The allegations related to the subject radiologist are discussed second, followed by concerns related to the facility's response to the OIG Hotline case referral, and concludes with other issues associated with radiology addenda.

The OIG determined that there was evidence of EHR manipulation by the radiologist who holds the position of Medical Imaging Service Manager (Division Manager). Interpersonal conflicts between a staff radiologist and the subject radiologist led the Division Manager to direct a technical administrator to delete a completed and verified magnetic resonance imaging (MRI) report against Veterans Health Administration (VHA) guidelines.[2] The MRI was originally read by a staff radiologist with a normal result. The original report was deleted enabling the subject radiologist to read the MRI and enter a new radiology report with an abnormal result. Subsequently, an external radiologist reviewed the disputed study and agreed with the initial interpretation of normal results. The patient and primary care provider were informed of both normal and abnormal results, and the patient received appropriate care and treatment.

Although not part of the original allegations, the OIG team determined that facility leaders at multiple levels failed to successfully manage or address the impact of ongoing identified interpersonal conflicts within the Medical Imaging Service and did not follow up on

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[1] Because the complainant was anonymous and did not provide a definition of gross errors, the OIG defined gross error, within the context of this report, as an error that increases a patient's risk for an adverse clinical outcome such as death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level care resulting from or contributed to by medical care or services delivered by VA providers. The OIG recognizes that in addition to the potential for adverse clinical outcomes, avoidable delays in treatment associated with the deficiencies discussed in this report may impact the convenience and quality of care received by veterans. This report focuses on patient harm in terms of adverse clinical outcomes.

[2] While facility radiologists were unable to access and modify signed, final radiology reports in patients' EHRs, several technical administrators, designated staff at the facility, and other Veterans Integrated Service Network 12 facility technical administrators had the ability to do so.

recommendations intended to improve service wide relationships made by a staff psychologist in an assessment of the Medical Imaging Service.

The OIG team also identified concerns related to intimidation of staff radiologists. During the on-site visit, staff radiologists reported to the OIG that they felt pressure on two occasions to comply with instructions given by the Division Manager to add addenda in radiology reports to update an interpretation made in the past by another staff radiologist. In one case, the staff radiologist acknowledged disagreeing with the interpretation documented in the addendum. The staff radiologists complied with the instructions, even when they disagreed, and did not escalate their concern.

In interviews with facility leaders, the OIG learned that the Medical Imaging Service had among the lowest All Employee Survey scores in the facility. All Employee Survey scores in the Medical Imaging Service identified ongoing departmental issues for which the service's action plan lacked identifiable solutions to improve areas of staff concern, targeted goals, and a plan to monitor for progress.

Antagonistic interactions between the Division Manager and the subject radiologist caused tension throughout the Medical Imaging Service and created a tense, uncomfortable work environment.[3] The OIG team is concerned that ongoing interpersonal conflicts, coupled with the lack of defined plans for resolution or improvement of departmental issues, have the potential to adversely affect patient care.

With respect to the allegations from the anonymous complainant, the OIG did not substantiate that the subject radiologist added addenda to cover gross errors that resulted in delays in treatment and contributed to adverse clinical outcomes for two specific patients. While the subject radiologist updated the original readings, the OIG team found no evidence that the clinical outcome of either patient's treatment would have changed if these findings were reported in the original imaging results. The OIG team did not substantiate that the subject radiologist's use of addenda was misleading in either case. The subject radiologist's use of addenda in both radiology reports was within VHA guidelines. The OIG team found no evidence that the subject radiologist failed to meet acceptable levels of performance. Additionally, the OIG team determined that peer reviews of the subject radiologist were performed in accordance with VHA policy.

The OIG team determined that Veteran Integrated Service Network and facility leaders failed to conduct a thorough and impartial oversight review per VA requirements in their response to the September 2018 OIG Hotline case referral that was forwarded to the facility and Veteran

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[3] The Division Manager is a radiologist who directly supervises all staff radiologists.

Integrated Service Network leaders for VHA review and action related to the subject radiologist.[4] The investigation process used by facility leaders risked the integrity of the review and risked identifying the complainant who requested anonymity.

During the inspection, the OIG team determined that the date and location of addenda in radiology reports may make transparent communication of clinical information more difficult. Addenda location within the radiology report is based on software configuration and cannot be altered by individual radiologists.

While not misleading in content, the location and title of amended radiology reports at the facility differed from other EHR clinical notes with addenda. This variation raises the possibility of clinicians who are unfamiliar with radiology reports not being able to readily identify that a radiology report has been amended. In an attempt to bring this issue to the attention of the National Radiology Program Office, staff mistakenly entered the request into a database used by the Office of Information and Technology that cannot be accessed by National Radiology Program Office staff. Therefore, no action had been taken by National Radiology Program Office staff to address the concern at the time of the OIG's inspection.

The OIG made eight recommendations. Two recommendations were directed to the Under Secretary for Health related to development of VHA's new EHR with addenda insertion, deletion, and consistent formatting for radiology reports and the Division Manager's directing the deletion of an imaging report; two recommendations to the Veteran Integrated Service Network 12 Director related to picture archiving and communication system practices and oversight of OIG Hotline case referrals; and four recommendations to the Facility Director related to the correction of the imaging study of a patient with conflicting interpretations discussed in this report, oversight and management of the Medical Imaging Service, evaluation of the Medical Imaging Service's workplace culture, and evaluation of the need for training on workplace intimidation and the process for employee reporting of concerns.[5]

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[4] VA Directive 0701, *Office of Inspector General Hotline Complaint Referrals*, January 15, 2009. "Case referrals are reviewed and reported back to the OIG in accordance with this directive..." When the OIG receives a hotline complaint, the allegations are reviewed and, if determined necessary, relevant information is forwarded to VHA for VISN and facility leaders' review and response. For confidential or anonymous complainants, the OIG protects the identity of the complainant. The directive requires that VHA responses include "[e]vidence of an independent review by an official separate from and at a higher grade than the subject/alleged wrongdoer." Additionally, facility leaders "who receive hotline case referrals should not attempt to identify the complainant."

[5] The recommendation directed to the Under Secretary for Health was submitted to the Executive in Charge who has the authority to perform the functions and duties of the Under Secretary for Health.

Comments

The Under Secretary for Health and the Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided an acceptable action plan (see appendixes A, B, and C). The OIG will follow upon the planned and recently implemented actions to ensure that they have been effective and sustained.

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Contents

Abbreviations

EHR	electronic health record
CPRS	Computerized Patient Record System
MRI	magnetic resonance imaging
OIG	Office of Inspector General
PACS	picture archiving and communications system
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture

Manipulation of Radiology Reports and Leadership Failures
in the Medical Imaging Service at the Clement J. Zablocki
VA Medical Center, Milwaukee, Wisconsin

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to review
(a) allegations from an anonymous complainant that a radiologist (subject radiologist) placed misleading addenda in two patients' electronic health records (EHR) to cover up gross errors that resulted in delayed care, and that facility leaders were aware of and tolerated this practice; and (b) the adequacy of facility leaders' response to the OIG's query related to the allegations at the Clement J. Zablocki VA Medical Center (facility) in Milwaukee, Wisconsin.

Background

Facility

The facility, part of Veteran Integrated Service Network (VISN) 12, is classified by VHA as Level 1a— high complexity.[1] From October 1, 2017, through September 30, 2018, the facility served 64,350 patients and had a total of 468 hospital operating beds, including 196 inpatient beds, 150 domiciliary beds, and 113 community living center beds.

As of July 2019, the OIG was informed that the Medical Imaging Service had 61 employees. The service offers diagnostic imaging, computed tomography, magnetic resonance imaging (MRI), bone density scans, nuclear medicine imaging, ultrasound, and interventional radiology. From October 1, 2017, through September 30, 2018, the service performed over 87,000 exams.

Radiology

Radiology is a branch of medicine that uses imaging technology to view structures inside the human body. Radiologists are physicians who use imaging studies like radiography, computed tomography, MRI, and ultrasound to diagnose, screen, and treat disease.[2] After an imaging study is completed, a radiologist reviews the images and prepares a radiology report with the findings. Radiology reports convey information between the radiologist who interprets, or "reads" the imaging study, and the ordering provider. Ordering providers typically access radiology reports in the patient's EHR.

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[1] The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex. VHA Office of Productivity, Efficiency and Staffing, http://opes.vssc.med.va.gov/Pages/Facility-Complexity-Model.aspx. (The website was accessed November 25, 2019, and is an internal VA website not publicly accessible.)

[2] MedlinePlus, *Imaging and Radiology*. https://medlineplus.gov/ency/article/007451.htm. (The website was accessed on June 6, 2019.)

The radiologist's impression is considered the most important section of the radiology report, as it offers the ordering provider critical information used for decisions regarding the patient's care.[3]

Diagnostic Errors in Radiology

Studies show that radiologists, on average, make real-time diagnostic errors in reading 3–5 percent of their daily imaging studies.[4] Radiologic interpretation leading to a diagnosis is not an automated process, but a human one, based on complex cognitive processes subject to a wide variety of errors.[5] Diagnostic errors are usually multifactorial including increased workload, rising quality expectations, cognitive biases, and system factors, such as lighting issues, distractions, and work schedules.[6]

Radiology Software

The OIG met with National Radiology Program Office staff who provided information on the variety of software programs that may be used to produce a final radiology report. The picture archiving and communication system (PACS) "is a medical imaging technology used primarily in healthcare organizations to securely store and digitally transmit electronic images and clinically relevant reports."[7] Several manufacturers provide PACS software and each VISN decides which PACS facilities within the VISN will use. Six different PACS vendors are used throughout the Veterans Health Administration (VHA).[8]

Radiologists use dictation software to dictate, edit, and sign reports. The PACS and dictation software are configured with the Veterans Information Systems and Technology Architecture

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[3] Radiological Society of North America, *How to Read Your Radiology Report.* https://www.radiologyinfo.org/en/info.cfm?pg=article-read-radiology-report. (The website was accessed on June 6, 2019.)

[4] Lee, Cindy, et al, "Cognitive and System Factors Contributing to Diagnostic Errors in Radiology", *American Journal of Roentgenology*, 201, No. 3 (September 2013): 611–617. https://www.ajronline.org/doi/10.2214/AJR.12.10375. (The website was accessed on May 20, 2019.)

[5] Bruno, Michael, et al., "Understanding and Confronting Our Mistakes: The Epidemiology of Error in Radiology and Strategies for Error Reductions*,*" *Radiographics*, 35, No. 6 (October 2015): 1677–1693. https://pubs.rsna.org/doi/10.1148/rg.2015150023. (The website was accessed May 29, 2019.)

[6] Lee, Cindy, et al. Diagnostic error is "defined as a diagnosis that is missed, wrong, or delayed as detected by some subsequent definitive test or finding." System factors are "problems with policies and procedures, inefficient processes, teamwork, communication, and technical and equipment failures." Cognitive errors refer to missing an anomaly when interpreting an imaging study.

[7] Radiological Society of North America, *PACS (Picture Archiving and Communication System)*. https://searchhealthit.techtarget.com/definition/picture-archiving-and-communication-system-PACS. (The website was accessed on June 5, 2019.)

[8] VHA uses Carestream, Phillips, McKesson, Vista Rad, Agfa and Acuo-Visage PACS systems.

(VistA) Imaging system and the Computerized Patient Record System (CPRS) to generate radiology reports.[9] The location of addenda in radiology reports depends on the configuration set up between the PACS, dictation system, VistA Imaging, and CPRS.

Facility PACS Administration

The facility employs a PACS administrator who directly reports to a Supervisory Radiologic Technologist. The PACS administrator is a Certified Radiologic Technologist whose PACS duties comprises 49 percent of the position. The PACS administrator, the first line technical support for the PACS system, provides technical guidance, maintenance, and troubleshooting services. Eleven other individuals at the facility, as well as the other PACS administrators in VISN 12, had the same access to the PACS system as the facility PACS administrator.

Integrity of the EHR

According to policy, VHA must maintain complete and accurate patient health records in an electronic format to serve as a basis to plan patient care and support diagnoses.[10] The Joint Commission requires facilities to have written polices to maintain "the integrity of health information against loss, damage, unauthorized alteration, unintentional change, and accidental destruction."[11] VHA policy requires the facility to create and monitor systems "to ensure accurate, timely, and complete health records."[12]

Report Addenda

VHA allows clinicians to enter addenda into patients' EHRs to clarify information, correct errors, document ongoing treatment discussions, and for supervisory oversight purposes. The addendum must be linked to the original document and authenticated in an approved manner. An addendum may be entered by someone other than the original author.[13]

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[9] VHA Vista Imaging Overview, "VistA Imaging system integrates clinical images, scanned documents and other non-textual data into the patients EHR." https://www.va.gov/health/imaging/overview.asp. (The website was accessed on June 6, 2019). VistApedia, What is CPRS? "CPRS is a comprehensive VistA program, which allows clinicians and others to enter and view orders, progress notes and discharge summaries, problem lists, view results and reports in the patients EHR." http://www.vistapedia.net/index.php?title=What_is_CPRS%3F. (The website was accessed on June 6. 2019).

[10] VHA Handbook 1907.01, *Health Information Management and Health Records*, May 19, 2015.

[11] Joint Commission Chapter Information Management, Standard IM.02.01.03: "*The Hospital Maintains the Security and Integrity of Health Information*."

[12] VHA Handbook 1907.01.

[13] VHA Handbook 1907.01.

Radiologists add addenda to reports for a variety of reasons. When new information becomes available to the radiologist after the radiology report has been signed, an addendum may be completed. This may include new findings not originally detected, newly available comparison studies that alter the radiologist's original impression, or correction of a technical error, such as the right or left side of the body.[14]

Allegations and Related Concerns

On August 17, 2018, the OIG received an anonymous complainant's allegations:

- Two patients experienced delays in treatment due to the actions of a radiologist who placed misleading addenda in radiology reports.
- The radiologist placed these addenda to cover gross errors.
- Leaders were aware and tolerant of the radiologist's behavior.

The OIG referred the allegations related to the subject radiologist, with an additional request for information on the radiology addenda process and facility reviews of the subject radiologist (OIG Hotline case referral), to facility leaders on September 4, 2018. A response was received on November 7. In their response, facility leaders did not substantiate that the subject radiologist falsified medical records (by placing misleading addenda) or that delays in patient care occurred.

The OIG determined VISN and facility leaders failed to conduct a thorough review and impartial analysis of the allegations. The process used by facility leaders risked the integrity of the review and risked identifying the complainant who requested anonymity. Therefore, the OIG initiated an inspection to review the allegations and address additional concerns based upon the facility's response:

- Radiology documentation in the EHR was not transparent and the process used to enter addenda was vulnerable to change (or manipulation).

- Changes to the initial level of peer reviews may avoid triggering necessary evaluation and monitoring.

- The process used by the VISN and facility to respond to the OIG Hotline case referral was not in compliance with the applicable VA Directive.[15]

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[14] Baccei, Steven, et al., "Reducing Radiology Report Addenda Using Provisionally Signed Status," *Journal of the American College of Radiology,* 12, No.1. (January 2015): 108–110. https://www.umassmed.edu/globalassets/radiology/radiology-addenda-item-15.pdf. (The website was accessed on March 11, 2019.)

[15] VA Directive 0701, *Office of Inspector General Hotline Complaint Referrals*, January 15, 2009.

During the inspection, the OIG team also identified issues with the management and impact of ongoing personnel conflicts within the Medical Imaging Service.[16]

Scope and Methodology

The OIG initiated the inspection on February 22, 2019, and conducted a site visit April 16–18, 2019.

The OIG team interviewed VISN and facility leaders as well as facility staff knowledgeable about the events under discussion.[17] The period of documents reviewed was July 2012 through April 2019. The team reviewed multiple and various documents, reports, policies and meeting minutes. The period for patient cases reviewed was July 2012 through January 2018. [18]

Within the context of this report, the OIG team defined "gross errors" as an error resulting in patients' increased risk for an adverse clinical outcome, such as death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level care resulting from or contributed to by medical care or services delivered by VA providers. The OIG recognizes that in addition to the potential for adverse clinical outcomes, avoidable delays in treatment associated with the deficiencies discussed in this report may impact the convenience and quality of care received by veterans. This report focuses on patient harm in terms of adverse clinical outcomes.

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[16] The OIG team received information regarding two cases that were outside the study period where the subject radiologist reportedly made diagnostic errors. The OIG determined that facility leaders were aware of these reported errors and planned to conduct a focused clinical care review of positron emission tomography-computed tomography readings completed by the subject radiologist.

[17] OIG interviewees included the VISN Deputy Chief Medical Officer, VISN Program Manager, Facility Director, Chiefs of Staff, Quality Management, Surgery, Medicine, and Emergency Department, Associate Chief of Staff, Medical Imaging Service Manager (Division Manager), Administrative Officer to the Chief of Staff, Medical Imaging Service administrative officer, staff radiologists, Medical Imaging Service staff supervisors, Risk Manager, PACS administrator, Medical Information Systems staff, and staff from the National Radiology Program Office.

[18] The documents the OIG team reviewed were relevant VA, VHA, and facility policies and procedures, EHRs, credentialing and privileging documents, VetPro documents, radiologist workload and number of radiology report addenda in the EHR by radiologists, case referral documents, radiologist ongoing professional practice evaluation documents, patient safety documents, peer review documents, peer review committee minutes, quarterly peer review reports, medical executive committee minutes, Medical Imaging Service needs assessment, VHA PACS information, All Employee Survey Scores, survey action plan, various emails related to inspection topics and select, relevant articles from medical literature. VHA Handbook 1100.19, *Credentialing and Privileging,* October 15, 2012. "VetPro is an internet-enabled data bank for the credentialing of VHA health care practitioners that facilitates completion of a uniform, accurate, and complete credentials file." Ongoing Professional Practice Evaluation is the on-going monitoring of privileged practitioners to confirm quality of care given. The VA All Employee Survey is done annually of the VA workforce experience. The data are anonymous and confidential.

In the absence of current VA or VHA policy, the OIG team considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

During the inspection, OIG team members identified concerns with manipulation and vulnerability of the EHR and management of the Medical Imaging Service. The OIG determined that the manipulation of the record was egregious and presented a significant impact for patient safety and quality of care. Therefore, this report first describes the inspection findings related to the integrity of the radiology reports in the EHR and management of the Medical Imaging Service. The allegations related to the subject radiologist are discussed second, followed by concerns related to the facility's response to the OIG Hotline case referral, and concludes with other issues associated with radiology addenda.

1. Radiology Report Manipulation and Vulnerability

The OIG team found no evidence that individual staff radiologists were able to alter the contents of original radiology reports in the EHR but did find evidence of manipulation of the EHR by the Medical Imaging Service Manager (Division Manager).[19] The OIG team found the Division Manager had an imaging staff member assist him in deleting a completed report in the EHR. The OIG discovered vulnerabilities in the EHR system related to deletion of records and lack of oversight and internal controls.

Inability of Staff Radiologists to Alter Original Reports

After reviewing information provided in the facility's response to the OIG Hotline case referral, the OIG team identified concerns that staff radiologists had the ability to make changes to their

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[19] The Division Manager is a radiologist who directly supervises all staff radiologists including the subject radiologist.

original reports by "un-verifying" radiology reports.[20] However, the OIG team determined that staff radiologists were unable to alter the content of the original radiology report.

When interviewed, the PACS administrator and staff radiologists indicated that once a radiology report is dictated and completed in the facility PACS software, the report is signed by the interpreting radiologist, and the report goes into a verified status.[21] When a radiology report has been verified, the only option available to a radiologist to add additional information is through the use of an addendum. The original content of the report is not available to the radiologist for editing. When a radiologist completes an addendum, the PACS software used to dictate radiology reports automatically adds it to the original report. A radiologist does not have the ability to independently un-verify a report, change the date or time stamp of the report outside of PACS, or delete a verified report.

Alteration of the EHR by Designated Administrative Staff

While staff radiologists could not un-verify a report, the OIG team learned through interviews, that the facility PACS administrator, designated radiology staff, biomedical engineering staff, and other VISN 12 facilities' PACS staff had the ability to un-verify a report and add, change, or delete information in the original radiology report. The PACS administrator is the primary go-to person for any questions or changes that need to be made to the report. Any changes or updates to the report are saved and can be accessed in VistA by special request through information technology staff. A provider reviewing EHR radiology report results will be unaware that a report was deleted and archived as there is no indication of the deletion in the EHR.

Manipulation of the EHR by Deletion of a Record

During interviews, the OIG team was told the PACS administrator deleted a completed and verified MRI report in August 2018 at the direction of the Division Manager. Reportedly, the deletion of the verified report allowed the subject radiologist to read the imaging study and document new results in the EHR. The report that had been originally read and verified by another staff radiologist was no longer visible in the EHR. There was no notation in the EHR that another radiology report for the same MRI had been read and the results documented but then deleted. VHA Handbook 1907.01 states, "[e]lectronically-signed documents may never be administratively deleted except under certain limited circumstances as designated by the Privacy Officer or HIM [health information management] professional."

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[20] When a report is in an un-verified status, changes can be made to the information in the radiology report.

[21] The software generates the term "verified" when the report has been signed off on as final by the radiologist. Per the Vista Activity Log, when the report is verified, the system automatically creates a date and time stamp on the report at the time of completion.

Medical Imaging Service staff told the OIG team that the subject radiologist confronted a staff radiologist actively reading an MRI study and asked the staff radiologist to stop the reading so that the subject radiologist could read the MRI. The subject radiologist was assigned to read MRI studies on the day in question. This resulted in a verbal disagreement between the subject radiologist and the staff radiologist. The staff radiologist completed the interpretation and verified a report indicating normal results.

To resolve this conflict, the Division Manager asked the PACS administrator to delete the staff radiologist's report and directed the subject radiologist to enter a different interpretation, thereby effectively manipulating the EHR. The Division Manager stated the report was deleted because the staff radiologist who read the MRI was not assigned to read MRI studies that day. The PACS administrator reported to the OIG team being uncomfortable with the deletion of the report, but complied because of the supervisory role of the Division Manager. The PACS administrator also said that although the report was deleted and replaced, the original report was archived, though not viewable in the EHR.

The ordering provider had read and acted on the original report prior to its deletion, including notifying the patient of the normal results and developing a plan of care. The initial MRI report and the second MRI report, which indicated abnormal results, provided contradictory information that prompted the ordering provider to contact the Division Manager. The OIG was informed that because of the discrepancy between the results provided by the staff radiologist and the subject radiologist, the Division Manager contacted a radiologist at an outside facility to review and provide an opinion on the MRI study. The opinion of the external consultant was that the staff radiologist's initial report with normal results was the correct reading. Prior to the resolution of the discrepancy in the two readings, the ordering provider put in a consult to a specialty provider. The patient was seen and assessed by the specialty provider, who performed a review of the MRI images, which was in agreement with the initial MRI report. Although it was determined that the initial MRI report was correct, the second report, which included an abnormal result, remained in the EHR. At the time of the OIG inspection, no addendum had been made to the imaging report available in the EHR to reflect the agreed upon impression.

The patient was notified of both normal and abnormal MRI results. The OIG team determined the patient had no delay in care or adverse clinical outcome as a result of the incorrect reading. The deletion of the MRI report, while a single reported event, was in violation of VHA policy and is indicative of how the EHR can be manipulated. The actions by the Division Manager, in response to a conflict involving the subject radiologist, resulted in manipulation of a patient's EHR, which had the potential to adversely affect the patient's care.

Vulnerability in the EHR

During the inspection and staff interviews, the OIG team discovered EHR vulnerabilities and lack of oversight and internal controls. As noted above, VHA Handbook 1907.01 states that only in limited circumstances can an electronically signed record be deleted, and that circumstance must be designated by the Privacy Officer or a health information management professional.

The PACS administrator has the ability to delete a radiology report. Eleven other staff members at the facility had the same access as the PACS administrator to the PACS system. Additionally, other PACS administrators within VISN 12 had access. Although deleted reports are archived, there is no process in place to know if a radiology report was deleted. Access to archived reports can only be made through a request to information technology staff. While not required by policy, there were no audits of deletions or modifications of radiology reports in the EHR or of the PACS administrator's work.

2. Management of Medical Imaging Service

Although not part of the original allegations, the OIG team determined that leaders at multiple levels failed to effectively manage the impact of interpersonal conflicts spanning more than five years within the Medical Imaging Service. The Joint Commission requires facility leaders maintain a culture of safety and quality because "disruptive behavior that intimidates others and affects morale or staff turnover can be harmful to patient care."[22] The ongoing interpersonal conflict between the Division Manager and the subject radiologist extended throughout the service. Medical Imaging Service staff reported that this conflict created a tense, uncomfortable work environment.

The OIG team also identified concerns related to

- Lack of facility leaders' follow-up of a needs assessment,
- Intimidation of medical staff,
- Low All Employee Survey scores within the Medical Imaging Service, and
- Interpersonal conflicts between Medical Imaging Service staff.

Needs Assessment

The OIG team determined that facility leaders failed to successfully follow up on recommendations made in a staff psychologist's July 2018 assessment of the Medical Imaging

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[22] The Joint Commission Standard LD 03.01.01 "Leaders create a culture of safety and quality throughout hospital." Schyve, Paul M, MD, "The Governance Institute," *Leadership in Healthcare Organizations, A Guide to Joint Commission Leadership Standards*, Page 20, Winter 2009.

Service. Leaders support successful patient outcomes through creation of a transparent and trusting environment that encourages staff to bring their concerns to management.[23] The OIG team noted that a lack of timely implementation of the staff psychologist's recommendations by the Division Manager and follow-up by facility leaders prevented needed improvements in the Medical Imaging Service.

As reported to the OIG, a facility staff psychologist was tasked by the Chief of Staff to assess the Medical Imaging Service to identify potential areas of improvement in communication, leadership, and teamwork within the service.[24] The assessment identified "unprofessional and ineffective communication, poor boundaries, lack of team cohesion, perceived inequities regarding workload distribution and leadership support, lack of personal accountability, and low morale."[25]

The needs assessment report was submitted to the Chief of Staff, Division Manager, and Medical Imaging Service staff, with recommendations to establish expectations for professionalism within the department and leadership coaching. A plan for intervention was to be developed through ongoing discussions with the Division Manager and Medical Imaging Service staff. The recommended discussions with the staff psychologist were suspended by the Division Manager in November 2018, reportedly due to the extended leave of two staff radiologists. The discussions had not been reimplemented as of December 30, 2019. The Chief of Staff stated in an interview with the OIG team that the process had been ongoing but had not followed up with the staff psychologist to see if anything further needed to be done.

Intimidation of Medical Staff

Facility medical staff bylaws acknowledge that unacceptable behavior, such as intimidation of staff, is detrimental to patient care.[26] During the on-site visit, the OIG team learned that on two occasions, staff radiologists felt pressure when the Division Manager instructed them to add addenda to radiology reports to update an interpretation made in the past by another staff radiologist. In one case, the staff radiologist acknowledged being directed as to specific details to include in the addendum and disagreeing with the interpretation documented in the addendum. The staff radiologists complied with the instructions, even when they disagreed, and did not escalate their concern.

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[23] VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value,* August 2, 2013.

[24] The Chief of Staff requested this assessment upon learning that issues in Medical Imaging Service previously identified remained unresolved.

[25] Department of Radiology Needs Assessment, July 2018.

[26] Facility Bylaws and Rules of the Medical Staff, February 2015.

The OIG team found intimidation was occurring in the Medical Imaging Service as evidenced by staff radiologists' statements that they felt pressure from the Division Manager to add radiology report addenda even when they disagreed with the interpretation and action.[27] This behavior has the potential to undermine the integrity of the EHR, erode trust with leaders, and compromise the independence of licensed providers.

Low All Employee Survey Scores

In interviews with facility leaders, the OIG learned that the Medical Imaging Service had among the lowest survey scores in the facility. Key signs of organizational health are employees' attitudes about the workplace, supervisors, and leaders. "Recent studies in healthcare indicate that managers can improve patient care experiences by improving employee satisfaction." In a review of October 1, 2017–September 30, 2018, survey scores, Medical Imaging Service scores for all elements were lower than VHA, VISN 12, and facility scores. The Medical Doctor/Nurse Practitioner workgroup was the least satisfied in the Medical Imaging Service.[28]

The Facility Director told the OIG team that there was not a specific solution to address low survey scores in Medical Imaging Service and attributed low scores to conflicts between the Division Manager and the subject radiologist. The Chief of Staff was also aware of the low scores and employee concerns in Medical Imaging Service. The OIG was informed that the Chief of Staff worked with the service's administrative officer to address concerns voiced by other radiology staff. The OIG concluded, based on interviews with the Facility Director and Chief of Staff, that addressing low survey scores was important and leaders should have an action plan in place to improve these scores. The Facility Director and Chief of Staff have instituted numerous facility-wide initiatives to improve employee engagement scores including expectations to share survey results with employees, develop action plans based on employee feedback, supervisory rounding with direct reports, and quarterly focus group meeting expectations. Facility leaders track department-level compliance and includes these expectations

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[27] "Intimidating and disruptive behaviors can foster medical errors, contribute to poor patient satisfaction and to preventable adverse outcomes, increase the cost of care, and cause qualified clinicians, administrators and managers to seek new positions in more professional environments. .... Intimidating and disruptive behaviors include overt actions such as verbal outbursts and physical threats, as well as passive activities such as refusing to perform assigned tasks or quietly exhibiting uncooperative attitudes during routine activities. Intimidating and disruptive behaviors are often manifested by health care professionals in positions of power. Such behaviors include reluctance or refusal to answer questions, return phone calls or pages; condescending language or voice intonation; and impatience with questions. (2) Overt and passive behaviors undermine team effectiveness and can compromise the safety of patients." The Joint Commission. *Behaviors that undermine a culture of safety*. Sentinel Event Alert Issue No. 40. Joint Commission. July 9, 2008. http://www.jointcommission.org/assets/1/18/SEA_40.PDF. (The website was accessed on October 16, 2019).

[28] For the All Employee Survey, workgroups may be defined as individuals who report to a given supervisor or who work together on a regular basis. The Medical Doctor/Nurse Practitioner workgroup for the Medical Imaging Service consisted of all the radiologists in the facility.

in the performance plans of department managers, including the Medical Imaging Service Manager. The Division Manager was unable to articulate specific actions that addressed the low satisfaction among the Medical Doctor/Nurse Practitioner workgroup and blamed the scores from that workgroup on the subject radiologist. The OIG team reviewed the Medical Imaging Service's action plan and found it lacked identifiable solutions to address areas of staff concern within the service, targeted goals, and a plan to monitor progress.

Interpersonal Conflicts

During the site visit, the OIG team learned of antagonistic interactions between the Division Manager and staff radiologists that caused tension throughout the Medical Imaging Service.

Facility medical staff bylaws recognize the impact of a provider's interactions with others on patient care and encourages providers to maximize patient safety through behaving in a professional manner.[29] Disruptive behavior interferes with the organization's ability to create a blame-free environment for discussing safety issues.[30] Although there is no standard definition of disruptive behavior, the Agency for Healthcare Research and Quality, when defining disruptive behavior, notes "… most authorities include any behavior that shows disrespect for others, or any interpersonal interaction that impedes the delivery of patient care."[31] The Agency for Healthcare Research and Quality further states "…workplace culture that tolerates demeaning or insulting behavior is likely to be one in which workers are "named, blamed and shamed" for making an error."[32] The OIG team considers that disruptive behavior, combined with a troubled workplace environment in the Medical Imaging Service, has the potential to negatively affect patient care.

The OIG team interviewed 14 Medical Imaging Service staff members who worked directly with the Division Manager. Eleven staff members expressed concerns related to interpersonal conflicts in the Medical Imaging Service, including

- Ongoing adversarial relationships between the Division Manager and staff radiologists that caused tension in the department,

- Strained relationships between staff radiologists that impacted service morale, and

- Frustrations with the Division Manager's management style.

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[29] Facility Bylaws and Rules of the Medical Staff.

[30] Agency for Healthcare Research and Quality, *Disruptive and Unprofessional Behavior*, January 2019, https://psnet.ahrq.gov/primers/primer/15/Disruptive-and-Unprofessional-Behavior. (The website was accessed on May 16, 2019.)

[31] Agency for Healthcare Research and Quality.

[32] Agency for Healthcare Research and Quality.

Staff reported the adversarial relationship between the Division Manager and the subject radiologist, both of whom remain employed at the facility, was long-standing, ongoing, and caused tension in the service. The Chief of Staff reportedly advised the Division Manager on multiple occasions how to manage the subject radiologist and coached the Division Manager on how to act appropriately as a leader. The OIG team reviewed numerous documents and correspondence over the last two years between multiple facility staff addressing this interpersonal conflict. During interviews with the OIG team, both the Chief of Staff and the Division Manager shared the opinion that the relationship between the Division Manager and the subject radiologist was beyond repair.

A July 2018 needs assessment by the staff psychologist included feedback that Medical Imaging Service staff perceived time that should be used for patient care was "wasted on interpersonal drama" and reported feeling "pulled or manipulated to take sides in conflict situations."[33] In addition to the needs assessment, the facility allocated other resources outside the Medical Imaging Service to address these issues, including fact-finding investigations, EEO complaints, administrative reviews, and the OIG Hotline case referral.

3. Alleged Gross Errors and Misleading Addenda

The OIG team did not substantiate the allegations that the subject radiologist made gross errors that resulted in treatment delays, placed misleading addenda in two patients' EHRs, and that leaders were tolerant of this practice.

The OIG team reviewed Patients 1 and 2's radiology reports and determined the addenda placed by the subject radiologist contained content consistent with VHA policy and facility radiologists' practice.[34] The review included errors by the subject radiologist identified in imaging reports on Patients 1 and 2, use of addenda within the Medical Imaging Service, and an assessment of the competence of the subject radiologist.

Alleged Errors in the Subject Radiologist's Reports

In mid-summer 2015, the subject radiologist read Patient 1's computed tomography angiogram of the chest and abdomen. The report by the subject radiologist did not note a coronary artery aneurysm that was subsequently found on a late summer 2015 angiogram by a different staff radiologist.

The subject radiologist read Patient 2's MRI of the pelvis in late 2016 and did not report a mass in the pelvic region. A subsequent MRI in early spring 2017, read by a different staff radiologist,

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[33] Department of Radiology Needs Assessment, July 2018.

[34] VHA Handbook 1907.01 allows for the use of addenda as needed.

found evidence of a soft tissue mass that was suspicious for a recurrence of a leiomyosarcoma that was not reported in the subject radiologist's late 2016 report. A biopsy confirmed the diagnosis of a recurrent leiomyosarcoma in early spring 2017.

To determine if either patient experienced delays that contributed to adverse clinical outcomes, the OIG team conducted interviews with facility leaders, Medical Imaging Service staff, and reviewed patients' EHRs. The OIG team determined the care and clinical outcomes of Patients 1 and 2 were not adversely affected by the findings missed by the subject radiologist in their imaging exams.

Addenda Use

The subject radiologist's use of addenda in the radiology reports for both patients was within VHA guidelines.[35] VHA allows the addition of addenda to radiology reports when it is necessary to clarify or add information to the original documents.[36] In interviews, staff radiologists at the facility confirmed a practice of using addenda to add to or clarify information not included in the original radiology report.

After the discovery of the coronary artery aneurysm in Patient 1's August 2015 angiogram, the subject radiologist added the following addendum to the July 2015 report:

> Case reviewed. Small left coronary artery aneurysm that has increased in size on the current study of 08/25/2015. Clinical service aware.

Although worded differently than the findings in the August 2015 angiogram, the July 2015 report addendum added information regarding the subsequent findings of a coronary artery aneurysm and did not change the final impression of the original report.

Patient 2's December 2016 MRI report addendum, entered by the subject radiologist, addressed findings without altering the initial impression:

> Case reviewed. Soft tissue density in the location of the right sciatic nerve presumed secondary to posttreatment change.

The OIG team determined the addenda for Patients 1 and 2 contained content that was in alignment with VHA guidelines and provided updated clinical information.[37] The OIG found no indication that these addenda were entered to mislead the reader or cover up for errors as the subject radiologist did not alter the original impression.

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[35] VHA Handbook 1907.01.

[36] VHA Handbook 1907.01.

[37] VHA Handbook 1907.01

Competence and Leaders' Alleged Tolerance of Poor Practice

The two patient cases provided the OIG with a limited review of the subject radiologist's work. To ensure patients are cared for by qualified professionals, VHA's credentialing and privileging process includes monitoring and surveillance of the professional competence of staff who provide patient care services at the facility.[38] The OIG team reviewed the subject radiologist's October 2016–September 2018 credentialing and privileging file to determine if the facility had previously identified concerns related to competence. The subject radiologist met performance expectations with no concerns identified related to clinical competence.

A review of the professional competence of a provider is completed on a semiannual basis through the ongoing professional practice evaluation process.[39] Measures of competency evaluated can be used to identify practice trends that impact quality of care. Ongoing professional practice evaluations include reviews of clinical procedures, EHR reviews, direct observation, and monitoring of diagnostic and treatment techniques.[40] Facility leaders are responsible for evaluating and acting upon concerns identified during the process.[41]

If concerns with a provider's competence are identified, a non-protected management review is initiated by the service chief and findings from the review are integrated into a service-specific performance improvement plan.[42] When a service chief cannot determine competence of the provider during this process, several options exist within the facility medical bylaws. At the facility, during the time frame at issue, these options included extending the time of the management review, modifying the criteria, or terminating some or all of the provider's privileges.[43]

When interviewed by the OIG team, the Chief of Staff had no concerns with the competency of the subject radiologist. The OIG team found no evidence that the ongoing professional practice evaluation triggered non-protected management reviews, modifications or changes to the subject radiologist's privileges, or requests for professional practice investigations.

The OIG did not substantiate that the errors made by the subject radiologist were gross errors that delayed treatment in such a way as to adversely impact patient outcomes or that the subject

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[38] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. Credentialing refers to the process of screening and evaluating a provider's qualifications and credentials, such as license, education, and experience. Privileging is the process by which a licensed provider is permitted by law and the facility to independently practice and provide specialized patient care within the scope of their license.

[39] VHA Handbook 1100.19. VHA defines "competency" as "demonstration of an individual having the requisite or adequate abilities or qualities capable to perform up to a defined expectation."

[40] Facility Medical Center Memorandum 11-84, *Credentialing and Privileging*, February 2017.

[41] Facility Medical Center Memorandum 11-84.

[42] Facility Bylaws and Rules of the Medical Staff.

[43] Facility Bylaws and Rules of the Medical Staff.

radiologist used addenda to cover up errors. Therefore, the allegation of leaders' tolerance of this behavior was also not substantiated.

4. Modifications Made to Peer Review Levels

The OIG team determined that changes made by the peer review committee (committee) to the initial levels of care assigned to the subject radiologist's peer reviews for Patients 1 and 2 were not an attempt to avoid triggering further evaluation and monitoring of the radiologist. During the period of this review, the subject radiologist had four peer reviews presented to the committee, two of which had the levels reduced. The changes were made in accordance with the committee process, and the OIG team determined the final levels assigned to Patients 1 and 2 were reasonable. In addition, the OIG team determined that regardless of the reduction in assigned initial peer review levels, the subject radiologist did not meet facility-established triggers for non-protected management reviews or additional interventions.

Peer review for quality management is a non-punitive process to evaluate the quality of care provided at VA medical facilities.[44] This type of review is not used for administrative personnel actions and is confidential and protected from disclosure outside of the quality management process.[45] Peer review for quality management can provide immediate or long-term improvements in care that contribute to organizational improvements and better patient outcomes.[46]

VHA requires the initiation of a peer review when specific concerns about a provider's quality or appropriateness of care are identified, or when patients experience negative or unexpected outcomes. The peer review process starts with an initial review of the episode of care completed by a health care provider who has comparable education, training, experience, licensure, clinical privileges, or scope of practice as the provider being reviewed. The reviewer assigns a "level of care" based on their assessment of the provider's clinical decisions and quality of care provided.

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[44] VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. This directive was in effect during the time of the events discussed in this report but has been rescinded and replaced with VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. In the 2018 directive, Level 2 is defined as "… most experienced and competent clinicians might have managed the case differently, but it remains within the standard of care." Updates made in the 2018 directive do not contain substantive changes from the previous directive in requirements that affect issues discussed in this report.

[45] Federal law provides confidentiality for records and documents created as part of VHA's medical quality assurance program in 38 U.S.C. § 5705, *Confidentiality of Medical Quality-Assurance Records,* and its implementing regulations 38 C.F.R. §§ 17.500–17.511. This program includes systematic health care reviews carried out by or for VHA for the purposes of improving the quality of medical care. The peer review process is part of VHA's medical quality assurance program and, as such, documents generated through its processes are confidential and privileged. VHA Directive 1190.

[46] VHA Directive 2010-025.

The following levels of care are used by the initial reviewer and in evaluation and discussion of the initial review by the committee:[47]

- Level 1: "most experienced, competent practitioners would have managed the case in a similar manner"

- Level 2: "most experienced and competent clinicians might have managed the case differently"

- Level 3: "most experienced, competent practitioners would have managed the case differently"

The committee may choose to maintain, decrease, or increase the level of care assigned by the initial reviewer. The provider under review is invited to provide a written response to issues identified during the initial review if it is given a level 2 or 3. The provider may also choose to appear before the committee prior to a committee decision on a final level of care. In the event of a final level of 2 or 3, the committee may provide specific recommendations for improving the providers clinical practice. The provider's supervisor is responsible for confidential communication of the results of the final committee decision, along with any appropriate follow-up needed.[48]

A facility staff member reported that while some changes were made to initial peer review level of care assignments, it was usually decreased. Facility staff were not aware of trends or patterns in peer review level changes by the committee.

When interviewed, staff stated there are defined criteria for triggering non-protected management reviews of provider care when concerns are identified during the peer review process. During the period of time the events discussed in this report occurred, the 2013 version of the facility's policy, *Peer Review for Quality Management*, was updated with a 2017 version.[49] As a result of the update, the policies contained different criteria for triggering non-protected management reviews (see table 1). According to VHA and facility policies, a review would be initiated if a provider met the trigger criteria in a successive 12-month period.[50]

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[47] VHA Directive 2010-025.

[48] VHA Directive 2010-025.

[49] Facility Memorandum, *Peer Review for Quality Management*, July 2013. Facility Memorandum, *Peer Review for Quality Management*, April 2017.

[50] VHA Directive 2010-025. "Non-protected" reviews include activities such as management reviews and administrative investigations and are not protected under 38 U.S.C. § 5705. These types of reviews may be used for actions that may affect personnel status or clinical privileges. Facility Memorandum, *Peer Review for Quality Management*, July 2013. Facility Memorandum, *Peer Review for Quality Management*, April 2017.

Table 1. Criteria for Triggering Non-Protected Reviews

Facility Memorandum, *Peer Review for Quality Management*, July 2013	Facility Memorandum, *Peer Review for Quality Management*, April 2017
Two peer review level 3 final committee assignments	Two peer review level 3 final committee assignments
Three level 2 and one level 3 final committee assignments	Three level 2 final committee assignments
Four level 2 final committee assignments	Four level 2 final committee assignments

Source: OIG analysis and comparison of 2013 and 2017 facility memorandums

The subject radiologist had peer reviews for both patients identified in the allegation presented to the committee between October 2015 and April 2019.

The OIG team conducted an in-depth EHR review of the care provided to both Patient 1 and 2 and determined the final peer review levels assigned to both cases by the committee were reasonable.

5. VISN and Facility's Response to the OIG's Hotline Case Referral

The OIG team determined that VISN and facility leaders failed to conduct a thorough and impartial oversight review as required by the VA Directive noted in the OIG Hotline case referral directions.[51] The investigation process used by facility leaders risked the integrity of the review and risked identifying the complainant who requested anonymity. The OIG requested the facility review the complaint alleging that the subject radiologist falsified the medical records of Patients 1 and 2 and provide the OIG with information on peer reviews and radiology addenda. In November 2018, the OIG received the response from the VISN which concluded the allegation that EHRs were falsified was unsubstantiated. During review of the response, the OIG team identified concerns related to the investigation process, protecting the anonymity of the complainant, and VISN oversight.

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[51] VA Directive 0701 states. "Case referrals are reviewed and reported back to the OIG in accordance with this directive..." When the OIG receives a hotline complaint, the allegations are reviewed and, if determined necessary, relevant information is forwarded to VHA for VISN and facility leaders' review and response. For confidential or anonymous complainants, the OIG protects the identity of the complainant. The directive requires that VHA responses include "[e]vidence of an independent review by an official separate from and at a higher grade than the subject/alleged wrongdoer." Additionally, facility leaders "who receive hotline case referrals should not attempt to identify the complainant."

Facility's Investigation Process

The OIG team found the facility did not provide evidence of a thorough review of the allegation that the subject radiologist falsified medical records to cover gross errors. VA Directive 0701 requires that VA facilities and program offices conduct an independent review of the allegations by an official "separate from and at a higher grade than the subject/alleged wrongdoer."[52] As a part of the facility's investigation, the Chief of Staff engaged a number of staff in varied positions and pay grades, including the alleged wrongdoer, to gather information in response to the allegation.

The OIG was informed that the Division Manager, an official at a higher grade than the alleged wrongdoer, was asked to review the cases of Patients 1 and 2, to include the use of addenda in the radiology reports, and provide a written summary of findings. The Division Manager was also asked to provide information regarding peer reviews specific to the subject radiologist. The Division Manager complied with these requests; however, the Chief of Staff reported choosing not to include the Division Manager's conclusions in the facility's response that was subsequently submitted to the OIG. When asked why this material was excluded from the facility response, the Chief of Staff stated that the Division Manager's conclusions regarding the use of addenda in the radiology reports of Patients 1 and 2 reflected a difference in clinical opinion and did not support the allegation of falsification of medical records.

The only evidence in the response submitted to the OIG to support facility leaders' determination that the allegation of EHR falsification was unsubstantiated was provided by the subject radiologist. The Chief of Staff reported acting independently in making the decision to exclude the higher-grade official's statement from the facility's response.

By only using information obtained from the subject of the hotline case referral, facility leaders failed to provide the OIG with a review conducted by an official separate from and at a higher grade than the alleged wrongdoer, which did not comply with VA Directive.[53]

Anonymity of Complainant

In interviews with the OIG, the Chief of Staff reported sharing details from the anonymous complainant's allegations with the subject radiologist to allow the subject radiologist to provide input and a defense. In responding to the allegations, the subject radiologist wrote that while the complainant chose to remain anonymous, there was only one individual who had knowledge of both patient cases since they went through the confidential peer review process. The subject radiologist identified an individual by name. The OIG team determined that when the Chief of

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[52] VA Directive 0701.

[53] VA Directive 0701.

Staff shared the allegations with the subject radiologist, the anonymity of the complainant may have been jeopardized.

VISN Oversight

VA Directive requires VA officials, to include those at the VISN, to ensure a proper review of hotline complaints referred to them by the OIG.[54] VISN 12 also received the OIG Hotline case referral and directed the facility to draft a response. The VISN directed the facility to look into the allegations, provide a written summary of findings, and provide a draft response to the VISN for review. The VISN did not provide guidance to the facility about how to conduct the investigation when the referral was received. Facility leaders sent their response to the VISN for review. A VISN staff member reported that the VISN adopted the facility response and forwarded it to the OIG without changes. Facility leaders stated no discussion occurred between the VISN and facility surrounding the subject radiologist responding to the allegations prior to the submitted response. The OIG team determined that VISN staff did not provide proper oversight when they failed to ensure that the facility's response was based on an investigation performed in accordance with VA Directive.

6. Other Issues: Addenda Format, Placement, and Transparent Communication

During review of the radiology reports of Patients 1 and 2, the OIG team discovered the note titles and location of addenda within radiology reports may make the additional information difficult for clinicians who were not familiar with the configuration to find in the EHR.

According to the manager of clinical informatics and medical technology, it is common within VHA for the EHR clinical notes with addenda to have "Addendum to…" inserted in advance of the original note title (see figure 1). Amended radiology reports retain the original note title (see figure 2).

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[54] VA Directive 0701.

Figure 1. CPRS Clinical Note list example
Source: OIG EHR review and analysis

Figure 2. CPRS Radiology Report list example
Source: OIG EHR review and analysis

Unlike other clinical notes in the facility EHR, where the addenda have an amended note title, the only notation to indicate that addenda have been added to a radiology report is made within the report itself, and not the note title (see figure 3). Amended radiology reports contain the statement "***THIS IS AN AMENDED REPORT***" at the top of the body of the report (see figure 4).

Figure 3. CPRS Note Addendum example
Source: OIG EHR review and analysis

Addenda for non-radiology reports are located after the original note, signatures, and date (see figure 3). The addenda made to radiology reports are located within the body of the report just prior to the radiologist's impression (see figure 4).
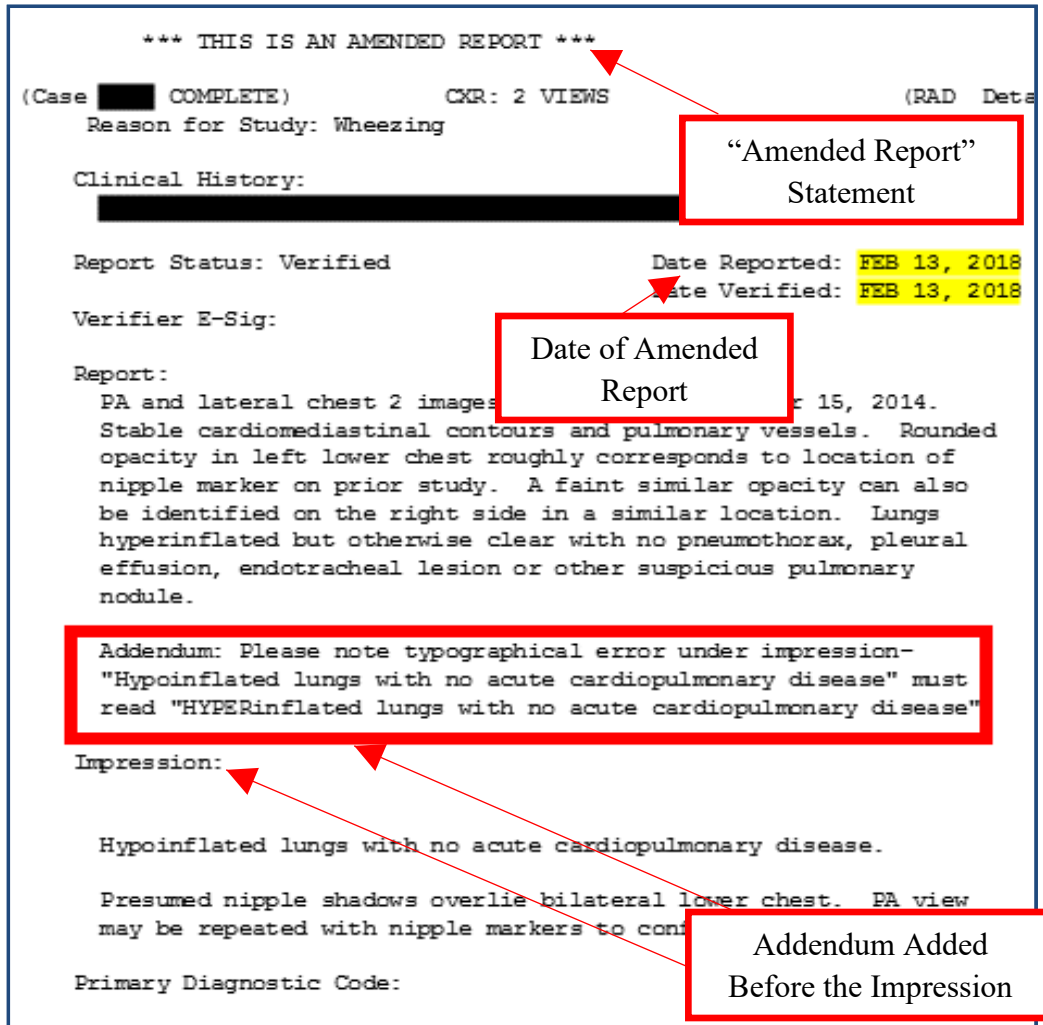
Figure 4. Facility Radiology Report with an Addendum
Source: OIG EHR review and analysis

In addition to the variations described above, the OIG team learned that additions of addenda to radiology reports replace the original verification date/time stamp with the date of the addendum (see figure 4). Once an addendum is added, a provider reviewing the report is unable to determine the date/time the report was originally verified without the help of information technology staff or requesting higher access.

The OIG team was told on-site that when an addendum is added to a radiology report, a CPRS view alert stating "Imaging Results Amended" is automatically sent to the ordering provider as a mandatory alert notification.[55] In addition to this alert, radiologists reported they usually notify

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[55] Mandatory notifications cannot be turned off by ordering providers.

the ordering physician of changes or have already spoken with them about the change prior to entering the addendum.

The OIG team concluded that the multiple variations in the format of radiology reports, in comparison to other clinical notes/reports in the EHR, may pose a challenge for clinicians who are unfamiliar with the layout of a radiology report when navigating a patient's EHR. Additionally, the inability to see the original verification date/time stamp may pose a challenge for clinicians to track the timeline of care in the EHR. While these challenges may make communication of clinical information more difficult, the OIG team did not find a lack of transparency in the presentation of the information.

VHA Knowledge of the Issue

Due to OIG concerns with the location of addenda in radiology reports and conversion of the original date to the addended date, the OIG team interviewed staff from the National Radiology Program Office to determine if the addenda format used at the facility is used throughout VHA and if concerns with the layout had been reported. The OIG learned the location of addenda in the radiology report varied throughout VHA facilities and was dependent on the type of PACS and dictation software used and how it was configured with VistA Imaging and CPRS. National Radiology Program Office staff stated that each medical center in a VISN typically used the same PACS software.

Through an interview with the National Radiology Program Office, the OIG team learned that staff at the Columbia VA Health Care System (HCS), South Carolina, reported the same issue to the National Radiology Program Office regarding possible confusion with addenda placement in radiology reports in 2017. Columbia VA HCS staff were concerned that an addendum inserted in the middle of the report, before the impression section, might confuse providers reading the report, especially when multiple addenda were added. In response to this concern, staff at the National Radiology Program Office instructed radiology service staff at the Columbia VA HCS to electronically submit a New Service Request.[56] According to a staff radiologist at the Columbia VA HCS, a request had been entered. Email correspondence related to the topic was reviewed by the OIG team. The email included a ticket number for a request but lacked specifics regarding the content of the request. Further, VA Radiology programmers were unable to find a New Service Request with the corresponding ticket number in the database used to track VistA Radiology Package changes that were needed. However, the programmers did identify a ticket with that number in another database used by the Office of Information and Technology that

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[56] VHA defines a New Service Request as, "New Service Requests are requests for products, product enhancements, and changes to information systems that the Office of Information and Technology maintains." Facility leadership stated that Requirements Development and Management staff support the request process and maintain a central repository for all New Service Requests.

cannot be accessed by National Radiology Program Office staff, therefore no action had been taken by National Radiology Program Office staff to address the concerns at the time of the OIG's inspection. In the process of researching this ticket, the National Radiology Program Office staff identified an opportunity to provide clarification to the field on the proper submission of National Service Requests to ensure they are entered into the proper database that would result in action.

Conclusion

The OIG determined that there was evidence of EHR manipulation by the Division Manager. Interpersonal conflicts between a staff radiologist and the subject radiologist led the Division Manager to direct the PACS administrator to delete a completed and verified MRI report. This MRI study was previously read by another staff radiologist (with a normal result). Against VHA guidelines, the report was deleted enabling the subject radiologist to read the imaging study and enter a new radiology report into the EHR (with an abnormal result). Subsequently, an external radiologist reviewed the disputed study and agreed with the initial interpretation of normal results. The patient and primary care provider were informed of both the normal and abnormal results; the patient received appropriate care and treatment.

Facility leaders at multiple levels failed to manage or address the impact of ongoing identified interpersonal conflicts within the Medical Imaging Service. The OIG team found that facility leaders did not follow up on recommendations made in a staff psychologist's assessment of the Medical Imaging Service.

Staff radiologists reported feeling pressure to comply with instructions given by the Division Manager to add addenda in radiology reports. The radiologists complied with the instructions, even when they disagreed, and did not escalate their concerns.

Although low All Employee Survey scores in the Medical Imaging Service identified ongoing departmental issues, the service's action plan lacked identifiable solutions to improve areas of staff concern within the department, targeted goals, and a plan to monitor for progress.

Antagonistic interactions between the Division Manager and the subject radiologist caused tension throughout the Medical Imaging Service and created a tense, uncomfortable work environment. The OIG team is concerned that ongoing interpersonal conflicts, coupled with the lack of defined plans for resolution or improvement, have the potential to adversely affect patient care.

With respect to the allegations from the anonymous complainant, the OIG team did not substantiate that the subject radiologist made addenda to cover gross errors that resulted in delays in treatment and contributed to adverse clinical outcomes for two specific patients. While the subject radiologist updated the original readings, the OIG team found no evidence that the

outcome of either patient's treatment would have changed if these findings were reported in the original imaging results. The OIG team did not substantiate that the subject radiologist's use of addenda was misleading in these cases. The subject radiologist's use of addenda in both radiology reports was within VHA guidelines. The OIG team found no evidence the subject radiologist failed to meet acceptable levels of performance.

The OIG team determined that peer reviews of the subject radiologist were performed in accordance with VHA policy. The OIG team determined that VISN and facility leaders failed to conduct a thorough and impartial oversight review per VA requirements in their response to the OIG Hotline case referral. The investigation process used by facility leaders risked the integrity of the review and risked identifying an anonymous complainant. The Chief of Staff independently decided to allow the subject radiologist to review and respond to the allegations.

The variations in the format of radiology reports, in comparison to other clinical notes/reports in the EHR, may pose a challenge for clinicians who are unfamiliar with the layout of a radiology report. While this may make communication of clinical information more difficult, the OIG team did not find a lack of transparency in the presentation of the information. Addenda location within the radiology report is based on software configuration and cannot be manipulated by individual radiologists. In an attempt to bring this issue to the attention of the National Radiology Program Office, staff mistakenly entered the request into a database used by the Office of Information and Technology that could not be accessed by National Radiology Program Office staff. Therefore, no action had been taken by National Radiology Program Office staff to address the concern at the time of the OIG's inspection.

Recommendations 1–8

1. The Under Secretary for Health ensures that the planning and implementation of the new electronic health record includes a process for addenda insertion, deletion, and consistent formatting for radiology reports.[57]

2. The Under Secretary for Health reviews Veterans Health Administration policy related to management of health information in the electronic health record, evaluates the circumstances that led to the Division Manager's decision to direct the deletion of a completed and verified imaging report, and takes action, as indicated.

3. The Clement J. Zablocki VA Medical Center Director ensures a review of the radiology report for the patient with conflicting imaging study results and confirms that the most accurate impression is evident in electronic health record.

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[57] The recommendation directed to the Under Secretary for Health was submitted to the Executive in Charge who has the authority to perform the functions and duties of the Under Secretary for Health.

4. The Veterans Integrated Service Network Director reviews access, management, and the Veterans Integrated Service Network oversight of the Clement J. Zablocki VA Medical Center picture archiving and communication system practices, and takes action to remedy issues identified during the review, as indicated.

5. The Clement J. Zablocki VA Medical Center Director reviews the oversight and management of the Medical Imaging Service, confers with human resources, makes recommendations for improvement as indicated, and monitors progress.

6. The Clement J. Zablocki VA Medical Center Director completes an evaluation of the Medical Imaging Service's culture, morale, and team cohesion, develops an action plan for improvement, and monitors progress.

7. The Clement J. Zablocki VA Medical Center Director evaluates the need for Medical Imaging Service staff to receive training on workplace intimidation and the process for employee reporting of concerns, and takes actions, as indicated.

8. The Veterans Integrated Service Network Director makes certain that future hotline case referrals are investigated in accordance with Veterans Affairs policy related to Office of Inspector General Hotline complaint referrals, and provides oversight of facility responses.

Appendix A: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: February 21, 2020

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, Manipulation of Radiology Reports and Leadership Failures in the Medical Imaging Service at Clement J. Zablocki VA Medical Center - Milwaukee, Wisconsin (VIEWS 02408863)

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Manipulation of Radiology Reports and Leadership Failures in the Medical Imaging Service at Clement J. Zablocki VA Medical Center - Milwaukee, Wisconsin. Attached are the action plans which address recommendations 1 and 2. Comments in response to recommendations 3-8 are also attached and have been provided by the Acting Director, Great Lakes Health Care System and Director, Clement J. Zablocki VA Medical Center.

2. The Veterans Health Administration (VHA) National Radiology Program Office (NRPO) is highly involved with the modernization initiative that establishes an integrated clinical service line which creates common structures, roles, and responsibilities within Radiology and Nuclear Medicine Services, Veteran Integrated Service Networks, and VHA Central Office. These actions will improve communication and implementation of policy and guidance. NRPO is actively working to configure and optimize the new electronic health record to create efficiencies and improve processes.

3. I am pleased that the OIG team found that the patient received appropriate care and treatment. VHA plans to evaluate the circumstances that led to the decision to direct the deletion of a completed and verified imaging report and may assess the organizational culture and conditions which contributed to the situation.

4. If you have any questions, please email Karen Rasmussen, M.D., Director for GAO-OIG Accountability Liaison at VHA10EGGOALAction@va.gov.

(*Original signed by:*)
Richard A. Stone, M.D.
Attachments

Under Secretary for Health Response

Recommendation 1

The Under Secretary for Health ensures that the planning and implementation of the new electronic health record includes a process for addenda insertion, deletion, and consistent formatting for radiology reports.

Concur.

Target date for completion: November 2020

Under Secretary for Health Comments

The Veterans Health Administration (VHA) National Radiology Program Office (NRPO) in collaboration with the Office of Electronic Health Records Modernization (OEHRM) will work closely to identify and implement a process for addenda insertion, deletion, and consistent formatting for radiology reports. NRPO has initiated the collaboration with OEHRM.

Recommendation 2

The Under Secretary for Health reviews Veterans Health Administration policy related to management of health information in the electronic health record, evaluates the circumstances that led to the Division Manager's decision to direct the deletion of a completed and verified imaging report, and takes action, as indicated.

Concur.

Target date for completion: June 2020

Under Secretary for Health Comments

The Veterans Health Administration (VHA) National Radiology Program Office in collaboration with the Veterans Integrated Service Network (VISN) and Medical Center Director will evaluate imaging policies/procedures and provide guidance for imaging and report correction processes within the electronic health record.

VHA's Office of Workforce Management will work in collaboration with the VISN and Medical Center Director to evaluate the circumstances that led to the decision making and determine if administrative actions should be taken.

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: February 11, 2020

From: Acting Director, VA Great Lakes Health Care System (10N12)

Subj: Healthcare Inspection—Manipulation of Radiology Reports and Leadership Failures in the Medical Imaging Service at the Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin

To: Director, Office of Healthcare Inspections (54HL05)
         Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Healthcare Inspection-Manipulation of Radiology Reports and Leadership Failures in the Medical Imaging Service at the Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin.

2. Regarding recommendation 8, the VISN has a standardized process that ensures hotline case referrals are investigated in accordance with VA Directive 0701 however, this process was deviated from in this instance at the VISN office. VISN 12 would like to emphasize that re-education on the process and on requirements for VA Directive 0701 has occurred with Medical Center Directors, Performance Improvement Chiefs and VISN 12 administrative staff.

3. The VISN Acting Quality Management Officer can be contacted at 708-492-3900 if there are additional questions or if further clarification is needed.[1]

(*Original signed by:*)
Shavetta R. Williams
Acting Director, VA Great Lakes Health Care System (10N12)

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[1] For privacy, the phone extension was changed for the public report.

VISN Director Response

Recommendation 4

The Veterans Integrated Service Network Director reviews access, management, and the Veterans Integrated Service Network oversight of the Clement J. Zablocki VA Medical Center picture archiving and communication system practices, and takes action to remedy issues identified during the review, as indicated.

Concur.

Target date for completion: November 30, 2020

Director Comments

The Veterans Integrated Service Network (VISN) Director will create a Standard Operating Procedure (SOP) document to address alteration of medical imaging reports and/or images, based on the requirements found in VHA Handbook 1097.01 [1907.01]. The SOP will address appropriate access, the management and oversight reviews of the Clement J Zablocki VA Medical Center's picture archiving and communication system practices. The Veterans Integrated Service Network (VISN) Director will take action to remedy issues identified during any of the oversight reviews. The SOP will include the requirement that if any report is deleted or modified after it has been verified, the Chief or Supervisory Technologist, QA [Quality Assurance] Technologist or PACs Administrator who has access to these keys will notify the HIMS [Health Information Manager] and/or Privacy Officer, and notify the ordering provider of the change, so that appropriate modifications can be made as necessary to the patient's management. Also, the SOP will include that notification of the ordering provider will occur verbally and at the time the modification or deletion is determined to be warranted. This communication will be documented in writing at the time the modification is made by a note in CPRS that describes what modification was made, and the ordering provider will be added as a co-signer. In order to ensure oversight of this process, the spreadsheet data of this process will be forwarded to and reviewed at the VISN 12 Radiology Steering Committee meetings on a bimonthly basis by the Clement J Zablocki VA Medical Center. Education on the SOP to the Clement J Zablocki VA Medical Center's Radiology Service Chief will occur at the VISN 12 Radiology Steering Committee meeting. The VISN 12 Radiology Steering Committee meeting will monitor any deleted or reported reports for compliance with the SOP for 6 consecutive months.

Recommendation 8

The Veterans Integrated Service Network Director makes certain that future hotline case referrals are investigated in accordance with Veterans Affairs policy related to Office of Inspector General Hotline complaint referrals, and provides oversight of facility responses.

Concur.

Target date for completion: March 31, 2020

Director Comments

The Veterans Integrated Service Network (VISN) Director would like to report that the standardized process that ensures hotline case referrals are investigated in accordance with VA Directive 0701, was deviated from in this instance and we would like to emphasize that re-education on the process and on requirements for VA Directive 0701 has occurred with Medical Center Directors, Performance Improvement Chiefs and VISN 12 administrative staff. A VISN 12 Standard Operating Procedure (SOP) will be created that includes the requirements of VA Directive 0701 and assigns responsibility for appropriate review, approval and submission of Office of Inspector General Hotline complaint referrals in VISN 12. This includes the oversight of facility responses. All staff in VISN 12 with responsibilities in the SOP for Office of Inspector General Hotline complaint referrals will be educated on the requirements.

Appendix C: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: February 4, 2020

From: Director, Clement J. Zablocki VA Medical Center (695/00)

Subj: Healthcare Inspection—Manipulation of Radiology Reports and Leadership Failures in the Medical Imaging Service at the Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin

To: Acting Director, VA Great Lakes Health Care System (10N12)

1. I have reviewed the draft report of the Office of Inspector General's Manipulation of Radiology Reports and Leadership Failures in the Medical Imaging Service at the Clement J. Zablocki VA Medical Center. We concur with all recommendations.

2. Please see the attached response to the recommendations identified in the review.

3. I appreciate the opportunity for this review as a continuing process to improve care to our Veterans.

4. If additional information is needed, please contact our Quality Manager at 414-384-2000[1]

(*Original signed by:*)
Daniel S. Zomchek, Ph.D., FACHE
Medical Center Director

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[1] For privacy, the phone extension was changed for the public report.

Facility Director Response

Recommendation 3

The Clement J. Zablocki VA Medical Center Director ensures a review of the radiology report for the patient with conflicting imaging study results and confirms that the most accurate impression is evident in electronic health record.

Concur.

Target date for completion: March 31, 2020

Director Comments

The Clement J. Zablocki VA Medical Center Director will direct Quality Management to coordinate an external review of the conflicting imaging study with the VISN 12 Radiology Lead to recommend to the facility Chief of Staff (COS) which impression should be included in the electronic health record. The COS will facilitate the implementation of any changes in accordance with VHA Handbook 1907.01.

OIG Comment

The OIG considers this recommendation open to allow the submission of documentation to support closure.

Recommendation 5

The Clement J. Zablocki VA Medical Center Director reviews the oversight and management of the Medical Imaging Service, confers with human resources, makes recommendations for improvement as indicated, and monitors progress.

Concur.

Target date for completion: April 30, 2020

Director Comments

The Clement J. Zablocki VA Medical Center Director, in consultation with human resources, will coordinate an external management review of the oversight and management of the Medical Imaging Service. Any resulting actions will be included in an action plan and will be followed to completion.

OIG Comment

The OIG considers this recommendation open to allow the submission of documentation to support closure.

Recommendation 6

The Clement J. Zablocki VA Medical Center Director completes an evaluation of the Medical Imaging Service's culture, morale, and team cohesion, develops an action plan for improvement, and monitors progress.

Concur.

Target date for completion: June 15, 2020

Director Comments

Upon completion of the management review and resulting actions from Recommendation 5, the Clement J. Zablocki VA Medical Center Director will engage the facility Equal Employment Opportunity Program Manager to conduct a Climate Survey and Assessment of the Medical Imaging Service. The results of the assessment will drive the development of an action and monitoring plan for improvement of culture, morale, and team cohesion. The action plan will be followed until completion.

Recommendation 7

The Clement J. Zablocki VA Medical Center Director evaluates the need for Medical Imaging Service staff to receive training on workplace intimidation and the process for employee reporting of concerns, and takes actions, as indicated.

Concur.

Target date for completion: March 31, 2020

Director Comments

The Clement J. Zablocki VA Medical Center Director, in consultation with the facility Lead Psychologist and Equal Employment Opportunity Program Manager, will identify and conduct appropriate training for the Medical Imaging Service supervisory and non-supervisory staff on workplace intimidation and the process for employee reporting of concerns.

OIG Comment

The OIG considers this recommendation open to allow the submission of documentation to support closure.

Glossary

aneurysm. A weakening of an artery wall that allows the artery to balloon out or widen abnormally.[1]

computed tomography. An imaging procedure that uses a series of x-rays taken from different angles of the body and uses a computer to create cross-sectional images (slices) of the bones, blood vessels and soft tissues inside the body. Computed tomography scan images are more detailed than regular x-rays.[2]

impression. The radiologist combines the findings, patient clinical history and indication for the imaging study and provides a diagnosis.[3]

Leiomyosarcoma. A type of cancer that affects the smooth muscle of the body. Leiomyosarcoma tumors most commonly occur in the abdomen.[4]

MRI. A type of noninvasive imaging technology that uses a magnetic field and radio waves to create a detailed image of the organs and tissues in the body.[5]

ultrasound. An imaging study that uses sound waves to produce pictures of the inside of the body.[6]

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[1] What is an aneurysm? American Heart Association website. https://www.heart.org/en/health-topics/aortic-aneurysm/what-is-an-aneurysm. (The website was accessed on June 13, 2019.)

[2] Computed tomography scan. Mayo Clinic website. https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675. (The website was accessed on June 13, 2019.)

[3] How to Read Your Radiology Report. Radiological Society of North America. https://www.radiologyinfo.org/en/info.cfm?pg=article-read-radiology-report. (The website was accessed on June 6, 2019.)

[4] Soft tissue sarcoma. Mayo Clinic website. https://www.mayoclinic.org/diseases-conditions/leiomyosarcoma/cdc-20387733. (The website was accessed on June 13, 2019.)

[5] Magnetic resonance imaging (MRI). Mayo Clinic website. https://www.mayoclinic.org/tests-procedures/mri/about/pac-20384768. (The website was accessed on June 13, 2019.)

[6] General ultrasound. RadiologyInfo.org website. https://www.radiologyinfo.org/en/info.cfm?pg=genus. (The website was accessed on June 13, 2019.)

OIG Contact and Staff Acknowledgments

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