



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Pathology Oversight Failures
at the Veterans Health Care
System of the Ozarks in
Fayetteville, Arkansas



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Executive Summary

The VA Office of Inspector General (OIG) received allegations in late 2017 concerning issues within the Pathology and Laboratory Medicine Service (Path and Lab) at the Veterans Health Care System of the Ozarks (facility) in Fayetteville, Arkansas. The OIG Office of Healthcare Inspections initiated a healthcare inspection in spring 2018 after examining additional allegations related to the Path and Lab Service Chief, Dr. Robert M. Levy, misdiagnosing patients' pathological specimens that adversely affected outcomes and altering quality management documents to conceal his errors. It was also alleged that a facility leader did not adequately monitor Dr. Levy's clinical practice and failed to address misconduct. Shortly thereafter, the OIG Office of Investigations began a criminal investigation of Dr. Levy's actions. The healthcare inspection was paused in deference to that investigation.

Apart from the OIG's inspection, the facility initiated action to remove Dr. Levy from federal service. On October 13, 2017, Dr. Levy appeared to be impaired during work hours and was removed from the clinical setting. His privileges were summarily suspended due to concerns that aspects of his clinical practice did not meet accepted standards and potentially constituted an imminent threat to patient welfare. While the facility was preparing revocation paperwork, Dr. Levy was arrested on March 1, 2018, during duty hours, in the parking lot of a local post office on suspicion of driving while intoxicated. Dr. Levy's removal was finalized in July 2018.

While completing the necessary steps to remove Dr. Levy, the facility initiated a review of his patient cases. When more errors than expected were identified, facility leaders contacted a Veterans Health Administration (VHA) official for assistance and a [clinical episode review team](#) (CERT) was convened.¹ The review was expanded and after finding additional errors in previous years, the CERT determined that a 100 percent [look-back](#) review of all Dr. Levy's cases from the start of his service at the facility in September 2005 was necessary.² A look-back review team of pathologists reviewed almost 34,000 cases. Clinical reviewers then evaluated the cases determined to have errors to assess the impact on patient care. According to VHA policy, if an [adverse event](#) occurred that "resulted in or is reasonably expected to result in death or serious

¹ The underlined terms are hyperlinks to a glossary.

² Dr. Levy started his practice at the facility as a locum tenens (temporary) provider in September 2005. After approximately one month, he transitioned to a full-time employee and assumed the Path and Lab Service Chief position.

injury,” facility leaders should conduct an [institutional disclosure](#) to inform the patient of the circumstances of the event.³

Final results of the look-back review revealed slightly more than 3,000 errors, including 589 major diagnostic discrepancies interpreted by Dr. Levy during his time at the facility.⁴ Two examples of patients who had major diagnostic discrepancies illustrate the fatal consequences of Dr. Levy’s actions:

One patient underwent a [prostate biopsy](#) in 2012 that Dr. Levy reported to be benign. Look-back reviewers in 2018 identified cancer in two of the six biopsy specimens. At the time the patient was notified of the cancer diagnosis in 2018, treatment was limited to [palliative care](#). The patient died in late 2020 ([patient 3](#)).

A second patient was treated for [small cell cancer](#) after Dr. Levy made the diagnosis in 2014. The patient died about a year later. The look-back review determined that the patient had [squamous cell cancer](#) of the lung, not small cell cancer. Treatment options for squamous cell lung cancer included surgery, which was not offered to the patient ([patient 5](#)).

Dr. Levy had previously been removed from clinical practice at the facility in 2016 because of a high blood alcohol content test during working hours, but returned several months later after attending a treatment program. As part of his return, he agreed to regular testing for drug and alcohol use.⁵ All Dr. Levy’s daily or weekly urine and blood tests were negative for the presence of drugs and alcohol. During the October 2017 episode noted above, Dr. Levy was observed to be drowsy, glassy eyed, slurring his words, and with an unsteady gait. Urine and blood tests at that time were reported to be negative.

After his 2018 removal, Dr. Levy admitted to OIG criminal investigators to being an alcoholic for 30 years and after his 2016 removal from clinical practice, buying a substance online that was similar to alcohol but more potent, and that was not detectable using routine drug and alcohol

³ VHA Directive 2005-049, *Disclosure of Adverse Events to Patients*, October 27, 2005, rescinded and replaced by VHA Directive 2008-002, *Disclosure of Adverse Events to Patients*, January 18, 2008, rescinded and replaced by VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012, rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The policies contain similar language related to adverse events and institutional disclosures.

⁴ The look-back review team categorized its findings according to the level of discrepancy: (0) no deficiency or diagnostic error; (1) minor disagreement, practice acceptable, reviewer still comfortable; (2) disagreement in diagnosis with minimal or no potential negative impact on patient care; and (3) major diagnostic discrepancy with potential for negative impact on patient care/treatment. The OIG initiated a hotline in March 2021 that included a review of facility processes and progress in responding to cases categorized as level 2 or level 3 during the look-back review.

⁵ As part of Dr. Levy’s treatment program, he was obliged to submit to random testing after resuming his duties in October 2016.

testing methods.⁶ After further investigation into Dr. Levy's misdiagnoses and misconduct associated with his care of veteran patients, criminal charges were filed in the Western District of Arkansas in August 2019. Approximately a year later, in 2020, Dr. Levy pleaded guilty to involuntary manslaughter and mail fraud.

In January 2021, Dr. Levy was sentenced to 20 years in prison followed by three years supervised release, and ordered to pay approximately \$498,000 in restitution to VA. He appealed the sentence one week later. With the closure of the Office of Investigations case, the OIG's Office of Healthcare Inspections completed its review and issues its findings in this report.

The enormous number of serious diagnostic errors by Dr. Levy was the result of his failure to interpret specimens correctly. The errors remained undetected for years in part because of his manipulation of pathology quality management data and deficiencies in quality management processes. While the OIG recognizes that impaired providers should be offered assistance in appropriate situations, senior leaders missed opportunities to address Dr. Levy's impairment. Facility leaders failed to promote a culture of accountability. The OIG found a culture in which staff did not report serious concerns about Dr. Levy in part, because of a perception that others had reported or they were concerned about reprisal. Any one of these breakdowns could cause harmful results. Occurring together and over an extended period of time, the consequences were devastating, tragic, and deadly.

Deficiencies in Quality Management Processes

The OIG found that deficiencies in the facility's quality management processes contributed to thousands of diagnostic errors that occurred throughout Dr. Levy's tenure.

As Path and Lab Service Chief, Dr. Levy was responsible for the facility's Path and Lab quality management program that included an "on-going, planned, systematic, and objective process for the monitoring and evaluation of the quality improvement plan."⁷ Dr. Levy developed quality management policies and controlled all aspects of the quality management program in a service with only one other pathologist (Staff Pathologist, a subordinate of Dr. Levy), which made the process susceptible to subversion. Dr. Levy was chairperson for three pathology quality management committees that reviewed information about pathology cases and practices. Facility documentation indicated that the process for reporting pathology quality management data was to forward the data to facility leaders through the three committees.

⁶ Dr. Levy also noted the substance was a pigment solvent and that on one occasion, he developed stroke-like symptoms after ingesting it.

⁷ VHA Handbook, 1106.1, *Pathology and Laboratory Medicine Service Procedures (P&LMS)*, June 4, 2003; VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service Procedures*, October 6, 2008; VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016. The three handbooks contain similar language related to the pathology quality management program.

Dr. Mark Worley, Chief of Staff from late 2012 through summer 2018, who was Dr. Levy's supervisor, indicated that the Path and Lab manager compiled the data that he signed and presented for Dr. Levy's [privileging](#).⁸ This information included results of a required [10 percent peer review](#) of his cases that was done by the Staff Pathologist.⁹ The involvement of a subordinate in the peer review process of a supervisor creates an inherent conflict of interest.¹⁰ According to VHA policy, certain pathology findings require a second review by another pathologist. For example, a diagnosis of a new malignancy requires a second read before a final report is issued.¹¹ When a statement of concurrence of a cancer diagnosis is entered into a patient's record, the treating provider and the patient have more confidence in the accuracy of the finding, knowing that two qualified pathologists have reviewed the specimen. It was determined that Dr. Levy was entering concurrence statements into some patients' electronic health records (EHR) when a second pathologist had not agreed with the interpretation or diagnosis.

Collaborative discussions are helpful to reduce pathology interpretive errors.¹² Several interviewees noted a strained relationship between Dr. Levy and the Staff Pathologist. Results of second reads between the two, including the 10 percent peer reviews, were communicated by sticky notes, which provided Dr. Levy the opportunity to alter or ignore the results. The use of informal documentation did not allow ready tracking or promote accountability.

When a disagreement with an interpretation by a second pathologist reveals a major diagnostic discrepancy, a third pathologist should be consulted. An external non-VHA pathology group may be consulted for the third opinion. After resolution of a disagreement, an amended report is entered into the patient's EHR as needed. The amended report may indicate a change that is not

⁸ The OIG refers to Dr. Worley as the Chief of Staff in this report; the OIG was informed that he retired from federal service in the summer 2018. VHA Handbook 1100.19, *Credentialing and Privileging*, March 6, 2001; VHA Handbook 1100.19, *Credentialing and Privileging*, October 2, 2007; VHA Handbook 1100.19, *Credentialing and Privileging*, November 14, 2008; VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. VHA providers must undergo credentialing—a screening and evaluating process to determine qualifications to practice (licensure, education, training, experience, current competency and health status). Dr. Levy was initially privileged in October 2005.

⁹ VHA Handbook 1106.1, 2003; VHA Handbook 1106.01, 2008; VHA Handbook 1106.01, 2016. The handbooks required a 10 percent peer review; however, the 2016 version added the requirement of a random selection of cases.

¹⁰ VHA Directive 2008-004, *Peer Review for Quality Management*, January 28, 2008, rescinded and replaced by VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010, rescinded and replaced by VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. The OIG likens this situation to the confidential peer review process where a peer reviewer must withdraw “from review of cases where there is a conflict of interest or, for any other reason, the reviewer is unable to conduct an objective, impartial, accurate, and informed review.”

¹¹ VHA Handbook 1106.1, 2003; VHA Handbook 1106.01, 2008; VHA Handbook 1106.01, 2016. The handbooks contain the requirement for a second read of a new malignancy.

¹² Anne Paxton, “Evidence drives guideline on reducing interpretive error,” *CAP Today*, July 2015.

clinically significant or one that is clinically significant.¹³ The submitting provider and the chief of staff must be notified of pathological diagnostic changes affecting a patient's treatment.

One of the pathology quality management committees (Tissue Committee) that Dr. Levy chaired was responsible for reporting the number of major diagnostic discrepancies (those that could affect the patient's clinical care) to facility leaders. From November 2009 through September 2017, the Tissue Committee meeting minutes reflected *zero* major discrepancies without evidence of discussion of the zero findings among committee members. The OIG concluded that such documentation appeared to reflect a failure among fellow committee members and facility leaders to dispute the data.

Additionally, facility quality management staff had the ability to generate reports of major diagnostic discrepancy cases from VHA's computer system that had been coded as such in the patient's EHR. However, major diagnostic discrepancy reports were not generated for many years of Dr. Levy's tenure. Facility leaders were aware that a patient received incorrect treatment in 2014 related to a failed communication to treating providers of an amended pathology report that reflected a major diagnostic discrepancy. Therefore, the OIG would have expected more intensive surveillance of amended pathology reports and major diagnostic discrepancies by facility quality management staff in the later years of Dr. Levy's tenure.

In support of Dr. Levy's initial core privileges, the facility received four positive references (three from his most recent place of employment). However, at the time Dr. Levy was hired in 2005, he disclosed a previous conviction in 1996 related to driving while intoxicated. A review of his application packet revealed a short stay (approximately eight months) at his previous place of employment. While the OIG recognizes that neither of these facts would bar consideration of Dr. Levy as a potential candidate, the OIG is concerned that a rigorous process was not in place to better evaluate his clinical competency at the time he was hired. Given the information in Dr. Levy's application documents, his initial position as a [locum tenens](#) provider, immediate elevation to a service chief position, and a high error rate identified by the look-back review team for his probationary period (the first two years of his employment), it appears that facility leaders' efforts were insufficient to determine the quality of Dr. Levy's pathology practice.

The OIG concluded that had facility leaders conducted a more robust evaluation of Dr. Levy's cases, the evaluation would have likely identified deficiencies similar to the look-back review. The consequences of failing to attain a high level of scrutiny during a pathology provider's probationary period are considerable. Therefore, the OIG proposes a review of VHA's competency process for providers in locum tenens positions, newly hired specialty care providers such as pathologists, and newly hired service chiefs to confirm that evaluations accurately reflect the clinical competency of providers who are privileged. Identification of diagnostic errors

¹³VHA Handbook 1106.1, 2003; VHA Handbook 1106.01, 2008; VHA Handbook 1106.01, 2016. The handbooks contain similar language regarding reviews by a third pathologist, clinically significant additions to pathology reports, and provider notification.

during the initial hiring period would have provided facility leaders the opportunity to immediately address Dr. Levy's performance or not approve his permanent appointment.

Incorporating clinical information to evaluate a provider's ongoing competency is an integral component of a facility's [credentialing](#) and biennial privileging process.¹⁴ The Chief of Staff, who became Dr. Levy's supervisor in 2012, included Dr. Levy's 10 percent peer review, as an element of his [ongoing provider practice evaluation](#). The OIG questions whether the 10 percent peer review would accurately reflect a pathologist's competency given the look-back review results that identified large numbers of errors.

Because the facility's 10 percent peer review process did not identify the extent of diagnostic errors that the look-back review revealed, the OIG explored VHA guidance on the matter. According to the 2016 VHA pathology handbook, the cases for the 10 percent peer review must be randomly selected.¹⁵ According to the College of American Pathologists, "there is evidence that targeted review (review of a specific type of case) is more efficient at finding important diagnostic discrepancies or errors than randomly selecting cases for review."¹⁶

Focusing at least a portion of the 10 percent peer review on cases that carry a higher risk of interpretation error or that can result in clinically significant consequences to a patient could be more effective in identifying errors. Due to the critical nature of accurate pathology diagnoses, VHA should evaluate the need to provide additional instructions to facilities on the methodology for selecting cases for peer reviews.

The look-back results including the 589 major diagnostic discrepancies during Dr. Levy's tenure are not congruent with the data (including the 10 percent peer reviewed cases) facility leaders relied on to determine Dr. Levy's competency and biennial reprivileging over a 12-year span.

Inadequate Management of an Impaired Provider

The OIG acknowledges that an impaired provider should be offered assistance when appropriate in recognizing and managing the causes of the impairment. However, as the facility's

¹⁴ VHA Handbook 1100.19, 2001; VHA Handbook 1100.19, 2007; VHA Handbook 1100.19, 2008; VHA Handbook 1100.19, 2012.

¹⁵ VHA Handbook 1106.01, 2016.

¹⁶ College of American Pathologists, "About us," accessed December 29, 2020, <https://www.cap.org/about-the-cap>. The College of American Pathologists is an organization of board-certified pathologists. Association of Directors of Anatomic and Surgical Pathology, "Interpretive Diagnostic Error Reduction in Surgical Pathology and Cytology," accessed February 9, 2021, <https://documents.cap.org/documents/ider-faqs.pdf>.

management of the impaired provider policy states, the process of assistance must be “consistent with the protection of patients.”¹⁷

It appears that prior to March 2016, facility leaders failed to consider the impact on patients of a possibly impaired provider who was a service chief in control of pathology quality management processes. The OIG also noted multiple lapses in the facility’s management of reports of behaviors that were likely related to Dr. Levy’s impairment.

The Chief of Staff described to the OIG episodic, informal reports related to Dr. Levy’s smelling like alcohol or other possible signs of impairment that he said were not actionable (for example, a provider mentioned possible impairment issues that had occurred a few days prior during a conversation in an elevator or the hallway). On one occasion in March 2014, the Chief of Staff went to evaluate Dr. Levy after receiving a complaint that Dr. Levy smelled of alcohol. Dr. Levy gave an implausible excuse for his smelling like alcohol (drinking a lot of juice). The Chief of Staff did not smell alcohol and did not take further action.

In 2015, there were two reported incidents:

- In September, staff reported that Dr. Levy had an odor of alcohol, “red” eyes, and hand tremors when reviewing biopsy slides during an [interventional radiology](#) procedure.
- In October, during a fact-finding review of the September incident, the fact-finders noted that Dr. Levy smelled of mouthwash, had red glassy eyes, and exhibited hand tremors.

VA’s drug-free workplace policy indicates that “an essential element in assuring a drug-free workplace is drug testing.”¹⁸ The policy also recognizes that physicians, dentists, nurses, pharmacists, and other healthcare workers could cause patient death or injury should they use drugs and determined that staff in these occupations should be subject to drug testing.¹⁹

However, the policy focuses on illegal drugs and does not address routine mandatory testing for alcohol.

According to a facility report, at the time of the second 2015 incident, Dr. Levy voluntarily agreed to testing. Testing did not occur because misinformation was provided about the facility’s authority to do so. While VA does not have the authority to routinely conduct mandatory alcohol testing, the OIG was informed that in 2015, testing employees for alcohol on a voluntary basis was permissible. However, facility managers were unaware and misinformed by facility human resources staff about obtaining a volunteered blood alcohol content test. The fact-finding review

¹⁷ Facility Memorandum 11-11-89, *Management of the Impaired Licensed Independent Practitioner (LIP)*, March 7, 2011; Facility Memorandum 11-089, *Management of the Impaired Licensed Independent Practitioner (LIP)*, March 31, 2014; Facility Memorandum 17-11-089, *Management of Impaired Licensed Independent Practitioner (LIP)*, March 31, 2017. “The purpose of this process is assistance and rehabilitation, rather than discipline, to aid a practitioner in retaining or regaining optimal professional functioning, consistent with the protection of patients.”

¹⁸ VA Directive/Handbook 5383, *VA Drug-Free Workplace Program*, December 23, 2004.

¹⁹ VA Directive/Handbook 5383, 2004; VA Directive/Handbook 5383, September 13, 2006.

was completed but no further action was taken and no inquiries were made to the Office of General Counsel or other VA experts.

In March 2016, Dr. Levy was reported for signs of impairment, agreed to testing, and was discovered to have a high blood alcohol content level. He was immediately removed from clinical care. The OIG did not find evidence of a comprehensive, retrospective review of Dr. Levy's cases at the time of the 2016 removal. After completing a treatment program, Dr. Levy was allowed to return to work several months later.

Had facility leaders taken the opportunities that presented as early as March 2014 to vigorously address allegations of impairment and adequately review Dr. Levy's clinical competency, his removal may have occurred sooner. An extensive review of Dr. Levy's cases and assessment of his competency prior to reinstatement in 2016 would likely have revealed results similar to the look-back review and may have averted the facility's decision to return Dr. Levy to clinical practice. The Chief of Staff informed the OIG that the lack of evidence of patient adverse clinical outcomes factored into the decision that allowed Dr. Levy to return to clinical service in October 2016.

Before Dr. Levy's return to practice in October 2016, facility leaders were alerted of concerns that he had subverted the Path and Lab quality management program, had repeatedly misrepresented second reviews of cases, and was deficient in communication with providers when there were significant changes in diagnoses. Although a limited review of Dr. Levy's 2015 and 2016 cases was conducted by a pathologist and found to be satisfactory by the Chief of Staff, the OIG did not find evidence that concerns related to Dr. Levy's subversion of the pathology quality management process were fully examined prior to his return.

The OIG also noted that other information the facility collected as part of Dr. Levy's reappraisal for privileging may not have been reliable. Available reappraisal summaries included peer comments of support from physicians who were not pathologists. They made very positive comments about Dr. Levy's practice.²⁰ The OIG questions how Dr. Levy's "peers" were able to opine on the six competency domains. As non-pathologists, they were likely not fully aware of pathology quality management requirements or whether Dr. Levy had the requisite skills to competently interpret specimens.

Based on healthcare workers' responsibility for the safety of patients, the OIG concluded that VHA should explore the development of a mandatory alcohol testing policy for individuals including healthcare workers who perform functions that would put patients at risk should the employee work while impaired.

²⁰ Facility Memorandum 11-114, *Focused and Ongoing Professional Practice Evaluations (FPPE and OPPE)*, June 9, 2013. The facility policy identifies several categories for evaluation including patient care, medical/clinical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and system-based practice, which the OIG interpreted as the "competencies" discussed in the peer comments.

Failure of Facility Leaders to Foster a Culture of Accountability

After Dr. Levy admitted to the OIG of a 30-year problem with alcohol and the more recent use of a substance with similar effects but not detectable by routine testing, the OIG grew concerned about facility staff having observed signs of impairment earlier than 2016 but not formally reporting them as required.²¹ When interviewed, staff who observed impaired behaviors shared concerns about reporting including fear of reprisal. An [administrative investigation board](#) was initiated in 2018 and evaluated the facility's culture related to quality and safety reporting.²² The administrative investigation board found a lack of transparency in the pathology quality management processes and communication delays.

The OIG determined that facility leaders did not foster a culture of accountability to staff. A failure of facility leaders to vigorously explore or take action may promote perceptions that reporting will have no effect. Not aggressively addressing reports can also discourage staff from complying with the facility's policy to report subsequent observations of possibly unsafe treatment. The OIG concluded that facility leaders did not meet VHA's goal to establish an "environment in which staff act with integrity to achieve accountability."²³

The OIG made 10 recommendations to the Under Secretary for Health. Recommendations addressed competency processes for newly hired and temporary providers as well as service chiefs, pathology quality management processes including evaluation of the required Path and Lab 10 percent peer review, revision of guidance related to amended pathology reports, inclusion of an alert process for amended reports in VHA's new record system, and the consulting process with external, non-VHA pathology groups. The OIG also recommended that the Office of General Counsel and the Office of Human Resources and Administration/Operations, Security & Preparedness be consulted about taking administrative actions for VHA leaders who were involved in matters related to Dr. Levy, as appropriate. Two recommendations focused on alcohol testing and the management of impaired healthcare workers.

Two recommendations addressed to the Facility Director focused on peer references during the reappraisal and reprivileging processes and evaluation of the facility's psychological safety climate and the reporting of concerns about unsafe patient care.

²¹ Facility Memorandum 11-11-89, 2011; Facility Memorandum 11-089, 2014; Facility Memorandum 17-11-089, 2017. As noted above, the substance was a pigment solvent that resulted in Dr. Levy's developing stroke-like symptoms.

²² VA Directive 0700, *Administrative Investigations*, March 25, 2002.

²³ VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value*, August 2, 2013. The directive which was in effect during part of the time the events discussed in this report. It was rescinded in 2019 to avoid "conflict with modernization efforts as they are being rolled out as part of the new VHA governance process."

Comments

The Under Secretary for Health and the Veterans Integrated System Network and Facility Directors concurred with the recommendations and provided acceptable action plans (see appendixes D, E, and F). The OIG considers all recommendations open and will follow up on the planned and recently implemented actions to ensure that they have been effective and sustained.



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

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Abbreviations

EHR	electronic health record
FPPE	focused professional practice evaluation
NEO	National Enforcement Office
OPM	Office of Personnel Management
OPPE	ongoing professional practice evaluation
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) received allegations in late 2017 from a confidential complainant concerning issues within the Pathology and Laboratory Medicine Service (Path and Lab) at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas (facility).¹

The OIG referred the 2017 allegations to Veterans Integrated Service Network (VISN) 16. While waiting for the response to the query, the OIG received additional allegations that the Path and Lab Service Chief, Dr. Robert M. Levy, misdiagnosed patients' pathological specimens, which adversely affected outcomes, and altered quality management documents to conceal his errors. Dr. Levy was expected to examine tissue and body fluid specimens and based on his interpretation, to accurately make diagnoses such as cancer. Providers of all specialties relied on the results of these interpretations to guide decision-making regarding treatment planning.²

Additionally, Dr. Mark Worley, Chief of Staff from late 2012 through summer 2018, allegedly did not adequately monitor Dr. Levy's clinical practice and failed to address misconduct.³ In spring 2018, when the OIG initiated a healthcare inspection to evaluate facility leaders' actions related to the oversight of Dr. Levy, the OIG team learned that facility leaders had started to take steps to remove Dr. Levy from federal service.

Also in 2018, a separate division of the OIG, the Office of Investigations, began a criminal investigation into Dr. Levy's actions. The healthcare inspection was paused in deference to the criminal investigation. Dr. Levy subsequently admitted to OIG investigators that he had been an alcoholic for 30 years and purchased a substance, 2-methyl-2-butanol (2M-2B), online that could be ingested, was similar to alcohol but more potent, and was not detectable using routine drug and alcohol testing methods.⁴

According to the facility, prior to completing the steps required to remove Dr. Levy in 2018, a review of his cases was initiated. When more diagnostic errors than expected were identified, a facility and a VISN leader contacted a Veterans Health Administration (VHA) official for

¹ In 2015, the OIG received allegations regarding employee misconduct that included a complaint specific to Dr. Levy reading slides while under the influence of alcohol. The OIG Office of Healthcare Inspections contacted VISN 16 and received a response from the facility through the VISN. According to the response, a fact-finding review had been conducted. Dr. Levy's use of alcohol could not be determined due to conflicting reports from staff and the "provider who works closest to Dr. Levy" denied smelling alcohol. Dr. Levy agreed to be tested for alcohol; however, the facility did not test Dr. Levy at the time of the reported incident but planned to do so if another episode occurred. Oxford Lexico, "Definition for pathology," accessed March 18, 2021, <https://www.lexico.com/en/definition/pathology>. Pathology is the branch of medicine that involves the laboratory examination of body tissues for diagnostic purposes.

² "The Pathology Report." Johns Hopkins Medicine, accessed March 31, 2021, <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/the-pathology-report>.

³ The OIG refers to Dr. Worley as the Chief of Staff in this report; the OIG was informed that he retired from federal service in the summer 2018.

⁴ Dr. Levy also noted that 2M-2B was a pigment solvent and that, on one occasion, he developed symptoms similar to those of a stroke after ingesting it.

assistance and a [clinical episode review team](#) (CERT) was convened.⁵ The CERT determined that a [look-back](#) review of all pathology cases that Dr. Levy interpreted during the years he practiced at the facility (September 2005–October 2017) was warranted. The CERT designated a chairperson to coordinate a team of pathologists to complete the look-back review.

Pathologists who conducted the look-back review evaluated almost 34,000 cases interpreted by Dr. Levy and noted slightly more than 3,000 errors, including 589 major diagnostic discrepancies.⁶ As the look-back review results were received, the CERT tasked a clinical review team to assess if discrepancies adversely affected patient outcomes.⁷ As of March 15, 2021, according to facility documents, 34 patients were identified as needing [institutional disclosures](#) because an [adverse event](#) had occurred.

Criminal charges associated with Dr. Levy’s care for patients were filed in August 2019. In 2020, Dr. Levy pleaded guilty in the Western District of Arkansas to one count each of involuntary manslaughter and mail fraud.

On January 22, 2021, Dr. Levy was sentenced to 20 years in prison, three years of supervised release, and ordered to pay VA approximately \$498,000 in restitution for defrauding the government.⁸ With the closure of the Office of Investigation’s criminal case, the OIG healthcare inspection team could complete its review and issues its findings in this report as to Dr. Levy’s errors that caused patient adverse clinical outcomes.⁹ Those findings, discussed in the results section, focus on VHA policy and facility leaders’ failures to adequately address quality management deficiencies, identify and respond to an impaired provider, and foster a culture of accountability.

⁵ The underlined terms are hyperlinks to a glossary. VHA Directive 2005-049, *Disclosure of Adverse Events to Patients*, October 27, 2005, rescinded and replaced by VHA Directive 2008-002, *Disclosure of Adverse Events to Patients*, January 18, 2008, rescinded and replaced by VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012, rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The 2005 directive does not discuss large-scale disclosure or CERT. The 2008 directive discusses large-scale disclosure and consultation with a Clinical Risk Assessment Advisory Board. The 2012 handbook does not use the term CERT but describes a subject matter expert panel and a Clinical Review Board. The 2018 directive introduces the term CERT. Although the 2018 directive was not issued until October, VHA and facility interviewees used the 2018 term, CERT, to describe the panel that convened in May 2018. The OIG also uses the 2018 directive term CERT to describe the convened panel.

⁶ The number of cases does not represent the total number of individual patients as some patients may have received multiple tests or procedures. The look-back team established criteria for the review. Major diagnostic discrepancy is described as a difference in interpretation with potential for negative impact on patient care/treatment.

⁷ During an interview, the OIG learned that the clinical review team consisted of two VISN 16 facility chiefs of staff and a rotating third member who had subject matter expertise relative to the case under review.

⁸ Dr. Levy appealed the sentence; as of May 26, 2021, the appeal was pending.

⁹ Within the context of this report and the patients reviewed, the OIG considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level of care. The OIG recognizes that patients may have experienced unquantifiable distress when informed they had received an incorrect diagnoses.

Scope and Methodology

The OIG team conducted a facility site visit on May 30–31 and July 16–18, 2018. Interviews included VA, VHA, VISN 16, and facility leaders and other individuals knowledgeable of relevant matters such as pathology services, quality management, and human resources.

The OIG team reviewed relevant VA and VHA policies and external documents as well as more than 43,500 email messages and their attachments. After VHA completed the look-back review in 2019, the OIG team evaluated and analyzed the results. The OIG did not conduct an independent evaluation of the look-back review data provided by VHA and did not assess the facility's process and progress in responding to the look-back results in this report.¹⁰ The OIG team assessed patient electronic health records (EHRs) identified in the look-back review or allegations that may have resulted in an adverse clinical outcome. A factor that limited the team's analysis was the facility managers' inability to produce all relevant Path and Lab quality management plans or policies for the time of the events under discussion due to the passage of time.

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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.

¹⁰ The OIG initiated a hotline in March 2021 that included a review of facility processes and progress in responding to cases categorized as level 2 or level 3 during the look-back review.

Timeline of Events

Figure 1 lists events pertinent to Dr. Levy’s employment, reports of signs of possible impairment, actions taken by the facility, initiation and results of the look-back review, and legal actions.

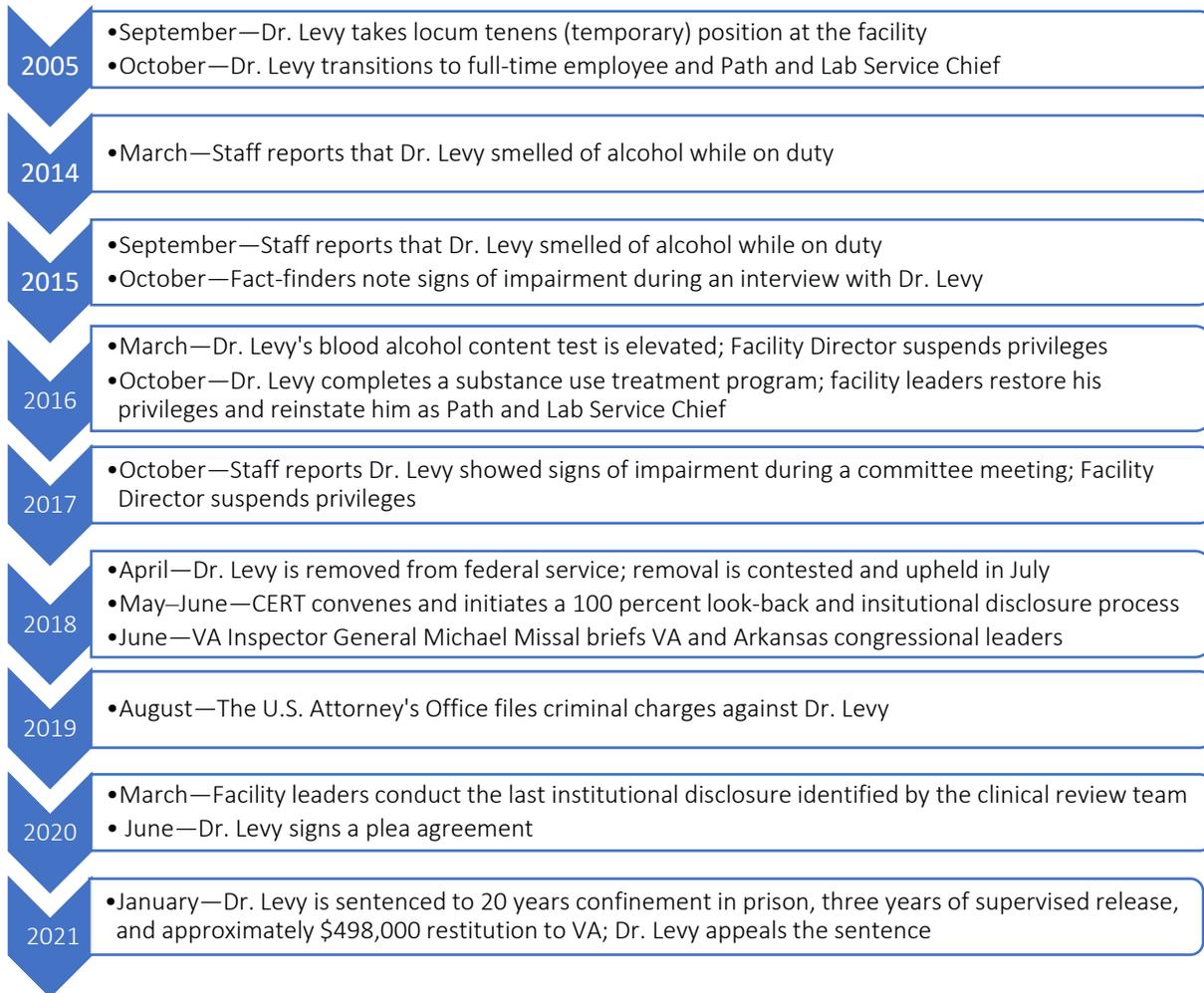


Figure 1. Pertinent events regarding Dr. Levy from September 2005 through January 2021

Source: Events described in the timeline are a compilation of data received from the facility pursuant to document requests from the OIG, review of emails, and interviews.

Inspection Results

Pathologists are physicians who are trained to examine tissue ([anatomic pathology](#)) and body fluid ([clinical pathology](#)) specimens and, based on their interpretations, to make diagnoses, such as cancer.¹¹ Pathological diagnoses represent a critical factor in determining a patient's care; therefore, interpretations must be as accurate as possible.¹²

This report focuses on the three following findings:

1. Dr. Levy's misdiagnoses led to suboptimal treatment and patient death.
2. Deficiencies were found in quality management oversight and the management of an impaired provider that contributed to inadequate processes to ensure Dr. Levy's competency.
3. Facility leaders failed to create an environment that would promote accountability at all staff and management levels and the reporting of concerns affecting patient care.

1. Pathology Misdiagnoses by Dr. Levy Led to Suboptimal Treatment and Patient Death

The OIG substantiated that Dr. Levy's misdiagnoses of patients' pathological specimens resulted in numerous adverse clinical outcomes including suboptimal treatment and patient death. Diagnostic errors can lead providers to consider and offer incorrect treatment options that fail to address the specific disease process and could negatively affect the patient's prognosis. Healthy patients could receive unnecessary treatment that may carry significant risks.

VHA's CERT initiated a comprehensive look-back review in June 2018 to reread all pathology cases that Dr. Levy had initially interpreted in 2005 through his removal from clinical practice in 2017. VHA and non-VHA pathologists used standardized criteria to categorize the results into four levels:

0 No deficiency or diagnostic error

1 Minor disagreement, practice acceptable, reviewer still comfortable

¹¹ Merriam-Webster, "pathologist," accessed January 11, 2021, <https://merriam-webster.com/dictionary/pathologist>. VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016. VHA includes "surgical pathology, cytopathology, immunohistochemistry, diagnostic [electron microscopy], Mohs surgery, and autopsy pathology" under the scope of anatomic pathology.

¹² Brunye T. et al., "Accuracy is in the eyes of the pathologist: The visual interpretative process and diagnostic accuracy with digital whole slide images," *Journal of Biomedical Informatics* 66, (February 2017): 171-9.

2 Disagreement in diagnosis with minimal or no potential negative impact on patient care

3 Major diagnostic discrepancy with potential for negative impact on patient care/treatment

Table 1 shows the numbers of each discrepancy level for all reviewed autopsy, [cytology](#), and [surgical pathology](#) cases.

Table 1. Number of Cases in VHA Look-Back Review and Discrepancy Levels

Case	Level 0	Level 1	Level 2	Level 3	Not Applicable*	Total
Autopsy	6	13	9	3	1	32
Cytology	4,569	412	334	122	1,404	6,841
Surgical Pathology	19,139	3,194	2,097	464	2,135	27,029
Total	23,714	3,619	2,440	589	3,540	33,902

Source: OIG analysis of VHA look-back review for Dr. Levy's September 2005–October 2017 cases

*Note: Not applicable cases are those without a slide in the file for microscopic examination. A member of the look-back review team stated such cases should not be included when calculating diagnostic error rates.

Interviewees informed the OIG that the clinical review team determined that not all level 3 cases resulted in adverse events requiring institutional disclosures. Overall, 34 patients were identified as needing institutional disclosures. When interviewed, the leader of the clinical review team opined that the disparity between the number of level 3 cases and institutional disclosures was likely due, in part, to the persistent follow-up by treating providers and the type of services offered. Two examples of patients who received institutional disclosures are provided below:¹³

One patient underwent a [prostate biopsy](#) in 2012 that was reported by Dr. Levy to be benign. Look-back reviewers in 2018 identified cancer in two of the six biopsy specimens. At the time the patient was notified of the cancer diagnosis in 2018, treatment was limited to [palliative care](#). The patient died in late 2020 ([patient 3](#)).

A second patient was treated for [small cell cancer](#) after Dr. Levy made the diagnosis in 2014. The patient died about a year later. The look-back review team determined that the patient had [squamous cell cancer](#) of the lung, not small cell cancer. Treatment options for squamous cell lung cancer included surgery, which was not offered to the patient ([patient 5](#)).

¹³ Additional details for these two patients and three other examples are provided in appendix A.

2. Deficiencies in Facility Leaders' Quality Management Oversight and the Management of an Impaired Provider

During its review of the allegations received in 2017 and 2018, the OIG team identified incidents that raised concerns about facility leaders' oversight of Dr. Levy's clinical practice related to the Path and Lab quality management program and the evaluation of signs and symptoms of impairment.

VHA pathologists are required to document and authenticate test results in patient EHRs, which allows providers who enter orders to view the results and contact the appropriate pathologist with any questions or concerns.¹⁴ VHA pathologists must also notify ordering providers when results are available for review.¹⁵ VHA requires that all first diagnoses of a malignancy (excluding skin squamous and basal cell cancers) be confirmed by a second pathologist.

Additionally, 10 percent of certain category of cases—surgical pathology (including [Mohs surgery](#)), [fine needle aspiration](#), and [cytopathology](#) cases—must be selected and read by a second pathologist for quality management purposes ([10 percent peer review](#)).¹⁶ When there is a disagreement between the first and second pathologist (discrepancy), a third opinion must be expeditiously obtained.¹⁷

Changes that are clinically significant that would modify the original diagnosis must be immediately reported to the patient's healthcare provider and the submitting physician; if the change affects the patient's treatment, the Path and Lab Service Chief and Chief of Staff or Director of Clinical Services must also be notified.¹⁸

¹⁴ VHA Handbook 1106.1, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, June 4, 2003, rescinded and replaced by VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, October 6, 2008, rescinded and replaced by VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016. The three policies have the same or similar language related to authentication.

¹⁵ VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009, rescinded and replaced by VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015. "All test results must be communicated by the diagnostic provider to the ordering provider, or designee, within a time-frame that allows for prompt attention and appropriate action to be taken." The two policies have the same or similar language related to communication of test results.

¹⁶ VHA Handbook 1106.1, 2003; VHA Handbook 1106.01, 2008; VHA Handbook 1106.01, 2016. The 2016 handbook contains similar language as the 2003 and 2008 versions related to the 10 percent peer review documentation and category of cases but added that cases be randomly selected. The 2016 handbook specifically references Moh's surgery when discussing the random retrospective quality management peer review.

¹⁷ VHA Handbook 1106.1, 2003; VHA Handbook 1106.01, 2008; VHA Handbook 1106.01, 2016. The three handbooks contain the same language related to disagreements and third opinions.

¹⁸ Dr. Levy was a practicing pathologist as well as the Path and Lab Service Chief. He was responsible for reporting all pathological diagnostic changes that affected a patient's treatment, including cases he reviewed, to the Chief of Staff. VHA Handbook 1106.1, 2003; VHA Handbook 1106.01, 2008; VHA Handbook 1106.01, 2016. The three handbooks contain similar language regarding Chief of Staff and provider notification of clinically significant additions to pathology reports.

The discussion that follows highlights actions taken by facility leaders from Dr. Levy's hiring to dismissal and the missed opportunities or inadequate steps taken that, if addressed, could have resulted in Dr. Levy's earlier removal or minimized the impact on patients.

2005–2007

Prior to 2005, Dr. Levy received his undergraduate degree from Emory University, in Atlanta, Georgia and completed his medical education at the University of Chicago, Illinois, Pritzker School of Medicine. According to the curriculum vitae he provided to VA with his application, he finished a residency in pathology at the University of California, San Francisco, in 1997 and a fellowship in hematopathology at Duke University, Durham, North Carolina, in 2002. After a tour of duty in the U.S. Air Force, he worked in Mississippi and Florida and joined the facility as a [locum tenens](#) (temporary) pathologist in September 2005. On his Declaration for Federal Employment, Dr. Levy disclosed a 1996 conviction for "DUI [driving under the influence] (alcohol)."

In a memo dated September 13, 2005, the then Facility Director granted Dr. Levy [temporary privileges](#) to begin "on or about September 19, 2005."¹⁹ According to the look-back review results, Dr. Levy reviewed his first pathological specimen on September 16, 2005. Dr. Levy successfully underwent the [credentialing](#) and [privileging](#) process and transitioned to a full-time position as Path and Lab Service Chief, subject to a two-year probationary period starting October 16, 2005.²⁰ When interviewed by the OIG, Dr. Levy indicated he was the only pathologist at the facility for the first few years of his employment.

Dr. Levy was initially granted privileges in October 2005 for a six-month period. Reprivileging occurs every two years prior to expiration.²¹ In March 2006, Dr. Levy's initial privileges were extended until October 2007 to complete a full two-year period.²²

As Path and Lab Service Chief, Dr. Levy was responsible for the facility's Path and Lab quality management program that included an "on-going, planned, systematic, and objective process for

¹⁹ *Bylaws and Rules of the Medical Staff of the Department of Veterans Affairs Medical Center Fayetteville, Arkansas*, April 15, 2005. The bylaws allowed for a temporary appointment for emergent or urgent care needs. The then Facility Director noted that Dr. Levy's temporary privileges would last no longer than 45 work days, which is consistent with the timeframe for temporary privileges outlined in the credentialing and privileging directive that was in effect in 2005, VHA Directive 1100.19, *Credentialing and Privileging*, March 6, 2001.

²⁰ *Bylaws and Rules of the Medical Staff*, 2005. Requirements for the initial application included an active license, "education, relevant training and/or experience, board certification preferred, current competence, physical and mental health status, English language proficiency, professional liability insurance ([for] contractors), and proof of identity." Other documents for submission were citizenship documents and three references. One of the references had to be from the current employer or most recent one.

²¹ VHA Handbook 1100.19, 2001; VHA Handbook 1100.19, *Credentialing and Privileging*, October 2, 2007, rescinding and replaced by VHA Handbook 1100.19, *Credentialing and Privileging*, November 14, 2008, rescinded and replaced by VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. The four handbooks contain the same or similar language regarding reprivileging expiration.

²² Dr. Levy's privileges were renewed in 2007.

the monitoring and evaluation of the quality improvement plan.”²³ Documentation from 2007 indicated that the process for reporting pathology quality management data was to collect and forward the data to facility leaders through the three committees that Dr. Levy chaired:

- Path and Lab Quality Management Committee (Path and Lab Quality Improvement Committee)
- Tissue Committee and Blood Usage Review (Tissue Committee)
- Tumor Board²⁴

OIG Analysis of Facility Leaders’ Actions Related to Quality Management Including Credentialing and Privileging

According to documents reviewed, the facility received four references dated September 2005 that supported the granting of Dr. Levy’s core privileges in October—three from his most recent place of employment in Naples, Florida, and one from a radiologist in Hattiesburg, Mississippi. The references included positive comments about Dr. Levy’s fitness for duty and competency. Facility documentation supporting Dr. Levy’s privileging in March 2006 indicated that a pathologist conducted a peer review. No practice concerns were noted. The then Chief of Staff and then Facility Director agreed to the extension of Dr. Levy’s privileges.

As noted above, a look-back review team evaluated all Dr. Levy’s cases beginning with his time as locum tenens. Between September 2005 and the date that his core privileges were granted in October 2005, the look-back review team identified nine level 2 diagnostic errors in 161 cases (5.59 percent). For the remaining two-and-one-half months in 2005—after he was hired as Path and Lab Service Chief—Dr. Levy’s level 2 and 3 diagnostic errors numbered 43 of 481 cases (8.94 percent). According to information provided by the facility, no institutional disclosures resulted from cases Dr. Levy reviewed in calendar year 2005.²⁵

From 2006 through 2007, the look-back review team identified 489 level 2 and 3 diagnostic errors of 5,601 cases (8.73 percent) that resulted in five institutional disclosures.

Facility leaders did not identify practice concerns during the 2005–2007 time frame. Based on the results of the look-back review, it appears that facility leaders’ efforts were insufficient to determine the quality of Dr. Levy’s pathology practice during the probationary period.

²³ VHA Handbook, 1106.1, 2003; VHA Handbook, 1106.01, 2008; VHA Handbook 1106.01, 2016. All three handbooks contain similar language regarding a service chief’s responsibility for pathology quality management programs.

²⁴ The facility used different names for these committees during Dr. Levy’s 12-year service chief tenure. The OIG uses the names Path and Lab Quality Improvement Committee, Tissue Committee, and Tumor Board for consistency purposes.

²⁵ All subsequent references to institutional disclosure numbers reflect information provided to the OIG from the facility. The OIG confirmed the information via an EHR review.

In his 2005 application documents, Dr. Levy disclosed a 1996 conviction related to driving while intoxicated and a short stay (approximately eight months) at his previous workplace. The OIG recognizes that neither of these facts would have precluded consideration of Dr. Levy as a potential candidate, but may have raised concerns in the setting of a locum tenens provider, who was immediately elevated to the Path and Lab Service Chief position, with no other provider with the same training and privileges in the specialty area of pathology at the facility. The OIG concluded that had facility leaders conducted a more robust evaluation of Dr. Levy's cases, such as a 100 percent review for a specified period of time when he was newly hired or still on probation, the evaluation would have likely identified deficiencies similar to the look-back review. This would have provided facility leaders the opportunity to address his performance or not approve his permanent appointment.

2008–2011

The OIG team learned from an interview that a second pathologist (Staff Pathologist) was hired at the facility in 2008. According to another interviewee, Dr. Levy and the Staff Pathologist (Dr. Levy's subordinate) conducted each other's VHA-required 10 percent peer review.²⁶ The Staff Pathologist reported to OIG interviewers that a strained relationship began with Dr. Levy in approximately 2010. Other interviewees also described Dr. Levy and Staff Pathologist's relationship as strained.

During this time frame, service chiefs were to consider relevant facility- and provider-specific data that used defined criteria when recommending the continuation of privileges. According to the October 2007 and November 2008 credentialing and privileging handbooks, service chiefs overseeing pathologists could include the 10 percent peer review data when selecting criteria for pathology providers' practice evaluations.²⁷

OIG Analysis of Facility Leaders' Actions Related to Quality Management Including Reprivileging

The OIG inspection team reviewed summary privileging documents. Dr. Levy's full privileges were reappointed without deletion or modification. As reported by the facility, the provider profile data from this period were unavailable because they were destroyed in accordance with VA records management program.²⁸ Although the OIG was unable to review the provider

²⁶ VHA Handbook 1106.1, 2003; VHA Handbook 1106.01, 2008; VHA Handbook 1106.01, 2016.

²⁷ VHA Handbook 1100.19, 2007, VHA Handbook 1100.19, 2008. "Ongoing reviews conducted by service chiefs must be comprised of activities with defined criteria that emphasize the facility's performance improvement plan, appropriateness of care, patient safety, and desired outcomes" subject to confidentiality rules. The two handbooks contain the same language related to ongoing reviews.

²⁸ VA Records Control Schedule 10-1 January 2020. VHA Directive 6300, *Records Management*, September 22, 2011. VHA has established a records management program that defines the roles and responsibilities for all VHA personnel in response to VA policy.

profile, based on the summary sheet and continued approval of privileges, facility leaders did not identify concerns. The OIG noted that incorporating the results of the 10 percent peer review conducted by the Staff Pathologist into Dr. Levy's practice evaluation would create a conflict of interest that could have been exacerbated by the strained relationship between the Staff Pathologist and Dr. Levy.²⁹

Although Dr. Levy's practice evaluations did not reveal concerns at the time, the look-back review team identified 1,000 level 2 and 3 diagnostic errors of the 10,898 cases Dr. Levy reviewed (9.18 percent) that resulted in the need for seven institutional disclosures for the four-year period.

2012–2013

During an interview with the OIG, the Chief of Staff stated he was a psychiatrist, was hired in December 2012, and oversaw all service chiefs at the facility, including Dr. Levy. As Chief of Staff, he assumed the responsibility for recommending Dr. Levy's reprivileging via the Professional Standards Board and the [Executive Committee of the Medical Executive Council](#), which then submitted the request to the Facility Director for final action.³⁰

Per VHA requirements, as Path and Lab Service Chief, Dr. Levy was "responsible for developing the criteria for the delineation of privileges for the care delivered within the individual service and ensuring that appropriate resources are available to support those privileges."³¹ VHA policy does not specifically address the establishment of criteria or reappraisal and privileging process for service chiefs who practice and undergo competency evaluation.³²

The VHA handbook outlines general requirements for all provider reappraisals including peer references and indicates that they are

[b]est obtained from those of the same discipline or profession who practice with, and know the practitioner's practice. If possible, at least one of the peer references

²⁹ VHA Directive 2008-004, *Peer Review for Quality Management*, January 28, 2008, rescinded and replaced by VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010, rescinded and replaced by VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. The OIG likens this situation to the confidential peer review process where a peer reviewer must withdraw "from review of cases where there is a conflict of interest or, for any other reason, the reviewer is unable to conduct an objective, impartial, accurate, and informed review." The three directives have the same or similar language related to a peer reviewer's conflict of interest.

³⁰ During Dr. Levy's tenure, his immediate supervisor was the individual who held the position of chief of staff. At the facility, the Executive Committee of the Medical Executive Council was also known as the Executive Committee of the Clinical Executive Board. The OIG uses the term Executive Committee of the Medical Executive Council when discussing the committee.

³¹ VHA Handbook 1100.19, 2008; VHA Handbook 1100.19, October 15, 2012.

³² VHA Handbook 1100.19, 2008; VHA Handbook 1100.19, October 15, 2012.

needs to be obtained from someone of the same discipline or profession who can speak with authority on the practitioner's clinical judgment, technical skill, etc.

The handbook further states

In instances where at least one peer reference cannot be obtained from a peer of the same profession or a professional with comparable privileges, assistance for the peer reference needs to be sought from the VISN CMO [chief medical officer] or VHA Program Director for the profession.³³

In addition to the 10 percent peer review data, other activities noted in the 2012 VHA handbook included "direct observation, clinical discussions, and clinical pertinence reviews that, if documented, [could] also be incorporated into the on-going monitoring process" needed for reappraisal.³⁴

OIG Analysis of Facility Leaders' Actions Related to Quality Management Including Reprivileging

The inspection team reviewed the summary reprivileging request and approval document from September 2013. Facility leaders recommended approval with no concerns for the previous two years.

In an interview, the Chief of Staff indicated that the Path and Lab manager compiled the data that he, as Dr. Levy's supervisor, signed and presented for Dr. Levy's reprivileging. The Chief of Staff noted that although he was not a pathologist, he had completed medical school and did not find it difficult to evaluate physicians from different specialties such as pathology. However, the OIG determined that the Chief of Staff would not have the subject matter expertise with similar training and privileging to delineate the criteria and evaluate the competency of a pathologist.

The peer references that were submitted to the Chief of Staff during his consideration of Dr. Levy's reprivileging in 2013 were not completed by pathologists.³⁵ The OIG would have expected at least one peer reference be obtained from a pathologist.

A portion of Dr. Levy's 2013 ongoing evaluation was based on concurrence with his interpretations and diagnosis by a peer. According to an interviewee, the Staff Pathologist who

³³ VHA Handbook 1100.19, 2008; VHA Handbook 1100.19, 2012. Both handbooks contain the same language related to seeking assistance from the VISN CMO.

³⁴ VHA Handbook 1100.19, 2012.

³⁵ The Chief of Staff received two peer references from surgeons. One surgeon indicated that Dr. Levy was a "very competent and professional clinical pathologist. No concerns regarding 6 competencies." The other surgeon noted that Dr. Levy was an "excellent clinician. No concerns regarding 6 competencies." Facility Memorandum 11-114, *Focused and Ongoing Professional Practice Evaluations (FPPE and OPPE)*, June 9, 2013. The facility policy identifies several categories for evaluation including patient care, medical/clinical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and system-based practice, which the OIG interpreted as the "competencies" discussed in the peer comments.

was a subordinate of Dr. Levy conducted the required 10 percent peer review of certain categories of specimens.³⁶ Both the Chief of Staff and the Staff Pathologist indicated during OIG interviews that the relationship between Dr. Levy and the Staff Pathologist was strained over this two-year period. The Chief of Staff noted that the strain interfered with collegial discussion. The Staff Pathologist expressed concerns about disagreeing with Dr. Levy because he evaluated the Staff Pathologist's performance.

The OIG recognizes the challenges associated with the competency evaluations of a service chief in a small department by a chief of staff with a different specialty from the service chief. However, the Chief of Staff did not receive a peer reference for Dr. Levy from providers of the same profession or a professional with comparable privileges as required.³⁷ Further, a subordinate's evaluation of a supervisor's cases for the 10 percent peer review could result in a disagreement between the subordinate and supervisor. This could interfere with the subordinate providing an objective, impartial assessment of the supervisor's work leading to a conflict of interest.³⁸

Although Dr. Levy's practice evaluations did not reveal concerns in 2012 and 2013, the look-back review team identified 494 level 2 and 3 diagnostic errors of the 4,425 cases reviewed by Dr. Levy (11.16 percent) that resulted in the need for 11 institutional disclosures arising from cases Dr. Levy reviewed in this two-year period.

2014

Two events occurred in 2014 that the OIG considered to be red flags that should have raised facility leaders' concerns related to Dr. Levy's competency. As Path and Lab Service Chief, he was in charge of reporting pathology quality management data to facility leaders including information related to his own pathology practices, which made the process susceptible to subversion. The first event relates to the communication of changed pathology results and the second involves reports that Dr. Levy was possibly impaired during work hours.

Providers Unaware of a Misdiagnosis

In early 2014, Dr. Levy diagnosed a patient's [lymph node](#) biopsy as diffuse large B cell lymphoma. Dr. Levy's documentation in the patient's EHR indicated that a member of the surgical team was notified of the results and that the Staff Pathologist agreed with the diagnosis. Approximately five days after making the original diagnosis, Dr. Levy entered a supplemental

³⁶ VHA Handbook 1106.01, 2008.

³⁷ VHA Handbook 1100.19, 2008; VHA Handbook 1100.19, 2012.

³⁸ VHA Directive 2010-025, 2010; VHA Directive 1190, 2018.

report into the patient's EHR indicating a diagnosis of non-small cell carcinoma.³⁹ The oncology physician initiated a treatment plan for lymphoma. Approximately five months later, after receiving treatment for lymphoma, the patient developed pneumonia and was admitted to the facility. His condition further deteriorated and a palliative care consult was requested.

While reviewing the patient's EHR, the palliative care consultant noticed the early 2014 amended pathology report with the non-small cell cancer diagnosis and included it in the palliative care consult note. Two days later, the patient and a family member were notified of the changed diagnosis. The facility completed a review of the case and an institutional disclosure was conducted a few days prior to the patient's death in summer. The acting Assistant Chief of Medicine who conducted and documented the institutional disclosure included the Chief of Staff as a recipient on the EHR disclosure note. The Chief of Staff acknowledged receipt of the notification (see appendix A, [patient 1](#)).

OIG Analysis of Facility Leaders' Actions Related to Quality Management

Lack of Communication and Documentation of Amended Pathology Results

VHA requirements in 2014 for communicating changed pathology results indicated that “the patient's health care provider and the submitting physician must be immediately notified of the modification and the issuance of a new report” when results were clinically significant. Additionally, if the change in diagnosis affected treatment, “the Chief or Director [of] Pathology and Laboratory Medicine Service, must also advise the Chief of Staff.”⁴⁰ The facility's anatomic pathology continuous quality improvement plan also indicated that “All new malignancies (except squamous cell and basal cell carcinoma of skin) and unexpected findings are reported to the physician, and this contact is noted within the final pathology report.”⁴¹

The OIG noted that Dr. Levy documented notifying a member of the surgical team in the patient's EHR of the initial lymphoma diagnosis but did not document notifying the Chief of Staff or a member of the treating team when he entered a supplemental report that contained a change in diagnosis. Lack of notification to the treating team is also evidenced by the patient receiving treatment for the original diagnosis rather than the amended one. According to VHA

³⁹ The OIG noted the use of the terms *supplementary* and *supplemental* in documents and interviews when there were descriptions of changes to pathology reports. The OIG considers the terms equivalent and will use *supplemental* in this report.

⁴⁰ VHA Handbook. 1106.01; 2008; VHA Handbook 1106.01, 2016. The two handbooks contain the same or similar language related to modifications of the original diagnosis when changes are clinically significant that would affect a patient's treatment; such modifications must be immediately reported to the patient's healthcare provider and the submitting physician. The Chief of Staff must also be advised.

⁴¹ Facility Procedure 101, *Anatomic Pathology Continuous Quality Improvement/Quality Management Plan*, November 20, 2009.

policy, Dr. Levy should have contacted the provider and Chief of Staff because the amended report changed the initial diagnosis and affected treatment options. According to the facility anatomic pathology continuous quality improvement plan, Dr. Levy should have documented notifying the provider in the final pathology report.⁴²

Dr. Levy's failure to correctly diagnose this patient's cancer led to inappropriate chemotherapy and radiation treatment for lymphoma. The cancer was subsequently identified as a different type of cancer. Had Dr. Levy made the proper notifications and documentation when he corrected his error, the patient's treating team would have stopped the unwarranted lymphoma treatment plan and provided more appropriate care.

Although Dr. Levy documented in the patient's EHR that the Staff Pathologist agreed with the lymphoma diagnosis, the Staff Pathologist indicated in an interview with the OIG about not agreeing with the lymphoma diagnosis and informing Dr. Levy of the disagreement. The 2020 plea agreement supports the Staff Pathologist's assertion that Dr. Levy was notified of the disagreement via a hand-delivered letter. To be consistent with VHA policy, Dr. Levy should have consulted with a third pathologist to resolve the disagreement rather than enter a concurrence statement in the patient's EHR.⁴³

Additionally, according to VHA policy, "all cases with unexpected diagnoses of clinical significance, and diagnoses of malignancy not previously established (excluding skin squamous and basal cell carcinomas), must be reviewed by a second pathologist prior to issuance of the final report."⁴⁴ For this patient, there is no EHR documentation that a second pathologist was consulted and concurred with the new diagnosis of non-small cell carcinoma.⁴⁵

The Chief of Staff was aware of the delay in communication of the amended pathology report when the patient's institutional disclosure was conducted in summer 2014. The OIG would have expected facility leaders to closely monitor communication and documentation of second reads and amended reports thereafter. However, a facility staff member interviewed by the inspection team indicated that oversight of pathology did not improve after the patient's death in 2014. Consistent with this observation, a facility quality management staff member reported during a 2018 facility management review that oversight of pathology by quality management staff was minimal until late 2017.

⁴² VHA Handbook, 1106.01; 2008; VHA Handbook 1106.01, 2016; Facility Procedure 101, 2009.

⁴³ VHA Handbook 1106.01, 2008, VHA Handbook 1106.01, 2016. The two handbooks contain similar language related to obtaining a third opinion when there is a disagreement.

⁴⁴ VHA Handbook 1106.01, 2008; VHA Handbook 1106.01, 2016. The two handbooks contain the same language about a second pathologist's review. The 2016 handbook adds a requirement of documentation of the second pathologist's concurrence in the final pathology report.

⁴⁵ When a statement of concurrence of a cancer diagnosis is entered into a patient's record, the treating provider and the patient have more confidence in the accuracy of the finding, knowing that two qualified pathologists have reviewed the specimen.

Pathology Committee Reporting

Dr. Levy continued to chair the three pathology quality management committees. Documentation indicated that the process for reporting pathology quality management data was to collect and forward the data to facility leaders through the three committees.

The Path and Lab continuous quality improvement plan that Dr. Levy initiated and implemented in 2009 outlined the structure of the three pathology committees. The OIG noted that Dr. Levy was not only the chair but also the only pathologist and only provider on the intradepartmental Path and Lab Quality Improvement Committee. Other members included Path and Lab staff who were Dr. Levy's subordinates—the laboratory manager, quality manager/assistant laboratory manager, two technologists, and the laboratory information manager.⁴⁶ Committee members did not have the same level of knowledge as a pathologist. Dr. Levy's subordinates may not have been comfortable in questioning or challenging the anatomic pathology data that Dr. Levy submitted to the committee that was reviewed during committee meetings.

The Path and Lab Quality Improvement Committee was to meet quarterly and review discrepancies related to the 10 percent peer review as well as monitor minor and major surgical pathology and cytopathology discrepancies.⁴⁷ Dr. Levy submitted a report (anatomic pathology summary monitor) to the Path and Lab quality management committee that included the results of the 10 percent peer review and external consultants' reviews of interpretation disagreements between pathologists. According to an interviewee, the data that Dr. Levy reported were not reviewed by other Path and Lab committee members or staff. The data from the summary monitors were reported to the Tissue Committee, which was also chaired by Dr. Levy.

The Path and Lab continuous quality improvement plan also required that the Tissue Committee monitor "minor and major discrepancies in surgical pathology and cytopathology" specimens.⁴⁸ Similarly, the facility 2013 bylaws charged the Tissue Committee with the "monitoring and evaluation of all surgical procedures performed at the health care system (inpatient and ambulatory) on the basis of agreement or disagreement among the pre-operative, post-operative

⁴⁶ Facility Procedure 101, 2009.

⁴⁷ Facility Procedure 101, 2009. Minor discrepancies were "small change in diagnosis that is with minimal, if any, clinical relevance" and major discrepancies were "(1) significant change between the original diagnosis and review interpretation with (2) potential serious impact on treatment or prognosis."

⁴⁸ Facility Procedure 101, 2009. The OIG team was informed that major diagnostic discrepancies should be designated with a tissue committee (TC) code in the EHR final pathology report—TC8. The code is trackable, which allows monitoring of the number of major diagnostic discrepancies. Although the 2009 plan did not include reference to TC8 codes (the plan included references to TC1-7), a course of practice was established by the Tissue Committee when it began using a table in its meeting minutes to document TC codes in late 2009. The table included an entry designated TC8 (final versus consulting diagnoses) and data were entered each month thereafter into the TC8 box (see appendix B). As such, the OIG would have expected documentation that was inputted into the meeting minutes for TC8 coded reports to accurately reflect the number of major diagnostic discrepancies.

and pathological diagnoses.”⁴⁹ After Tissue Committee meeting minutes were signed by Dr. Levy, data were forwarded to facility leaders for their review and approval. As the chair of both committees, Dr. Levy had the opportunity to manipulate the flow of data.

Other than a table in an attachment to the Tissue Committee meeting minutes, the OIG did not find evidence of the monitoring of disagreements between the original diagnosis and review interpretation. The table listed eight items with designated codes some of which referred to differences in diagnosis or disagreements (see [appendix B](#)).⁵⁰ The inspection team examined the facility’s November 2009–November 2014 Tissue Committee meeting minutes and found that the items in the table referring to differences and disagreements were *zero* for all years.⁵¹

Attendees at the Tissue Committee during the time at issue generally included three other physicians and facility quality management staff. The OIG concluded the repeated documentation of zero disagreements in the table in the attachment without further documentation of discussion in the meeting minutes appeared to reflect a failure among committee members to dispute the data.

Because of the high risk of adverse clinical outcomes associated with pathology misdiagnoses, the OIG would have expected facility quality management staff to have surveilled or initiated close surveillance of the documentation of changes in diagnosis after the patient’s misdiagnosis in 2014. However, interviewees informed the OIG that facility quality management staff were not embedded in the Path and Lab processes and were not involved in the collection and analysis of the pathology quality management data, which contributed to a failure to detect Dr. Levy’s errors. Had the facility quality management service been providing more comprehensive oversight, pathology data could have been analyzed and trended within the context of a broader quality framework.

Reports of Alcohol on Dr. Levy’s Breath in March

The Chief of Staff documented meeting with Dr. Levy in March 2014 after receiving reports of the smell of alcohol on Dr. Levy’s breath. He did not smell alcohol on Dr. Levy who denied drinking on duty. Dr. Levy claimed that any alcohol smell was from a juice mixture he drank to lose weight. Dr. Levy agreed to stop drinking the mixture and declined referral to the Employee

⁴⁹ *Bylaws and Rules of the Medical Staff of the Department of Veterans Affairs Medical Center Fayetteville, Arkansas*, August 20, 2013.

⁵⁰ The number of TC codes was collected and displayed in the meeting minutes table for every month in rows. Committee members and facility leaders could view the monthly data and compare it to available data presented for previous months.

⁵¹ *Bylaws and Rules of the Medical Staff of the Department of Veterans Affairs Medical Center Fayetteville, Arkansas*, March 5, 2008; *Bylaws and Rules of the Medical Staff of the Department of Veterans Affairs Medical Center Fayetteville, Arkansas*, August 1, 2011; *Bylaws and Rules of the Medical Staff, 2013*. The 2008 bylaws did not specify the frequency of Tissue Committee meetings. The 2011 and 2013 bylaws mandated that the Tissue Committee meet 10 times per year. Between November 2009 and November 2014, the Tissue Committee met at least 10 times per year except in 2009 when it met nine times.

Assistance Program, stating that he did not need assistance. In his interview with the OIG, the Chief of Staff indicated he did not take other actions.

OIG Analysis of Facility Leaders' Actions Related to a Possibly Impaired Provider

The facility's 2011 policy on the management of an impaired [licensed independent practitioner](#) articulates "an obligation to protect patients from harm" and defined impairment as

the inability or immediately impending inability of a health professional to practice his or her health profession in a manner that conforms to the minimum standards of acceptable and prevailing practice for that health profession due to the health professional's substance abuse, chemical dependency, physical or mental illness.⁵²

The OIG considers Dr. Levy's proposed explanation for the reports of his smelling like alcohol implausible. It is unlikely that drinking juice to lose weight would result in a smell of alcohol on Dr. Levy's breath. While the Chief of Staff was unaware of the misdiagnosed patient in early 2014 when evaluating Dr. Levy for a possible impairment, four months later he was aware of the two events. Together, the pathology misdiagnosis and reports that Dr. Levy smelled of alcohol merited additional oversight and action.

The OIG concluded that Dr. Levy's position as Path and Lab Service Chief and a pathologist responsible for the interpretation of large numbers of patient tests warranted a high level of concern about his ability to function safely. There should have been a correspondingly high level of activity to investigate reports of possible impairment and protect patients from potentially unsafe practices. The OIG would have expected the Chief of Staff to initiate a retrospective review of Dr. Levy's cases to evaluate his ability to practice competently.

Of the 2,665 cases reviewed by Dr. Levy in 2014, the look-back review team identified 291 level 2 and 3 diagnostic errors (10.92 percent) that resulted in the need for three institutional disclosures.

2015

In 2015, a fact-finding review was initiated after several staff reported Dr. Levy smelled of alcohol.

⁵² Facility Memorandum 11-11-89, *Management of the Impaired Licensed Independent Practitioner (LIP)*, March 7, 2011, rescinded and replaced by Facility Memorandum 11-089, *Management of the Impaired Licensed Independent Practitioner (LIP)*, March 31, 2014, rescinded and replaced by Facility Memorandum 17-11-089, *Management of the Impaired Licensed Independent Practitioner (LIP)*, March 31, 2017. The three policies contained the same definition of impairment.

Reports of Alcohol on Dr. Levy's Breath in September

In accordance with his every two-year reprivileging cycle, Dr. Levy's privileges were renewed in late summer 2015.⁵³ A few weeks later, on September 29, staff reported that Dr. Levy had an odor of alcohol, "red" eyes, and hand tremors while reviewing the adequacy of specimens for biopsy slides obtained during an interventional radiology procedure.

The Chief of Staff informed the OIG that he was the designated acting Facility Director on the day the 2015 incident occurred. Additionally, he initiated a fact-finding review and selected the Chief of Dental Service and the Risk Manager to investigate the incident.

Fact-Finding Review in October

When interviewing Dr. Levy on October 1, 2015, the fact-finding reviewers noted that Dr. Levy smelled of mouthwash, had red glassy eyes, and exhibited hand tremors. One fact-finding reviewer further indicated that Dr. Levy consented to a blood alcohol content test but testing was not done. Documentation reflected that the fact-finders consulted with a human resource officer about the blood alcohol content testing and accepted the response that the testing was not permissible despite consent.⁵⁴ During an OIG interview, a fact-finding reviewer discussed being surprised that a blood alcohol content test could not be obtained and acknowledged not elevating the question to the Chief of Staff because the human resource officer was considered to be the subject matter expert on the issue.

Dr. Levy explained to the fact-finding team that the smell of alcohol was related to his drinking large amounts of home-pressed juice on a daily basis. He indicated that his shaking hands were due to a medical condition, [essential tremors](#). The fact-finding report indicated that while several staff reported smelling the odor of alcohol approximately weekly or monthly and for at least seven years, two laboratory managers reported that they had never smelled alcohol on Dr. Levy.

The fact-finding team documented reviewing Dr. Levy's [ongoing professional practice evaluations](#) (OPPE) from fiscal years 2013, 2014, and 2015, which reflected "no areas of concern." Faced with conflicting accounts from laboratory staff, the fact-finding team indicated they could not substantiate that Dr. Levy was "under the influence" while on duty. The fact-finding team recommended that supervisors "be educated on and consistently follow [facility guidance] regarding drug testing when there is a reasonable suspicion that an employee may [be using] illegal drugs whether off or on duty," and that facility "[l]eadership should

⁵³ VHA Handbook 1100.19, 2012.

⁵⁴ Office of Personnel Management, *Alcoholism in the Workplace: A Handbook for Supervisors*, accessed July 1, 2019, <https://www.opm.gov/policy-data-oversight/worklife/reference-materials/alcoholism-in-the-workplace-a-handbook-for-supervisors/>. Federal agencies generally "do not have the authority to conduct mandatory alcohol testing."

explore the possibility of implementing a [policy] regarding alcohol testing when a staff member appears impaired.”⁵⁵

OIG Analysis of Facility Leaders’ Actions Related to Quality Management

The fact-finding team did not request additional reviews of Dr. Levy’s previous interpretations of cases and did not recommend that a focused care review, such as a [focused professional practice evaluation](#) (FPPE), be conducted or that Dr. Levy be proctored to ensure that he performed quality reviews of pathology slides.⁵⁶ The Chief of Staff told the OIG that he received the fact-finding results in November 2015 that concluded the allegations against Dr. Levy could not be substantiated given the conflicting witness statements. He further indicated that he did not confer with human resource specialists or the Office of General Counsel. Dr. Levy continued interpreting pathological specimens and performing Path and Lab Service Chief duties.

The OIG acknowledges that although the Chief of Staff may not have had sufficient evidence to suspend Dr. Levy’s privileges in 2015 based on the results of the fact-finding review alone, he was also aware of the events of 2014 (failed notification of an amended pathology report to a treating provider and reports of the smell of alcohol on Dr. Levy). The OIG considers the evidence contained in the 2015 fact-finding review report in conjunction with the 2014 events sufficient to justify a review of the quality of Dr. Levy’s practice to fulfill the facility’s “obligation to protect patients from harm.”⁵⁷ The Chief of Staff’s options for clinical reviews included requesting an FPPE, proctoring, and a review of more than the routine 10 percent peer review of cases required for quality management purposes.

OIG Analysis of Facility Leaders’ Actions Related to a Possibly Impaired Provider

The OIG identified other concerns related to the administrative aspects of managing a potentially impaired provider:

- The human resource official did not provide accurate information on permissible actions.
- Not all Path and Lab staff who were knowledgeable about Dr. Levy’s conduct and worked with him were interviewed.
- Although indicators of impairment were insufficient to suspend privileges, other actions should have been exhausted to ensure patient safety.

Based on interviews with the Chief of Staff and a human resource staff member who worked at the facility in 2015, the OIG concluded that the fact-finding reviewers received incorrect

⁵⁵ Facility Memorandum 2013-05-38, *Drug-Free Workplace Program*, May 1, 2013, was rescinded and replaced by Facility Memorandum 16-05-38, *Drug-Free Workplace Program*, April 1, 2016. Both memorandums contained the same or similar language related to testing for illegal drugs. According to the Chief of Staff, a policy was not developed specific to alcohol testing because a policy was not required to address a single provider’s action.

⁵⁶ VHA Handbook 1100.19, 2012.

⁵⁷ Facility Memorandum 11-089, 2014.

information from the human resource official. Had the fact-finders conferred with the Chief of Staff on the day Dr. Levy was interviewed, other actions likely could have been explored. Both the Chief of Staff and the facility human resource staff member who worked at the facility in 2015 told the OIG that because Dr. Levy consented, it was allowable to obtain a blood alcohol content level.

The OIG determined that inaction in 2015 was, in part, due to facility managers' confusion related to testing for alcohol. VA's drug-free workplace policy indicates that "an essential element in assuring a drug-free workplace is drug testing."⁵⁸ The policy also recognized that physicians, dentists, nurses, pharmacists, and other healthcare workers could cause patient death or injury should they use drugs and determined that staff in these occupations should be subject to testing.⁵⁹ However, the policy focuses on illegal drugs and does not address mandatory testing for alcohol.

The OIG determined that the fact-finding reviewers did not interview all available Path and Lab staff knowledgeable about Dr. Levy's past conduct and signs of possible impairment.⁶⁰ The fact-finders indicated that they could not substantiate the allegation because of conflicting accounts from laboratory staff. The OIG team interviewed two long-term Path and Lab employees who reportedly were not interviewed during the 2015 fact-finding review. These employees told the OIG that Dr. Levy smelled of bourbon or like an alcoholic prior to 2015. Had additional, knowledgeable staff been interviewed, their testimony may have factored into a different weighing of the evidence and allowed the fact-finders to make a definitive determination.

The facility's 2011 policy on the management of the impaired licensed independent practitioner was re-issued in 2014, shortly after the Chief of Staff evaluated Dr. Levy for reports of smelling like alcohol, and restated the "obligation to protect patients from harm."⁶¹ While facility leaders and staff may not have known the exact etiology of Dr. Levy's 2015 behavior, the signs he exhibited during the two incidents in September and October 2015 were indicator(s) of a possible impairment including alcohol intoxication.⁶²

Dr. Levy, as a practicing pathologist, was responsible for interpreting medical tests by reviewing specimens and rendering diagnoses upon which providers relied to make treatment decisions affecting patient care. The Equal Employment Opportunity Commission (EEOC) recognizes that individuals who are in positions that can threaten the safety of others if working while impaired

⁵⁸ VA Directive/Handbook 5383, *VA Drug-Free Workplace Program*, December 23, 2004.

⁵⁹ VA Directive/Handbook 5383, 2004; VA Directive/Handbook 5383, September 13, 2006.

⁶⁰ The facility provided a list of staff who were interviewed by the fact-finding reviewers in 2015.

⁶¹ Facility Memorandum 11-11-89, 2011; Facility Memorandum 11-089, 2014; Facility Memorandum 17-11-089, 2017. The three policies contained the same language regarding the facility's obligation to protect patients and definition of impairment.

⁶² Office of Personnel Management, *Alcoholism in the Workplace*, 2019.

need to be closely scrutinized. The EEOC states that after returning from rehabilitative treatment, testing for alcohol would be appropriate for “an employee who provides direct patient care, performs medical procedures, or *interprets medical test results*” [italics added to original text for emphasis]. While Dr. Levy was not in rehabilitation in 2015, the OIG notes that the EEOC’s specific reference to healthcare providers, including those who interpret medical tests, shows a high level of concern for such employees should their abilities be compromised by an impairment.⁶³

The Office of Personnel Management notes that federal agencies generally do not have the authority to conduct mandatory alcohol testing. However, staff in certain positions and those who perform tasks could endanger public safety if they were to perform their job duties under the influence of alcohol. Agencies who manage such employees may require mandatory and random alcohol testing because of public safety concerns.⁶⁴ The OIG considers the risk posed by an impaired healthcare worker to a patient to be a similar risk. Therefore, it would be prudent for VA to explore a policy related to mandatory and random alcohol testing of healthcare workers.

In addition to the actions previously outlined, the Chief of Staff could have requested a Physical Standards Board examination. The facility’s 2014 policy defined the Physical Standards Board as the “responsible board for determining the physical fitness for appointment or retention in VA employment and for recommending action based on [an] examination of findings.”⁶⁵ The policy further states that “in cases of known or suspected impairment due to physical, mental illness or chemical dependence, the Chief of Staff may request an assessment by the Physical Standards Board and the Employee Health Physician” and that the “Chief of Staff may request the Medical Center Director to authorize a physical examination.”⁶⁶ When queried on this matter, a facility manager informed the OIG team that a Physical Standards Board was not convened at any time for Dr. Levy. Had an examination been conducted and a Physical Standards Board convened, the members of the board could have investigated and provided additional information to further evaluate the allegations, concerns, and complaints related to Dr. Levy’s signs of impairment.

The OIG concluded that there should have been a high level of concern relative to Dr. Levy’s ability to function safely matched with commensurate urgency to investigate the quality of his work and more intensely scrutinize reports of impairment.

⁶³ U.S. Equal Employment Opportunity Commission, *Health Care Workers and the Americans with Disabilities Act*, February 26, 2007, accessed December 14, 2020, <https://www.eeoc.gov/laws/guidance/health-care-workers-and-americans-disabilities-act>.

⁶⁴ Office of Personnel Management, *Alcoholism in the Workplace*, 2019.

⁶⁵ Facility Memorandum 11-089, 2014. Facility Memorandum 17-11-089, 2017. The 2017 policy contained the same language related to requesting such an examination.

⁶⁶ Facility Memorandum 11-089, March 31, 2014; Facility Memorandum 17-11-089, March 31, 2017. The two policies have the same language related to authorization of a physical examination.

Of the 2,909 cases reviewed by Dr. Levy in 2015, the look-back review team identified 342 level 2 and 3 diagnostic errors (11.76 percent) that resulted in the need for four institutional disclosures.

2016

Reports of possible impairment by additional staff in 2016 resulted in a safety evaluation of Dr. Levy, including blood alcohol content tests that indicated he was legally intoxicated while on duty. This initiated a number of events that are discussed in this section, including the following:

- Facility leaders suspended Dr. Levy's privileges and notified VA leaders.
- Dr. Levy completed a treatment program and was approved to return to his previous duties.
- The Staff Pathologist notified the Chief of Staff that Dr. Levy subverted the facility's quality management program including falsifying concurrences on pathology reports.
- The Staff Pathologist also notified the National Enforcement Office (a component of the VHA Path and Lab National Program Office) that Dr. Levy had made diagnostic errors and subverted the facility's quality management program.
- A VISN 16 pathologist, who assumed the service chief responsibilities for the facility's Path and Lab (Acting Path and Lab Chief–VISN 16), completed a limited review of Dr. Levy's 2015 and 2016 cases.⁶⁷
- Dr. Levy was reinstated in October with monitoring; a full evaluation of the Staff Pathologist's allegations that Dr. Levy subverted the pathology quality management process had not been completed.

Given the number of incidents that occurred in 2016, the OIG provides an analysis of each group of events immediately following the discussion of the facts.

Elevated Blood Alcohol Content Level While on Duty in March

On March 22, 2016, approximately four and a half months after the completion of the 2015 fact-finding review, Dr. Levy exhibited signs of impairment while reviewing pathology slides during a liver biopsy procedure that was being performed by an interventional radiologist. Staff reported to the Chief of Staff that Dr. Levy was abrupt, loud, slurring his words, and difficult to understand. The interventional radiologist and other staff reported that Dr. Levy had

⁶⁷ The VISN 16 Path and Lab Consultant was detailed to the facility in an acting capacity during Dr. Levy's absence. Interviewees and facility documents referred to this position as the facility's Interim Path and Lab Medical Director and as the Acting Chief of Path and Lab. The OIG will use the term Acting Path and Lab Chief–VISN 16.

- Deferred to his subordinate, a cytology technician, to interpret slides;
- Loudly reported results in front of the patient; and
- Asked for additional specimens to review, even though he had just told the interventional radiologist the specimens were sufficient, prompting the removal of the biopsy needle.

According to documentation provided by the facility, the Chief of Staff went to Dr. Levy's office. After speaking with Dr. Levy, the Chief of Staff completed a form entitled "*Supervisory Checklist Potential Symptoms of Acute Impairment*" to determine if a referral to the facility's Employee Health was appropriate.⁶⁸ He checked several items on the list related to Dr. Levy's signs of impairment—agitated; wide swings in emotions; unusual flare-ups or outbreaks of anger; slurring of speech (mild); alcohol-like breath; and bloodshot and glazed over, glassy eyes. The Chief of Staff also indicated on the form that Dr. Levy

- Exhibited mild [ataxia](#) (impaired coordination),
- Reported drinking a few beers the previous night, and
- Agreed to both a urine drug screen and a blood alcohol content test.

The Chief of Staff escorted Dr. Levy to Employee Health that same day where laboratory testing was performed including a blood alcohol level. When interviewed by the OIG, a staff member in Employee Health discussed conducting a safety evaluation of Dr. Levy based on the Chief of Staff's concerns that Dr. Levy was impaired. However, according to the staff member, the purpose of a safety evaluation was not to determine whether the employee is impaired but whether the employee was safe to return to work. Dr. Levy was interviewed and asked to perform physical tasks to evaluate balance and coordination. No issues were identified that prevented him from returning to work. Later that day, the Employee Health staff member was notified that Dr. Levy's blood alcohol content test result was 397.6 mg/dL. On the Chief of Staff's recommendation, the Facility Director [summarily suspended](#) Dr. Levy's privileges and placed him in an administrative role that removed Dr. Levy from the clinical setting.

⁶⁸ VA Office of Human Resources Employee Relations and Performance Management. *Supervisory Checklist, Potential Symptoms of Acute Impairment*. As noted on the checklist, it may be used "to aid supervisors in identifying whether an employee may be acutely impaired" and in "determining whether it is appropriate to refer the employee to the Employee Assistance Program (EAP) or Occupational Health for further evaluation, or to justify a request for drug testing under the Reasonable Suspicion component of the Federal Drug-Free Workplace Program," accessed April 16, 2021, <https://vaww.va.gov/OHRM/EmployeeRelations/DFWP/ImpairCheck.doc>. (The website is an internal one that is not accessible to the public). The facility incorporates the duties and responsibilities of Occupational Health under the title of Employee Health. For purposes of this report, the term Employee Health will be used.

Suspension of Clinical Privileges

The Facility Director sent Dr. Levy a notification letter dated March 22, 2016, that his privileges were suspended because aspects of his clinical practice did not meet “accepted standards of practice and potentially constitute[d] an imminent threat to patient welfare.”

An [issue brief](#), dated March 23, 2016, was sent to VISN leaders that indicated a retrospective review was planned.⁶⁹ Three days after the event, the Facility Director notified the VISN 16 Director, the VHA Deputy Under Secretary for Health for Operations and Management, the Office of the Medical Inspector, and the VA Office of General Counsel that a facility physician had been involved in “egregious performance” and that he came to work “to provide care and diagnosis to patients with a blood alcohol content level above the legally intoxicated level.” The Facility Director also sent formal letters to Dr. Levy’s state licensing boards notifying them of the March event. All recipients of the notification were informed that they could request the physician’s name and further information by submitting a letter consistent with the Privacy Act. The OIG was informed that the facility did not receive requests for additional information.

In early April 2016, an attorney for Dr. Levy submitted a statement to facility leaders indicating Dr. Levy’s unusual behavior in March was caused by the side effects of over-the-counter pseudoephedrine and its interaction with his prescription blood pressure medication. The statement included the assertion that the elevated blood alcohol content level “was caused by isopropanol in Dr. Levy’s blood resulting from his ketogenic diet.”

The facility’s Professional Standards Board met in early April 2016 and discussed Dr. Levy’s alleged impairment, including his consent to undergo blood alcohol content testing. The Professional Standards Board noted in its meeting minutes that members expressed concern regarding what would have happened if Dr. Levy had refused to undergo blood alcohol content testing. Members also questioned the employee’s rights in such a situation as “alcohol abuse is covered under [reasonable accommodation\[s\]](#).”⁷⁰ Ultimately, the Professional Standards Board voted to continue the summary suspension of Dr. Levy’s privileges.

Two weeks later, members of the facility’s Executive Committee of the Medical Executive Council voted unanimously to recommend to the Facility Director that Dr. Levy’s privileges be revoked. Notably, they also agreed that if Dr. Levy sought treatment through one of his state

⁶⁹ VHA, *10N Guide to VHA Issue Briefs*, updated September 2015. Updates related to the March 23, 2016 issue brief were sent to VISN leaders on March 25, October 12, and November 3, 2016.

⁷⁰ The Chief of Staff attended the April 2016 meeting. The OIG interpreted “reasonable accommodation” to refer to provisions in the Americans with Disabilities Act (ADA) and the Rehabilitation Act that employers must accommodate individuals with certain impairments.

medical boards and submitted to monitoring, the recommendation would include his then being returned to duty.⁷¹

Dr. Levy's privileges were not revoked and he was not removed from federal service in 2016. When interviewed by the OIG team, the Chief of Staff discussed several factors that influenced the decision:

- Dr. Levy was a retired Air Force officer in good standing.⁷²
- There was a lack of evidence of patient harm.
- Physicians who complete recovery programs have a good success rate (approximately 85 percent).
- Discussions with VHA officials included consideration of whether actions would comply with the Americans with Disabilities Act and the Rehabilitation Act.⁷³

Dr. Levy contacted the Louisiana State Board of Medical Examiners (Louisiana Board) and informed the board that his alleged behavior and the high blood alcohol content levels were due to an interaction of blood pressure and over-the-counter sinus medications, along with a special diet.⁷⁴ In April, the Louisiana Board recommended a formal inpatient evaluation and provided Dr. Levy a list of facilities that offered such an evaluation. The evaluation was completed and residential treatment was recommended. When the Louisiana Board informed Dr. Levy that inpatient treatment was recommended, it also advised Dr. Levy to refrain from practicing medicine in any capacity until he completed treatment and was cleared to return to work.⁷⁵

At the facility, the Staff Pathologist agreed to assume Path and Lab Director duties in Dr. Levy's absence.⁷⁶ After the Staff Pathologist resigned from the interim Path and Lab Director position,

⁷¹ At the time of the March 2016 suspension, Dr. Levy was licensed in four states: Louisiana, Mississippi, Florida, and California. The facility was unable to validate the Director's response to the Executive Committee of the Medical Executive Council recommendations. Dr. Levy was, however, reinstated in October 2016.

⁷² The OIG did not verify the Chief of Staff's assertion related to Dr. Levy's military status.

⁷³ U.S. Equal Employment Opportunity Commission, 2007. The Americans with Disabilities Act and the Rehabilitation Act provide protections for individuals with disabilities from discrimination. Under the Americans with Disabilities Act, an individual in recovery with a substance use disorder would be considered an individual with a disability if the disorder "currently substantially limits a major life activity, was substantially limiting in the past, or is regarded as substantially limiting. An employer may not discriminate against, and may need to accommodate, a qualified applicant or employee with past or present substantial limitations relating to [the disorder] who can competently perform his job and can comply with uniformly-applied employer conduct rules prohibiting employees from [using substances] at work or being [impaired due to substance use] at work." Federal employees are assured the same protections by Section 501 of the Rehabilitation Act.

⁷⁴ The OIG considers Dr. Levy's explanation for his alleged behavior implausible.

⁷⁵ As recommended, Dr. Levy entered and completed a treatment program. During document reviews, the OIG healthcare inspection team noted different terms used to describe Dr. Levy's treatment program that he attended in summer 2016. The OIG uses the generic term *treatment* when referring to the program that he completed.

⁷⁶ VHA Handbook, 1106.01, 2016. A Path and Lab Director must be in place to meet requirements.

Acting Path and Lab Chief–VISN 16 reported being detailed to the facility at the beginning of July.

OIG Analysis of Facility Leaders' Actions Related to an Impaired Provider's Suspension of Clinical Privileges

The OIG concluded that the Employee Health staff member's evaluation and laboratory testing on March 22, 2016, removal from clinical practice, and notification of the state licensing boards and VHA officials were reasonable actions. According to information provided by the facility, steps were taken to name a Path and Lab Director.

The Chief of Staff, a psychiatrist who reported treating patients with drug and alcohol addiction, noted in an interview with the OIG, a blood alcohol content level of 397.6 mg/dL was high enough to induce coma in a person without tolerance to alcohol. Additionally, Dr. Levy's ability to pass the Employee Health examination with such a high blood alcohol content level was consistent with a long-term user of alcohol who had built up tolerance to its effects.

The March 23, 2016, issue brief to the VISN stated that a retrospective review was to be completed. The Staff Pathologist reported to the OIG team that the Chief of Staff asked him to review a random sample of 20 percent of Dr. Levy's cases. According to the Staff Pathologist, the review was random and did not focus on difficult cases. The Staff Pathologist indicated during an [administrative investigation board](#) interview that the 20 percent review identified no errors.⁷⁷ When asked for the results of the 20 percent review, facility managers denied knowledge of a 2016 review by the Staff Pathologist and opined that if such a review was done, it was an unofficial one.

The OIG concluded that facility leaders did not meet their obligation to “protect patients from harm” after the March 2016 incident. The April 2016 Professional Standards Board minutes reflect that board members were concerned about whether Dr. Levy had a right to a reasonable accommodation. However, the OIG questions whether the Professional Standards Board fully understood the protections that may be granted by the Americans with Disabilities Act or Rehabilitation Act as those statutes protect against workplace discrimination based on past alcohol addiction and do not protect employees currently abusing alcohol after a serious alcohol-related incident at work.⁷⁸ Regardless of Dr. Levy's status under the Americans with Disabilities Act or Rehabilitation Act, the facility had a duty to ensure patient safety. A review of Dr. Levy's cases would have allowed facility leaders to determine the scope of patient risk

⁷⁷ The facility convened an administrative investigative board in 2018 to evaluate the overall culture, psychological safety, and “delays in communication and system processes” in the Path and Lab service.

⁷⁸ “Applying Performance and Conduct Standards to Employees with Disabilities.” U.S. Equal Employment Opportunity Commission, accessed March 4, 2021, [Applying Performance and Conduct Standards to Employees with Disabilities | U.S. Equal Employment Opportunity Commission \(eeoc.gov\)](#). The Americans with Disabilities Act defines a disability as “a physical or mental impairment that substantially limits one or more of the major life activities of an individual; a record of such an impairment; [and] being regarded as having such an impairment.”

created by Dr. Levy's use of alcohol and consider what oversight measures might be needed to protect patients should he be returned to practice.⁷⁹ Concern about Dr. Levy's protections appeared to be a primary consideration to determine whether revocation of his privileges was warranted.

Based on a suspicion of long-term use of alcohol coupled with the knowledge of the 2014, 2015, and 2016 events as previously discussed, the OIG would have expected the Facility Director and Chief of Staff to immediately initiate a comprehensive (for example, 100 percent review for a specified period of time), retrospective review of Dr. Levy's cases. Such a review would have allowed an evaluation of whether Dr. Levy's impairment had affected his ability to previously diagnose pathological specimens.

Allegations of Subversion of the Pathology Quality Management Process

In a July 2016 email, Dr. Levy notified the facility's Path and Lab staff, including the Staff Pathologist, that he would be returning to duty in several weeks. On July 22, 2016, the Chief of Staff received an email from the Staff Pathologist outlining concerns about Dr. Levy returning to a position of authority based on past conduct. Additionally, the Staff Pathologist alleged that Dr. Levy had subverted the Path and Lab quality management program, had repeatedly misrepresented second reviews of cases, and was deficient in communication with providers when there were significant changes in diagnoses.

Four days later, the Chief of Staff forwarded the Staff Pathologist's email to the Acting Path and Lab Chief—VISN 16. In response to the Chief of Staff's request for recommendations as to how to look into the concerns, the Acting Path and Lab Chief—VISN 16 agreed to complete a review and indicated having pulled multiple cases that Dr. Levy had interpreted.

The Acting Path and Lab Chief—VISN 16 reviewed 45 of Dr. Levy's cases from fall 2015 through early 2016 considered to be "high risk or had an unusual diagnosis without an outside consult."⁸⁰ The Acting Path and Lab Chief—VISN 16 disagreed with four of Dr. Levy's diagnoses and entered modified reports (a report with a clinically significant change in diagnosis) into the patients' EHRs in August 2016. The EHR documentation included

⁷⁹ U.S. Equal Employment Opportunity Commission, 2007; U.S. Department of Education, Office for Civil Rights, "American with Disabilities Act (ADA)," accessed March 4, 2021, <https://www2.ed.gov/about/offices/list/ocr/docs/hq9805.html>. The ADA "gives civil rights protections to individuals with disabilities that are like those provided to individuals on the basis of race, sex, national origin, and religion. It guarantees equal opportunity for individuals with disabilities in employment, public accommodations, transportation, State and local government services, and telecommunications." U.S. Equal Employment Opportunity Commission, "The Rehabilitation Act of 1973, Section 501 and 503," accessed March 4, 2021, <https://www.eeoc.gov/statutes/rehabilitation-act-1973>. The Rehabilitation Act of 1973 section 501 "prohibits employment discrimination against individuals with disabilities in the federal sector."

⁸⁰ The facility provided a definition of a high-risk case within the context of Acting Path and Lab Chief—VISN 16's review—a lung biopsy, prostate biopsy, fine needle aspiration, or one with a request to rule out cancer.

notification of the modified reports to the Chief of Staff.⁸¹ When interviewed by the OIG team, the Chief of Staff indicated that the Acting Path and Lab Chief–VISN 16 had found some minor discrepancies and some major, but none affected the quality of the patients’ care.

On August 12, 2016, the Staff Pathologist sent another email to the Chief of Staff, listing 76 prostate biopsy cases dating back to 2009, claiming that Dr. Levy falsely indicated in the final pathology reports that the Staff Pathologist had concurred with the diagnosis. Additionally, the Staff Pathologist listed 27 cases noting disagreement with Dr. Levy regarding the presence or absence of malignancy, or the final classification of malignancy. The Staff Pathologist indicated that the 103 cases did not represent all cases of disagreement between the two pathologists, that there was a large number of additional, significant missed diagnoses, and the Staff Pathologist recommended the Chief of Staff review more of Dr. Levy’s cases:⁸²

If you have a qualified pathologist review these cases it might prove helpful in establishing Dr. Levy’s competency and leadership/mentorship abilities in the [facility] anatomic pathology laboratory. In my opinion, if you want to make sure that no veterans have been harmed by Dr. Levy’s diagnoses, then I would pursue a 100% case review of his past surgical and cytology sign outs for the last 4 years. If 100% case review is not feasible the[n] at a minimum the review should be pursued on all negative prostate biopsies, all negative CT [computerized tomography] guided biopsies, all negative lymph node biopsies, all negative endobronchial biopsies, and all biopsies/excisions of pigmented skin [lesions](#).

OIG Analysis of Facility Leaders’ Actions Related to Subversion Allegation

Overall, the OIG did not find evidence that the Chief of Staff fully investigated the Staff Pathologist’s allegation that Dr. Levy subverted the facility’s Path and Lab quality management program. The Acting Path and Lab Chief–VISN 16 confirmed that the facility’s Path and Lab method of communication for second reads between the Staff Pathologist and Dr. Levy was by sticky notes, which the OIG concluded, did not permit formal tracking of information or promote accountability. The Staff Pathologist further reported to an OIG interviewer being unaware whether Dr. Levy obtained a third reviewer’s opinion to resolve disagreements between the two

⁸¹ According to Facility Procedure 206-A, *Anatomic Pathology Supplemental and Modified Reports*, August 24, 2016, issued by the Acting Path and Lab Chief–VISN 16, a *modified* report is entered in a patient’s EHR “when there is a clinically significant change in the diagnosis.” A *supplemental* report is issued when the “information does not change the diagnosis in a way that would impact the patient’s treatment.”

⁸² The Staff Pathologist informed the OIG that prior to Dr. Levy’s suspension in 2016, notification to Dr. Levy of a disagreement with his interpretation or reading of a case was informal (Staff Pathologist gave Dr. Levy “Post-It notes”). Staff Pathologist eventually started to keep copies of the notes.

pathologists and did not know when Dr. Levy entered concurrence statements clarifying diagnoses into patients' EHRs.⁸³

While at the facility, the Acting Path and Lab Chief–VISN 16 implemented a form for documenting second reads that allowed improved tracking of concurrences and results. The Acting Path and Lab Chief–VISN 16 also issued procedures that defined supplemental and modified reports and clarified the methodology for generating the 10 percent peer review cases.⁸⁴ However, the OIG did not find evidence that Dr. Levy's methods for preparing and reporting pathology data to leaders were reviewed or that attempts were made to validate whether concurrence statements Dr. Levy entered into patients' EHRs accurately reflected a second pathologist's review.

Additionally, during the years 2015 and 2016, Tissue Committee members continued to accept, and facility leaders did not question, Tissue Committee reports that repeatedly indicated zero major diagnostic discrepancies. A more comprehensive, retrospective review of Dr. Levy's cases and his possible subversion of the quality management process likely would have revealed clinical errors similar to the look-back team results.

In regard to the Acting Path and Lab Chief–VISN 16 2015–2016 review findings, the OIG team evaluated the four cases with major diagnostic discrepancies that required modified reports. The OIG found that the patients did not experience adverse clinical outcomes—defined as death, a progression of disease, worsening prognosis, suboptimal treatment or a need for higher level of care. However, the OIG recognizes that the patients may have experienced unquantifiable distress when informed they had received an incorrect diagnosis. It is likely that the patient who was incorrectly informed of recurrent cancer experienced some distress both after being told about the cancer diagnosis and after being informed that the diagnosis was incorrect (see appendix A [patient 4](#)).

Additionally, the OIG compared the 45 case numbers that Acting Path and Lab Chief–VISN 16 reviewed to the 103 case numbers submitted by the Staff Pathologist and determined there was no overlap. Based on documentation provided by the facility, the OIG concluded the Staff Pathologist's cases of concern were not reviewed in 2016 prior to Dr. Levy's return. The Chief of Staff expressed concern that the Staff Pathologist was trying to get Dr. Levy fired. Additionally, the Staff Pathologist would not share the methodology used for selecting cases with the Chief of Staff. However, within the context of the subversion allegation, the OIG determined that the Chief of Staff's basis for not exploring the Staff Pathologist's concerns prior to Dr. Levy's return was not a reasonable justification for inaction.

⁸³ VHA Handbook 1106.01, 2008; VHA Handbook 1106.01, 2016. The two handbooks contain the same or similar language related to the need for a third pathologist's opinion when the first two reviewers disagree and the documentation of a concurrence statement.

⁸⁴ Facility Procedure 101, July 2016; Facility Procedure 206-A, August 2016.

Notification of the National Enforcement Office in August

On August 23, 2016, the Staff Pathologist sent an email to a VHA National Enforcement Office (NEO) staff member with language similar to the July 22 email to the Chief of Staff that Dr. Levy had made diagnostic errors and subverted the facility's quality management program.⁸⁵ The email to the NEO staff member included an "appeal to someone in authority at VISN 16 to seriously consider my allegations, and to make sure that no veteran has suffered a misdiagnosis by my former service chief and medical director of anatomic pathology services."⁸⁶

When interviewed by the OIG, the NEO staff member said that at the time the Staff Pathologist's email was received, a NEO site visit was already planned at the Chief of Staff's request. During the August 30–31, 2016, site visit, the NEO staff member reported meeting with the Staff Pathologist and subsequently communicated the Staff Pathologist's concerns to possibly five people—the direct supervising national enforcement officer (NEO supervisor), a NEO pathologist, the Acting Path and Lab Chief–VISN 16, the Chief of Staff, and the Path and Lab National Program Office Director. When interviewed, the NEO supervisor indicated the Path and Lab National Program Office Director was not informed about the August site visit as there did not appear to be an emergency situation.⁸⁷

OIG Analysis of Path and Lab National Program Office Responsibilities and Duties Related to Oversight of Dr. Levy

The VHA Path and Lab National Program Office establishes policies applicable to VHA clinical laboratories and provides guidance to senior leaders on related issues.⁸⁸ Laboratories that conduct non-research testing must comply with the [Clinical Laboratory Improvement](#)

⁸⁵ VA National Pathology and Laboratory Medicine Services (P&LMS) Home, accessed April 28, 2021, <http://vaww.lab.med.va.gov/index.asp>. (This is an internal website not accessible to the public.) VHA's Path and Lab National Program Office has four components (offices). NEO is one of the four components. NEO staff conduct routine site visits to VA medical facilities to evaluate compliance with mandated Clinical Laboratory Improvement Amendments that regulate laboratory testing. The head of NEO reports to the Path and Lab National Program Office Director.

⁸⁶ VHA Handbook 1106.01, 2016. Although Staff Pathologist referenced "someone in authority at VISN 16" in the email, NEO staff are not part of the VISN but part of National Path and Lab program office.

⁸⁷ The NEO staff member reported that three non-conformances related to laboratory procedures were identified. Two were corrected while on-site. The facility provided a corrective action plan for the third finding.

⁸⁸ VA Pathology and Laboratory Medicine Services (P&LMS). *About Pathology and Laboratory Medicine*, accessed April 16, 2021, http://vaww.lab.med.va.gov/components/About_P_LMS.asp. (This is an internal website not accessible to the public.)

Amendments (CLIA).⁸⁹ NEO is a component of the Path and Lab National Program Office and oversees “the quality of services provided by [VHA] Clinical Laboratories as well as laboratory compliance with regulatory, accreditation, and policy guidelines.”⁹⁰ VHA laboratories must comply with both CLIA requirements and VHA Path and Lab policies.⁹¹

During OIG interviews, a national program office leader and NEO officials indicated that their inspections focused on adherence to CLIA and not the competency of individual pathologists. The NEO staff member and supervisor told the OIG team that overseeing the competency of providers and taking action related to providers’ performance lay with facility and VISN leaders. This interpretation of the role of a national program office is consistent with a comment by the current Acting Under Secretary for Health in a January 2021 VA OIG report that “facilities may utilize information from consultations in their deliberation processes to determine appropriate privileging or personnel actions...[S]uch specialty experts cannot usurp authority of medical facility Directors for personnel or privileging actions.”⁹²

Preparing for Dr. Levy’s Reinstatement in October

Although Dr. Levy originally cooperated with the Louisiana Board to address his impairment issues, he entered into a Recovery Contract Agreement in September 2016 with the Mississippi State Board of Medical Licensure through the Mississippi Physician Health Program (Mississippi Program). According to the terms of the Recovery Contract Agreement, Dr. Levy agreed “not to prescribe, dispense or administer to staff, family members, or [himself] any drug having addiction-forming or addiction-sustaining liability.” He further agreed “to abstain completely from the use of any medications, alcohol and other mood-altering substances

⁸⁹ Centers for Disease Control and Prevention, *Clinical Laboratory Improvement Amendments (CLIA)*, accessed May 14, 2021, <https://www.cdc.gov/clia/about.html>. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations outline federal standards related to specimens for health assessment or to diagnose, prevent, or treat disease. VHA Directive 1106, *Pathology and Laboratory Medicine Service*, October 13, 2005, rescinded and replaced by VHA Directive 1106, *Pathology and Laboratory Medicine Service*, April 5, 2013, rescinded and replaced by VHA Directive 1106, *Pathology and Laboratory Medicine Service*, July 27, 2018. The three directives contain similar language related to VHA responsibilities pursuant to CLIA regulations. While VHA is exempt from CLIA regulations promulgated by the Department of Health and Human Service, the Secretary of Veterans Affairs was required to publish regulations that would “establish standards equal to that applicable to other medical facility laboratories.” The Secretary of Veterans Affairs delegated authority to the Under Secretary for Health to issue regulations implementing requirements and standards for VHA laboratories.

⁹⁰ VA Pathology and Laboratory Medicine Services (P&LMS). *About Pathology and Laboratory Medicine*. VHA Handbook, 1100.16, *Accreditation of Veterans Health Administration Medical Facility and Ambulatory Programs*, September 22, 2009; was rescinded and replaced by VHA Directive, 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017. The handbook and the directive indicate that laboratory accreditation is mandatory; accrediting bodies include the College of American Pathologists or The Joint Commission.

⁹¹ VHA Directive 1106, 2005; VHA Directive 1106, 2013; VHA Directive, 2018. All three directives contain the same or similar language related to VHA meeting “the requirements of CLIA-88 and applicable VA requirements.”

⁹² VA OIG, *Healthcare Inspection—Thoracic Surgery Quality of Care Issues and Facility Leaders’ Response at the C. W. Bill Young VA Medical Center in Bay Pines, Florida*, January 13, 2021, <https://www.va.gov/oig/pubs/VAOIG-18-01321-56.pdf>. The Acting Under Secretary for Health, Dr. Richard Stone, served as the VHA Executive in Charge prior to January 20, 2021.

including nonapproved over-the-counter medications.” Additionally, Dr. Levy agreed to submit to random urine and blood testing for the presence of drugs and alcohol.⁹³

According to facility documentation, the Acting Path and Lab Chief–VISN 16 completed the review of Dr. Levy’s cases considered to be high risk (discussed previously). The review was completed prior to Dr. Levy’s return in October 2016.⁹⁴

On October 12, 2016, the Chief of Staff recommended to the Facility Director that Dr. Levy’s clinical privileges be reinstated. The Chief of Staff informed the Facility Director that the Professional Standards Board had reviewed the actions mandated by the Mississippi Program and concurred with the plan for monitoring Dr. Levy. Planned monitoring included random weekly body fluid screening for alcohol; daily online contacts with the state board; work place monitoring, frequent observation and quarterly reports to the Mississippi Program; monthly calls to the Mississippi Program; attendance at monthly Alcohol Anonymous meetings; and scheduled revisits to the Mississippi Program.

The Chief of Staff reported that all Dr. Levy’s licenses were active and unrestricted, except for Louisiana, which was “inactive [and] in good standing.” According to the Chief of Staff’s letter to the Facility Director, Dr. Levy had completed a three-month inpatient treatment program and a six-week professional recovery tract. The Chief of Staff agreed to act as Dr. Levy’s monitor, make quarterly reports to the Mississippi Program, and enact a random blood screening process through Employee Health. The Facility Director agreed and permitted Dr. Levy to return to his pathology position on October 12, 2016.⁹⁵

OIG Analysis of Facility Leaders’ Actions Related to Dr. Levy’s Approaching Reinstatement

The OIG acknowledges that the Chief of Staff’s decision to reinstate Dr. Levy in October 2016 was based on an understanding that no patients had experienced harm as well as Dr. Levy’s successful completion of a treatment program. The OIG has concerns, however, regarding the reinstatement of Dr. Levy to a position with leadership responsibilities in light of

⁹³ According to the terms of the contract, Dr. Levy was required to provide specimens at random times. Positive screens would be reported to the Mississippi State Board of Medical Licensure.

⁹⁴ According to the facility’s timeline, the Acting Path and Lab Chief–VISN 16 completed the review of cases in September 2016. As noted above, the review identified four cases that required modified reports indicating a change in diagnosis.

⁹⁵ The return to service on October 12, 2016, was not initially in accordance with the Mississippi Program agreement for monitoring Dr. Levy’s practice. According to the Chief of Staff’s October 27, 2016, letter to the Mississippi Program, facility leaders were unaware that Dr. Levy could not practice until he had the Mississippi Program’s approval.

- The Staff Pathologist’s July 2016 allegation of subversion of the Path and Lab quality management program that was not more fully investigated, and
- A limited review of 45 cases by Acting Path and Lab Chief–VISN 16 revealed the need for four modified reports (8.9 percent error rate).

An extensive review of Dr. Levy’s cases and assessment of his competency prior to reinstatement in 2016 would likely have revealed results similar to the look-back review and may have averted the facility’s decision to return Dr. Levy to clinical practice.

Monitoring Dr. Levy Following His Reinstatement

In a letter addressed to the Director of the Mississippi Program dated October 27, 2016, the Chief of Staff summarized the processes put in place to assure Dr. Levy’s compliance with the Mississippi Program’s workplace monitoring provisions.⁹⁶ These monitoring activities included the following:

- Daily face-to-face interaction every morning with the Chief of Staff, a board-certified psychiatrist with experience treating patients with substance use disorders
- Random visits by the Chief of Staff to Dr. Levy’s work area
- Random and frequent testing for substance use⁹⁷
- Initiation of an FPPE to include “a 100% review of a specified number of surgical and cytology cases”⁹⁸

In accordance with the Mississippi Program’s monitoring plan, the Chief of Staff also agreed to complete evaluation forms that included an assessment for irritability, irresponsibility, inability, isolation, and incidental behaviors, and submit the report quarterly.⁹⁹

⁹⁶ “About AMF,” Arkansas Medical Foundation, accessed February 6, 2021. <http://arkmedfoundation.org/about-amf/>. The Foundation facilitates the Arkansas Medical Society Physicians’ Health Committee whose goal is to assist physicians in overcoming addiction. On October 27, 2016, Dr. Levy also signed a contract with the Arkansas Medical Foundation, which is funded partially by the Arkansas State Medical Board. The contract contained similar terms as the Mississippi Program and extended for up to a five-year period. In contrast, the Mississippi Program contract was for the life of his medical practice.

⁹⁷ United States District Court Western District of Arkansas Fayetteville Division, *U.S. v. Robert Morris Levy, Superseding Indictment*. According to information published in the criminal indictment notice regarding Dr. Levy, all of his daily or weekly 42 urine and blood tests were negative for the presence of drugs and alcohol.

⁹⁸ The FPPE plan outlined a review of approximately 250 surgical and cytology cases.

⁹⁹ Although the Chief of Staff’s agreement with the Mississippi Program was to submit quarterly reports, he provided OIG inspectors with copies of forms that were submitted more frequently than the agreed-upon time frame and through April 2018 (which included the period of suspension). Between January and October 2017, the Chief of Staff reported no issues. In October 2017, Dr. Levy’s privileges were suspended. However, he remained on campus and the Chief of Staff continued to submit reports to the Mississippi Program through April 2018. The form dated January 3, 2017, was marked as the December quarterly progress report.

Upon Dr. Levy's return, an FPPE with specific criteria for review was completed to assess his competency. The goal was to evaluate approximately 250 cases and was scheduled to last for a 90-day period, from October 12, 2016, through January 12, 2017. According to information provided by the facility, the FPPE was rated successful and signed on December 19, 2016. In an attachment to the FPPE, the reviewer provided a list of 20 cases with "problems" but "no major errors which would have a significant patient impact."

OIG Analysis of Facility Leaders' Actions Related to the Monitoring of Dr. Levy

The OIG determined that the facility's plan for monitoring was reasonable. However, the prudence of facility leaders' decision to terminate the FPPE approximately three weeks early is questionable given the circumstances of his reinstatement. In light of the 20 cases with identified "problems" the OIG would have expected the Chief of Staff to request a rigorous review of Dr. Levy's cases and extend or restructure the FPPE rather than terminate it before the planned end date.

According to the look-back review results, Dr. Levy reviewed a total of 494 cases during the abbreviated October 12–December 19, 2016, FPPE period. Of the 494 cases, the look-back review team identified 69 level 2 and 3 diagnostic errors (13.97 percent) that resulted in the need for one institutional disclosure.

The OIG is concerned that the results of the look-back review that included all Dr. Levy's cases reveal markedly different results from the FPPE review. VHA should consider the extent of the evaluation process for providers who return to practice after a leave of absence. Based on the look-back results, a partial review was not a good indicator of Dr. Levy's competency.

Dr. Levy was in the clinical setting for approximately two-and-one-half months at the beginning of 2016 and about two and one-half months at the end of 2016. During that period, Dr. Levy reviewed 1,084 cases; the look-back review team identified 147 level 2 and 3 diagnostic errors (13.56 percent) that resulted in the need for one institutional disclosure.

2017

The Chief of Staff continued to monitor Dr. Levy daily during work hours. In October, however, new reports of impairment resulted in Dr. Levy's privileges being suspended a second time. Facility leaders also became increasingly concerned about his clinical competency as additional information was revealed about high error rates.

Reprivileging in July

According to the Chief of Staff, he had been Dr. Levy's supervisor for approximately four-and-one-half years when he approved Dr. Levy's request for reprivileging in summer 2017. Facility documents reflect that when determining Dr. Levy's competency to practice, the Chief of Staff continued to rely on the criteria and data that were provided by Dr. Levy and the Path and Lab

staff. The Chief of Staff also continued to accept non-pathologist peer references to support Dr. Levy's reprivileging, which was not in alignment with VHA policy.¹⁰⁰

OIG Analysis of Facility Leaders' Actions Related to Quality Management

While VHA policy does not define the individual in charge of determining OPPE criteria for service chiefs, two memorandums from the VHA Deputy Under Secretary were issued in 2016 that related to the clinical practice of chiefs of staff and solo providers.¹⁰¹ The first memorandum addressed OPPE for chiefs of staff relative to competency determinations. In order to "to ensure credibility" of the OPPE process for a chief of staff, a reviewer outside of the provider's facility and supervisory chain of command should conduct the evaluation. The second memorandum addressed OPPE for solo practitioners and indicated that evaluations be based on reviews by another provider with similar training and privileges.

The OIG concluded that chiefs of staff and solo practitioners in clinical practice are similarly positioned to service chiefs relative to competency determinations. A chief of staff, a solo practitioner, and a service chief would not have a peer at the facility that could conduct such a determination. The guidance provided in the two memorandums could be applied to the evaluation process for service chiefs and incorporated into VHA policy.

Second Suspension of Dr. Levy's Privileges in October

On October 13, 2017, the Chief of Staff was informed by attendees of the Tumor Board that Dr. Levy, the chair of the committee, appeared to be impaired.¹⁰² The Chief of Staff went to Dr. Levy's office to assess his condition. Using the *Supervisory Checklist Potential Symptoms of Acute Impairment*, he documented that Dr. Levy was drowsy, had glassy eyes, slurred his words, repeated nonsense words and phrases, and had an unsteady gait. The Chief of Staff also documented escorting Dr. Levy to Employee Health for a safety evaluation and a random drug screen. Dr. Levy gave his consent for a blood alcohol content test. Both the drug screen and the blood alcohol content were reported to be negative (no illegal drugs and zero alcohol level).¹⁰³

¹⁰⁰ VHA Handbook 1100.19, 2008; VHA Handbook 1100.19, 2012. The two handbooks contain the same language related to peer references.

¹⁰¹ VHA Handbook 1100.19, 2008; VHA Handbook 1100.19, 2012. Deputy Under Secretary for Health Operations and Management, *OPPE and Peer Review for Quality Management for Chiefs of Staff*, May 27, 2016; Deputy Under Secretary for Health Operations and Management, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

¹⁰² The OIG reviewed documents that were submitted to the Mississippi Program and found that the Chief of Staff did not identify issues with Dr. Levy's behavior between January 3, 2017, and October 2, 2017. Nancy L. Keating et al. "Tumor Boards and the Quality of Cancer Care," *Journal of the National Cancer Institute* 105, (January 16, 2013): 113–21. A tumor board is a group of practitioners involved in the care of patients with cancer that may include "surgeons, medical oncologists, radiation oncologists, pathologists, social workers, and palliative care specialists" who meet to discuss various aspects of patients' diagnoses and treatments.

¹⁰³ According to court documents, Dr. Levy began purchasing 2M-2B in 2017; the substance was not detectable by routine drug and alcohol testing processes.

The Chief of Staff further noted that the Employee Health Clinic Manager who conducted the safety evaluation determined that it was unsafe for Dr. Levy to return to work. Based on the Chief of Staff's recommendation, the Facility Director summarily suspended Dr. Levy's privileges due to concerns that aspects of his clinical practice did not meet accepted standards and potentially constituted an imminent threat to patient welfare. This ended Dr. Levy's clinical care responsibilities and he was assigned to nonclinical duties at the facility.

Also, on October 13, 2017, the Staff Pathologist provided the Chief of Staff with a five-page list of Dr. Levy's cases that the Staff Pathologist had reviewed since Dr. Levy's reinstatement (October 2016—October 2017) that were cause for concern. The list included multiple cases in which there were various types of disagreement between Dr. Levy's interpretations of the slides and those of the Staff Pathologist.¹⁰⁴

According to information provided to the OIG team by the facility, the Acting Path and Lab Chief—VISN 16 reviewed an extra 10 percent of Dr. Levy's previous three months of cases based on a recommendation from the Path and Lab National Program Office Director.¹⁰⁵ Additionally, the Acting Path and Lab Chief—VISN 16 re-reviewed the cases that had been submitted for Dr. Levy's OPPE from October 1, 2016, through September 30, 2017.¹⁰⁶

In response to the notice of the summary suspension of his privileges, Dr. Levy submitted a letter, indicating that his demeanor on October 13, 2017, was caused by a migraine headache and attached records of an evaluation at a local hospital emergency department that he visited four days later. Discharge diagnoses were cephalgia (head pain) and migraine headache.

On October 30, 2017, the Professional Standards Board recommended revocation of Dr. Levy's privileges, an action subsequently adopted by the Executive Committee of the Medical Executive Council and approved by the Facility Director on November 7, 2017. The Facility Director approved the revocation of privileges because Dr. Levy failed to recognize personal impairment and performed clinical duties on October 13, 2017, while impaired.

¹⁰⁴ The Staff Pathologist's list included three cases that Dr. Levy diagnosed a malignancy and the Staff Pathologist believed there were no malignancies, 11 cases that Dr. Levy diagnosed no malignancy (benign) and the Staff Pathologist believed there were malignancies, and seven prostate biopsy cases for which Dr. Levy called all parts benign, but the Staff Pathologist believed at least one part contained cancer. The Patient Safety Manager was notified of the same list about six weeks later.

¹⁰⁵ OPPE documentation reflects that the extra 10 percent review of cases from period 4 (July 1, 2017, through September 30, 2017) indicated that Dr. Levy did not meet satisfactory thresholds for either the 10 percent peer review diagnostic concordance or the major discrepancies by peer review monitors.

¹⁰⁶ OPPE documentation reflects that the re-review of cases did not meet a satisfactory threshold but exceeded 0.7 percent.

Growing Concern Related to Dr. Levy's Error Rates

In a November 29, 2017, email to the Chief of Staff, the Acting Path and Lab Chief–VISN 16 reported the results of the review of Dr. Levy's cases (79 anatomic pathology cases and 15 cytology cases) as recommended by the Path and Lab National Program Office Director and identified a higher than expected error rate. The rate was above the 0.7 percent threshold that would typically trigger a review of a VHA pathologist's practice.¹⁰⁷ A facility laboratory manager reported that the Acting Path and Lab Chief–VISN 16 re-assessed Dr. Levy's OPPE data from October 1, 2016, through September 30, 2017, and found that "some of the disagreements that were classified as minors should have been classified as major."¹⁰⁸

Concerned about the Acting Path and Lab Chief–VISN 16 findings, the Chief of Staff asked Path and Lab managers to conduct a review of modified reports and tasked the newly appointed Administrative Path and Lab Chief to review information received from the non-VHA consulting pathology group to identify when major discrepancies had occurred. On December 15, 2017, the Chief of Staff notified Dr. Levy that an FPPE for cause would be initiated.¹⁰⁹

OIG Analysis of Facility Leaders' Actions Related to the Quality Management Reviews of Dr. Levy's Cases

After the second suspension, facility leaders began to recognize Dr. Levy was inaccurately reporting major discrepancies as minor discrepancies. Facility leaders took appropriate actions to explore these concerns including consulting with the Path and Lab National Program Office Director, initiating retrospective reviews, and ordering a review of consult results from the non-VHA pathology group.

The facility's review of pathology cases sent to the non-VHA pathology consulting group revealed that Dr. Levy did not consistently enter final reports into patients' EHRs in a way that would optimally alert providers of changes in diagnosis and allow tracking of major diagnostic discrepancies. According to VHA policy, when a disagreement between pathologists arises, an external pathology group may be consulted to obtain an expert opinion.¹¹⁰ Additionally, a look-back review team member stated an expert opinion may be requested when a pathologist

¹⁰⁷ *Requirements for Peer Review of Solo Practitioners*, 2016. Guidance from the VA path and lab program suggested an error rate exceeding 0.7 percent be viewed with concern. Facility leaders, however, remained responsible to determine when actions and responses were needed when the error rate exceeded the threshold.

¹⁰⁸ Both the 2009 and 2016 facility's *Anatomic Pathology Continuous Quality Improvement/Quality Management Plans*, define minor discrepancies as "small change in diagnosis that is with minimal, if any, clinical relevance" and major discrepancies were "(1) significant change between the original diagnosis and review interpretation with (2) potential serious impact on treatment or prognosis."

¹⁰⁹ The OIG found no evidence that an FPPE was implemented. An FPPE is not a retrospective review but a review of current practice. Dr. Levy did not read pathological specimens after October 13, 2017; therefore, the facility did not have the opportunity to conduct the planned FPPE.

¹¹⁰ VHA Handbook 1106.01, 2016.

finds a specimen challenging to interpret. After the expert opinion is received, a final, amended report is entered into the patient's EHR. If there is a significant change from the working diagnosis that requires a change in treatment, the pathologist must communicate the amended diagnosis to the Chief of Staff and the provider treating the patient.¹¹¹

VHA officials discussed the use of two types of amended reports (modified and supplemental reports). One of the officials told the OIG that modified reports should be used when there is a change in diagnosis because the entry of a modified report generates an automatic notification to the ordering provider; a supplemental report does not generate an automatic notification.¹¹² Entering a modified report also allows input of a code designating a change in diagnosis that may be used by quality management staff for tracking purposes. One of the officials also indicated that Dr. Levy was using supplemental reports rather than entering modified reports.

VHA policy does not give clear guidance related to amended pathology reports (supplemental and modified). The policy requires that additions to the final anatomic pathology report be clearly indicated, but it does not distinguish between the use of supplemental and modified reports.¹¹³ Providing specific guidance to pathologists on this matter may increase the use of modified reports with improved notification to providers and tracking of major diagnostic discrepancies. Additionally, ensuring that the results of reports from non-VHA consulting groups are provided not only to Path and Lab staff but also to recipients outside of Path and Lab may also improve the ability to monitor and track the correct use of supplemental and modified reports.

The look-back review data were not congruent with the data that facility leaders relied on to determine Dr. Levy's competency and reprivileging. Data reported in Dr. Levy's 2017 OPPE indicating zero major discrepancies was found to be incorrect during a re-review by the facility. The Tissue Committee meeting minutes prior to Dr. Levy's October 2017 suspension, continued to reflect the incorrect reporting of zero major discrepancies and no documentation of discussion or questions about the discrepancies by committee members.

Of the 2,138 cases reviewed by Dr. Levy in 2017, the look-back review team identified 214 level 2 and 3 diagnostic errors (10.01 percent) that resulted in the need for three institutional disclosures.

¹¹¹ VHA Handbook 1106.01, 2016.

¹¹² When a modified report is entered, the pathologist may also enter a tissue code (TC8) that would allow tracking of changes in diagnoses of final pathology reports for quality management purposes.

¹¹³ VHA Handbook 1106.01, 2016. While VHA does not clearly define supplemental and modified reports, Acting Path and Lab Chief-VISN 16 issued Facility Procedure 206-A, August 2016 while at the facility that defined modified and supplemental reports: a *modified* report is entered in a patient's EHR "when there is a clinically significant change in the diagnosis." A *supplemental* report is issued when the "information does not change the diagnosis in a way that would impact the patient's treatment."

2018

The extent of Dr. Levy's errors and his ability to conceal them began to surface in early 2018. Facility leaders determined that Dr. Levy should be removed from federal service. Before removal could be completed, he was arrested off-campus during duty hours. As the magnitude of the errors became apparent, VHA initiated a comprehensive, retrospective review.

In a January 2018 memo from the Chief of Staff, the Facility Director was notified that the Executive Committee of the Medical Executive Council recommended permanent revocation of Dr. Levy's privileges for "failure to provide appropriate pathological diagnoses and failure to recognize impairment while making clinical decisions." The Facility Director concurred with this recommendation. While the facility was preparing revocation paperwork, Dr. Levy was arrested on March 1, 2018, during duty hours, in the parking lot of a local post office on suspicion of driving while intoxicated. According to Fayetteville District Court documents, Dr. Levy submitted to a "chemical test of his breath." The test results could not be obtained, however, due to an "interfering substance" in the breath samples. A drug recognition evaluation completed by a law enforcement officer concluded that Dr. Levy was intoxicated with central nervous system depressants.¹¹⁴

In April 2018, Dr. Levy was notified of the interim Facility Director's decision to remove him from federal service for unprofessional conduct. Dr. Levy filed a grievance. A grievance examiner was appointed. According to a facility human resource officer, a hearing was held on June 4, 2018, and the decision to remove Dr. Levy was upheld. Consistent with a letter dated July 3, 2018, the VISN 16 Director notified Dr. Levy that the removal action was sustained.¹¹⁵

Look-Back Review: Dr. Levy's 2005–2017 Cases

The CERT initially recommended a two-year look-back period.¹¹⁶ Because reviews revealed concerns with the quality of Dr. Levy's care extending as far back as 2012, the look-back review period was extended to examine all cases Dr. Levy had reviewed from the time of his first specimen reading in 2005 through October 13, 2017. A leader was designated to coordinate the 100 percent look-back review in June 2018. The look-back review team, composed of VHA and non-VHA pathologists, was provided standardized criteria to categorize the results of their reviews.¹¹⁷

¹¹⁴ In June 2018, Dr. Levy was found not guilty of the March 2018 driving while intoxicated charge. In an interview with OIG investigators in July 2018, Dr. Levy admitted that he began purchasing 2M-2B in 2017. In August 2018, additional testing of urine that was collected on the day of the arrest was positive for 2M-2B.

¹¹⁵ The OIG was informed that the Chief of Staff retired from federal service in the summer 2018.

¹¹⁶ VHA Handbook 1004.08, 2012; VHA Directive 1004.08, 2018.

¹¹⁷ The look-back review team categorized its findings according to the level of discrepancy: (0) no deficiency or diagnostic error; (1) minor disagreement, practice acceptable, reviewer still comfortable; (2) disagreement in diagnosis with minimal or no potential negative impact on patient care; and (3) major diagnostic discrepancy with potential for negative impact on patient care/treatment.

Upon receiving results of the look-back review, the CERT tasked a clinical review team to assess if discrepancies adversely affected patient outcomes. According to VHA policy, if an adverse event occurred that “resulted in or is reasonably expected to result in death or serious injury,” facility leaders should conduct an institutional disclosure to inform the patient of the circumstances of the event.¹¹⁸

Reviewing pathologists identified 2,440 level 2 cases, and 589 cases with level 3 major discrepancies for cases interpreted by Dr. Levy throughout his tenure. The clinical review team determined that facility leaders needed to conduct 34 institutional disclosures with patients, their family, or personal representatives (see table 2).¹¹⁹

¹¹⁸ VHA Directive 2005-049, 2005; VHA Directive 2008-002, 2008; VHA Handbook 1004.08, 2012; VHA Directive 1004.08, 2018.

¹¹⁹ As the look-back review team submitted results and the clinical review team identified patients needing institutional disclosures, facility staff began conducting the disclosures. The first institutional disclosure occurred in 2018 and the most recent one was conducted in 2020.

Table 2: Number of Level 2 and 3 Anatomic Pathology Cases and Number of Patients Identified as Needing Institutional Disclosures by Year

Calendar Year	Dr. Levy's Total Cases	Total Cases Less N/A Cases	Level 2 Cases	Level 2 Error Rate (%)	Level 3 Cases	Level 3 Error Rate (%)	Levels 2 and 3 Combined Error Rate (%)	Institutional Disclosures by Year
2005 (~one month locum tenens)	174	161	9	5.59	0	0.00	5.59	0
2005 (post-locum tenens)	518	481	37	7.69	6	1.25	8.94	0
2006	2,711	2,486	139	5.59	29	1.17	6.76	1
2007	3,582	3,115	260	8.35	61	1.96	10.30	4
2008	4,403	3,148	241	7.66	60	1.91	9.56	0
2009	2,710	2,551	179	7.02	50	1.96	8.98	3
2010	2,867	2,703	193	7.14	42	1.55	8.69	3
2011	2,634	2,496	175	7.01	60	2.40	9.42	1
2012	2,226	2,093	172	8.22	43	2.05	10.27	6
2013	2,647	2,332	241	10.33	38	1.63	11.96	5
2014	2,918	2,665	243	9.12	48	1.80	10.92	3
2015	3,069	2,909	271	9.32	71	2.44	11.76	4
2016	1,141	1,084	117	10.79	30	2.77	13.56	1
2017	2,302	2,138	163	7.62	51	2.39	10.01	3
Total/Average	33,902	30,362	2,440	8.04	589	1.94	9.98	34

Source: OIG analysis of VHA pathology look-back review results

Note: Not applicable cases are those without a slide in the file for microscopic examination. A member of the look-back team stated these cases should not be included when calculating diagnostic error rates.

OIG Analysis of Facility Leaders' Actions Related to Look-Back Review Results

The OIG acknowledges VHA and facility leaders recognized the need to do a comprehensive, retrospective review of all of Dr. Levy's cases. The review was efficiently coordinated and organized.

As noted above, facility leaders approved Dr. Levy's competency and biennial reprivileging over 12 years, based on multiple criteria including the 10 percent peer review. No concerns were identified. The look-back review results and the need for institutional disclosures are not congruent with the information provided to facility leaders to make the determination to continue privileges. Because the facility's 10 percent peer review process did not identify the extent of

diagnostic errors that the look-back review revealed, the OIG reviewed VHA guidance related to the 10 percent peer review.

While VHA's 2008 pathology handbook did not specify the methodology for selecting cases for the mandated 10 percent peer review, the facility's 2009 continuous quality improvement plan required random case selection.¹²⁰ In 2016, VHA re-issued the pathology handbook and specified the cases for the 10 percent peer review be randomly selected.¹²¹ According to the College of American Pathologists, "there is evidence that targeted review (review of a specific type of case) is more efficient at finding important diagnostic discrepancies or errors than randomly selecting cases for review."¹²²

Focusing at least a portion of the 10 percent peer review on cases that carry a higher risk of interpretation error or that can result in clinically significant consequences to a patient could be more effective in identifying errors. Due to the critical nature of accurate pathology diagnoses, VHA should evaluate the need to provide additional instructions to facilities on the methodology for selecting cases for peer reviews.

The OIG acknowledges that the facility's failure to recognize flawed quality management practices was complicated by Dr. Levy's efforts to conceal his errors; however, it is uncertain that the 10 percent peer review process would have been successful in identifying his high error rate even absent his untruthfulness.

2019

Criminal Charges

In August 2019, Dr. Levy was arrested after being indicted by a federal grand jury in the Department of Justice Western District of Arkansas "on 12 counts of wire fraud, 12 counts of mail fraud, four counts of making false statements in certain matters, and three counts of involuntary manslaughter."¹²³

As noted in the Department of Justice press release, the results of Dr. Levy's urine and blood tests that were submitted from November 2016 through June 2018 to meet the terms of his monitoring contract with a state licensing board were negative. However, he was subsequently

¹²⁰ VHA Handbook 1106.01, 2008; Facility Procedure, *Anatomic Pathology Continuous Quality Improvement/Quality Management Plan*, 2009.

¹²¹ VHA Handbook 1106.01, 2016.

¹²² College of American Pathologists, "About us," accessed December 29, 2020, <https://www.cap.org/about-the-cap>. The College of American Pathologists is an organization of board-certified pathologists. Association of Directors of Anatomic and Surgical Pathology, "Interpretive Diagnostic Error Reduction in Surgical Pathology and Cytology," accessed February 9, 2021, <https://documents.cap.org/documents/ider-faqs.pdf>.

¹²³ United States District Court Western District of Arkansas Fayetteville Division, *U.S. v. Robert Morris Levy, Superseding Indictment*.

found to have purchased 2M-2B, “a chemical substance that enables a person to achieve a state of intoxication but is not detectable in routine drug and alcohol testing methodology.”¹²⁴

According to the Department of Justice press release of indictment charges, Dr. Levy

- Schemed “to defraud the Department of Veterans Affairs (VA) and to obtain money and property from the VA in the form of salary, benefits, and performance awards he would not have received had the VA known” about the intentional “non-compliance with the drug and alcohol testing program;”
- “Concealed a material fact and made material false and fraudulent representations;”
- “Made false statements to a special agent” of the OIG on two occasions;
- Entered information in a patient’s electronic health record that he knew to be false and “making a false statement during a grievance hearing related to his employment;” and
- Caused “the death of three patients through entering incorrect and misleading diagnoses and, on two occasions,” falsified EHRs by entering that a second pathologist concurred with Dr. Levy’s diagnoses.¹²⁵

2020

Plea Agreement

In June 2020, Dr. Levy agreed to plead guilty to one count of mail fraud and one count of involuntary manslaughter.¹²⁶ The crime of mail fraud includes the use of mail communications “in the foreseeable furtherance of a scheme and intent to defraud another of either property or services involving a material deception.”¹²⁷

Dr. Levy placed an online order for 2M-2B that was delivered to his home in Arkansas in July 2017 from Virginia via a commercial interstate carrier. Dr. Levy used 2M-2B to achieve a state

¹²⁴ Department of Justice United States Attorney Western District of Arkansas, “Fayetteville Doctor Arrested on Charges of Wire Fraud, Mail Fraud, Making False Statements, and Involuntary Manslaughter,” news release, August 20, 2019, <https://www.justice.gov/usao-wdar/pr/fayetteville-doctor-arrested-charges-wire-fraud-mail-fraud-making-false-statements-and>.

¹²⁵ Making False Statements, and Involuntary Manslaughter, August 20, 2019.

¹²⁶ United States District Court Western District of Arkansas Fayetteville Division, *U.S. v. Robert Morris Levy, Plea Agreement*; [18 U.S.C. § 1341](#); [18 U.S.C. § 1112](#).

¹²⁷ Congressional Research Service, *Mail and Wire Fraud: A Brief Overview of Federal Criminal Law*, February 11, 2019.

of intoxication that would not be detectable during routine blood and urine testing.¹²⁸ The ordering and ingestion of 2M-2B was “in furtherance of the scheme to defraud” the government of money and benefits that Dr. Levy would not have received had facility leaders been aware of his failure to comply with the monitoring program.¹²⁹

Involuntary manslaughter “is the unlawful killing of a human being without malice” that either occurs in the commission of an unlawful, non-felony crime or a lawful act that is carried out “without due caution or circumspection” that might produce death.¹³⁰

In early 2014, Dr. Levy failed to take necessary steps to fully analyze a tissue sample and entered an incorrect diagnosis in a patient’s EHR.¹³¹ He also entered a false statement in the EHR that another facility pathologist “reviewed this case and concurs” (see appendix A, [patient 1](#)).¹³² Dr. Levy could reasonably foresee that the patient’s doctors would consider another pathologist’s concurrence with Dr. Levy's diagnosis as an indication that the diagnosis was correct.

Providers implemented treatment based on the initial diagnosis of lymphoma. A few days later, Dr. Levy changed the diagnosis after an additional, but still incomplete evaluation of the tissue sample. The second diagnosis (non-small cell carcinoma) was also incorrect. The treating providers were not aware of a change in diagnosis. The patient continued to be treated for the initial incorrect diagnosis and died approximately five months later.

2021

Sentencing

On January 22, 2021, Dr. Levy was sentenced to 20 years in prison and three years of supervised release. The court also ordered restitution of approximately \$498,000 to VA based on Dr. Levy’s defrauding the facility and receiving his salary and benefits after reinstatement in 2016. Within a week, Dr. Levy filed a notice of appeal of his sentence. The appeal was pending as of May 26, 2021.

¹²⁸ *U.S. v. Robert Morris Levy, Plea Agreement*. Dr. Levy informed a non-VHA physician in 2018 that he used 2M-2B “to obtain the effects of alcohol without triggering a positive test” during his monitoring for drugs and alcohol program.

¹²⁹ *U.S. v. Robert Morris Levy, Plea Agreement*.

¹³⁰ 18 U.S.C. § 1112.

¹³¹ *U.S. v. Robert Morris Levy, Plea Agreement*.

¹³² *U.S. v. Robert Morris Levy, Plea Agreement*. The Staff Pathologist notified Dr. Levy by a hand-delivered letter of not concurring with the initial diagnosis.

3. Failures by Facility Leaders to Create a Culture of Accountability and Responsibility for Staff to Report Concerns Affecting Patient Care

The OIG determined that facility leaders did not model a culture of accountability and provide conditions that promoted psychological safety (the belief that it is safe to speak up about a problem without fear of reprisal). Facility leaders failed to create an environment that fostered safe and open communication.

According to a 2013 VHA policy, “a [just culture](#) [is one] in which employees are mindful of inherent risks within their surroundings, and are empowered to bring concerns forth to leadership, confident that they will be addressed without fear of reprisal.”¹³³ VHA leaders are responsible for a just culture. That mandate extends, and is largely implemented, by individual medical center leaders who are the driving force behind a facility’s culture and facilitate the “environment in which staff act with integrity to achieve accountability.”¹³⁴ Facility policy states “any individual within the organization has the responsibility to report concerns regarding unsafe treatment by [an] LIP [licensed independent practitioner].”¹³⁵

After Dr. Levy admitted to OIG investigators that he had a long-standing (30-year) problem with substance use, the OIG grew concerned about facility staff having knowledge of impairment behaviors but not reporting them as required.¹³⁶ The Facility Director conducted an administrative investigation board in summer 2018 to “evaluate the overall culture and psychological safety within [Path and Lab] and that may have prevented staff from bringing forward quality and safety issues to Leadership.”¹³⁷ The administrative investigation board found a lack of transparency in some pathology quality management processes and communication delays.¹³⁸

During the OIG’s review of facility documentation and interviews, the team learned that incidents related to Dr. Levy’s impairment behaviors were noticed by multiple staff prior to the 2015 fact-finding review, which was the first event reported to the OIG that the facility took

¹³³ VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value*, August 2, 2013. The directive, which was in effect during part of the time the events discussed in this report occurred, was rescinded in 2019 to avoid “conflict with modernization efforts as they are being rolled out as part of the new VHA governance process.”

¹³⁴ VHA Directive 1026, 2013.

¹³⁵ Facility Memorandum 11-11-89, 2011; Facility Memorandum 11-089, 2014; Facility Memorandum 17-11-089, 2017. The three facility memorandums contain the same wording related to the responsibility to report unsafe treatment.

¹³⁶ Facility Memorandum 11-11-89, 2011; Facility Memorandum 11-089, 2014; Facility Memorandum 17-11-089, 2017.

¹³⁷ VA Directive 0700, *Administrative Investigations*, March 25, 2002.

¹³⁸ The facility’s administrative investigation board recommended proceeding with a redesign of the Path and Lab quality management program, evaluation of the OPPE process for two-person services (one of whom is the Chief of the service), and training for Path and Lab supervisors and managers.

overt action to investigate reports that Dr. Levy smelled of alcohol. Staff who observed impaired behaviors shared the following about reporting:

- A staff member, who was told whistleblowers were fired, was worried about reprisal and did not know how to challenge a doctor
- Reporting was not the staff's responsibility and if reported, probably would have been told it was being handled
- Issues were not reported because staff thought others were reporting
- After reporting, a staff member felt belittled

During an interview with the OIG, a former Path and Lab manager acknowledged receiving up to a dozen reports about Dr. Levy but wanted to handle the matter at the lowest level. In response to the reports, the manager searched Dr. Levy's office and did not find anything. The manager did not elevate the matter, in part thinking it was being reported by others.

The Chief of Staff informed the OIG that he received one or two unofficial reports about possible problems (for example, a provider mentioned Dr. Levy's possible impairment issues that had occurred a few days prior during a conversation in an elevator or the hallway) but could not investigate them because the behaviors had occurred days before the reporting. According to one staff member's understanding, the Chief of Staff did not initiate action against Dr. Levy because treating providers did not lodge complaints.

The failure of facility leaders to robustly explore or take actions after the 2015 reports of impaired behavior and subsequent events may have discouraged staff from continued efforts to comply with the facility's policy to report other observations of Dr. Levy's impairment. The OIG concluded that facility leaders did not meet VHA's goal to establish an "environment in which staff act with integrity to achieve accountability."¹³⁹ Facility leaders should create an atmosphere where staff are free to comment on problems and promote honest, open discussions of clinical or administrative practice that affect patient care without fear of reprisal.

¹³⁹ VHA Directive 1026, 2013.

Conclusion

Dr. Levy's misdiagnosis of pathology cases resulting in adverse clinical outcomes—suboptimal treatment and patient death—is undisputed. The look-back review team identified errors in slightly more than 3,000 cases, including 589 level 3 major diagnostic discrepancies and 2440 level 2 diagnostic errors. Of those cases, facility leaders and managers identified 34 patients who needed institutional disclosures.

The OIG determined that the number of major diagnostic discrepancies was the result of Dr. Levy's failure to interpret specimens correctly that went undetected in part because of his efforts to conceal the errors, and manipulation of pathology quality management data. Deficiencies in quality management processes and managing a potentially impaired provider, as well as facility leaders' failure to foster a culture of accountability that encouraged reporting without reprisal contributed to Dr. Levy's errors continuing for many years. Any one of these breakdowns could cause harmful results. Occurring together and over an extended period of time, the consequences were devastating, tragic, and deadly.

The OIG identified gaps in both FPPE and OPPE processes. Dr. Levy came to the facility as a locum tenens provider and was immediately elevated to the Path and Lab Service Chief position. He was a provider in the specialty care area of pathology with no other facility pathologist for the first several years of his tenure. Based on the results of the look-back review, it appears that facility leaders' efforts were insufficient to determine the quality of Dr. Levy's pathology practice during the probationary period. The OIG concluded that had facility leaders conducted a more robust evaluation of Dr. Levy's cases, the assessment would have likely identified deficiencies similar to the look-back review. This would have allowed facility leaders the opportunity to address his performance early in his tenure or not approve his permanent appointment.

Service chiefs develop FPPE and OPPE criteria for care delivered within the individual service.¹⁴⁰ VHA policy does not specifically address the establishment of criteria or reappraisal and privileging process for service chiefs who practice and undergo competency evaluation.¹⁴¹ However, VHA's Deputy Under Secretary for Health Operations and Management issued guidance related to the clinical practice of chiefs of staff and solo providers.¹⁴² The OIG concluded that chiefs of staff in clinical practice and solo providers are similarly positioned to service chiefs and would not have a peer at the facility who could conduct an evaluation. The Deputy Under Secretary's guidance could be incorporated into VHA policy.

¹⁴⁰ VHA Handbook 1100.19, 2008; VHA Handbook 1100.19, 2012.

¹⁴¹ VHA Handbook 1100.19, 2008; VHA Handbook 1100.19, 2012.

¹⁴² *OPPE and Peer Review for Quality Management for Chiefs of Staff*, 2016; *Requirements for Peer Review of Solo Practitioners*, 2016.

The peer references discussed in this report submitted during consideration of Dr. Levy's reprivileging process were not completed by providers of the same profession or a professional with comparable privileges as required.¹⁴³ The OIG would have expected at least one peer reference be obtained from a pathologist.

Dr. Levy and his subordinate, Staff Pathologist, completed each other's VHA-required pathology quality management 10 percent peer review.¹⁴⁴ Peer review data were incorporated into Dr. Levy's performance evaluation. Incorporating the results of the 10 percent peer review conducted by the Staff Pathologist into Dr. Levy's practice evaluation would create a conflict of interest.

The facility's 10 percent peer review did not identify the extent of diagnostic errors that the look-back review revealed. VHA policy states the 10 percent peer review for specified cases must be randomly selected.¹⁴⁵ According to the College of American Pathologists, "there is evidence that targeted review (review of a specific type of case) is more efficient at finding important diagnostic discrepancies or errors than randomly selecting cases for review."¹⁴⁶ Focusing at least a portion of the 10 percent peer review on cases that carry a higher risk of interpretation error or that can result in clinically significant consequences to a patient could be more effective in identifying errors. VHA should evaluate the need to provide additional instructions to facilities on the methodology for selecting cases for peer reviews.

The facility's review by a VHA pathologist in 2017 of the external consulting group's reports revealed that Dr. Levy did not consistently enter final reports into patients' EHRs in a way that would optimally alert providers of a change in diagnosis and allow tracking of major diagnostic discrepancies. The OIG found that VHA policy does not give clear guidance to pathologists related to amended reports that distinguishes between modified and supplemental reports.¹⁴⁷ Providing specific guidance to pathologists on this matter may increase the use of modified reports with improved notification to providers and tracking of major diagnostic discrepancies. Directing the results of reports from non-VHA consulting pathologists to recipients outside of Path and Lab staff may also improve the ability to monitor and track the correct use of supplemental and modified reports.

The OIG acknowledges that the facility's failure to recognize flawed processes was complicated by Dr. Levy's efforts to conceal his errors. As Path and Lab Service Chief, he was in charge of developing the Path and Lab quality management policies and chaired three facility committees that discussed pathology data. The pathology data were forwarded to facility leaders. While

¹⁴³ VHA Handbook 1100.19, 2008; VHA Handbook 1100.19, 2012.

¹⁴⁴ VHA Handbook 1106.1, 2003; VHA Handbook 1106.01, 2008; VHA Handbook 1106.01, 2016.

¹⁴⁵ VHA Handbook 1106.01, 2016.

¹⁴⁶ College of American Pathologists, "About us;" Association of Directors of Anatomic and Surgical Pathology, "Interpretive Diagnostic Error Reduction in Surgical Pathology and Cytology."

¹⁴⁷ VHA Handbook 1106.01, 2016.

being chair of the three committees was not an intrinsic deficiency of process, it put Dr. Levy in a position to control and manipulate the reporting and flow of pathology quality management data presented to facility leaders with few limitations.

The OIG found that there should have been grave concerns about Dr. Levy's potential impact on patients matched with commensurate urgency to investigate the quality of his work and more intensely scrutinize reports of his impairment.

The OIG identified a deficiency in staff knowledge related to blood alcohol content testing that led to a failure of Dr. Levy being tested despite consent during the 2015 fact-finding review. VA does not have guidance related to testing staff for alcohol and "has no authority under its administrative regulations to order an employee to undergo a blood test or breathalyzer test for suspected use of alcohol" without consent.¹⁴⁸ Based on healthcare workers' responsibility for the safety of patients, VHA should consider a policy addressing voluntary and mandatory alcohol testing that requires such testing for its employees who hold safety-sensitive positions.

The OIG determined that facility leaders did not foster a culture of accountability that created a safe environment with open communication that encouraged reporting of problems without fear of reprisal. The OIG learned several reasons staff did not report including having the perception that others had reported or were concerned about reprisal. The failure of facility leaders to take meaningful action after reports of impaired behavior may have preempted further attempts to raise issues of concern. Facility leaders should create an atmosphere where staff are free to comment on ways to improve care and have honest, open discussions to better clinical or administrative practice.

¹⁴⁸ OHRM Employee Relations & Performance Management Newsletter, September – October 2013, "Dealing with Those Under the Influence of Alcohol on Duty and Using Sobriety Tests."

Recommendations 1–12

1. The Under Secretary for Health ensures that the Veterans Health Administration competency process for locum tenens, newly hired specialty care providers, and newly hired service chiefs is evaluated to confirm that the results of the assessment accurately reflects the clinical competency of providers who are privileged, and takes action, as indicated.
2. The Under Secretary for Health reviews current Veterans Health Administration credentialing and privileging policies to assess guidance related to service chiefs' ongoing professional practice evaluation and takes action, as indicated.
3. The Under Secretary for Health reviews Veterans Health Administration policies to ensure that if facility leaders elect to incorporate pathology 10 percent peer reviews into the performance evaluations of a Pathology and Laboratory Medicine Service Chief, those reviews are performed by a peer without a conflict of interest and takes action, as indicated.
4. The Under Secretary for Health evaluates the use and methodology of the Pathology and Laboratory Medicine Service 10 percent peer review for effectiveness as a quality management tool, and takes action, as indicated.
5. The Under Secretary for Health evaluates Veterans Health Administration guidance related to amended pathology reports' terminology, use, and entry of such reports into patients' electronic health records, and revises guidance, as appropriate.
6. The Under Secretary for Health confirms that provisions are included in the Veterans Health Administration record modernization program that ensure amended pathology report alerts are directed to designated facility staff and leaders.
7. The Under Secretary for Health evaluates Veterans Health Administration quality management processes related to external, non-VHA pathology consultant assessments and ensures that facility leaders, the specialty care provider, and requesting providers are notified of the results of such reviews and a tracking process is in place.
8. The Under Secretary for Health confers with the Office of General Counsel and the Office of Human Resources and Administration/Operations, Security, & Preparedness to determine whether administrative action is warranted for Veterans Health Administration leaders who did not adequately perform their duties with respect to the issues within this report, and takes action, as appropriate.

9. The Under Secretary for Health explores the development of a mandatory alcohol testing policy for individuals including healthcare workers who perform functions that would put patients at risk should the employee work while impaired.
10. The Under Secretary for Health evaluates Veterans Health Administration's guidance related to impaired healthcare workers and ensures that it addresses the circumstances under which alcohol and or drug testing may be performed; the extent of a retrospective review of care if one is indicated; and the availability of advisors who are knowledgeable on the management of an impaired provider, and takes action, as indicated.
11. The Veterans Health Care System of the Ozarks Director verifies that peer references obtained during the reappraisal and reprivileging processes are in alignment with VHA Handbook 1100.19, *Credentialing and Privileging*.
12. The Veterans Health Care System of the Ozarks Director evaluates the psychological safety climate to ensure facility staff, patients, and the general public are empowered to report concerns and unsafe patient care without fear of reprisal and takes action, as needed.

Appendix A: Patient Case Summaries and Analysis

Patient 1. Incorrect Diagnosis Led to a Patient's Inappropriate Cancer Treatment

The patient, who was in their 60s in early 2014, underwent a lymph node biopsy.¹⁴⁹ Dr. Levy entered the biopsy results into the EHR: “[lymph node, right supraclavicular, excision: diffuse large B Cell lymphoma].”¹⁵⁰ Dr. Levy’s EHR documentation indicated that a member of the surgical team was notified of the results the next day and the Staff Pathologist had reviewed the case and concurred with the findings.

The patient was treated for lymphoma with multiple cycles of chemotherapy and radiation. Several months later, the patient developed brain lesions consistent with cancer and was treated with cranial irradiation. The patient developed pneumonia and died in summer 2014.

Approximately two weeks prior to the patient’s death, a palliative care consult was requested. While reviewing the patient’s EHR, the palliative care consultant noticed a pathology report entered by Dr. Levy five days after the entry of the initial interpretation, that indicated a diagnosis different from lymphoma: “[supplementary diagnosis: lymph node, excision; metastatic non small cell carcinoma]” and included the information from the amended pathology report in the consult note.¹⁵¹ Two days later, the patient and a family member were notified of the different diagnosis.

One of the facility’s physicians noted that “the new and correct diagnosis of metastatic non small cell cancer was not likely communicated to the appropriate providers. The ongoing treatment was for Lymphoma.” Secondary to the misdiagnosis and the miscommunication, an institutional disclosure was conducted prior to the patient’s death to formally notify the family of the change in diagnosis. The EHR documentation reflected that “[Chief of Staff] although not present was fully aware of, and in agreement with the disclosure, as was regional counsel.”

In August 2018, the look-back review team assessed the discrepancy between the original diagnosis by Dr. Levy and the final diagnosis as a level 3. One of the look-back reviewers entered the following pathology note into the patient’s EHR:

[Findings are consistent with a metastatic small cell carcinoma. In the setting of a lung mass, a lung primary is favored.]¹⁵²...The patient died...after completing

¹⁴⁹ Additional information related to this patient’s case is discussed in the *2014—Providers Unaware of a Misdiagnosis* section of this report. The OIG uses the singular form of they (their) for the purpose of patient privacy.

¹⁵⁰ Bracketed words were in uppercase in original text, the OIG modified to lowercase for readability.

¹⁵¹ Bracketed words were in uppercase in original text, the OIG modified to lowercase for readability. The second diagnosis of non-small cell carcinoma was also incorrect.

¹⁵² Bracketed words were in uppercase in original text, the OIG modified to lowercase for readability.

chemotherapy for Diffuse Large B cell Lymphoma. TC8. [The Staff Pathologist] never concurred with the original reported diagnosis of lymphoma.

Providers based treatment on an incorrect cancer diagnosis. Dr. Levy entered a supplemental report (not a modified report) and did not document the treating physician was notified of the change in diagnosis.¹⁵³ No actions were taken to address a change in diagnosis and treatment for lymphoma continued.

Dr. Levy's misdiagnosis led to the patient receiving chemotherapy and radiation for lymphoma when his cancer was ultimately identified to be a small cell carcinoma.

The initial pathology report states the Staff Pathologist agreed with the original diagnosis. However, the 2020 plea agreement supports the Staff Pathologist's assertion of disagreeing with the initial diagnosis and Dr. Levy's awareness of the disagreement.¹⁵⁴

Patient 2. Incorrect Report of a “Completely Excised” Lesion Resulted in an Adverse Clinical Outcome

The patient, who was elderly with a medical history of heart disease, diabetes, and Parkinson's disease, was seen by an assigned primary care provider in summer 2007. General Surgery service was consulted for a “large facial lesion and one very large lymph node on [the] right side of [the] neck...” with a probable diagnosis of skin cancer. The next month, the surgeon indicated that the “[skin changes]...present [for] a couple of months...right cheek 1.1 cm verrucoid lesion with rolled [margin](#)” should be removed.¹⁵⁵ The patient agreed.

Approximately one week later, the surgeon submitted the “entire lesion” to pathology for examination. Dr. Levy reported that the specimen demonstrated “invasive, moderately differentiated squamous cell carcinoma [cancer] with ulceration, completely excised.” In late 2007, the patient was seen by a member of the oncology team for return of the tumor at the site of the complete excision and lymph nodes in the neck (a 1.7 cm x 1.0 cm mass involving the skin and a 2.8 x 2.9 x 3.3 cm mass in the neck). In early 2008, the patient underwent a wide dissection of the neck.¹⁵⁶ Once clinically stable after the surgery, the patient was discharged to a nursing

¹⁵³ Facility Procedure, *Anatomic Pathology Continuous Quality Improvement/Quality Management Plan*, 2009, “All new malignancies (except squamous cell and basal cell carcinoma of skin) and unexpected findings are reported to the physician, and this contact is noted within the final pathology report.”

¹⁵⁴ *U.S. v. Robert Morris Levy, Plea Agreement*.

¹⁵⁵ Merriam-Webster, “Definition of verrucous,” accessed January 2, 2021, <https://www.merriam-webster.com/medical/verrucous>. A verrucous lesion is one that is characterized by warty formations.

¹⁵⁶ The patient underwent an excision of the right salivary gland while preserving the facial nerve; a right neck dissection; removal of large face cancer, with subsequent reconstruction removing part of the chest muscle and muscle from the side of the patient's head to create flaps and skin graft.

home. The patient died approximately 19 months after admission to the nursing home. According to an EHR note, the death was unrelated to the excision of the skin lesion.

The look-back review team determined that the diagnoses in the original pathology report indicating that the tumor was “completely excised” was in error; the “tumor [was] basically present at the margin. [Perineural invasion](#) may indicate the need for radiotherapy and wider excision.” The discrepancy was assessed to be a level 3. An institutional disclosure was made to the patient’s family in October 2018.

The failure to identify positive margins delayed the patient’s best chance for successful treatment of the cancer.

Patient 3. Incorrect Diagnosis Denied a Patient the Opportunity for Optimal Therapy

The patient, who was in their 70s, had abnormal [prostate-specific antigen](#) (PSA) levels: 7.61 in fall 2010 and 7.01 in early 2011.¹⁵⁷ Almost a year later, the patient was seen in the urology clinic for an abnormal (PSA) level of 6.93. In early 2012, the patient had a prostate biopsy that Dr. Levy reported to be benign.

In fall 2014, the patient was seen by an assigned primary care provider who noted (1) a PSA of 9.01 that was elevated from prior tests and (2) the 2012 biopsy was reportedly negative. The physical exam, that did not include a prostate examination, was positive for hip pain. The primary care provider noted a weight loss of more than five pounds but made no additional comment on the PSA level. The patient had chronically elevated PSA tests after the 2012 biopsy.

In May 2018, a look-back reviewer amended the 2012 pathology report to include the diagnosis of [adenocarcinoma](#). The look-back review team assessed the discrepancy as a level 3. In June 2018, an institutional disclosure was conducted and the patient and a family member were informed that the initial pathology interpretation of the prostate biopsy in 2012 was found to have prostate cancer in two of the six cores.

Also, in summer 2018, the patient was seen in a urology clinic at another VHA medical facility and was diagnosed with prostate cancer with widespread metastasis. Given the patient’s late diagnosis, treatment options were limited to palliative care.¹⁵⁸ The patient died in late 2020.

The 2012 negative prostate biopsy was a factor that delayed clinicians’ making the correct diagnosis that would have given the patient an opportunity to receive optimal treatment.

¹⁵⁷ The OIG uses the singular form of they (their) for the purpose of patient privacy.

¹⁵⁸ VHA Directive 1139. *Palliative Care Consult Teams (PCCT) and VISN Leads*, June 14, 2017. Palliative care is the provision of comfort-oriented services balanced with life-prolonging measures.

Patient 4. Incorrect Patient Diagnosis of Cancer

The patient, who was in their 60s, had a history of squamous cell cancer that was treated with radiation and chemotherapy in 2015.¹⁵⁹ The patient had a biopsy of the left mandible (jaw bone) in early 2016, that Dr. Levy diagnosed as recurrent squamous cell cancer with metastasis to the jaw bone (mandible). One month later, the patient's otolaryngologist (ear, nose, throat) surgeon recommended removal of the mandible and ordered chest, abdomen, and pelvis imaging studies. All scans were negative for evidence of metastatic cancer. The patient declined to undergo major surgery to remove the cancer from the mandible, choosing instead to "let nature take its course."

Approximately five months after the surgeon's recommendation, the patient consulted with palliative care providers and considered the possibility of additional radiation to the jaw. The patient was referred to the community and was about to be evaluated for radiation therapy when the Acting Path and Lab Chief–VISN 16 reviewed the case and found that the biopsy specimen did not demonstrate evidence of cancer. The patient was informed of the change in diagnosis and commented to a clinic nurse "here all this time I thought I was dying and I've been so worried." The patient did not undergo radiation.

A more formal disclosure, an institutional disclosure, was not conducted. EHR documentation indicated that in summer 2016, the Acting Path and Lab Chief–VISN 16 informed the Chief of Staff about Dr. Levy's misdiagnosis. The look-back review team subsequently assessed the discrepancy as a level 3. The patient died almost four years after the diagnosis was corrected.

Based on the patient's comments to the clinic nurse and the OIG's experience with other patients receiving similarly bad prognoses, the team strongly suspects that the patient was distressed by the news of recurrent cancer and may have made decisions or taken actions not otherwise pursued.

Patient 5. Incorrect Diagnosis Denied a Patient the Opportunity for Optimal Therapy

The patient was elderly with a medical history that included prostate cancer (treated by removal of the prostate), [peripheral vascular disease](#), diabetes, high blood pressure, and depression. The patient had a right lung mass, which was evaluated over several years with chest images. In summer 2014, a left-sided lung mass was identified and biopsied the following month. Dr. Levy interpreted the biopsy as small cell cancer. The patient was treated with six rounds of chemotherapy followed by [stereotactic radiosurgery](#). Approximately one year later, the patient clinically declined over a two-week period, was admitted to the facility, and died the following month.

¹⁵⁹ The OIG uses the singular form of they (their) for the purpose of patient privacy.

The look-back review team determined that the diagnoses of small cell cancer was incorrect and squamous cell cancer of the lung was the correct diagnosis. The discrepancy was assessed as a level 3. In September 2018, an institutional disclosure was conducted and the family was informed of the change in diagnosis.

Treatment options for squamous cell lung cancer included surgery, which was not offered to the patient for the diagnosis of small cell lung cancer.¹⁶⁰ The patient was not provided an accurate diagnosis and was deprived of the opportunity for effective treatment.

¹⁶⁰“What Is Lung Cancer?” American Cancer Society, accessed January 2, 2021, <https://www.cancer.org/cancer/small-cell-lung-cancer/about/what-is-small-cell-lung-cancer.html>. Small cell and non-small cell lung cancers, such as squamous cell, are treated differently. “Treating Small Cell Lung Cancer” American Cancer Society, accessed April 21, 2021, <https://www.cancer.org/content/dam/CRC/PDF/Public/8711.00.pdf>.

Appendix B: Example of Tissue Committee Meeting Minutes Table with TC1–8 Codes

Review Period:		TISSUE SURGICAL CASE REVIEW												Attachment 1	
		Goal	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	
1. a. Surgical Report	Total # of Surgical Cases	NA	180	179	136	126	32**	159	223	150	147	139	142		
	Total # of Major Surgical Cases	NA	120	51	50	52	13	73	94	66	60	67	78		
b. Pathology Tissue Report (total accessions) n=100%		NA	327	296	290	296	287	409	414	422	386	384	386		
(TC1) Preoperative/post diagnoses differ significantly		<5%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%		
(TC2) Postop and final path diagnoses in disagreement		<5%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%		
(TC3) Unexpected neoplasm discovered		<5%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%		
(TC4) Frozen section diagnosis differs from final path DX		<5%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%		
(TC5) Insufficient tissue submitted		<2%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0.26%	
(TC6) Lost Tissue		<2%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%		
(TC7) Any unusual circumstance		N/A	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%		
(TC8) Final diagnosis versus consultation diagnosis		<5%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%		
2. Anatomic Pathology Statistics and Turn-Around-Time Reports															
a. Autopsy rate (# autopsies/ # VA deaths)		30%	0/5	0/4	0/3	0/4	0/11	2/13	1/14	0/6	0/6	0/14	1/8		
b. Autopsy Turn-Around-Time (Ave TAT)		30 days	N/A	N/A	N/A	N/A	N/A	2.0	23.0	N/A	N/A	N/A	6.0		
c. Major disagreement in diagnosis (Autopsy)		<5%	No												
d. Non-GYN Turn Around Time (Avg)		2 days	1.90	2.00	1.67	1.92	2.05	2.13	2.51	1.71	1.93	2.00	1.60		
e. Surgical Pathology Turn Around Time (Avg)		2 days	1.04	1.04	0.99	0.94	0.87	0.93	0.99	0.88	1.04	0.86	0.88		
f. GYN Turn Around Time (Avg)		14 days	5.20	2.90	7.50	3.30	2.80	8.10	4.10	6.60	3.98	4.10	6.40		
g. Frozen Section Turn Around Time(uncomplicated)		20 min	0	0	0	0	0	0	0	0	0	0	0		

Figure B.1. Example of Facility Tissue Committee meeting minutes table depicting TC codes for one of the 12-month periods at issue
 Source: Facility

Appendix C: Federal Law and Policies Regarding Impaired Providers

Drug-Free Federal Workplace

On September 15, 1986, President Ronald Regan issued an executive order that federal employees “refrain from the use of illegal drugs.” The order noted that drug use was having “adverse effects upon a significant proportion of the national work force” and “can pose a serious health and safety threat to members of the public and to other Federal employees.”¹⁶¹ Each agency was charged with developing a plan that would achieve “the objective of a drug-free workplace with due consideration of the rights of the government, the employee, and the general public.”¹⁶²

Office of Personnel Management Guidance on Alcohol Testing

The Office of Personnel Management (OPM), in cooperation with the Department of Health and Human Services, developed an online handbook for supervisors “designed to foster a better awareness [among] supervisors, managers, and human resource personnel of the issues surrounding alcoholism and alcohol abuse...as it relates to the Federal workplace.”¹⁶³ In the handbook, OPM discusses the subject of alcohol testing. According to OPM, federal agencies generally “do not have the authority to conduct mandatory alcohol testing.” “Although some agencies may have the equipment and trained personnel to administer an alcohol test, such a test would be voluntary” and within the context of “a violation of motor vehicle and traffic rules.”¹⁶⁴

OPM refers to the Department of Transportation’s (DOT) issuance of “rules regarding alcohol testing for certain groups of employees such as those who are required to possess a Commercial Driver’s License, and certain employees in aviation-related positions.” The DOT “rules call for mandatory alcohol testing, using EBTs [Evidentiary Breath Tests], of applicants for identified positions and in cases of reasonable suspicion of alcohol use, and for random testing of employees in these positions.” The handbook advises “agencies conducting this type of testing [to] have a specific program spelled out in agency policy.”¹⁶⁵

The handbook further states that “[a]n agency may conduct voluntary alcohol testing” and “[i]f intoxication is indicated by the test, the agency may use it as a basis for some type of administrative action, such as sending the employee home, or taking disciplinary action. An

¹⁶¹ Executive Order 12564, *Drug-free Federal workplace*, September 15, 1986, accessed December 30, 2020, <https://www.archives.gov/federal-register/codification/executive-order/12564.html>.

¹⁶² Executive Order 12564.

¹⁶³ Office of Personnel Management, *Alcoholism in the Workplace: A Handbook for Supervisors*.

¹⁶⁴ Office of Personnel Management, *Alcoholism in the Workplace: A Handbook for Supervisors*.

¹⁶⁵ Office of Personnel Management, *Alcoholism in the Workplace: A Handbook for Supervisors*.

agency may not take disciplinary action solely because an employee declines to undergo a voluntary alcohol test.”¹⁶⁶

The handbook also provides steps supervisors may take “when an employee is apparently under the influence or intoxicated at work.” OPM provides agencies various options depending on the situation. “If the employee is performing, or required to perform, safety-sensitive duties,” including “performing patient care activities, he or she must be restricted from performing these duties.” Further,

If the employee is willing, he or she may be sent to the health unit for observation or a possible assessment. Health unit personnel may be able to offer a medical judgment that, in their opinion, the employee is intoxicated. They may also be able to conduct a voluntary alcohol test... Unless the employee is in a job with specific medical or physical requirements, [the supervisor] cannot order the employee to undergo any type of medical examination, including an EBT. Examples of the types of jobs that may have specific medical requirements include police officers, certain vehicle operators, air traffic controllers, and various direct patient-care personnel.¹⁶⁷

OPM recognizes that “while an employee’s decision to drink is [his or her] personal business... when the use or abuse of alcohol interferes with the employee’s ability to perform his or her duties, the employer does have legitimate concerns, including the proper performance of duties, health and safety issues, and employee conduct at the workplace.”¹⁶⁸

The handbook emphasizes the important role supervisors have “in dealing with alcohol problems in the workplace.” The supervisor’s “role is not to diagnose the alcohol problem but to exercise responsibility in dealing with the performance or conduct problem, hold the employee accountable, refer the employee to the EAP [Employee Assistance Program], and take any appropriate disciplinary action.” OPM recommends the “most effective way to get an alcoholic to deal with the problem is to make the alcoholic aware that his or her job is on the line and that he or she must get help and improve performance and conduct, or face serious consequences, including the possibility of losing his or her job.”¹⁶⁹

Among the signs to look for indicating the employee may have issues with alcohol, the handbook specifically lists the following:

- The smell of alcohol
- Staggering, or an unsteady gait

¹⁶⁶ Office of Personnel Management, *Alcoholism in the Workplace: A Handbook for Supervisors*.

¹⁶⁷ Office of Personnel Management, *Alcoholism in the Workplace: A Handbook for Supervisors*.

¹⁶⁸ Office of Personnel Management, *Alcoholism in the Workplace: A Handbook for Supervisors*.

¹⁶⁹ Office of Personnel Management, *Alcoholism in the Workplace: A Handbook for Supervisors*.

- Bloodshot eyes
- Smell of alcohol on the breath
- Mood and behavior changes such as excessive laughter and inappropriate loud talk
- Excessive use of mouthwash or breath mints
- Avoidance of supervisory contact especially after lunch
- Tremors
- Sleeping on duty

The handbook recognizes that while any one of these signs may not mean the employee is an alcoholic, “when there are performance and conduct problems coupled with any number of these signs, it is time to make a referral to the EAP for an assessment so that the employee can get help if it is needed.”¹⁷⁰

VA’s Occupational Health Service

VA’s handbook related to its occupational health service states “only those persons who demonstrate that they are physically, cognitively and emotionally capable of performing the essential functions of their position [without risk to self or others] are to be employed and retained in VA.”¹⁷¹ The handbook outlines categories of employees who must undergo a “pre-placement physical examination to determine the physical, cognitive and emotional fitness of applicants for appointment in VA.” Physicians hired under Title 38 are included in this group.¹⁷²

According to the handbook,

A directed or special physical examination may be required to solve questions of physical, cognitive or emotional ability to perform the essential duties of a position satisfactorily. An examination may also be necessary to determine physical, cognitive and emotional fitness to resume duty after illness [or injury]...Failure of the employee to submit to a directed or special physical examination or to sign [an] authorization [to release information] form may result in disciplinary action, including removal from employment¹⁷³

Under certain circumstances, an employee may be ordered to undergo a special physical examination when “the agency has a reasonable belief, based on objective evidence, that there is

¹⁷⁰ Office of Personnel Management, *Alcoholism in the Workplace: A Handbook for Supervisors*.

¹⁷¹ VA Handbook 5019/1, *Employee Occupational Health Service*, August 3, 2017. This handbook was originally issued in 2015. The 2017 version did not rescind the 2015 version but updated certain items and designated modifications by square brackets.

¹⁷² VA Handbook 5019/1.

¹⁷³ VA Handbook 5019/1.

a question about an employee’s continued capacity to meet the medical standards or physical requirements of a position.”¹⁷⁴

The handbook indicates that based on the results of the examination, a Physical Standards Board may be convened to determine the ability of the person to meet the requirements of the job.¹⁷⁵ The Physical Standards Board is responsible for determining the physical, cognitive, and emotional fitness of referred employees, and “for recommending action based on examination findings.”¹⁷⁶ The Chief of Staff’s Office is “permitted adequate opportunity for comment or recommendation on the findings.”¹⁷⁷

VA’s Employee/Management Relations Policy

VA’s policy on employee relations programs acknowledges that

Public interest requires the maintenance of high standards of employee integrity, conduct, effectiveness, and service to the public. When such standards are not met, prompt and appropriate disciplinary or other corrective action will be taken. The policy of VA is to maintain standards of conduct and efficiency that will promote the best interests of the service.¹⁷⁸

To assist in determining the appropriate penalty for adverse actions brought against agency employees, VA established a Table of Penalties applicable to Title 5 and Title 38 employees. The range of penalties listed are intended “to be used as a guide in administering discipline to help assure that like disciplinary action is taken for like offense.”¹⁷⁹

The Table of Penalties includes a section related to alcohol and drug offenses and list “reporting to or being on duty while under the influence of alcohol” as an offense. Recommended penalties for first, second, and third alcohol-related offenses range from reprimand, suspension, and removal (see table C.1.)

¹⁷⁴ VA Handbook 5019/1.

¹⁷⁵ VA Handbook 5019/1. “A Physical Standards Board will consist of a minimum of three physicians with appropriate professional expertise to make a fitness determination. However, when an unusual dental problem is under consideration, one physician will be replaced by a dentist.”

¹⁷⁶ VA Handbook 5019/1.

¹⁷⁷ VA Handbook 5019/1.

¹⁷⁸ VA Handbook 5021, *Employee/Management Relations*, April 15, 2002.

¹⁷⁹ VA Handbook 5021, *Employee/Management Relations*, April 15, 2002; VA Handbook 5021/15, Part I, Appendix A (July 19, 2013). Guide is underlined in original text.

Table C.1. Alcohol-Related Offenses and Recommended Penalties

Alcohol-Related Offenses	First Offense Minimum to Maximum	Second Offense Minimum to Maximum	Third Offense Minimum to Maximum
Unauthorized possession of alcoholic beverages while on VA premises.	Reprimand 7 days	14 days Removal	Removal
Unauthorized use of alcoholic beverages while on VA premises.	Reprimand 14 days	14 days Removal	Removal
Reporting to or being on duty while under the influence of alcohol.	Reprimand Removal	14 days Removal	Removal
Sale or transfer of an alcoholic beverage while on VA premises or in a duty status, or while any person involved is in a duty status.	14 days Removal	Removal	

Source: Excerpt from VA Handbook 5021, Employee/Management Relations, April 15, 2002. The number of days refers to calendar days of suspension.

The handbook further instructs that

Removal action will be taken whenever required by law or regulation or whenever warranted by the facts in the individual case. Normally, progressively more severe penalties will be administered before removal action is initiated, unless the offense is so serious that it warrants removal action. The severity of the penalty will be that which is required to correct the attitude or conduct of the employee or to correct the situation.”¹⁸⁰

VA’s Policy on Unlawful Discrimination

In 2017, the then VA Secretary issued a policy statement that affirmed VA’s position against unlawful discrimination and commitment to vigorously enforcing “all applicable Federal EEO [Equal Employment Opportunity] laws, regulations, executive orders, and management directives to ensure equal opportunity in the workplace for all VA employees.”¹⁸¹

Discrimination based on “disability in employment, State and local government, public accommodations, commercial facilities, transportation, and telecommunications” is prohibited by the Americans with Disabilities Act.¹⁸² The Americans with Disabilities Act defines an individual with a disability as “a person who has a physical or mental impairment that

¹⁸⁰ VA Handbook 5021, *Employee/Management Relations*, April 15, 2002; VA Handbook 5021/15, Part I, Appendix A (July 19, 2013). Guide is underlined in original text.

¹⁸¹ Equal Employment Opportunity, Diversity and Inclusion, No FEAR, and Whistleblower Rights and Protection Policy Statement (July 5, 2017).

¹⁸² U.S. Department of Justice, Civil Rights Division, Disability Rights Section, *A Guide to Disability Rights Laws*, February 2020.

substantially limits one or more major life activities, a person who has a history or record of such an impairment, or a person who is perceived by others as having such an impairment.” Federal employees are assured the same protections by Section 501 of the Rehabilitation Act. The Equal Employment Opportunity Commission (EEOC) issued a fact sheet to explain how the Americans with Disabilities Act might apply to particular situations involving employees in the healthcare field.¹⁸³

The EEOC fact sheet noted that employees with alcoholism may meet the Americans with Disabilities Act definition of individuals with disabilities and that “an employer may not discriminate against, and may need to accommodate, a qualified applicant or employee with past or present substantial limitations relating to alcoholism who can competently perform” the job.¹⁸⁴ However, workplaces where health care staff with disabilities are employed pose unique safety questions and concerns where errors may result in health consequences to patients. And, “to be qualified to perform a job under the Americans with Disabilities Act, an individual must satisfy the requisite skill, experience, education, and other job-related requirements (“qualification standards”) of the position held or desired, and be able to perform the job’s essential functions with or without a reasonable accommodation.”¹⁸⁵

VA Policy on Illegal Drug Use

As mandated by President Regan’s 1986 executive order discussed above, VA issued policy establishing a drug-free workplace program.¹⁸⁶ The policy recognized the unique responsibilities for VA employees who provide patient care:

Drug usage by VA’s health care staff, such as physicians, dentists, nurses, pharmacists, therapists, and medical machine and laboratory technicians, could result in the loss of patients’ lives or patient injury...in view of the sensitive nature of the [VA’s] work and the fact that [its] programs have an enormous impact on the lives of millions of Americans, VA has a compelling obligation to take the necessary steps to eliminate illegal drug use from its workplace.¹⁸⁷

¹⁸³ U.S. Equal Employment Commission, *Health Care Workers and the Americans with Disabilities Act*, February 26, 2007, accessed December 14, 2020, <https://www.eeoc.gov/laws/guidance/health-care-workers-and-americans-disabilities-act>; Rehabilitation Act of 1973 (Pub. L. 93-112), section 501 prohibits employment discrimination against individuals with disabilities in the federal sector.

¹⁸⁴ U.S. Equal Employment Commission, *Health Care Workers and the Americans with Disabilities Act*. “To be qualified to perform a job under the ADA, an individual must satisfy the requisite skill, experience, education, and other job-related requirements (“qualification standards”) of the position held or desired, and be able to perform the job’s essential functions with or without a reasonable accommodation.”

¹⁸⁵ U.S. Equal Employment Commission, *Health Care Workers and the Americans with Disabilities Act*.

¹⁸⁶ VA Directive 5383, *VA Drug-Free Workplace Program*, December 23, 2004; VA Handbook 5383, *VA Drug-Free Workplace Program*, December 23, 2004.

¹⁸⁷ VA Directive 5383.

The policy requires that supervisors receive training to recognize and address illegal drug use by employees, and to “be provided information regarding referral of employees to the EAP, procedures and requirements for drug testing, and behavioral patterns that give rise to a reasonable suspicion that an employee may be using illegal drugs.” Among other requirements, the policy provides that supervisors shall “[i]nitiate a reasonable suspicion test, after first making appropriate factual observations and documenting those observations and obtaining approval from the higher level supervisor;...[and] [i]nitiate appropriate disciplinary action upon a finding of illegal drug use.”¹⁸⁸ The policy also requires higher level supervisors to “review and concur, in advance, with all reasonable suspicion tests ordered under their supervision.”¹⁸⁹

The policy requires that disciplinary action be initiated “against any employee found to use illegal drugs but shall not discipline an employee who voluntarily admits to illegal drug use.”¹⁹⁰ Action is required to be initiated if an employee refuses to obtain counseling or rehabilitation through EAP “after having been found to use illegal drugs; or having been found not to have refrained from illegal drug use after a first finding of illegal drug use.”¹⁹¹

For purposes of random testing for controlled substances, the policy provides a list of VA positions deemed to be testing designated positions for the following reasons:

- They require the “highest degree of trust and confidence.”¹⁹²
- The positions are characterized by critical safety or security responsibilities as related to the mission of VA.
- Their job functions associated “directly and immediately relate to public health and safety, the protection of life and property, law enforcement, or national security.”¹⁹³

VHA physician positions are identified as testing designated positions within the policy.¹⁹⁴

The policy also provides grounds for conducting reasonable suspicion testing. “Reasonable suspicion testing may be required of any employee in a position which is **designated** for random

¹⁸⁸ VA Handbook 5383.

¹⁸⁹ VA Handbook 5383.

¹⁹⁰ VA Handbook 5383. “A fundamental purpose of VA’s drug testing program is to assist employees who themselves are seeking treatment for drug use. For this reason, VA will not initiate disciplinary action against any employee who meets all three of the following “safe harbor” conditions: (a) Voluntarily identifies him/herself as a user of illegal drugs prior to being identified through other means; (b) Obtains counseling or rehabilitation through an [EAP]; and (c) Thereafter refrains from using illegal drugs...Since the key to this provision’s rehabilitative effectiveness is an employee’s willingness to admit his or her problem, this provision will not be available to an employee who is asked to provide a urine sample when required, or who is found to have used illegal drugs...and who thereafter requests protection under this provision.”

¹⁹¹ VA Handbook 5383.

¹⁹² VA Handbook 5383.

¹⁹³ VA Handbook 5383.

¹⁹⁴ VA Handbook 5383.

testing when there is a reasonable suspicion that the employee uses illegal drugs whether on or off duty.”¹⁹⁵

VA’s Lack of a Formal Alcohol Testing Policy

In response to discovering that a number of VA facilities were “using reasonable suspicion testing under the provisions of the Drug-Free Workplace Program... to require employees to undergo testing for alcohol use,” the VA Office of Human Resources Management (OHRM) issued guidance in the September–October 2013 edition of the OHRM Employee Relations & Performance Management Newsletter.¹⁹⁶ In an article entitled, “Dealing with Those Under the Influence of Alcohol on Duty and Using Sobriety Tests,” OHRM stated the provisions of VA Handbook 5383, *VA Drug-Free Workplace Program*, apply only to illegal drug use and do not “cover testing for suspicion of being under the influence of alcohol.”¹⁹⁷ The article notes that

There is presently no VA policy that authorizes alcohol testing for its employees, so the VA has no authority under its administrative regulations to order an employee to undergo a blood test or breathalyzer test for suspected use of alcohol.¹⁹⁸

However, while VA does not have the authority to order an alcohol test, the employee can be asked to undergo voluntary testing.

If a supervisor suspects an employee is under the influence of alcohol, it is recommended that the supervisor ask the employee about drinking alcohol and explores further if the answer is yes. If the employee responds “no,” the supervisor must assess “if it is safe for the employee to remain on duty,” or needs to be escorted to Occupational Health if there are concerning behaviors.¹⁹⁹ “If it is found that the employee should not remain on duty,” the employee should not be allowed to drive home. The supervisor should document the events immediately what transpired.²⁰⁰

The article notes that while “alcoholism is considered a disability under the Rehabilitation Act, alcoholic employees are held to the same standards of performance and behavior to which other employees are held, even if the behavior is related to the employee’s alcoholism.”²⁰¹ This is supported by a federal judge’s finding in a 1998 court case that “Where such behavior would

¹⁹⁵ VA Handbook 5383. **Designated** is bolded and underlined in original text. “Reasonable suspicion testing may also be required of an employee in a **non-testing designated** position when there is a reasonable suspicion of on-duty use or on-duty impairment” (bolded, underlined words appear as such in original text).

¹⁹⁶ OHRM Employee Relations & Performance Management Newsletter, September – October 2013, “Dealing with Those Under the Influence of Alcohol on Duty and Using Sobriety Tests” (underline in original text).

¹⁹⁷ OHRM Employee Relations & Performance Management Newsletter.

¹⁹⁸ OHRM Employee Relations & Performance Management Newsletter, (underline in original text).

¹⁹⁹ OHRM Employee Relations & Performance Management Newsletter.

²⁰⁰ OHRM Employee Relations & Performance Management Newsletter.

²⁰¹ OHRM Employee Relations & Performance Management Newsletter.

lead to the discharge of an employee without an alcohol problem, so too may it warrant dismissal for an employee with an alcohol problem.”²⁰²

Lastly, a key point of the article was that “being at work under the influence of alcohol is not acceptable conduct for any employee and may rise to the level of criminal activity in some circumstances.” The supervisor “must deal with the performance or conduct problems associated with an employee who is under the influence of alcohol, hold the employee accountable, and take appropriate disciplinary action.”²⁰³

²⁰² OHRM Employee Relations & Performance Management Newsletter, citing *Livingston v. U.S. Postal Service* 99 FEOR 7025, 168 F.3d 490 (6th Circ. 1998).

²⁰³ OHRM Employee Relations & Performance Management Newsletter.

Appendix D: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: May 3, 2021

From: Acting Under Secretary for Health, Office of the Under Secretary of Health (10)

Subj: OIG Draft Report, Healthcare Inspection—Pathology Oversight Failures at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas (OIG 2018-02496-HI-0873) (VIEWS 04858183)

To: Director, Office of Healthcare Inspections (54HL04)

1. Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report, Healthcare Inspection: Pathology Oversight Failures at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas.
2. The Veterans Health Administration (VHA) concurs with the recommendations and provides action plans in the attachment. VHA also provides technical comments.
3. We are deeply saddened by the harm Dr. Levy committed against our Veterans. Our medically vulnerable patients trusted him with their care and several lost their lives due to his behavior. VHA condemns his actions and is committed to improving processes to ensure safe care for Veterans across the system.
4. VHA recently issued field guidance related to ongoing professional practice evaluation (OPPE) for specialty care providers, including pathologists, to standardize requirements with the goal of improving earlier detection of suboptimal performance. An important component of that initiative is a requirement for Service Chiefs' OPPEs to be sent to outside facilities to ensure objective and unbiased performance review, which addresses many of the issues described in this report. This new standard was formalized in a December 2020 VHA Memorandum and is being implemented nationally.
5. In addition, the National Pathology and Laboratory Medicine Service program office began a review of the existing requirements in VHA policy to ensure robust and consistent performance monitoring standards for pathologists practicing in VHA.
6. Comments regarding the contents of this memorandum may be directed to the GAO-OIG Accountability Liaison Office at VHA10BGOALACTION@va.gov.

Original signed by:

Richard A. Stone, M.D.

Attachments

OIG Addendum to the Under Secretary for Health Memo

During VHA's review of an OIG draft report, it is usual practice for VHA to submit comments that may disclose information that could change OIG findings in the final report.²⁰⁴ For this report, VHA provided the OIG comments referenced in the Under Secretary for Health's memo

²⁰⁴ VA OIG GM Directive 306, *Comments to Draft Reports*, April 10, 2014, amended April 24, 2019.

during the draft review phase. The OIG considered the comments and determined they did not change any findings in the report.

Under Secretary for Health Response

Recommendation 1

The Under Secretary for Health ensures that the Veterans Health Administration competency process for locum tenens, newly hired specialty care providers, and newly hired service chiefs is evaluated to confirm that the results of the assessment accurately reflects the clinical competency of providers who are privileged, and takes action, as indicated.

Concur.

Target date for completion: March 2022

Under Secretary for Health Comments

The provider in question was hired in 2005, many years prior to current policy and requirements. In 2007, the Joint Commission first defined the requirement for the competency process of Focused Professional Practice Evaluations (FPPE) for all newly privileged providers and providers who are granted new privileges at a facility. The FPPE requirement first became mandatory with publication in 2008 of VHA Handbook 1100.19, *Credentialing and Privileging*, mandating FPPE for all privileged providers including privileged contract providers (e.g., locum tenens providers), service chiefs with privileges, and privileged providers of all specialties. VHA Handbook 1100.19, states “all health care professionals who are permitted by law and the facility to practice independently,” which includes all privileged contract providers, privileged clinical service chiefs, and privileged specialty providers. If issues are identified, processes are available to address the identified clinical competency concerns including a FPPE for Cause, reduction of privileges, or revocation of privileges.

A new, draft Directive 1100.21, *Privileging*, replacing VHA Handbook 1100.19, is in the review and concurrence processes. Draft Directive 1100.21 proposes to address contractors and service chiefs by clearly defining the FPPE competency process for contractors (locum tenens), newly hired specialty care providers, and newly hired service chiefs. In draft Directive 1100.21, it is proposed that these positions are evaluated to confirm that the results of the assessment are accurate by clearly including the positions in the definition of “licensed independent practitioner” and outlining the processes for Focused Clinical Care Reviews and Focused Professional Practice Reviews. Draft Directive 1100.21 further proposes to outline the circumstances when those reviews should be completed by providers external to a facility.

VHA will evaluate compliance with Directive 1100.21 after policy implementation through the 2022 mandatory annual VA medical facility self-assessment tool to be completed in January. Assessment questions will be added related to these new processes. Veterans Integrated Service Network Chief Medical Officers (CMO) will review results of VA medical facility

self-assessments, assist with the development of corrective action plans and follow corrective action plans through completion. CMOs will incorporate findings into audit programs.

Recommendation 2

The Under Secretary for Health reviews current Veterans Health Administration credentialing and privileging policies to assess guidance related to service chiefs' ongoing professional practice evaluation and takes action, as indicated.

Concur.

Target date for completion: August 2021

Under Secretary for Health Comments

Due to unclear guidance in existing policy, on December 18, 2020, VHA published a memorandum, "Implementation of Enterprise-Wide Focused Professional Practice Evaluation (FPPE) and Ongoing Professional Practice Evaluation (OPPE) Specialty-Specific Clinical Indicators." The memorandum establishes requirements related to service chiefs, highlighted below:

"External Reviews: The facility Chief of Staff must ensure that another practitioner at the facility with equivalent specialized training and similar privileges as the practitioner being evaluated completes the FPPE/OPPE review.

It is required that a practitioner from another VHA medical facility with the same specialized training and similar privileges shall complete the FPPE or OPPE in the following circumstances:

- a. The practitioner is part of a "two-deep" service or specialty (i.e., only two individuals at the facility perform the privileges that have been granted), such that, without this outside review, they would be examining one another's clinical performance ***OR*** the practitioner is a "solo provider" (i.e., the only individual at the VHA medical facility who performs the privileges that have been granted);
- b. The practitioner is a supervisor of the service or section of specialty; or
- c. The practitioner is the facility Chief of Staff.

Note: If the review is for a clinical service chief, the results of the review shall be returned directly to the Chief of Staff. Furthermore, if the review is for the Chief of Staff, results should be returned to a pre-designated/applicable clinical service chief at the respective facility."

These requirements related to service chief reviews are further clarified in draft VHA Directive 1100.21, *Privileging*.

Recommendation 3

The Under Secretary for Health reviews Veterans Health Administration policies to ensure that if facility leaders elect to incorporate pathology 10 percent peer reviews into the performance evaluations of a Pathology and Laboratory Medicine Service Chief, those reviews are performed by a peer without a conflict of interest and takes action, as indicated.

Concur.

Target date for completion: December 2020

Under Secretary for Health Comments

This issue has been addressed through publication of the December 18, 2020 VHA memorandum, which specifies that 10 percent of Service Chief peer reviews must be sent outside the facility for external review to avoid conflict of interest. This requirement is further established in VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service*.

Recommendation 4

The Under Secretary for Health evaluates the use and methodology of the Pathology and Laboratory Medicine Service 10 percent peer review for effectiveness as a quality management tool, and takes action, as indicated.

Concur.

Target date for completion: May 2022

Under Secretary for Health Comments

The December 18, 2020 VHA memorandum specifies new ongoing professional practice evaluation (OPPE) standards for specialty providers, including pathologists. This has improved earlier standards to assure specialty-specific performance evaluation goals and quality metrics, which can be incorporated into the quality management program. The 10 percent requirement is developed specifically for Pathology and Laboratory Medicine Service (PLMS) providers and is currently under revision.

The National PLMS program office will review the new 10 percent OPPE methodology for overall effectiveness and take action, if indicated.

Recommendation 5

The Under Secretary for Health evaluates Veterans Health Administration guidance related to amended pathology reports' terminology, use, and entry of such reports into patients' electronic health records, and revises guidance, as appropriate.

Concur.

Target date for completion: March 2022

Under Secretary for Health Comments

The National Pathology and Laboratory Medicine Service program office will evaluate Veterans Health Administration guidance related to amended pathology reports' terminology, use, and entry of such reports into the patients' electronic health records and will develop and revise this guidance, as appropriate, to ensure patient safety.

Recommendation 6

The Under Secretary for Health confirms that provisions are included in the Veterans Health Administration record modernization program that ensure amended pathology report alerts are directed to designated facility staff and leaders.

Concur.

Target date for completion: May 2022

Under Secretary for Health Comments

The National Pathology and Laboratory Medicine Service program office will work with the VA Office of Electronic Health Record Modernization to ensure processes are in place in the new electronic health record, alerting relevant stakeholders when amendments to pathology reports are made that document clinically significant changes to the original reports.

Recommendation 7

The Under Secretary for Health evaluates Veterans Health Administration quality management processes related to external, non-VHA pathology consultant assessments and ensures that facility leaders, the specialty care provider, and requesting providers are notified of the results of such reviews and a tracking process is in place.

Concur.

Target date for completion: May 2022

Under Secretary for Health Comments

The National Pathology and Laboratory Medicine Service program office will evaluate quality management processes related to external, non-VHA pathology consultant assessments and define procedures that ensure relevant stakeholders are notified of significant discrepancies in interpretation that might affect patient care decisions, requiring tracking mechanisms to identify any outlier providers.

VHA pathologists routinely utilize outside consultation while interpreting complex tissue samples. This process is encouraged and helps maintain high quality patient care standards for Veterans.

Recommendation 8

The Under Secretary for Health confers with the Office of General Counsel and the Office of Human Resources and Administration/Operations, Security & Preparedness to determine whether administrative action is warranted for Veterans Health Administration leaders who did not adequately perform their duties with respect to the issues within this report, and takes action, as appropriate.

Concur.

Target date for completion: October 2021

Under Secretary for Health Comments

Human Capital Management will confer and collaborate with the appropriate VA and VHA offices to determine whether administrative actions are warranted and, as appropriate, take actions.

Recommendation 9

The Under Secretary for Health explores the development of a mandatory alcohol testing policy for individuals including healthcare workers who perform functions that would put patients at risk should the employee work while impaired.

Concur.

Target date for completion: March 2022

Under Secretary for Health Comments

Human Capital Management (HCM) will explore the development of a mandatory alcohol testing policy. HCM has already engaged the Office of General Counsel concerning the legality of such a program and to determine whether the desired goal may be accomplished through policy or regulation.

Recommendation 10

The Under Secretary for Health evaluates Veterans Health Administration's guidance related to impaired healthcare workers and ensures that it addresses the circumstances under which alcohol and or drug testing may be performed; the extent of a retrospective review of care if one is indicated; and the availability of advisors who are knowledgeable on the management of an impaired provider, and takes action, as indicated.

Concur.

Target date for completion: March 2022

Under Secretary for Health Comments

Human Capital Management and the Clinical Episode Review Team will evaluate current guidance related to impaired healthcare workers and address any inadequacies related to the guidance and availability of knowledgeable advisors.

Appendix E: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: April 1, 2021

From: Director, South Central VA Health Care Network (10N16)

Subj: Healthcare Inspection—Pathology Oversight Failures at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas

To: Under Secretary for Health

1. The South Central VA Healthcare Care Network has reviewed and concurs with the actions submitted by the Veterans Health Care System of the Ozarks, Fayetteville, AR, in response to the facility specific recommendations in the Pathology Oversight Failures Draft Report.
2. If you have additional questions or need for information, please call 601-206-6900.

Original electronically signed by:

Skye McDougall, PhD

Appendix F: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: March 23, 2021

From: Director, Veterans Health Care System of the Ozarks (564/00)

Subj: Healthcare Inspection—Pathology Oversight Failures at the Veterans Health Care System of the Ozarks in Fayetteville, Arkansas

To: Director, South Central VA Health Care Network (10N16)

1. I have reviewed the draft report for the Veterans Health Care System of the Ozarks and concur with the report, conclusions rendered, and the recommendations.
2. Please express my thanks to the team for their professionalism and assistance to us in our continuing efforts to improve the care we provide to our Veterans.

Original signed by

Kelvin L. Parks, MA
Medical Center Director

Facility Director Response

Recommendation 11

The Veterans Health Care System of the Ozarks Director verifies that peer references obtained during the reappraisal and reprivileging processes are in alignment with VHA Handbook 1100.19, Credentialing and Privileging.

Concur.

Target date for completion: June 30, 2021

Facility Director Comments

The Veterans Health Care System of the Ozarks will add to the current Credentialing and Privileging instruction sheet to the provider that the peer reference obtained must be from a provider of the same profession or a professional with comparable privileges. This will ensure peer references are obtained during the re-appraisal and re-privileging process to align with the VHA Credentialing and Privileging Handbook 1100.19 and any other applicable VHA guidance.

Recommendation 12

The Veterans Health Care System of the Ozarks Director evaluates the psychological safety climate to ensure facility staff, patients, and the general public are empowered to report concerns and unsafe patient care without fear of reprisal and takes action, as needed.

Concur.

Target date for completion: September 30, 2021

Facility Director Comments

To address the psychological safety climate of the staff in Pathology and Laboratory Medicine Service (P&LMS), National Center for Organization Development (NCOD) facilitated the rebuilding of the culture for P&LMS employees. This was initiated in April 2019 and was completed and closed January 2020. As a result, the All Employee Survey (AES) Data for FY 20 in the area of culture of safety showed significant improvement. The Veterans Health Care System of the Ozarks will also have an opportunity to evaluate the current state of psychological safety with the pending AES that will be released in June 2021 with results to be published before the end of FY21. Additionally, all staff are required to complete “Own The Moment” training in TMS [Talent Management System], and a stand down will be conducted to allow staff time to complete the training.

Veteran Health Care System of the Ozarks Leadership will review the “Just Culture Implementation and Sustainment Guide for Leaders” and “Leaders HRO Activity Checklist.”

The Medical Center Director has requested a High Reliability Organization (HRO) Leader Coach from the National Office, as well as a Site-Specific Assessment for the facility.

Veterans Health Care System of the Ozarks HRO lead has Master Clinical Team Training (CTT), and the facility is on target to begin CTT unit level training in August 2021. Veterans Healthcare System of the Ozarks will pilot a Patient Safety forum to openly discuss adverse events and Just Culture responses. This will facilitate follow-up discussion on psychological safety allowing it to occur with a trusted facilitator.

Other actions Veterans Health Care System of the Ozarks implemented to continue to empower staff to report are the following:

- Addition of the “Red Button” link (est. February 22, 2019) on the intranet home page to all reporting structures, example: Joint Patient Safety Reporting (JPSR), reports of contact, ethics consults, and compliance anonymous reporting
- Leadership rounding has increased at the main campus and the outpatient clinics. The Medical Center Director and PENTAD [top five leaders] members conduct rounding on the main campus 3-4 times per month, and at the [community-based outpatient clinics] (CBOC’s) a minimum of monthly.
- Employee Town Halls have increased from quarterly to every other month
- Medical Center Director 1:1 has been established as a way for staff to have an individual meeting with the Director. The event is held monthly and is available to staff and Veterans. This allows direct access to the Medical Center Director to address any issues or concerns that may arise.
- Patient Safety reports all JPSR events daily in morning report to the Pentad for review and recommendations.

To address the psychological safety climate to ensure patients, and the general public are empowered to report, Veterans Health Care System of the Ozarks evaluates the SHEP [Survey of Healthcare Experiences of Patients] and VSignals [Veterans Signals] data. This data is reported to leadership in morning report for transparency and follow-up. Other actions Veterans Health Care System of the Ozarks has implemented to empower patients and the public to report are the following:

- Inclusion of Veterans on the Veterans Voice Advisory Council
- Employee Town Halls have increased from quarterly to every other month
- Medical Center Director 1:1 has been established as a way for staff to have an individual meeting with the Director. The event is held monthly and is available to staff and Veterans. This allows direct access to the Medical Center Director to address any issues or concerns that may arise.
- Stakeholder briefings occur every other month in the form of a town hall with the following stakeholder groups: Congressional offices, Veteran Service Officers, Veteran Service Organizations, and local government officials. This allows direct access to the

leadership team for regular updates, question, concerns, and partnership on communications as needed.

Glossary

To return, press and hold alt+left arrow

10 percent peer review. The percentage of all [surgical pathology](#), [fine needle aspiration](#), [Mohs surgery](#) and [cytology](#) cases that must be randomly selected and read by a second pathologist for quality management purposes in VHA laboratories.²²⁸

adenocarcinoma. A cancerous tumor originating in glands.²²⁹

administrative investigation board. A process of gathering evidence and ascertaining facts about particular matters that is conducted when a “systematic, thorough, and objective analysis of evidence, documented in a manner that clearly conveys not only the facts found, but also the evidence from which those facts are ascertained” is needed.²³⁰

adverse event. A term used by VHA to describe specific events. “Untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or service provided within the jurisdiction of a medical facility, outpatient clinic, or VHA facility.”²³¹

anatomic pathology. “The study of organs and tissues to determine the cause and effects of certain diseases.” VHA includes surgical pathology, cytopathology, immunohistochemistry, diagnostic [electron microscopy], Mohs surgery, and autopsy pathology under the scope of anatomic pathology.²³²

ataxia. A lack of muscle control that affects coordination of voluntary movement like walking, picking up objects, or difficulty speaking. Some conditions that cause ataxia include overuse of alcohol, medications, stroke, tumor, and brain degeneration.²³³

biopsy. A diagnostic process of removing and examining cells, fluids, or tissues from a living organism.²³⁴

²²⁸ VHA Handbook 1106.01, 2016.

²²⁹ Merriam-Webster. “adenocarcinoma,” accessed January 4, 2021, <https://www.merriam-webster.com/dictionary/adenocarcinoma>.

²³⁰ VA Directive 0700, 2002.

²³¹ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

²³² “Anatomical Pathology,” Johns Hopkins Medicine, accessed May 5, 2021, <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/anatomical-pathology>; VHA Handbook 1106.01 (2016).

²³³ “Ataxia,” Mayo Clinic, accessed January 20, 2021, <https://www.mayoclinic.org/diseases-conditions/ataxia/symptoms-causes/syc-20355652>.

²³⁴ Merriam-Webster. “Definition of biopsy,” accessed January 4, 2021, <https://www.merriam-webster.com/dictionary/biopsy>.

clinical episode review team. A multidisciplinary group convened, by the Deputy Under Secretary for Health for Operations and Management, to conduct a “coordinated triage process for review of each potential adverse event that may require large-scale disclosure.” The CERT consults with subject matter experts to review and discuss the issues and makes a recommendation regarding disclosure.²³⁵

Clinical Laboratory Improvement Amendments. Laws, also known as CLIA, passed by Congress in 1988 that established “quality standards for all non-research laboratory testing performed on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health.”²³⁶

clinical pathology. A branch of pathology that “covers lab functions,” including specialty areas like clinical chemistry, toxicology and blood bank, that assist in diagnosing diseases to determine treatment.²³⁷

cytology. “The exam of a single cell type from a body fluid specimen most commonly used to diagnose cancer.”²³⁸

credentialing. A screening and evaluating process used to determine qualifications to practice that may include licensure, education, training, experience, current competency, and health status.²³⁹

essential tremors. A common movement disorder. The key feature is a tremor in both hands and arms present during action and when standing still. The tremor may cause problems with writing, drinking from a cup, or using tools including a computer.²⁴⁰

fine needle aspiration. The process used to retrieve a sample of cells and bits of tissue for examination by applying suction through a fine needle attached to a syringe.²⁴¹

focused professional practice evaluation. An evaluation process used for a new provider and a provider who requests new privileges, as well as when professional practice concerns are

²³⁵ VHA Directive 1004.08, 2018.

²³⁶ CLIA, May 2012.

²³⁷ “Clinical Pathology Overview,” University of Rochester Medical Center, accessed June 20, 2019, [Clinical Pathology Overview - Health Encyclopedia - University of Rochester Medical Center](#).

²³⁸ “Cytology,” Johns Hopkins Medicine, accessed April 21, 2021, <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/cytology>.

²³⁹ VHA Handbook 1100.19, 2008; VHA Handbook 1100.19, 2012.

²⁴⁰ “Tremor Fact Sheet,” National Institute of Neurological Disorders and Stroke, accessed November 18, 2020, <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Tremor-Fact-Sheet>.

²⁴¹ Merriam-Webster. “Definition of fine needle aspiration,” accessed January 9, 2021, <https://www.merriam-webster.com/medical/fine%20needle%20aspiration>.

identified regarding activities within the scope of the licensed independent practitioner's current privileges.²⁴²

institutional disclosure. A term used by VHA to describe a specific discussion with patients. "A formal process by which facility leaders, together with clinicians and other appropriate individuals, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in or is reasonably expected to result in death or serious injury."²⁴³

interventional radiology. A medical sub-specialty of radiology involving minimally invasive image-guided procedures to diagnose and treat.²⁴⁴

issue brief. A document submitted to VHA leaders that is meant "to provide clear, concise, and factual information about incidents that may impact patient care or generate media attention." The guide outlines examples of events that would trigger submission of an issue brief, includes a template for content to be included in the document, and gives instructions regarding follow-up information that should be provided as new developments occur.²⁴⁵

just culture. A term used in a VHA directive to signify a culture that learns and improves by openly identifying and examining its own weaknesses. In such a culture, employees feel safe and emotionally comfortable in the work environment. Employees will be able, and are expected, to perform to peak capacity. They must also be able to admit weakness, concern, or inabilities and to seek assistance when the quality and safety of care may be threatened. Individuals feel as accountable for maintaining this environment as they do for delivering outstanding care. They know that they are accountable for their actions but will not be blamed for system faults beyond their control. They accept accountability for developing and maintaining an environment that feels psychologically safe.²⁴⁶

lesions. "Abnormal change[s] in structure of an organ or part due to injury or disease."²⁴⁷

licensed independent practitioner. A person legally permitted to provide care, within the scope of their license and consistent with the clinical privileges approved by the facility. Examples of licensed independent practitioners include physicians, dentists, and psychologist.²⁴⁸

²⁴² VHA Handbook 1100.19, 2012.

²⁴³ VHA Directive 1004.08, 2018.

²⁴⁴ "What is Vascular and Interventional Radiology," Johns Hopkins Medicine, accessed January 20, 2021, https://www.hopkinsmedicine.org/interventional-radiology/what_is_IR.html.

²⁴⁵ VHA, *10N Guide to VHA Issue Briefs*, 2015.

²⁴⁶ VHA Directive 1026, 2013.

²⁴⁷ Merriam-Webster. "Definition of lesion," accessed January 2, 2021, <https://www.merriam-webster.com/dictionary/lesion>.

²⁴⁸ Facility Memorandum 17-11-089, 2017.

locum tenens. A healthcare provider who is temporary or short-term.²⁴⁹

look-back. A type of review. According to VHA policy, “A look-back is an organized process for identifying patients or staff with exposure to potential risk incurred through past clinical activities, with the explicit intent to notify them and offer care and recourse, as appropriate.”²⁵⁰

lymph node. Small, round clusters of cells that help the body fight off infection by trapping or filtering viruses or bacteria.²⁵¹

margin. The edges of a biopsy sample. Measured in relation to the tumor cells, this informs the pathologist as to whether the biopsy removed the entire tumor.²⁵²

Executive Committee of the Medical Executive Council. The committee that oversees processes for the credentialing and privileging of the medical staff, monitors medical staff ethics and self-governance actions to ensure the quality of services provided at the facility.²⁵³

Mohs surgery. A surgical technique for the removal of skin cancers (such as basal cell carcinoma and squamous cell carcinoma.)²⁵⁴

ongoing professional practice evaluation. An evaluation process used for the ongoing monitoring of privileged providers to “identify professional practice trends that impact the quality of care and patient safety.” VHA service chiefs select criteria to incorporate into the evaluation including “direct observation, clinical discussions, and clinical pertinence reviews...data must be practitioner specific, reliable, easily retrievable, timely, justifiable, comparable, and risk adjusted where appropriate.”²⁵⁵

palliative care. Medical care focused on “providing patients relief from pain and other symptoms of a serious illness, no matter the diagnosis or stage of disease.”²⁵⁶

²⁴⁹ Veterans Health Administration Locum Tenens Program Locum accessed January 31, 2019, https://www.va.gov/HEALTH/ISP/Locum_Tenens_Program.asp.

²⁵⁰ VHA Handbook 1004.08, 2012; VHA Directive 1004.08, 2018.

²⁵¹ “Swollen Lymph Nodes,” Mayo Clinic, accessed January 2, 2021, <https://www.mayoclinic.org/diseases-conditions/swollen-lymph-nodes/symptoms-causes/syc-20353902>.

²⁵² “An Example of a Melanoma Pathology Report,” Aim at Melanoma Foundation, accessed January 5, 2021, <https://www.aimatmelanoma.org/diagnosing-melanoma/pathology/example-melanoma-pathology-report/>.

²⁵³ *Bylaws and Rules of the Medical Staff*, 2011.

²⁵⁴ Merriam-Webster. “Definition of Mohs surgery,” accessed January 13, 2021 <https://www.merriam-webster.com/medical/Mohs%20surgery>.

²⁵⁵ VHA Handbook 1100.19, 2012.

²⁵⁶ “Palliative care,” Mayo Clinic, accessed January 21, 2021, <https://www.mayoclinic.org/tests-procedures/palliative-care/about/pac-20384637>.

perineural invasion. Cancer cells that touch or surround a nerve.²⁵⁷

peripheral vascular disease. The damage or blockage in the vessels that carry blood from the arm and leg muscles and the organs in and below the stomach area.²⁵⁸

privileging. A process in the VHA system by which a provider, licensed for independent practice, “is permitted by law and the facility to practice independently, to provide specified medical or other patient care services within the scope of the individual’s license, based on the individual's clinical competency as determined by peer references, professional experience, health status, education, training, and licensure. Clinical privileges must be facility-specific, practitioner-specific, and within available resources.” They are recommended by service chiefs and the Executive Committee of the Medical Staff and approved by the Director. Clinical privileges are granted for a period not to exceed two years.²⁵⁹

prostate. A partly muscular partly glandular body that secretes fluid, which is a major part of semen.²⁶⁰

prostate specific antigen. A protein which is made by the prostate gland and is often elevated above 4.0 ng/ml when prostate cancer is present but can also be elevated in several benign conditions.²⁶¹

reasonable accommodation[s]. “A change or adjustment to a job or work environment that permits a qualified applicant or employee with a disability to participate in the job application process, to perform the essential functions of a job, or to enjoy benefits and privileges of employment equal to those enjoyed by employees without disabilities.”²⁶²

small cell cancer. A cancer that makes up about 10-15 percent of all lung cancers. This type of cancer usually grows and spreads faster than non-small cell lung cancer and tends to respond well to chemotherapy and radiation therapy.²⁶³

²⁵⁷ Johnston M. Yu E. et al., “Perineural invasion and spread in head and neck cancer,” *Expert Review of Anticancer Therapy* (2012): 359-71.

²⁵⁸ Texas Heart Institute. “peripheral vascular disease,” accessed January 2, 2021, <https://www.texasheart.org/heart-health/heart-information-center/topics/peripheral-vascular-disease/>.

²⁵⁹ VHA Handbook 1100.19, 2012.

²⁶⁰ Merriam-Webster. “Definition of prostate gland,” accessed January 2, 2021, <https://www.merriam-webster.com/dictionary/prostate%20gland>.

²⁶¹ “Prostate-Specific-Antigen (PSA) Test,” National Cancer Institute, accessed January 5, 2021. <https://www.cancer.gov/types/prostate/psa-fact-sheet#what-is-the-psa-test>.

²⁶² U.S. Equal Employment Opportunity Commission, *Health Care Workers and the Americans with Disabilities Act*, 2007.

²⁶³ “What is Lung Cancer?” American Cancer Society.

squamous cell cancer. A subtype of non-small cell lung cancer. Non-small cell lung cancer makes up about 80-85 percent of all lung cancers. Squamous cells line the inside of the airways to the lungs.²⁶⁴

stereotactic radiosurgery. A surgical technique involving the use of narrow beams of radiation (as gamma rays) that are precisely targeted by stereotactic methods to destroy tumors or lesions especially of the brain.²⁶⁵

summarily suspended. A provider's privileges may be summarily suspended (immediately deferred) on a temporary basis, when the failure to take action may result in danger to the health of any individual or concerns related to a provider's specific practice patterns.²⁶⁶

surgical pathology. The evaluation of tissue removed from patients during surgical procedures to determine if a disease is present..²⁶⁷

temporary privileges. Privileges that are provisional and granted in the case of emergent or urgent patient care needs. The facility director may approve privileges for 45 days based on documentation of a current state license and other reasonable information that supports training and current competency.²⁶⁸

²⁶⁴ "What is Lung Cancer?" American Cancer Society.

²⁶⁵ Merriam-Webster Medical Definition. "Definition of stereotactic radiosurgery," accessed January 2, 2021, <https://www.merriam-webster.com/medical/stereotactic%20radiosurgery>.

²⁶⁶ VHA Handbook 1100.19, 2012.

²⁶⁷ "Surgical Pathology," John Hopkins Medicine, accessed January 13, 2021, <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/surgical-pathology>.

²⁶⁸ VHA Handbook 1100.19, 2001.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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Inspection Team	Clarissa Reynolds, NHA, MBA, Director John D. Daigh, Jr., MD Kathy Gudgell, JD, RN Sarah Lanks, JD Carol Lukasewicz, BSN, RN Andrew Waghorn, JD
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Other Contributors	Jennifer Baptiste, MD Elizabeth Bullock Virginia Booth, MSN Roneisha Charles, BS Jennifer Christensen, DPM Limin Clegg, PhD Marnette Dhooghe, MS Ariel Drobnes, LCSW, MBE Adam Hummel, MPPA Candy Jones Kara McDowell, BSN, RN Robin Moyer, MD Rhonda Omslaer, JD, BSN Kris Raper, Special Agent Natalie Sadow, MBA Amber Singh, PhD Robyn Stober, JD, MBA Laurie Thurber, MA, BA Sandra Vassell, MBA, RN
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