

#### DEPARTMENT OF VETERANS AFFAIRS

#### OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Facility Hiring Processes and Leaders' Responses Related to the Deficient Practice of a Radiologist at the Charles George VA Medical Center Asheville, North Carolina



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# **Executive Summary**

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate concerns identified by an OIG team during a Comprehensive Healthcare Inspection Program (CHIP) review at the Charles George VA Medical Center (facility), Asheville, North Carolina, in June 2018. The OIG team was informed that facility leaders had identified deficiencies related to the practice of a fee basis radiologist (subject radiologist) that resulted in an institutional disclosure to a patient in 2015 and a clinical disclosure to another patient in 2016. After questioning facility leaders about the circumstances surrounding the disclosures, the team identified possible gaps in the subject radiologist's initial professional competency evaluation and whether the facility had taken all required actions after identifying the deficient practices.

Additional concerns were subsequently identified related to the facility's oversight of the subject radiologist's performance during the six-month tenure.

#### **Event Summary**

The subject radiologist underwent the credentialing and privileging process in June 2014 and began providing care at the facility on July 2, 2014. A focused professional performance evaluation (FPPE) that should have been completed in 90 days was not completed for 174 days.<sup>3</sup> The FPPE identified concerns with the subject radiologist's interpretations of imaging studies. As a result, the subject radiologist's contract for services was not renewed in December 2014.

In an April 16, 2015, exit review memorandum (Exit Memorandum) that should have been completed within seven days of the provider's departure for state licensing board reporting purposes, the Chief of Imaging noted "significant deficiencies in [the subject radiologist's]

<sup>&</sup>lt;sup>1</sup> CHIP reviews are part of the OIG's overall efforts to ensure that the nation's veterans receive high-quality VA healthcare services. The reviews focus on key clinical and administrative processes and are performed approximately every three years for each facility. VA Office of Inspector General, *Publications*. https://www.va.gov/oig/publications/default.asp. (The website was accessed on August 15, 2018.)

<sup>&</sup>lt;sup>2</sup> VHA Handbook 5011/27, *Hours of Duty and Leave*, October 21, 2014. VA provides that healthcare professionals may be appointed on a fee basis when health services are not otherwise readily available, or when it is cost effective. VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. This handbook was in effect during the time frame of the disclosures discussed in this report; it was rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The 2012 and the 2018 policies contain the same or similar language to define adverse events. Institutional disclosure is a formal process of notification to a patient or patient's personal representative that an adverse event has happened during the patient's care and that has or is expected to result in serious injury or death. Clinical Disclosure, made as part of routine clinical care, of a "harmful or potentially harmful" event is the process in which the patient's provider informs the patient or patient's representative of the adverse event that occurred during their course of care.

<sup>&</sup>lt;sup>3</sup> The Professional Standards Board required the subject radiologist's FPPE report 90 days following the subject radiologist's first episode of patient care. The FPPE was not reported until December 23, 2014.

clinical practice as to raise reasonable concern for the safety of patients." <sup>4</sup> In May 2015, facility leaders requested a 100 percent review of the more than 2,000 imaging studies interpreted by the subject radiologist and set an August 2015 target date for completion of the review. The Patient Safety Manager was not notified of the request for the 100 percent review, nor of the results of the review. <sup>5</sup> Although the review was partially completed in 2016 and actions were taken to supplement patients' electronic health records (EHRs) with addenda, the results of the 2014–2016 review were not summarized and timely submitted to facility leaders. The Chief of Imaging told the OIG team that they felt they had managed the problem from a clinical standpoint and to do a full review and an aggregated report would be a "daunting task."

Two disclosures were made to patients (one institutional disclosure in 2015 and one clinical disclosure in 2016). After the 2018 CHIP inspection, OIG team members questioned facility managers about the circumstances surrounding the 2015 institutional disclosure. In response, facility leaders submitted an issue brief to the Veterans Integrated Service Network (VISN) outlining the actions taken to address the radiologist's deficient practices. Facility leaders solicited the National Teleradiology Program (NTP) to assist with the review of images, and the NTP provided a report to the facility leaders on July 30, 2018, which identified 43 imaging studies as "Not met standard (potential clinical impact/harm)." A VHA Clinical Episode Review Team was convened in August 2018, reviewed the facility results, and determined that a large-scale disclosure was not warranted. Facility leaders completed the 100 percent review in July 2018 and in September 2018, notified the subject radiologist of the intent to contact pertinent state licensing boards (SLBs). On January 25, 2019, the Facility Director issued notices to eight SLBs citing that the subject radiologist "so significantly failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients."

<sup>&</sup>lt;sup>4</sup> VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005. The Exit Memorandum should have been completed in early January 2015.

<sup>&</sup>lt;sup>5</sup> VHA Handbook 1050.01, *VHA National Patient Safety Improvement*, March 4, 2011. This handbook expired March 31, 2016 and has not been updated.

<sup>&</sup>lt;sup>6</sup> VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. This handbook was in effect during the timeframe of the disclosures discussed in this report. This VHA Handbook was rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The 2012 and the 2018 directives contain the same or similar language to define clinical and administrative disclosures.

<sup>&</sup>lt;sup>7</sup> VHA NTP provides remote teleradiology support for a VA medical facility requiring additional review and interpretation of imaging reports.

<sup>&</sup>lt;sup>8</sup> VHA Directive, 1004.08. The Clinical Episode Review Team is the team serving as the Deputy Under Secretary for Health for Operations and Management's coordinated triage process for review of each potential adverse event that may require large-scale disclosure.

#### **Facility Hiring Processes**

Facility leaders did not complete the credentialing and privileging of the subject radiologist per VHA requirements. Specifically, facility staff failed to ensure that, upon hire, references provided by the subject radiologist (1) were from an authoritative source ("qualified to provide authoritative information regarding training/experience, competence, health status"), and (2) included peer recommendations, with at least one from a current or most recent employer. The references used to approve the subject radiologist's request for privileges and appointment as a fee basis staff radiologist by the Facility Director included three non-radiology physicians and a non-physician radiology technician, and did not include a reference from a current or most recent employer. <sup>10</sup>

In June 2014, the subject radiologist, as part of the credentialing and privileging process, answered "no" to the question of having ever been notified of a judicial proceeding in which malpractice was alleged, despite being the named defendant in two tort claims related to clinical practice while previously employed at the James E. Van Zandt VA Medical Center, Altoona, Pennsylvania (Altoona). The two notices of final tort claim settlements were not posted on the National Practitioner Data Bank until 2016 and 2017, when the subject radiologist was no longer employed by VHA. VA Central Office, facility leaders, and managers told the OIG team that they were not aware of these tort claim actions until after the subject radiologist's contract for employment was not renewed, nor would they have known unless the subject radiologist self-disclosed or the claims were finally adjudicated and updated in the National Practitioner Data Bank. Additionally, in June 2014, the former Chief of Staff (COS) at Altoona signed an employment verification document and indicated that the subject radiologist was in good standing and had no disciplinary actions taken against clinical privileges. The Altoona Risk Manager told the OIG team that the subject radiologist retired from that facility in June 2014.

#### **Oversight of the Subject Radiologist**

Facility managers did not provide adequate oversight of the subject radiologist. Had the Chief of Imaging completed the initial FPPE in a timely manner as required, the subject radiologist's practices could have been discovered at the end of the 90-day timeframe rather than the 174-day timeframe.

<sup>&</sup>lt;sup>9</sup> CGVAMC, *Medical Staff Bylaws and Medical Staff Rules*, January 22, 2014, revised November 13, 2015. A peer recommendation is from an "individual(s) in the same professional discipline as the applicant reflecting their perception of the Practitioner's clinical practice, ability to work as part of a team, and ethical behavior…"

<sup>&</sup>lt;sup>10</sup> VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook expired October 31, 2017, and has not been updated.

<sup>&</sup>lt;sup>11</sup>VHA Handbook 1100.19.

<sup>&</sup>lt;sup>12</sup> VHA Handbook 1100.17, National Practitioner Data Bank (NPDB) Reports, December 28, 2009.

Facility managers did not have a tracking system in place for the FPPE process. The Professional Standards Board (PSB) and Medical Staff Executive Council did not follow up on action items identified in meeting minutes. The former COS told the OIG team that the follow-up was incomplete, and they did not include items for follow up on the agenda. Facility leaders initiated an issue brief detailing the review of the subject radiologist's practice only in response to the June 2018 OIG CHIP inspection.<sup>13</sup>

#### Leaders' Responses

Certain facility leaders did not take timely administrative action in response to inaccurate interpretations of radiology imaging and clinical documentation.

Based on an initial review of 30 imaging reports, on December 23, 2014, the PSB recommended that the Chief of Imaging conduct an in-depth review of the subject radiologist's casework and report the finding to the PSB. The Chief of Imaging provided the PSB the Exit Memorandum on April 16, 2015, 99 days beyond the required seven-day reporting period (106 days after the subject radiologist's departure on December 31, 2014). Because the contents of the Exit Memorandum were not reported to the Patient Safety Manager (practice raised reasonable concerns for patient safety), administrative reviews that would have been triggered by such a notification were not initiated.<sup>14</sup>

The Medical Staff Executive Council responded to the results of the Exit Memorandum on May 7, 2015, and noted deficiencies "in [the subject radiologist's] radiologic interpretations that were not consistent with generally accepted standards of care." Because the Chief of Imaging did not complete the in-depth review, in May 2015, the PSB requested a 100 percent review that involved the review of over 2,000 imaging reports and that included efforts to identify concerns for patient care. While the target date was August 2015, the Chief of Imaging stated that because of limited resources, a summary of this review (Review of Professional Practice—Subject Radiologist Memorandum) was not submitted until three years after the established target date on August 22, 2018. The Facility Director submitted the June 2018 Issue Brief regarding the subject radiologist's performance, only in response to the OIG CHIP team visit.

The facility's review of radiology data completed in August 2018 did not account for 19 imaging reports entered by the subject radiologist. However, the OIG team verified that facility radiologists completed the review of all the subject radiologist's imaging reports by

<sup>&</sup>lt;sup>13</sup> The OIG will not, for the purposes of this report, make recommendations regarding the FPPE process and the oversight of the Professional Standards Board and the Medical Staff Executive Council as this would be duplicative of efforts related to the OIG CHIP visit and subsequent recommendations.

<sup>&</sup>lt;sup>14</sup> VHA Handbook 1050.01. VHA requires all facility staff to report any unsafe condition of which they are aware, including the contents of the Exit Memorandum.

<sup>&</sup>lt;sup>15</sup> The facility uses the exit review memorandum to serve as documentation of the initial review phase in reporting departing providers to the SLB. VHA Handbook 1100.18.

October 2018, and facility radiologists did provide a concurrence rating to all the subject radiologist's imaging reports.

The findings from the Review of Professional Practice—Subject Radiologist Memorandum described the rating process as a scale of 1 to 3 with "1" defined as "most radiologists would interpret the same," "2" defined as "some radiologists would interpret differently," and "3" defined as "most radiologists would interpret differently." Facility and NTP radiologists reviewed for clinical impact all of the subject radiologist's imaging reports that were assigned a rating of "2" or "3."

Facility clinical specialists reviewed all imaging reports identified as having either potential clinical impact or clinical impact and identified no adverse clinical outcomes. <sup>16</sup> The acting COS and the former COS clinically reviewed those imaging reports with potential clinical impact and identified no adverse clinical outcomes. The disclosures that were issued were consistent with the findings of no adverse clinical outcomes. <sup>17</sup> Based on the VHA Clinical Episode Review Team recommendation, facility leaders did not initiate a large-scale disclosure. The Clinical Episode Review Team also noted that VISN and facility leadership had addressed the performance of the subject radiologist. Facility radiologists documented discrepant findings in the patients' EHRs.

The OIG made four recommendations related to credentialing and privileging requirements, SLB reporting, reporting of adverse events to the Patient Safety Manager, and potential administrative actions.

#### **Comments**

The VISN and Facility Directors concurred with the recommendations and provided acceptable action plans. (See appendixes E and F, pages 31–35.) The OIG will follow up on the planned actions until they are completed.

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<sup>&</sup>lt;sup>16</sup> Within the context of this report, the OIG considered an adverse clinical outcome to be death, a change in diagnosis, a change in the course of treatment, or a significant change in the patient's level of care.

<sup>&</sup>lt;sup>17</sup> The Chief of Imaging issued one institutional disclosure on October 2, 2015, with "no patient harm," and primary care service issued one clinical disclosure on February 25, 2016.

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#### **Abbreviations**

CHIP Comprehensive Healthcare Inspection Program

COS Chief of Staff

CT computerized tomography
EHR electronic health records

FPPE Focused Professional Practice Evaluation

GAO Government Accountability Office
LIP licensed independent practitioner

MRI magnetic resonance imaging

MSEC Medical Staff Executive Council
NPDB National Practitioner Data Bank
NTP National Teleradiology Program

OIG Office of Inspector General
PACT Patient Aligned Care Team

PCP primary care provider PSA prostate specific antigen

PSB Professional Standards Board

RCA root cause analysis
SLB state licensing board

VHA Veterans Health Administration

VISN Veterans Integrated Service Network



#### Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate concerns identified by an OIG team during a Comprehensive Healthcare Inspection Program (CHIP) review at the Charles George VA Medical Center (facility), Asheville, North Carolina, in June 2018. The OIG team was informed that facility leaders had identified deficiencies related to the practice of a fee basis radiologist (subject radiologist) that resulted in an institutional disclosure to a patient in 2015 and a clinical disclosure to another patient in 2016. The team then questioned whether the facility had fully evaluated the subject radiologist's initial professional competency or taken all required actions after identifying the deficient practices.

OIG staff further learned that facility leaders and managers failed to provide required oversight of the subject radiologist's performance. Specifically, OIG inspectors reviewed the facility's hiring and oversight of the subject radiologist and actions taken upon learning of the deficient practices.

#### **Background**

The facility, part of Veterans Integrated Service Network (VISN) 6 includes three community-based outpatient clinics located in Franklin, Rutherford County, and Hickory, North Carolina. VA classifies the facility hospital as Level 1c–Mid-High Complexity facility.<sup>20</sup> In 2018, the facility served 47,197 patients and had a total of 190 hospital operating beds, including 103 inpatient beds, 73 community living center beds, and 14 domiciliary beds. Comprehensive health care is provided through the spectrum of primary care, tertiary care, and long-term care in areas

<sup>&</sup>lt;sup>18</sup> CHIP reviews are part of the OIG's overall efforts to ensure that the nation's veterans receive high-quality VA healthcare services. The reviews focus on key clinical and administrative processes and are performed approximately every three years for each facility. VA Office of Inspector General, *Publications*. <a href="https://www.va.gov/oig/publications/default.asp">https://www.va.gov/oig/publications/default.asp</a>. (The website was accessed on August 15, 2018.)

<sup>&</sup>lt;sup>19</sup> VHA Handbook 5011/27, *Hours of Duty and Leave*, October 21, 2014. VA provides that healthcare professionals may be appointed on a fee basis when health services are not otherwise readily available, or when it is cost effective. VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. This handbook was in effect during the time frame of the disclosures discussed in this report; it was rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The 2012 and the 2018 policies contain the same or similar language to define adverse events. Institutional disclosure is a formal process of notification to a patient or patient's personal representative that an adverse event has happened during the patient's care and that has or is expected to result in serious injury or death. Clinical Disclosure, made as part of routine clinical care, of a "harmful or potentially harmful" event is the process in which the patient's provider informs the patient or patient's representative of the adverse event that occurred during their course of care.

<sup>&</sup>lt;sup>20</sup> 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.

of medicine, surgery, psychiatry, physical medicine and rehabilitation, neurology, oncology, dentistry, and geriatrics.

#### **Credentialing and Privileging**

VHA defines the procedures for the credentialing and privileging of all healthcare professionals who are permitted to practice independently—without supervision or direction, within the scope of the individual's license, and in accordance with individually granted clinical privileges.<sup>21</sup>

Credentialing refers to the systematic process of screening and evaluating qualifications to ensure that all licensed independent practitioner (LIP) applicants, including fee basis and contracted providers, meet the requirements for education, training, experience, competence, and health status.<sup>22</sup> This process also ensures that the applicant has the skills to fulfill the requirements of the position and to support the requested clinical privileges.<sup>23</sup>

Clinical privileging is the process by which facility leaders permit an LIP to provide medical care services within the scope of the individual's license. Clinical privileges must be specific, based on the individual's clinical competence, supported by a recommendation from the service chief and the Medical Staff Executive Council (MSEC), and approved by the facility director. LIPs are required to inform the VA of anything that would limit or adversely affect their privileges to include pending or proposed actions.<sup>24</sup>

#### **MSEC and Professional Standards Board**

The facility's Medical Staff Bylaws provide that the MSEC, chaired by the Chief of Staff (COS), serves as the Executive Committee of the medical staff, and must ensure the "authenticity and appropriateness" of the credentialing and privileging process. The MSEC receives and acts on reports and recommendations from the facility based Professional Standards Board (PSB) and from medical staff committees with quality of care responsibilities. <sup>25</sup> The MSEC delineates and reviews medical staff privileges and makes recommendations to the facility director.

<sup>&</sup>lt;sup>21</sup> VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook expired October 31, 2017 and has not been updated. These healthcare professionals are also referred to as licensed independent practitioners.

<sup>&</sup>lt;sup>22</sup> VHA Handbook 1100.19.

<sup>&</sup>lt;sup>23</sup> VHA Handbook 1100.19.

<sup>&</sup>lt;sup>24</sup> VHA Handbook 1100.19. Information related to the credentialing process is stored in VetPro, an internet-based repository, that allows an LIP applicant to electronically submit required information and facility staff to upload and verify relevant information.

<sup>&</sup>lt;sup>25</sup> CGVAMC, Medical Staff Bylaws and Medical Staff Rules, January 22, 2014, revised November 13, 2015.

The PSB, also chaired by the COS, is a standing committee of the MSEC established to evaluate and improve healthcare quality, review the professional qualifications of applicants for medical staff membership, and report variances to accepted standards of clinical performance by LIPs.

#### **National Practitioner Data Bank**

VHA requires facility directors to report physicians, dentists, and other licensed health care practitioners to the National Practitioner Data Bank (NPDB) for certain malpractice payments and certain clinical privileging actions. Facility directors must submit required reports involving paid malpractice claims to the NPDB within 30 days of receiving a conclusion from the VA Office of Medical-Legal Affairs. Property of the VA Office of Medical-Legal Affairs.

#### **State Licensing Board**

VHA requires facility directors to report to state licensing boards (SLBs) regarding employed or separated licensed health care providers whose "clinical practice or behavior so substantially fails to meet generally accepted standards of clinical practice as to raise reasonable concern for patient safety." Further, facility leaders have an obligation to notify the SLB of concerns regarding the clinical practice of current or former health care providers. (See appendix A for SLB reporting stages.) <sup>29</sup>

#### Radiology

Radiology is a medical subspecialty using digital imaging to diagnose and aid in the treatment of medical conditions. A radiologist reads and interprets each image and prepares a report of the medical findings and possible diagnosis.<sup>30</sup> Imaging modalities used for diagnostic reporting

<sup>&</sup>lt;sup>26</sup> VHA Handbook 1100.17, *National Practitioner Data Bank (NPDB) Reports*, December 28, 2009. This handbook was scheduled for recertification on or before the last working day of December 2014 and has not been recertified.

<sup>&</sup>lt;sup>27</sup> VHA Handbook 1100.17. The Office of Medical-Legal Affairs coordinates and convenes panels to review all paid malpractice claims to determine whether the standard of care was met and if the practitioner should be reported to the NPDB.

<sup>&</sup>lt;sup>28</sup> VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005. This handbook was scheduled for recertification on or before the last working day of December 2010 and has not been recertified. Generally-accepted standards of clinical practice are the level of ability and practice expected of competent professionals, as well as the moral and ethical behavior necessary to carry out those responsibilities.

<sup>&</sup>lt;sup>29</sup> VHA Handbook 1100.18.

<sup>&</sup>lt;sup>30</sup> Midwest Radiology Associates. *Basics of Radiology*. <a href="http://www.midwestrad.com/basics-of-radiology.html">http://www.midwestrad.com/basics-of-radiology.html</a>. (The website was accessed on November 6, 2018.)

include computerized tomography (CT), magnetic resonance imaging (MRI), and general radiology, such as x-rays and ultrasounds.<sup>31</sup>

Teleradiology is a system by which patient's radiographic images are transmitted electronically for review and reporting by off-site radiologists. The off-site radiologist then transmits the interpretation reports back to the facility.<sup>32</sup> The VHA National Teleradiology Program (NTP) provides remote teleradiology support for VA medical facilities requiring additional review and interpretation of imaging reports.<sup>33</sup>

#### **Prior OIG Reports**

A search of prior facility healthcare inspections from the last four years identified two OIG reports with similar issues.

Comprehensive Healthcare Inspection Program of the Charles George VA Medical Center, Asheville, North Carolina, Report No. 18-01140-312, October 16, 2018

The OIG identified two deficiencies in the processes for granting requested clinical privileges.<sup>34</sup>

- The OIG did not find evidence of a MSEC decision to recommend approval of privileges for 4 of 30 LIP profiles. Facility managers acknowledged lack of oversight as the reason for noncompliance. The OIG recommended the COS ensure that the MSEC minutes consistently reflect the documents reviewed and the rationale to recommend approval of clinical privileges for LIPs, and to monitor compliance. The Facility Director concurred with a target date for completion of December 31, 2018. The recommendation was closed on February 26, 2019.
- The OIG did not find evidence of completed focused professional performance evaluation (FPPE) for 5 of 10 LIP profiles. This resulted in inconsistent evaluation of the clinical competency of newly hired providers in delivering quality care. Facility managers stated a lack of administrative support, lack of a tracking mechanism to ensure

<sup>&</sup>lt;sup>31</sup> CT is radiography in which a three-dimensional image of a body structure is constructed by computer from a series of plane cross-sectional images made along an axis. MRI is a noninvasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radio waves. Ultrasound is the diagnostic or therapeutic use of ultrasound and especially a noninvasive technique involving the formation of a two-dimensional image used for the examination and measurement of internal body structures and the detection of bodily abnormalities. <a href="https://www.merriam-webster.com">https://www.merriam-webster.com</a>. (The website was accessed on November 7, 2018.)

<sup>&</sup>lt;sup>32</sup> VHA Patient Care Services, *Teleradiology*, 2016, <a href="https://www.patientcare.va.gov/diagnosticservices.asp">https://www.patientcare.va.gov/diagnosticservices.asp</a>. (The website was accessed on February 1, 2019.)

<sup>&</sup>lt;sup>33</sup> VHA Directive 1084, *Privileging for VHA Teleradiology*, December 5, 2014.

<sup>&</sup>lt;sup>34</sup> VA Office of Inspector General, *Comprehensive Healthcare Inspection Program Review of the Charles George VA Medical Center, Asheville, North Carolina*, Report No. 18-01140-312, October 16, 2018.

receipt of completed FPPEs, and turnover in key staff positions resulted in noncompliance. The OIG recommended the COS ensure that clinical managers initiate and complete FPPE for the determination of providers' privileges and monitor for compliance. The Facility Director concurred with the OIG recommendation and set a target date for completion of December 31, 2018. The recommendation was closed on September 18, 2019.

Combined Assessment Program Review of the Charles George VA Medical Center, Asheville, North Carolina, Report No. 15-00621-23, November 10, 2015

The OIG reviewed the credentialing and privileging processes and found that two of the 10 LIP folders contained nonallowed information. The OIG recommended that the Facility Director ensure that the LIP folders do not contain nonallowed information. The recommendation was closed on November 10, 2015.<sup>35</sup>

#### **Other Relevant Reports**

The Government Accountability Office (GAO), *Improved Policies and Oversight Needed for Reviewing and Reporting (VA) Providers for Quality and Safety Concerns*, GAO-18-63, November 2017, found that in selected facilities, reviews of providers' clinical care were not always documented or timely, and that there was inadequate oversight of these reviews.<sup>36</sup> Additionally, VHA facility leaders did not always report providers to the NPDB and SLB(s) in accordance with VHA policy and did not adequately oversee this reporting. The GAO made four recommendations:

- 1. The Under Secretary for Health should specify in VHA policy that reviews of providers' clinical care after concerns have been raised should be documented, including retrospective and comprehensive reviews.
- 2. The Under Secretary for Health should specify in VHA policy a timeliness requirement for initiating reviews of providers' clinical care after a concern has been raised.
- 3. The Under Secretary for Health should require VISN officials to oversee VAMC [VA medical center] reviews of providers' clinical care after concerns have been raised, including retrospective and comprehensive reviews, and ensure that VISN officials are conducting such oversight with the required

<sup>&</sup>lt;sup>35</sup> VA Office of Inspector General, *Combined Assessment Program Review of the Charles George VA Medical Center, Asheville, North Carolina*, Report No. 15-00621-23, November 10, 2015.

<sup>&</sup>lt;sup>36</sup> Government Accountability Office (GAO), *Improved Policies and Oversight Needed for Reviewing and Reporting (VA) Providers for Quality and Safety Concerns*, GAO-18-63, November 2017.

- standardized audit tool. This oversight should include reviewing documentation to ensure that these reviews are documented appropriately and conducted in a timely manner.
- 4. The Under Secretary for Health should require VISN officials to establish a process for overseeing VAMCs [VA medical centers] to ensure that they are reporting providers to the NPDB and SLB(s) and are reporting in a timely manner.

The VA concurred with all GAO recommendations on October 20, 2017, with target completion dates of September 2018 for Recommendations 1 and 2 and October 2018 for Recommendations 3 and 4. As of September 19, 2019, these recommendations remain open.

#### **OIG Concerns**

During a routine OIG inspection of the facility in June 2018, an OIG team was informed the facility was conducting a 100 percent review of the imaging studies read by the subject radiologist who had been on staff for approximately six months in 2014. Facility staff issued an institutional disclosure in 2015 and a clinical disclosure in 2016 pertaining to imaging studies interpreted by the subject radiologist. (See appendix B for the case summaries of the patients who received the disclosures.)<sup>37</sup> Facility leaders had not received the completed review, had not submitted an issue brief to the VISN, and had not initiated other administrative reviews related to identified concerns regarding the subject radiologist's practices.<sup>38</sup>

The OIG initiated an inspection to evaluate the circumstances surrounding the hiring and oversight of the subject radiologist, and actions taken after the contract was not renewed in December 2014.

<sup>&</sup>lt;sup>37</sup> VHA Handbook 1004.08.VHA requires providers to disclose, to a patient or a patient's representative, "harmful or potentially harmful adverse events." Disclosure of adverse events includes a discussion between the patient and the patient's providers regarding clinically significant facts that have or could result in future adverse clinical outcomes.

<sup>&</sup>lt;sup>38</sup> Issue briefs provide information intended to allow facility leaders to understand relevant policy requirements and determine whether the provided care met those requirements. Site visits conducted by oversight bodies trigger an issue brief. VA Deputy Under Secretary for Health for Operations and Management, *10N Guide to VHA Issue Briefs*, June 26, 2017. VA Mid-Atlantic Health Care Network (VISN 6) Durham, NC, *Issue Brief Policy*, June 28, 2015.

# **Scope and Methodology**

The OIG initiated the inspection on July 9, 2018, and conducted a site visit September 24–27, 2018.

For the time frame June 2014 to October 2018, OIG staff reviewed relevant VHA, VISN 6, and facility policies and procedures related to radiology, credentialing and privileging, FPPE, and NPDB. OIG staff also reviewed relevant policy related to PSB, SLB, adverse event disclosures, and administrative reviews.

The OIG team interviewed VA Central Office Quality, Safety and Value managers; VISN 6 Quality Management Officer and Risk Management Officer; VISN 6 Chief of Tertiary Care; facility COS, Chief of Imaging, Credentialing and Privileging Officer, Risk Manager, Patient Safety Officer, Clinical Applications Coordinator, Primary Care Service Line Manager, three Staff Support Specialists, two staff radiologists, three staff physicians, and one staff surgeon. The OIG staff also contacted two radiologists from the NTP and leaders at the James E. Van Zandt VA Medical Center Altoona, Pennsylvania (Altoona).

The OIG team identified two limitations associated with the inspection. The subject radiologist was contracted as a fee basis radiologist from June 2014 through December 2014, and (1) VHA staff who were interviewed in 2018 had incomplete memory of events, and (2) key leaders who were knowledgeable about the events were no longer with VHA.

The OIG team reviewed two patients' EHRs for the time frame May 2014 to October 2018, credentialing and privileging records, clinical disclosures, institutional disclosures, issue briefs, and VISN, national level, and external reviews. Additionally, the OIG reviewed reports generated by facility managers related to a review of the subject radiologist's imaging reports, and patient data derived from VA's Corporate Data Warehouse.

In the absence of current VA or VHA policy, the OIG 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 conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

# **Summary of Events and Concerns**

The subject radiologist underwent the credentialing and privileging process in June 2014 and began providing care at the facility on July 2, 2014. An FPPE that should have been completed in 90 days was not completed for 174 days.<sup>39</sup> The FPPE identified concerns with the subject radiologist's interpretations of imaging studies, including inaccurate readings, and missed findings such as osteomyelitis and a meniscus tear.<sup>40</sup> As a result, Human Resources did not renew the contract for services in December 2014. The PSB was aware on December 23, 2014, that the contract was not renewed, and recommended that the Chief of Imaging conduct an indepth review of the subject radiologist's casework and report the findings to the PSB. In an April 16, 2015, exit review memorandum (Exit Memorandum) that should have been completed within seven days of the provider's departure for SLB reporting purposes, the Chief of Imaging noted "significant deficiencies in [the subject radiologist's] clinical practice as to raise reasonable concern for the safety of patients." In May 2015, facility leaders requested a 100 percent review of the imaging studies and set an August 2015 target date for completion of the review. Neither the former nor current Patient Safety Manager were notified of the Exit Memorandum, the PSB's request for the 100 percent review, nor of the results of the review.

Although the review was partially completed in 2016 and actions were taken to supplement patients' EHRs, the results of the 2014–2016 review were not submitted to facility leaders. The Chief of Imaging told the OIG team that they felt they had managed the problem from a clinical standpoint and to do a full review and an aggregated report would be a "daunting task." Facility staff made two disclosures to patients (one institutional disclosure in 2015 and one clinical disclosure in 2016). After the 2018 CHIP inspection team members questioned facility managers about the circumstances surrounding the 2015 institutional disclosure, the Facility Director submitted an issue brief to the VISN outlining the actions taken to address the radiologist's deficient practices. Facility leaders had solicited the NTP to assist with the review of images but were not provided a report until July 30, 2018.

<sup>&</sup>lt;sup>39</sup> The PSB required the subject radiologist's FPPE report 90 days following the subject radiologist's first episode of patient care. The FPPE was not reported until December 23, 2014.

<sup>&</sup>lt;sup>40</sup> Osteomyelitis is an infection in the bone. Mayo Clinic, Osteomyelitis, <a href="https://www.mayoclinic.org/diseases-conditions/osteomyelitis/symptoms-causes/syc-20375913">https://www.mayoclinic.org/diseases-conditions/osteomyelitis/symptoms-causes/syc-20375913</a>. (The website was accessed on August 15, 2019.) A meniscus is cartilage that cushions the area of your knee between the shin and thigh bones. <a href="https://www.mayoclinic.org/diseases-conditions/torn-meniscus/symptoms-causes/syc-20354818">https://www.mayoclinic.org/diseases-conditions/torn-meniscus/symptoms-causes/syc-20354818</a>. (The website was accessed on August 15, 2019.)

<sup>&</sup>lt;sup>41</sup> VHA Handbook 1100.18.

<sup>&</sup>lt;sup>42</sup> VHA Handbook 1050.01, *VHA National Patient Safety Improvement*, March 4, 2011. This handbook expired March 31, 2016, and has not been updated.

<sup>&</sup>lt;sup>43</sup> The PSB requested an in-depth review on two occasions, December 23, 2014, and May 7, 2015. The latter request identified August 2015 as the target date for report of findings.

A VHA Clinical Episode Review Team was convened in August 2018, reviewed the facility results, and determined that a large-scale disclosure was not warranted. <sup>44</sup> Facility leaders completed the 100 percent review, and in September 2018, notified the subject radiologist of the intent to contact pertinent SLBs. On January 25, 2019, the Facility Director issued notices to eight SLBs and indicated that the subject radiologist "so significantly failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients." (See appendix C for a detailed timeline.)

# **Inspection Results**

To evaluate the circumstances surrounding the subject radiologist's practice while at the facility, the OIG assessed the facility's hiring process and oversight of this LIP.

#### 1. Facility Hiring Processes

The OIG determined that facility credentialing and privileging staff and the Chief of Imaging did not complete the credentialing and privileging of the subject radiologist per VHA and facility requirements. Specifically, the Chief of Imaging and the facility credentialing and privileging staff failed to ensure that, upon hire, the references provided by the subject radiologist were from an authoritative source regarding training/experience, competence, health status, and that the references included peer recommendations, with at least one from a current or most recent employer. Health status are competenced to the subject radiologist were from an authoritative source regarding training/experience, competence, health status, and that the references included peer recommendations, with at least one from a current or most recent employer.

The OIG identified that the Chief of Imaging recommended approval of the subject radiologist's request for privileges and medical staff appointment as a staff radiologist, and the PSB identified that the credentials contained "no adverse actions and good peer references."

The OIG determined that the references used by the Facility Director to approve the subject radiologist's request for privileges and medical staff appointment as a fee basis staff radiologist included three non-radiology physicians and a non-physician radiology technician, and did not include a reference from a current or most recent employer.<sup>47</sup> The references were not authoritative ("qualified to provide authoritative information regarding training/experience, competence, health status"). The references also did not include a peer recommendation from the

<sup>&</sup>lt;sup>44</sup> VHA Directive 1004.08. The Clinical Episode Review Team is the team serving as the Deputy Under Secretary for Health for Operations and Management's coordinated triage process for review of each potential adverse event that may require large-scale disclosure.

<sup>&</sup>lt;sup>45</sup> VHA Handbook 1100.19. CGVAMC, Medical Staff Bylaws.

<sup>&</sup>lt;sup>46</sup> CGVAMC, Medical Staff Bylaws.

<sup>&</sup>lt;sup>47</sup> VHA Handbook 1100.19.

same profession qualified to provide information about the scope of practice and level of performance as a radiologist.<sup>48</sup>

OIG staff also determined that the subject radiologist, on June 13, 2014, as part of the credentialing and privileging process, answered "no" to the question of having ever been notified of a judicial proceeding in which malpractice was alleged. 49 OIG staff found that the subject radiologist was employed at Altoona as a staff radiologist from May 8, 2011, to June 13, 2014. While employed at Altoona, the subject radiologist was the defendant named in the subject of two tort claims related to clinical practice. On January 28, 2014, the Director of Altoona notified the subject radiologist, then employed at Altoona, of the first claim, but the subject radiologist did not disclose this claim during the credentialing process. On June 20, 2014, the Director of Altoona notified the subject radiologist of a second claim, but the radiologist failed to notify the facility's credentialing staff of this new action. The two notices of final tort claim settlements were not posted on NPDB until 2016 and 2017, when the subject radiologist was no longer employed by VHA. VA Central Office staff, facility leaders, and managers told the OIG team that they were not aware of these tort claim actions until after the subject radiologist's fee basis contract had not been renewed, nor would they have known unless the subject radiologist self-disclosed or the claims were finally adjudicated and updated in the NPDB.

#### 2. Oversight of a Recently Hired Radiologist

The OIG determined that facility managers did not provide required oversight of the subject radiologist's performance. Specifically, the OIG found that the Chief of Imaging did not timely complete an FPPE as required within 90 days of the subject radiologist's first episode of care on July 2, 2014. VHA requires that facility leaders, including the service chiefs, initiate an FPPE for all LIPs new to the facility, and report to the MSEC for final recommendation on privileges. The criteria for the FPPE process are defined in advance, using objective criteria accepted by the applicant LIP, recommended by the service chief and MSEC, and approved by the director. FPPEs may include chart reviews, direct observation, or discussion with other individuals involved in the care of patients. The criteria accepted by the director of patients.

Additionally, the OIG determined that facility managers did not have a tracking system in place for the FPPE process, the PSB and MSEC did not follow up on action items identified in the

<sup>&</sup>lt;sup>48</sup> VHA Handbook 1100.19; CGVAMC, Medical Staff Bylaws.

<sup>&</sup>lt;sup>49</sup> VHA Handbook 1100.19.

<sup>&</sup>lt;sup>50</sup> VHA Handbook 1100.19.

<sup>&</sup>lt;sup>51</sup> VHA Handbook 1100.19.

meeting minutes, and facility leaders did not initiate an issue brief detailing the review of the subject radiologist's practice until after the June 2018 OIG CHIP inspection.<sup>52</sup>

The PSB reviews the recommendations of service chiefs to include the status and appropriateness of clinical privileges.<sup>53</sup> The PSB also reviews the findings and recommendations from the service chiefs at the end of an FPPE period and makes recommendations to the MSEC to accept an FPPE as concluded satisfactorily, amend clinical privileges/scope of practice, or extend the FPPE. The MSEC will concur or amend the recommendation and determine appropriate action.<sup>54</sup>

The Facility Director approved the appointment of the subject radiologist effective June 25, 2014, and based on the MSEC recommendation, the appointment required an FPPE 90 days following the first episode of care. The Chief of Imaging first reported the results of the subject radiologist's FPPE to the PSB on December 23, 2014, 84 days beyond the scheduled FPPE reporting date (174 days after the first episode of care). The Chief of Imaging reviewed, as part of the FPPE, 30 of the subject radiologist's diagnostic images/interpretations for "interpretation, timeliness, consistency of interpretations," and noted "unsatisfactory performance" and concerns about diagnostic interpretations, including "osteomyelitis not documented, sinus tract not describe [sic], meniscus tear not described." 56

The PSB found the subject radiologist's FPPE to be unsatisfactory and recommended the Chief of Imaging conduct an in-depth review of the subject radiologist's casework, particularly CTs, MRIs and chest x-rays, and report the findings to the PSB. VHA requires that service chiefs monitor the professional competency and performance of privileged providers and initiate FPPEs for practitioners new to the facility.<sup>57</sup> The Chief of Imaging acknowledged "We should have had a review at 90 days but wasn't done. It was done later in [the subject radiologist's] tenure," which was beyond the 90 days required by the MSEC and PSB.

The OIG team noted other concerns related to the FPPE process. When interviewed, a facility staff member told the OIG that there was no tracking mechanism for the FPPE schedule. Both the former and current Chiefs of Staff acknowledged failures in the PSB and/or MSEC. The

<sup>&</sup>lt;sup>52</sup> The OIG will not, for the purposes of this report, make recommendations regarding the FPPE process and the oversight of the Professional Standards Board and the Medical Staff Executive Council as this would be duplicative of efforts related to the OIG CHIP visit and subsequent recommendations.

<sup>&</sup>lt;sup>53</sup> CGVAMC, Medical Staff Bylaws.

<sup>&</sup>lt;sup>54</sup> CGVAMC, Medical Staff Bylaws.

<sup>&</sup>lt;sup>55</sup> The subject radiologist started interpreting images for the facility on July 2, 2014.

<sup>&</sup>lt;sup>56</sup> Osteomyelitis is an infectious disease of bone. A sinus tract is narrow, elongated channel that allows the escape of body fluids. A meniscus is fibrous cartilage with the knee joint. <a href="https://www.merriam-webster.com">https://www.merriam-webster.com</a>. (The website was accessed on March 7, 2019.)

<sup>&</sup>lt;sup>57</sup> VHA Handbook 1100.19.

former COS acknowledged it was "a fail" of the PSB and MSEC to not follow up with the Chief of Imaging regarding the requested 100 percent review; the current COS also noted that the PSB did not follow up to ensure a complete review of the subject radiologist's performance.

Facility leaders did not timely submit an issue brief to VISN 6, as is required for "significant clinical incidents/outcomes negatively affecting group [sic] or cohort" of patients.<sup>58</sup> VHA policy requires facility staff to report an incident "as soon as possible" and initiate a "heads up message" to facility and VISN leadership within one business day, while the incident is being researched.<sup>59</sup> The Facility Director initiated one issue brief detailing the review to VISN 6 on June 19, 2018, and only in response to the June 2018 OIG CHIP inspection.

#### 3. Leaders' Responses

The OIG determined that facility leaders did not take timely administrative action in response to inaccurate interpretations of radiology imaging and clinical documentation. Specifically, the OIG found that facility leaders and managers failed to timely complete the subject radiologist's Exit Memorandum, required by VHA to comply with SLB reporting requirements, during the mandatory reporting period of seven days after the employee's separation from the facility. Facility managers also failed to conduct and report the results to the PSB of the 100 percent clinical review of the subject radiologist's imaging reports until three years after the assigned target date. <sup>60</sup>

Additionally, facility leaders and managers failed to report the results of the subject radiologist's Exit Memorandum to either the former or current Patient Safety Manager to trigger timely administrative reviews. HAA provides for specific patient safety improvement procedures in efforts to promote patient safety and prevent adverse clinical outcomes. One such procedure is the root cause analysis (RCA), a multidisciplinary team approach to identify factors that contribute to healthcare related adverse events. The RCA reviews systems and identifies causes as to why a patient safety event occurred (or could occur) and must "identify at least one root

<sup>&</sup>lt;sup>58</sup> VA Mid-Atlantic Health Care Network (VISN 6) Durham, NC, *Issue Brief Policy*, June 28, 2015. VA Deputy Under Secretary for Health for Operations and Management, *10N Guide to VHA Issue Briefs*, June 26, 2017.

<sup>&</sup>lt;sup>59</sup> VA Deputy Under Secretary for Health for Operations and Management, *10N Guide to VHA Issue Briefs*. <sup>60</sup> The facility uses an exit memorandum to serve as documentation of the initial review phase in reporting departing providers to the SLB. VHA Handbook 1100.18.

<sup>61</sup> VHA Handbook 1050.01.

<sup>&</sup>lt;sup>62</sup> Within the context of this report, the OIG considered an adverse clinical outcome to be death, a change in diagnosis, a change in the course of treatment, or a significant change in the patient's level of care. VHA Handbook 1050.01. VHA Handbook 1050.01.

cause with a corresponding action and outcome measure."<sup>63</sup> All adverse events must be reported to the facility patient safety manager for documentation in the VHA Patient Safety Information System, and a determination of whether an RCA review is required.<sup>64</sup>

# Failure to Timely Complete Subject Radiologist's Exit Memorandum

On December 23, 2014, the Chief of Imaging reported to the PSB the review of 30 diagnostic images/interpretations as part of the FPPE process and had concerns about diagnostic interpretations. On the same day, the PSB recommended that the Chief of Imaging conduct an indepth review of the subject radiologist's casework and report the finding to the PSB. Facility managers did not renew the subject radiologist's appointment and did not take disciplinary actions.

The OIG found that the Chief of Imaging provided the PSB the Exit Memorandum on April 16, 2015, indicating that the subject radiologist "failed to meet generally accepted standards of practice to raise reasonable concern for the safety of patients." The Chief of Imaging submitted the Exit Memorandum to the PSB 99 days beyond the required seven-day reporting period (106 days after the subject radiologists' departure on December 31, 2014).

OIG staff further found that the Chief of Imaging presented the results of the review to the PSB on May 7, 2015, providing that "deficiencies were noted in [the subject radiologist's] radiologic interpretations that were not consistent with generally accepted standards of care." On May 7, 2015, the PSB recommended the Chief of Imaging perform a 100 percent review to identify concerns for patient care. The MSEC concurred and set a target date of August 2015. (See appendix C for a detailed timeline.)

#### Review of the Subject Radiologist's Imaging Reports

The OIG found that the Chief of Imaging did not conduct and report a 100 percent review of imaging reports in a timely manner. The Chief of Imaging reported the results from the requested 100 percent review of the subject radiologist imaging reports to the PSB/MSEC on August 22, 2018, three years after the PSB established target date of August 2015.

<sup>&</sup>lt;sup>63</sup> VA National Center for Patient Safety, "*Root Cause Analysis*," November 15, 2017. <a href="https://www.patientsafety.va.gov/professionals/onthejob/rca.asp">https://www.patientsafety.va.gov/professionals/onthejob/rca.asp</a>. (The website was accessed on January 15, 2019.) VHA Handbook 1050.01.

<sup>&</sup>lt;sup>64</sup> VHA Handbook 1050.01.

The Chief of Imaging told the OIG that, in 2015, facility radiologists could not have reviewed every imaging report; it became impractical based on time limitations. The former COS confirmed to the OIG that the 100 percent review was not completed timely likely due to the large number of imaging reports. The Chief of Imaging also told the OIG that the results of the 100 percent review were not reported to the PSB until prompted by the CHIP visit because the review was never aggregated into a full summary report.

The OIG found that after the CHIP team questioned facility managers about the 2015 institutional disclosure and circumstances surrounding the disclosure, the Facility Director submitted an issue brief to the VISN on June 19, 2018. The issue brief identified that from 2014 through 2016 the Chief of Imaging had performed a clinical review of the subject radiologist for "suspected sub-standard interpretations." The issue brief further noted that facility leaders were reviewing the clinical review of the subject radiologist imaging reports "for accuracy and completeness."

The Chief of Imaging presented the results of the 100 percent review on the subject radiologist to the PSB on August 22, 2018. This included reviews by facility radiologists, as well as NTP radiologists who were engaged to assist in the review June through July 2018. The Chief concurrently provided the PSB a summary of the 100 percent review on a memorandum dated August 21, 2018, titled "Review of Professional Practice—Subject Radiologist" (Review of Professional Practice).

#### **Facility Review and Recommendation**

OIG staff reviewed the Chief of Imaging's Review of Professional Practice provided to the PSB on August 22, 2018, the data provided by the facility managers (Radiology Review data), and data the OIG team obtained from the VA's Corporate Data Warehouse to evaluate the following:<sup>67</sup>

 Did VHA radiologists review 100 percent of the subject radiologist's imaging reports completed while employed at facility? <sup>68</sup>

<sup>&</sup>lt;sup>65</sup> Cases are assigned to radiology reports based on the imaging performed. Some images are assigned two or three cases based on anatomical regions (for example, CT chest / CT pelvis / CT abdomen). The image is interpreted (read) by the radiologist only once, but the resulting imaging report (same report) is included in all assigned cases. To minimize redundancy, the facility managers removed these "duplicate" cases from their review. For the purposes of this report, the term "case" means individual imaging reports.

<sup>&</sup>lt;sup>66</sup> The former COS served at the facility in that capacity from 2014 to 2018.

<sup>&</sup>lt;sup>67</sup> The VA Corporate Data Warehouse is VA's program for the standardization, consolidation and streamlining of clinical data systems. VA Health Services Research & Development, "Corporate Data Warehouse (CDW)." <a href="https://www.hsrd.research.va.gov/for\_researchers/vinci/cdw.cfm">https://www.hsrd.research.va.gov/for\_researchers/vinci/cdw.cfm</a>. (The website was accessed on July 9, 2019.)

<sup>&</sup>lt;sup>68</sup> Within this context, VHA radiologists included facility-based radiologists and NTP radiologists.

- Did VHA radiologists provide a rating to all the subject radiologist's imaging reports completed while employed at the facility?
- Did VHA radiologists review for clinical impact all of the subject radiologist's imaging reports that were assigned a rating indicating that some or most radiologists would interpret differently?
- Did facility clinicians review for adverse clinical outcomes all of the subject radiologist's imaging reports identified as having either "potential clinical impact"?
- Did facility radiologists document addenda to capture discrepant findings in the patients' EHR? <sup>69</sup>
- Did facility leaders respond to the identified deficiencies by reporting to the Patient Safety Manager and the SLB, per VHA requirements?

For additional detail on data and findings, see appendix D.

#### VHA Radiologists Review of Subject Radiologist's Imaging Reports

The Radiology Review data completed in August 2018, did not account for 19 imaging reports entered by the subject radiologist. However, the OIG team verified that facility radiologists completed the review of all of the subject radiologist's imaging reports by October 2018.

#### Facility Radiologists' Concurrence Ratings of Subject Radiologist's Imaging Reports

The OIG determined that facility radiologists provided a concurrence rating to all the subject radiologist's imaging reports, including the 19 images previously omitted from reporting.

The OIG compared findings from the Radiology Review data with the findings reported to the VHA Clinical Episode Review Team on August 6, 2018. The OIG team found that radiologists reviewed the imaging reports and assigned corresponding ratings to all 2,716 imaging reports.

#### Facility and NTP Radiologists' Review and Rating for Clinical Impact

The OIG determined that NTP radiologists reviewed for clinical impact all of the subject radiologist's imaging reports that facility radiologists assigned either a rating of "2–Some radiologists would interpret differently" or "3–Most radiologists would interpret differently."

The OIG also verified that in October 2018 facility radiologists reviewed all of the remaining 19 imaging reports with a 2 or 3 rating that were not included in the Radiology Review data. The

<sup>&</sup>lt;sup>69</sup> Adrian Brady, Risteárd Ó Laoide, Peter McCarthy, and Ronan McDermott, "Discrepancy and Error in Radiology: Radiology: Concepts, Causes and Consequences," *Ulster Medical Journal*, 81, no. 1 (2012): 3-9. "With respect to radiological investigations, the use of the term 'error' is often unsuitable; it is more appropriate to concentrate on 'discrepancies' between a report and a retrospective review of a film or outcome."

Chief of Imaging identified on the review that there was no clinical impact or potential clinical impact.

#### Review for Adverse Clinical Outcomes

The OIG determined that facility clinical specialists reviewed all imaging reports identified as having either potential clinical impact or possible clinical impact and identified no adverse clinical outcomes.<sup>70</sup>

The OIG confirmed that by early August 2018 the current acting COS and the former COS clinically reviewed the 69 imaging reports with potential/possible clinical impact, (43 imaging reports identified with potential clinical impact by the NTP and the 26 imaging reports identified with possible clinical impact by facility radiologists), consulted with subject matter experts, and identified no adverse clinical outcomes.

Facility policy requires open and prompt communication of adverse events with patients or their representatives. During a disclosure of adverse events, a provider discusses clinically significant facts with patients or their representatives about "the occurrence of a harmful adverse event, or an adverse event that could result in harm in the foreseeable future." The "attending [physician] or senior practitioner, or designee" must conduct the clinical disclosure. An institutional disclosure, performed by facility leaders, is a formal process addressing "serious injury or death, or those [cases] involving reasonably expected serious injury, or potential legal liability." The institutional disclosure must be documented in the patient's EHR. The risk manager or patient safety manager are responsible for notifying the COS immediately of a significant adverse event. See appendix A for additional information related to disclosures.

OIG staff found that the Chief of Imaging issued one institutional disclosure on October 2, 2015, and primary care service issued one clinical disclosure on February 25, 2016. (See appendix B for case summaries.)<sup>75</sup> The VHA Clinical Episode Review Team determined that a large-scale disclosure was not necessary and that VISN and facility leaders had addressed the performance of the subject radiologist.

<sup>&</sup>lt;sup>70</sup> The OIG reviewed for adverse clinical outcomes, rather than clinical impact alone.

<sup>&</sup>lt;sup>71</sup> CGVAMC Memorandum 637-2011-11-95, Disclosure of Adverse Events to Patients, February 2, 2011.

<sup>&</sup>lt;sup>72</sup> CGVAMC, Memorandum 637-2011-11-95.

<sup>&</sup>lt;sup>73</sup> CGVAMC, Memorandum 637-2011-11-95.

<sup>&</sup>lt;sup>74</sup> CGVAMC, Memorandum 637-2011-11-95.

<sup>&</sup>lt;sup>75</sup> Facility leaders identified "no patient harm" when issuing this institutional disclosure.

#### Documentation of Discrepant Findings in Patients' EHRs

The OIG determined that facility radiologists documented discrepant findings in the patients' EHR. VHA allows for changes to an EHR in certain circumstances to correct erroneous information. One such mechanism is an addendum. A provider enters an addendum when it is important to clarify information recorded in the original document or to add to the original document. Addenda are linked to the original documentation and may be entered by the original author or by another provider. Facility policy provides that immediately upon discovery of an erroneous entry, an addendum will be made to the patient EHR to clarify contradicting information. However, the facility's tracking of addended imaging reports was not complete. In November 15, 2018, the OIG requested the Quality Manager verify that all discrepant findings were addended in the patients' EHR. On December 14, 2018, the Risk Manager confirmed that all discrepant findings identified on the Radiology Review data had been addended in the patients' EHR.

#### Notification to Patient Safety Manager

The OIG determined that facility managers failed to notify the former or current Patient Safety Managers of the noted deficiencies in the subject radiologist's performance with potential risk of harm. The OIG team found that the PSB and MSEC responded to the results of the in-depth review on May 7, 2015, and noted "Deficiencies in [the subject radiologist's] radiologic interpretations were not consistent with generally accepted standards of care." However, facility managers reported that the former and current Patient Safety Managers were not notified of the results of the Exit Memorandum when it was reported to the PSB, the 100 percent review of cases, nor the results of Review of Professional Practice results when they were issued. Failure to notify the former and current Patient Safety Managers precluded documentation of potential patient safety events and consideration of a patient safety related administrative review such as an RCA.

Although facility clinicians identified no adverse clinical outcomes, the MSEC concluded that the clinical practice of the subject radiologist exhibited significant deficiencies that raised a reasonable concern for the safety of patients. The former facility COS acknowledged "the Safety Manager at the time was not a part of this (review)," and "perhaps a review of the credentialing and privileging processes would have been warranted." The current Patient Safety Manager was not aware that the subject radiologist's imaging reports were under review, and was not notified when the OIG CHIP discussed the performance concerns with facility leaders in June 2018. The

<sup>&</sup>lt;sup>76</sup> VHA Handbook 1907.01, Health Information Management and Health Records, March 19, 2015.

<sup>&</sup>lt;sup>77</sup> CGVAMC, Erroneous Electronic Progress Note, September 29, 2015.

<sup>&</sup>lt;sup>78</sup> VHA Handbook 1050.01.

<sup>&</sup>lt;sup>79</sup> VHA Handbook 1050.01.

Risk Manager and current Patient Safety Manager reported that they would have considered an RCA if informed that the subject radiologist was performing poorly.

The OIG found that because the former or current Patient Safety Managers were not informed, there was no review of the subject radiologist's significant clinical practice deficiencies from a patient safety perspective, and the systemic issues involving the PSB and MSEC tracking of both FPPE and committee action items were not identified until the OIG oversight inspections in 2018.

#### Notification to State Licensing Boards

The OIG determined that the Facility Director did not initiate reporting of the subject radiologist to SLBs until more than three years after the PSB and MSEC noted the deficiencies "in [the subject radiologist's] radiological interpretations that were not consistent with generally accepted standards of care."

On September 24, 2018, the Facility Director notified the subject radiologist of the ongoing performance review and the intent to contact the SLBs. On January 25, 2019, the Facility Director issued notices to eight SLBs citing that the subject radiologist "so significantly failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients."

#### Conclusion

Facility leaders and managers did not complete the credentialing and privileging of the subject radiologist per VHA requirements. Specifically, facility staff failed to ensure that, upon hire, the references provided by the subject radiologist were from an authoritative source, and that the references included peer recommendations, with at least one reference from a current or most recent employer.<sup>80</sup>

In June 2014, the subject radiologist, and as part of the credentialing and privileging process, answered "no" to the question of having ever been notified of a judicial proceeding in which malpractice was alleged, despite being the named defendant in two tort claims related to clinical practice while previously employed at another VHA facility. However, the two notices of final tort claim settlements were not posted on the NPDB until 2016 and 2017, when the subject radiologist was no longer employed by VHA.VA Central Office, facility leaders, and managers told the OIG team that they were not aware of these tort claim actions until after the subject radiologist's contract for employment was not renewed, nor would they have known unless the

<sup>80</sup> VHA Handbook 1100.19. CGVAMC, Medical Staff Bylaws.

<sup>81</sup> VHA Handbook 1100.19.

subject radiologist self-disclosed or the claims were finally adjudicated and updated in the NPDB.

Facility managers did not provide adequate oversight of the subject radiologist. Specifically, the OIG found that the Chief of Imaging did not timely complete an FPPE required within 90 days of the subject radiologist's first episode of care. Additionally, the OIG determined that facility managers did not have a tracking system in place for the FPPE process; the PSB and MSEC did not follow up on action items identified in meeting minutes; and that facility leaders initiated the June 2018 Issue Brief detailing the review of subject radiologist's practice only in response to the OIG CHIP inspection.

As the OIG recommended in the CHIP report that the facility leaders initiate a tracking mechanism for FPPEs and action items in MSEC and PSB committee meetings minutes in a recently published report, the OIG does not repeat the recommendation in this report.<sup>82</sup>

Facility leaders did not take timely administrative action in response to inaccurate interpretations of radiology imaging and clinical documentation. Facility managers and leaders failed to timely complete the subject radiologist's Exit Memorandum, required by VHA to comply with SLB reporting requirements, during the mandatory reporting period of seven days after the employee's separation from the facility; and failed to report the results to the PSB of the 100 percent clinical review of the subject radiologist's imaging reports until August 2018, three years after the assigned target date.<sup>83</sup>

The facility managers' review of radiology data completed in August 2018, did not account for 19 imaging reports entered by the subject radiologist. However, the OIG team verified that facility radiologists completed the review of all the subject radiologist's imaging reports by October 2018, and facility radiologists did provide a concurrence rating to all the subject radiologist's imaging reports.

Facility clinical specialists, including the acting COS and the former COS reviewed all imaging reports identified as having either potential clinical impact or clinical impact and identified no adverse clinical outcomes.

Additionally, OIG staff found that the Chief of Imaging issued one institutional disclosure on October 2, 2015, with "no patient harm," and primary care service issued one clinical disclosure on February 25, 2016. The VISN Clinical Episode Review Team recommended that no large-scale disclosure was necessary and that VISN and facility leadership had addressed the

<sup>&</sup>lt;sup>82</sup> VA Office of Inspector General, *Comprehensive Healthcare Inspection Program Review of the Charles George VA Medical Center*, *Asheville, North Carolina*, Report No. 18-01140-312, October 16, 2018.

<sup>&</sup>lt;sup>83</sup> The facility uses the exit review memorandum to serve as documentation of the initial review phase in reporting departing providers to the SLB. VHA Handbook 1100.18.

performance of the subject radiologist. Facility radiologists documented discrepant findings in the patients' EHRs.

Facility managers failed to notify the former or current Patient Safety Managers of the noted deficiencies in the subject radiologist's performance with potential risk of adverse clinical outcomes. <sup>84</sup> The PSB and MSEC responded to the results of the in-depth review on May 7, 2015, and noted deficiencies "in [the subject radiologist's] radiologic interpretations that were not consistent with generally accepted standards of care." Facility managers reported that the Patient Safety Manager was never notified while the 100 percent review of cases was being conducted, nor after the results were issued.

Subsequently, failure to notify the Patient Safety Manager precluded documentation as a patient safety event and consideration of a patient safety related administrative review such as an RCA <sup>85</sup>

The OIG also determined that the Facility Director did not initiate reporting of the subject radiologist to the SLBs until more than three years after the PSB and MSEC noted the deficiencies "in [the subject radiologist's] radiological interpretations that were not consistent with generally accepted standards of care."

#### Recommendations 1-4

- 1. The Charles George VA Medical Center Director verifies that facility managers adhere to Veterans Health Administration policy that outlines the credentialing and privileging process for licensed independent practitioners.
- 2. The Charles George VA Medical Center Director and managers meet all requirements of state licensing boards reporting.
- 3. The Charles George VA Medical Center Director ensures staff compliance with Veterans Health Administration policies related to reporting of all adverse events to the Patient Safety Manager.
- 4. The Charles George VA Medical Center Director confers with Human Resources regarding the actions taken by facility leaders and managers, related to the lack of oversight and failure to conduct credentialing and privileging per Veterans Health Administration requirements, and take administrative action(s) as necessary.

85 VHA Handbook 1050.01.

<sup>&</sup>lt;sup>84</sup> VHA Handbook 1050.01.

# **Appendix A: Additional Background Information**

#### **Disclosure of Adverse Events**

VHA defines adverse events as "untoward incidents, diagnostic or therapeutic misadventures, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services." VHA provides for three types of adverse event disclosures—clinical, institutional and large-scale. 87

Clinical disclosure, made as part of routine clinical care, of a "harmful or potentially harmful" event is the process in which the patient's provider informs the patient or patient's representative of the adverse event that occurred during their course of care. A clinical disclosure is not required but is appropriate for all adverse events that cause only minor harm, and that have no future health implications. VHA does not require documentation of a clinical disclosure in the EHR unless "harm is more than minor."88

Institutional disclosure is a formal process of notification to a patient or patient's personal representative that an adverse event has happened during the patient's care that has or is expected to result in serious injury or death. Facility leaders, in conjunction with clinicians and other appropriate individuals, are to initiate the institutional disclosure as soon as reasonably possible. This type of disclosure is to occur regardless of whether the adverse event was a result of an error.<sup>89</sup>

Large-scale disclosures generally involve system-based issues that affect multiple patients and adverse events that are clinically significant and involve actual or potential harm.<sup>90</sup>

#### **SLB Reporting Stages**

SLB reporting involves five stages: initial review, comprehensive review, decision, concurrence, and reporting. The purpose of the initial review is to determine if there may be substantial evidence that a licensed healthcare professional so significantly failed to meet generally accepted standards of clinical practice as to raise reasonable concern for patient safety. The initial review is generally completed by first and second level supervisors and must be conducted within seven days following the departure of the licensed healthcare professional from VHA employment. If the initial review indicates a reasonable concern for patient safety, the facility director is

<sup>86</sup> VHA Handbook 1004.08

<sup>87</sup> VHA Handbook 1004.08.

<sup>88</sup> VHA Handbook 1004.08.

<sup>89</sup> VHA Handbook 1004.08.

<sup>90</sup> VHA Handbook 1004.08.

responsible for immediately initiating the comprehensive review stage. The purpose of the comprehensive review stage is to determine if, in fact, substantial evidence exists, and involves the preparation of an SLB report file. The facility director must ensure the licensed healthcare professional is advised of the purpose of the comprehensive review as soon as it is practicable. The suggested time frame for completion of the comprehensive stage is 45 days. <sup>91</sup>

91 VHA Handbook 1100.18.

# **Appendix B: Case Summaries**

#### Patient A—Case Summary (Institutional Disclosure)

The patient, who was in their 60s at the time of the institutional disclosure, had a history of coronary artery disease, diabetes, kidney stones (also known as renal calculi), high blood pressure, high cholesterol, gastroesophageal reflux disease, and Barrett's esophagus. 92 In spring 2014, the patient was seen in the primary care clinic by their primary care provider (PCP) for a yearly examination and ongoing management of their chronic medical conditions. In fall 2014, the patient developed left-sided back pain and fever, and after calling the primary care clinic, they sought care at the facility Emergency Department. In the Emergency Department, the providers ordered laboratory tests and a CT scan. The subject radiologist read the CT scan image and reported no evidence of a kidney stone. The patient was treated for a urinary tract infection with antibiotics and discharged home. The patient was instructed to follow up with their PCP if they had continued pain, and the patient saw their PCP 11 days after the Emergency Department visit for continued dull flank (back) pain. The PCP felt the pain would continue to improve with time as it was likely that the patient had experienced a passed kidney stone. Two months later, the patient called the primary care clinic with concerns of another kidney infection and was instructed to come to the clinic to give a urine sample. The PCP reviewed the urinalysis results that showed red blood cells with some bacteria, and the PCP felt the results were more consistent with a kidney stone than infection. 93 Since the laboratory urinalysis test showed some bacteria, the patient was treated with antibiotics.

In the fall of 2015, an institutional disclosure note was placed in the patient's EHR indicating the patient was notified that the CT of the abdomen and pelvis performed in fall 2014 (noted above) "was erroneously interpreted as having no renal calculus [kidney stone] when in fact there was a ureteral calculus causing flank pain." <sup>94</sup> During the institutional disclosure discussion, the patient

<sup>92</sup> Kidney stone is a commonly used term for renal calculus and is an accumulation of calcium in the urinary track which can cause pain, blockage, infection, and other serious health conditions. National Institutes of Health, "Definition & Facts for Kidney Stones." <a href="https://www.niddk.nih.gov/health-information/urologic-diseases/kidney-stones/definition-facts.">https://www.niddk.nih.gov/health-information/urologic-diseases/kidney-stones/definition-facts.</a>. (The website was accessed on November 23, 2018.) Barrett's esophagus is a disorder where abnormal tissue in the tube between the mouth and stomach can cause problems such as chest pain, difficulty swallowing, and an increased risk of cancer. The Mayo Clinic, "Barrett's Esophagus." <a href="https://www.mayoclinic.org/diseases-conditions/barretts-esophagus/symptoms-causes/syc-20352841">https://www.mayoclinic.org/diseases-conditions/barretts-esophagus/symptoms-causes/syc-20352841</a>. (The website was accessed on February 20, 2019.) The OIG uses the singular form of they (their/them) to protect the patient's privacy.

<sup>&</sup>lt;sup>93</sup> Red blood cells in the urine are usually microscopic and can have multiple causes: infections of the urinary tract or kidneys, stones of the bladder or kidney, kidney disease, cancer, enlarged prostate, inherited disorders, kidney injury, medications, or strenuous exercise.

<sup>&</sup>lt;sup>94</sup> A ureteral calculus is a kidney stone that has moved into tube that flows urine from the kidney to the bladder.

was informed that the facility's urology service recommended a repeat CT scan of the abdomen and pelvis.

In fall 2015, the patient had the repeat CT of the abdomen and pelvis. <sup>95</sup> It revealed a new, non-obstructing 4-millimeter right kidney stone. <sup>96</sup> The PCP sent the patient the results on the next day and ordered a urology service consult. Seventeen days later, the PCP notified the patient that their urinalysis result was normal, and the urology service consult stated the patient's kidney stone required no further treatment or clinical evaluation.

#### Patient B—Case Summary (Clinical Disclosure)

The patient, who was in their 60s at the time of the clinical disclosure, had a history of high blood pressure, high cholesterol, chronic low back pain, and obesity who established care in the primary care clinic also known as the Patient Aligned Care Team (PACT) clinic in summer 2014. At that time, the patient had complaints of low back pain, and the PCP ordered an MRI examination for further evaluation. The patient also had laboratory tests that revealed an elevated prostate specific antigen (PSA) for which the patient was treated with antibiotics and a recheck of the PSA level.<sup>97</sup>

Two weeks later, the MRI examination was completed, and the subject radiologist read the study and reported some narrowing on the outside edges of the vertebrae. The PCP referred the patient to physical therapy for their mechanical back pain based on the MRI findings. In fall 2014, the PSA increased upon recheck of the level. The PCP then referred the patient to the urology service for further evaluation of the elevated PSA levels. The following month, the patient was seen by the urology service in consultation for their elevated PSA levels at which time the urologist recommended repeat PSA testing and follow-up evaluation in six months. In spring 2015, the patient saw the urologist in follow-up for their PSA level elevation. The patient continued regular follow-up with their PCP including monitoring their PSA levels.

In winter 2016, the PCP sent the patient a letter stating the patient's 2014 MRI had been rechecked in 2016, by another radiologist. The PCP notified the patient there was some concern a renal mass may have been present that was not originally reported in 2014, and radiology service was, at this time, advising a CT scan of the kidneys be performed. The PCP ordered this CT scan along with blood tests and a referral to urology service. The PACT team called the patient to review the new CT results. The patient had the CT scan performed in winter 2016, and a urology consultation appointment six days later. The kidney CT scan showed an enhancing

<sup>95</sup> The repeat CT scan was coordinated with another appointment at the patient request.

<sup>&</sup>lt;sup>96</sup> While the fall 2014 study was misread and there was no renal stone (but a ureteral stone), the fall 2015 study correctly identified a renal stone. It is unknown from the radiology reports whether the ureteral stone that was present in the fall 2014 study was still present in fall 2015.

<sup>&</sup>lt;sup>97</sup> PSA is a protein produced by tissues of the prostate, both cancerous and noncancerous tissues. High PSA levels can be associated with prostate cancer, enlarged prostate, and inflamed prostate.

mass of the left kidney measuring 4.4 centimeters (cm) x 4.3 cm and "worrisome for a renal cell carcinoma [cancer]." The patient was seen in urology clinic six days after the CT scan was performed, and the diagnostic and therapeutic options for the renal mass were discussed. The patient opted to proceed with a nephrectomy (removal of the kidney) after the risks and benefits were explained to them. Approximately three weeks later, the patient underwent left nephrectomy without complication. The pathology report on the renal mass stated that the patient had a renal oncocytoma. The patient did well post-operatively and was seen in urology clinic for a follow-up visit three weeks after surgery. The patient subsequently continued to receive follow-up monitoring with urology service for their elevated PSA values that were unrelated to the renal mass.

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<sup>&</sup>lt;sup>98</sup> Renal oncocytoma is a noncancerous growth in the kidney usually discovered by chance when patients are having imaging tests for other reasons. Renal oncocytoma can be hard to distinguish from renal cell cancer based on imaging studies thus a biopsy and/or surgery are generally needed to verify the diagnosis. National Institutes of Health, National Center for Advancing Translational Sciences, "Renal Oncocytoma." <a href="https://rarediseases.info.nih.gov/diseases/8477/renal-oncocytoma">https://rarediseases.info.nih.gov/diseases/8477/renal-oncocytoma</a>. (The website was accessed on January 16, 2019.)

# Appendix C: June 2014–January 2019 Timeline of Events

Date	Facility Event	Delinquency
June 25, 2014	Chief of Imaging recommended approval of subject radiologist's request for privileges and medical staff appointment as staff radiologist. PSB concurred and recommended MSEC approval with the Chief of Imaging to report FPPE 90 days following first episode of care (July 2, 2014).	In January and June of 2014, the Altoona Facility Director notified the subject radiologist about being named in two tort cases. <sup>99</sup>
December 23, 2014	Chief of Imaging reported the FPPE. The PSB found the FPPE incomplete and requests an indepth review.	FPPE reported 84 days past due date of September 30, 2014.
<b>December 31, 2014</b>	Facility managers did not renew the contract for the subject radiologist's appointment.	
April 16, 2015	Chief of Imaging provided an Exit Memorandum to the PSB noting "significant deficiencies in subject radiologist's clinical practice as to raise reasonable concern for the safety of patients."	Exit Memorandum submitted 99 days past due date of January 7, 2015.
May 7, 2015	Chief of Imaging presented results of the initial review of 30 of the radiologist's imaging interpretations: "Deficiencies were noted in [the subject radiologist's] radiologic interpretations that were not consistent with generally accepted standards of care." PSB recommended 100 percent review to identify concerns for patient care. MSEC concurred and provided a target date of August 2015.	
October 2, 2015	Facility leaders issued one institutional disclosure.	
February 25, 2016	Facility clinicians issued one clinical disclosure.	
June 7, 2018	OIG CHIP review	
June 19, 2018	Facility issued Issue Brief	
July 2, 2018	The former COS and the VISN 6 Chief Medical Officer presented the status of the 100 percent review to the Clinical Episode Review Team. Assistance was solicited from the NTP to provide assistance with the review.	
August 6, 2018	The former COS and the VISN 6 Chief Medical Officer presented the results of the 100 percent review to the Clinical Episode Review Team.	

<sup>&</sup>lt;sup>99</sup> The Altoona Facility Director sent the notifications of tort claims to the subject radiologist in January and June of 2014. It is unknown if the subject radiologist received these notices.

Date	Facility Event	Delinquency
August 22, 2018	Chief of Imaging presented "Final Findings and Recommendations" to PSB: "The comprehensive review shows multiple instances of erroneous interpretations that fall below the expectation of minimal competence. The recommendation was to report the findings to the SLB and NPDB." The MSEC concurred and recommended referral to the Facility Director to report the practitioner and deficiencies to the SLB.	100 percent review to identify concerns for patient care presented three years past due date of August 2015.
September 24, 2018	Based on the initial review, the Facility Director sent to the subject radiologist a Memorandum of Notification of Intent to Initiate SLB action.	Suggested time frame to complete initial review and begin steps for an SLB required Comprehensive Review begins 30 days from employee's departure from VHA. In this case the process took over 3 years. <sup>100</sup>
December 14, 2018	The facility managers confirmed to the OIG all discrepant findings identified on the complete review spreadsheet have been addended in the patients' EHR.	
January 25, 2019	The Facility Director notified eight SLBs of the concerns about the subject radiologist's clinical practices.	

Source: OIG staff analysis of facility reports and VHA and facility policy

<sup>&</sup>lt;sup>100</sup> VHA Handbook 1100.18.

## **Appendix D: Summary of VHA Data Review**

Review	Methodology and Findings	
VHA Radiologists Review of Subject Radiologist's Imaging Reports	The OIG team compared the Radiology Review data provided by the facility with independent data the OIG team obtained from the VA's Corporate Data Warehouse. The OIG identified 19 imaging reports that were not included in the Radiology Review data. 101 On October 11, 2018 the OIG provided the facility Risk Manager with the 19 identified imaging reports. The facility managers updated and returned a more complete report to the OIG. OIG team members confirmed that facility radiologists had previously reviewed seven of the 19 imaging reports, but those imaging reports were not included in the final review data. Facility radiologists re-reviewed the seven records, identified no clinical impact. The Chief of Imaging reviewed the remaining 12 imaging reports in October 2018, identified no clinical impact, and made no corrections to the patients' EHRs.	
Facility Radiologists' Concurrence Ratings of Subject Radiologist's Imaging Reports	The August 2018 Review of Professional Practice, submitted to the PSB, noted that the ratings were categorized on a scale of 1–3.	
	The standard exit review raised concerns about the accuracy and quality of the subject radiologist's reports. The review of cases both for specific concerns, and a non-specific sample showed more rated as 2 or 3 than generally expected. Cases were rated on a scale from 1 to 3. "1"- Most radiologists would interpret the same. "2" - Some radiologists would interpret differently. "3" - Most radiologists would interpret differently. The adverse trend mandated an extensive internal review by facility radiologists. A recent audit of Quality Management practices prompted a further comprehensive review with aggregation of findings. The results of this review indicated that 1271 (47%) of the subject radiologist's 2716 total cases were rated "2" or "3" by facility radiologists.	
	The OIG compared findings from the Radiology Review data with the findings reported to the VHA Clinical Episode Review Team on August 6, 2018. The OIG team found that radiologists reviewed the imaging reports and assigned corresponding ratings to all 2716 imaging reports. Additionally, in October 2018, the Chief of Imaging rated the imaging reports that were identified by the OIG team, through Corporate Data Warehouse data analysis, as not included in the Radiology Review data.	
Facility and NTP Radiologists' Review and Rating for Clinical Impact	The Review of Professional Practice stated  The adverse findings from the internal review led to consultation	
	with the NTP to provide an independent review of representative cases rated "2" or "3". NTP rated cases on a scale of 5 to 7. "5" - Met standard of care. "6" - Not met standard of care (no clinical impact). "7" - Not met standard of care (potential clinical impact/harm).	

<sup>&</sup>lt;sup>101</sup> When asked, the staff member who extracted the information from the regional for the facility's list of reports could not explain the difference in the number of regional data warehouse imaging reports and the number of corporate data warehouse imaging reports.

Review	Methodology and Findings
	The OIG compared these findings with the Radiology Review data and the VHA Clinical Episode Review Team report. The OIG identified that of the 1,271 imaging reports with an initial 2 or 3 rating by facility radiologists, the NTP reviewed 959 for clinical impact. Facility radiologists conducted a second review of the remaining 312 for clinical impact.
Review for Adverse Clinical Outcomes	The following are the results of the NTP radiologist's review for clinical impact of the 959 imaging reports:  Rated 5 - Met standard 788  Rated 6 - Not met standard (no clinical impact) 128  Rated 7 - Not met standard (potential clinical impact/harm) 43  The following are the results of the facility radiologist's review for clinical impact of the 312 imaging reports: 102  Met standard 223
	Not met standard (no clinical impact) 63  Not met standard (possible clinical impact/harm) 26

Source: OIG staff analysis of facility reports and reviews

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 $<sup>^{102}</sup>$  Facility radiologists' second review of the 312 imaging reports for clinical impact used the same rating criteria as the NTP without assigning a numerical value.

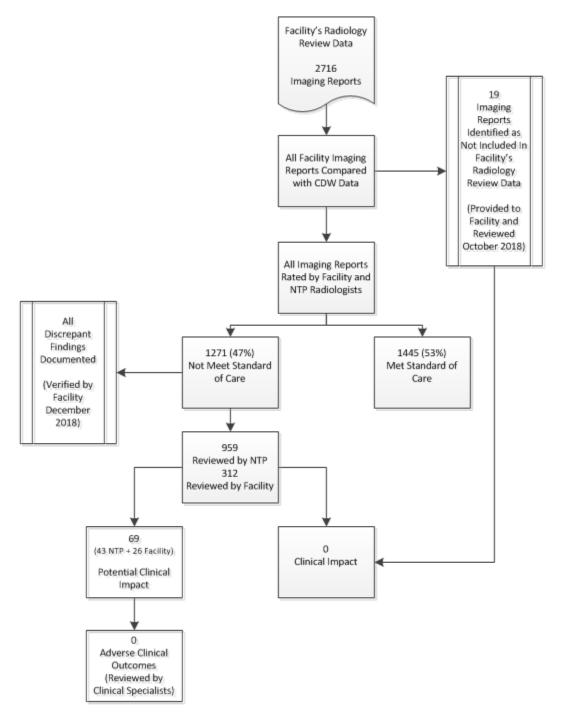


Figure 1. Facility review and recommendations Source: VA OIG analysis of facility Radiology Review data and Corporate Data Warehouse data

## **Appendix E: VISN Director Memorandum**

#### **Department of Veterans Affairs Memorandum**

Date: September 10, 2019

From: Director, VA Mid-Atlantic Health Care Network (VISN 6)

Subj: Healthcare Inspection—Facility Hiring Processes and Leaders' Responses Related to the

Deficient Practice of a Radiologist, Charles George VA Medical Center, Asheville, North Carolina

To: Director, Office of Healthcare Inspections (54HL07)

Director, GAO/OIG Accountability Liaison Office (VHA 10EG)

I concur with the findings and recommendations of the Charles George VA Medical Center regarding the Health Inspection - Facility Hiring Processes and Leaders' Responses Related to the Deficient Practice of a Radiologist, Charles George VA Medical Center.

(Original signed by:)

DEANNE M. SEEKINS, MBA, VHA-CM VA Mid-Atlantic Health Care Network Director, VISN 6

## **Appendix F: Facility Director Memorandum**

#### **Department of Veterans Affairs Memorandum**

Date: September 6, 2019

From: Director, Charles George VA Medical Center (637)

Subj: Healthcare Inspection—Facility Hiring Processes and Leaders' Responses Related to the Deficient Practice of a Radiologist, Charles George VA Medical Center, Asheville, North Carolina

To: Director, VA Mid-Atlantic Health Care Network, (VISN 6)

- 1. Charles George VA Medical Center has reviewed and concurs with this Health Inspection report.
- 2. We recognize opportunities for improvements in our practice and corrective actions are being fully implemented to address the recommendations.

(Original signed by:)

STEPHANIE YOUNG Medical Center Director

### **Comments to OIG's Report**

#### **Recommendation 1**

The Charles George VA Medical Center Director verifies that facility managers adhere to Veterans Health Administration policy that outlines the credentialing and privileging process for licensed independent practitioners.

Concur.

Target date for completion: November 29, 2019

#### **Director Comments**

The Credentialing and Privileging Office staff at the Charles George Veterans Affairs Medical Center (CGVAMC) is responsible for ensuring that all Credentialing and Privileging requirements, as outlined in VHA Handbook 1100.19, are met. These staff are utilizing a Privileging checklist tool to ensure that all appropriate requirements are met. The tool assists in ensuring that the steps in the processes for the national requirements for documentation on the mandated reviews at the facility-level and VISN-level are completed appropriately. This includes ensuring that the disposition is logged into the respective provider's VetPro electronic credentialing file utilizing the VHA Documentation of Review of Licensure/Certification/Registration Actions form. Outcomes are presented by the respective service chief to the Professional Standards Board (PSB) and approved by the Medical Executive Council (MEC). Chief of Staff office will conduct monthly audits of the tracking tool's appropriate utilization for three consecutive months. Target compliance is 90 percent.

#### **Recommendation 2**

The Charles George VA Medical Center Director and managers meet all requirements of state licensing boards reporting.

Concur.

Target date for completion: November 29, 2019

#### **Director Comments**

The Human Resources staff in consultation with the Credentialing and Privileging Office staff and the Risk Manager at the CGVAMC report practitioners to the Medical State Licensing Board (SLB) for paid claims as required by the Office of Legal and Medical Affairs. Medical SLB reporting is initiated when a licensed healthcare professional has been identified as performing substandard care per VHA Handbook 1100.18. The Professional Standards Board (PSB) make

the recommendation for reporting the deficiency with concurrence by Medical Executive Council (MEC) and final determination is made by the Medical Center Director. The OPPE/FPPE tracking tool is being utilized to ensure that all FPPEs are appropriately closed out with approval from PSB and concurrence by MEC. FPPEs that are not completed satisfactorily are reported by the service chief to PSB for action recommendations. MEC reviews the determination of PSB and sends recommendations forward to the Medical Center Director for final determination to include reporting to the appropriate Medical State Licensing Board. There were zero to be reported to the Medical State Licensing Board after review for compliance was conducted. The Administrative Assistant to the Chief of Staff will provide education to the Professional Standards Board members and Clinical Service Chiefs on the Medical State Licensing Boards requirements and track attendance. Target compliance is 90 percent.

#### **Recommendation 3**

The Charles George VA Medical Center Director ensures staff compliance with Veterans Health Administration policies related to reporting of all adverse events to the Patient Safety Manager.

Concur.

Target date for completion: November 29, 2019

#### **Director Comments**

The CGVAMC Patient Safety Manager will complete education on the Joint Patient Safety Reporting (JPSR) to all radiology staff. The Patient Safety Manager and Risk Manager will ensure that any institutional disclosures of adverse events to patients will have a JPSR entered. The Patient Safety Manager and Risk Manager (Patient Safety Manager back up) are meeting weekly to discuss cases, JPSRs and any institutional disclosures of adverse events to patients. The Patient Safety Manager will train the radiology staff regarding the process for reporting radiology related adverse events in the JPSR system and track attendance. Target for radiology staff training attendance is 90 percent.

#### **Recommendation 4**

The Charles George VA Medical Center Director confers with Human Resources regarding the actions taken by facility leaders and managers, related to the lack of oversight and failure to conduct credentialing and privileging per VHA requirements, and take administrative action(s) as necessary.

Concur.

Target date for completion: November 29, 2019

### **Director Comments**

The Chief of Staff has met with Human Resources staff regarding potential administrative action to be taken. Upon further review, appropriate administrative action will be determined.

# **OIG Contact and Staff Acknowledgments**

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