



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Facility Oversight and
Leaders' Responses Related
to the Deficient Practice of a
Pathologist at the Hunter
Holmes McGuire VA Medical
Center in Richmond, Virginia



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Executive Summary

The VA Office of Inspector General (OIG) conducted an inspection to evaluate concerns identified by an OIG team during a Comprehensive Healthcare Inspection Program (CHIP) review at the Hunter Holmes McGuire VA Medical Center (facility) in Richmond, Virginia, in January 2019.¹ During that inspection, the OIG learned that facility leaders had identified deficiencies related to the practice of a pathologist (subject pathologist), including the missed cancer diagnosis of a patient during a pathology quality review initiated in September 2017.²

As a result of that quality review, the Pathology and Laboratory Medicine Services (P&LMS) Chief initiated two retrospective reviews in October 2017 of the subject pathologist's nonmalignant prostate biopsy cases and found 10 additional malignancy misdiagnoses. In November 2017, the P&LMS Chief learned that the subject pathologist also misdiagnosed a malignant skin biopsy in September 2016. The identification of deficiencies resulted in an institutional disclosure and eight clinical disclosures.³

In November 2017, the Facility Director, at the recommendation of the Chief of Staff, summarily suspended the subject pathologist's clinical privileges pending the outcome of the comprehensive retrospective reviews. The suspension continued until the Facility Director notified the subject pathologist in May 2018 of termination from employment.

The subject pathologist filed an appeal of the termination with the Veterans Health Administration (VHA) Disciplinary Appeals Board in May 2018. The Disciplinary Appeals Board heard testimony and reviewed the evidence file in August 2018.⁴ In February 2019, upon the recommendation of the Disciplinary Appeals Board, the Acting Principal Deputy Under

¹ CHIP reviews are part of the OIG's overall efforts to ensure that the nation's veterans receive high-quality VA healthcare services. The reviews focus on key clinical and administrative processes and are performed approximately every three years for each facility. VA Office of Inspector General, "Publications" Oversight Reports, <https://www.va.gov/oig/publications/default.asp>. (The website was accessed on July 23, 2019.)

² VA Office of Inspector General, *Comprehensive Healthcare Inspection of the Hunter Holmes McGuire VA Medical Center, Richmond, Virginia*. Report No. 18-04679-239, September 27, 2019.

³ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. This handbook was in effect during the time frame of the disclosures discussed in this report; it was rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The 2012 and the 2018 policies contain the same or similar language to define and report adverse events.

⁴ 38 U.S.C. § 7461 (2017). The VHA Disciplinary Appeals Board hears certain appeals regarding adverse personnel action(s). VA Directive 5021, *Employee/Management Relations*, April 15, 2002. VA Directive 5021/1, *Employee/Management Relations*, March 5, 2004.

Secretary for Health ordered the reinstatement of the subject pathologist. The subject pathologist was reinstated, and clinical privileges were restored in March 2019.⁵

The OIG assessed whether facility leaders had fully reviewed the subject pathologist's cases and had taken all required actions after the identification of deficiencies. Pursuant to VHA policy, the P&LMS Chief performed a 10 percent quality review of surgical pathology cases, subsequently reporting the subject pathologist's initial prostate biopsy misdiagnosis to the Chief of Staff.⁶ The P&LMS Chief oversaw the completion of the required additional comprehensive clinical care reviews of all of the subject pathologist's nonmalignant prostate biopsy cases, which resulted in the identification of the additional 10 prostate biopsy misdiagnoses.

Following the first and second retrospective reviews, the OIG determined that the P&LMS Chief followed VHA policy regarding requests for external consultation, and reported asking three local pathologists at an outside university to perform secondary reviews of the 11 prostate biopsy cases that had been found to be misdiagnosed.⁷

The OIG determined that for all 12 misdiagnosed patients identified during the reviews, the P&LMS Chief completed supplemental reports and documented a verbal notification to the clinical service chief and each patient's care provider on the same day of the supplemental report.⁸ The OIG found that a facility provider appropriately notified 6 of the 12 patients within seven days of the supplemental report as required by VHA policy.⁹ However, facility providers notified 3 of the 12 patients after seven days, and the OIG found no documentation that the remaining three patients were notified of their new diagnoses.

Additionally, the OIG found that of the 12 patients, one patient who experienced an adverse clinical outcome, specifically, a worsening prognosis and a need for a higher level of care, did not have documented disclosures, and facility staff and leaders did not report any of the 12 patient misdiagnoses as adverse events to the patient safety manager. Further, the P&LMS Chief was unaware of the VHA requirement to report the 12 patients' misdiagnoses as adverse events to the VA Pathology Regional Commissioner.¹⁰ Although facility leaders reported the initial

⁵ The P&LMS Chief reported that the subject pathologist was placed on an FPPE for 100 percent review and accuracy was not identified as an issue.

⁶ VHA Handbook 1106.01, *Pathology and Laboratory Medicine Service (P&LMS) Procedures*, January 29, 2016.

⁷ VHA Handbook 1106.01.

⁸ VHA Handbook 1106.01.

⁹ VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.

¹⁰ VHA Handbook 1106.01. VA Pathology Regional Commissioners provide oversight and enforcement of the policies defined in VHA Handbook 1106.01 "and related directives under the direction of the P&LMS National Enforcement Officer and the National Director." VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. VHA Handbook 1004.08.

missed diagnosis and the diagnoses discovered in the first retrospective review to the Veterans Integrated Service Network in a “heads-up” notification, they did not complete an issue brief.¹¹

Facility leaders followed VHA and facility requirements to summarily suspend the subject pathologist from performing duties while conducting a comprehensive case review of the subject pathologist’s nonmalignant prostate biopsy readings. The P&LMS Chief reported this was concluded within a month from when the initial misdiagnosis was discovered.¹² However, the OIG found there was no documentation renewing the summary suspension between March 2018 and May 2018, when the Chief of Staff proposed the removal and revocation of the subject pathologist’s privileges.¹³

The facility Medical Executive Board, responsible for monitoring essential patient care operations, did not document a review of the subject pathologist’s comprehensive case review or the recommendation to revoke the subject pathologist’s privileges.¹⁴

Facility leaders did not comply with VHA’s mandated privileging processes. Specifically, upon the return of the subject pathologist following a successful appeal to the Disciplinary Appeals Board, the Facility Director approved the pathologist’s privileges prior to a formal recommendation from the Medical Professional Standards Committee or Medical Executive Board; facility leaders did not develop focused professional performance evaluation (FPPE) criteria prior to granting privileges to the subject pathologist; the P&LMS Chief failed to present FPPE results to the Medical Professional Standards Committee and Medical Executive Board; and the subject pathologist did not accept the FPPE criteria prior to its initiation.¹⁵

Facility leaders were unaware of who was responsible for a state licensing board (SLB) review. The former Facility Director told the OIG team that the Chief of Staff was responsible for performing the SLB review and was not aware of a requirement for the facility director to conduct an initial SLB review within seven days of a licensed independent practitioner’s

¹¹ Deputy Under Secretary for Health for Operations and Management, *10N Guide to VHA Issue Briefs*, June 26, 2017.

¹² VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This VHA Handbook was scheduled for recertification on or before the last working day of October 2017 and has not been recertified. Facility Policy 11-38, *Organizational Bylaws and Rules and Regulations of the Professional Staff*, October 14, 2015. Facility Policy 11-40, *Medical Executive Board*, Richmond VAMC, September 10, 2015.

¹³ VHA Handbook 1100.19. Facility Policy 11-38. The subject pathologist’s privileges remained suspended during this period, but the subject pathologist continued to do administrative work until removed from federal employment.

¹⁴ Facility Policy 11-40, *Medical Executive Board*, September 10, 2015. The Medical Executive Board is responsible for monitoring essential patient care operations. The OIG team did not make a recommendation regarding this issue as the sufficiency of MEB documentation was already addressed in a recommendation in VA Office of Inspector General, *Comprehensive Healthcare Inspection of the Hunter Holmes McGuire VA Medical Center, Richmond, Virginia*. Report No. 18-04679-239, September 27, 2019. The recommendation was closed.

¹⁵ VHA Handbook 1100.19. Facility Policy 011-015, *Medical Professional Standards Committee*, July 5, 2018. Facility Policy 011-040, *Medical Executive Council*, September 7, 2018.

termination. In interviews with the OIG, the Chief of Staff denied being a part of the SLB reporting process, and the Human Resources Chief stated that the facility director has the responsibility to make SLB reporting decisions. Neither the former Facility Director nor the Chief of Staff completed all elements of a VHA-required SLB review upon discovery of the subject pathologist's "egregious performance."¹⁶ Specifically, the Chief of Staff and the former Facility Director failed to initiate an SLB review and notify the SLB in which the subject pathologist was licensed, within the required time frames, and upon receipt of information suggesting that a practitioner's clinical practice may have met the reporting standard.¹⁷ Additionally, the former Facility Director did not document the decision to not report in a memorandum, nor ensure the completion of the required Provider Exit Review Form within seven calendar days of the subject pathologist's termination from the facility.¹⁸

From April to June 2017, the P&LMS Chief reviewed 9.4 percent of the subject pathologist's cases, which is slightly below VHA and the facility's 10 percent requirement. The OIG determined that the quarterly retrospective reviews and ongoing professional performance evaluations (OPPE) for P&LMS exceeded the required 10 percent standard collectively. The P&LMS Chief stated the reviews capture 10 percent of each pathologist's work and that the data are used to complete each pathologist's OPPE; however, the OIG found that the P&LMS Chief and other staff pathologists did not consistently review 10 percent of each pathologist's cases for the two reporting periods examined.¹⁹

The OIG made 10 recommendations related to communication of test results; disclosure of adverse events, including clinical and institutional disclosures; reporting of adverse events to the patient safety manager and the VA Pathology Regional Commissioner; issue brief policies; the summary suspension process for licensed independent practitioners; the credentialing and privileging process as related to the subject pathologist; state licensing board reporting; and quality reviews of the P&LMS pathologists' work.

¹⁶ VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards*, December 22, 2005. This Handbook was scheduled for revision or recertification on or before the last working day of December 2010 and has not been recertified. VHA Notice 2018-05, *Amendment to VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards*, February 5, 2018.

¹⁷ VHA Handbook 1100.18.

¹⁸ VHA Handbook 1100.18. VHA Notice 2018-05.

¹⁹ VHA Handbook 1106.01. Facility Policy 116909.458, *Professional Competency Assessment Includes Peer Review Evaluation*, March 29, 2016

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the findings and recommendations and provided acceptable action plans (see appendixes C and D). The OIG will follow up on the planned actions until they are completed.



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Abbreviations

C&P	credentialing and privileging
CDW	Corporate Data Warehouse
CHIP	Comprehensive Healthcare Inspection Program
DAB	Disciplinary Appeals Board
EHR	electronic health record
FPPE	focused professional practice evaluation
MEB	Medical Executive Board
MPSC	Medical Professional Standards Committee
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
P&LMS	Pathology and Laboratory Medicine Services
SLB	state licensing board
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted an inspection to evaluate concerns identified by an OIG team during a Comprehensive Healthcare Inspection Program (CHIP) review at the Hunter Holmes McGuire VA Medical Center (facility) in Richmond, Virginia, in January 2019.¹ The OIG learned that facility leaders had identified deficiencies related to the practice of a pathologist (subject pathologist) that resulted in an [institutional disclosure](#) and eight [clinical disclosures](#).² The OIG assessed whether facility leaders had fully reviewed the subject pathologist's cases and had taken all required actions after the identification of deficiencies.

Background

The facility, part of Veterans Integrated Service Network (VISN) 6, comprises the Hunter Holmes McGuire VA Medical Center and four community clinics located in Charlottesville, Fredericksburg, Emporia, and Spotsylvania County, Virginia. The facility is affiliated with Virginia Commonwealth University and served over 62,000 patients from October 1, 2017, through September 30, 2018. VHA classifies the facility as a Level 1a, most complex facility.³

Prior OIG Reports

In a September 27, 2019, report *Comprehensive Healthcare Inspection of the Hunter Holmes McGuire VA Medical Center, Richmond, Virginia*, the OIG determined the facility did not report professional practice evaluations to the Medical Professional Standards Committee as required. One recommendation relevant to this report was for the Chief of Staff to ensure:

The Medical Professional Standards Committee reviews and evaluates licensed independent practitioners' professional practice evaluations when recommending approval of privileges through the Medical Executive Council to the Director.⁴

¹ CHIP reviews are part of the OIG's overall efforts to ensure that the nation's veterans receive high-quality VA healthcare services. The reviews focus on key clinical and administrative processes and are performed approximately every three years for each facility. VA Office of Inspector General, "Publications" Oversight Reports, <https://www.va.gov/oig/publications/default.asp>. (The website was accessed on July 23, 2019.)

² VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. This handbook was in effect during the time frame of the disclosures discussed in this report; it was rescinded and replaced by VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. The 2012 and the 2018 policies contain the same or similar language to define and report adverse events.

³ The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex.

⁴ VA Office of Inspector General, *Comprehensive Healthcare Inspection of the Hunter Holmes McGuire VA Medical Center, Richmond, Virginia*. Report No. 18-04679-239, September 27, 2019. The recommendation was closed.

Summary of Events and Concerns

During a regularly scheduled CHIP inspection of the facility in January 2019, the OIG identified concerns related to the subject pathologist's missed cancer diagnosis of a patient during a [pathology](#) quality review initiated in September 2017.⁵ In October 2017, the Pathology and Laboratory Medicine Services (P&LMS) Chief initiated two retrospective reviews of the subject pathologist's nonmalignant [prostate](#) biopsy cases and identified 10 additional malignancy misdiagnoses. In November 2017, the P&LMS Chief learned that the subject pathologist also misdiagnosed a malignant skin biopsy in September 2016. (Details of the OIG's review of the 12 patients are provided in appendix A.)

In November 2017, the Facility Director, at the recommendation of the Chief of Staff, summarily suspended the subject pathologist's clinical privileges pending the outcome of the comprehensive retrospective reviews. The suspension continued until the Facility Director notified the subject pathologist in May 2018 of termination from employment.

The subject pathologist filed an appeal of the termination with the Veterans Health Administration (VHA) Disciplinary Appeals Board (DAB) in May 2018. The DAB conducted an evidentiary hearing in August 2018.⁶ In February 2019, at the recommendation of the DAB, the Acting Principal Deputy Under Secretary for Health ordered the reinstatement of the subject pathologist. The subject pathologist's employment was reinstated, and clinical privileges were restored in March 2019. (A detailed timeline of events is provided in appendix B.)

The OIG initiated an inspection to evaluate facility leaders' oversight of the subject pathologist, actions taken after the identification of the misdiagnoses, and the subject pathologist's subsequent suspension, termination, and reinstatement. The OIG also reviewed whether the P&LMS Chief performed the required quality review of pathology cases consistent with VHA and facility policies.

Scope and Methodology

The OIG initiated the inspection on June 20, 2019, and conducted a site visit on September 3 and 4, 2019. The review included data and documents from January 2015 through November 2019.

The OIG team interviewed facility leaders including the current and former Facility Directors; Chief of Staff; Associate Chief of Staff for Clinical Operations; Chief Nurse, Quality; and the Chiefs of P&LMS, Urology, and Human Resources.⁷ The OIG team also interviewed staff

⁵ VA Office of Inspector General, Report No. 18-04679-239.

⁶ 38 U.S.C. § 7461 (2017). The VHA Disciplinary Appeals Board hears certain appeals regarding adverse personnel action(s). VA Directive 5021, *Employee/Management Relations*, April 15, 2002. VA Directive 5021/1, *Employee/Management Relations*, March 5, 2004.

⁷ The OIG was told that the former Facility Director left the facility in October 2018 and that the current Facility Director started in March 2019.

pathologists, the Quality Management Physician, the Risk Manager, a patient safety manager, the Quality Manager for P&LMS, a human resources supervisor, and the subject pathologist. The team also interviewed the Director and Deputy Director of the VHA Medical Staff Affairs Program Office.

The OIG reviewed VHA and facility policies, pathology quality review reports, electronic health records (EHRs), credentialing and privileging documentation, and other relevant documents and medical literature. The OIG reviewed the meeting minutes of the Medical Executive Board (MEB) and the Medical Professional Standards Committee (MPSC).⁸ The OIG reviewed documents specifically related to the subject pathologist including the state licensing board (SLB) report, DAB documentation and transcripts, human resources documentation, and professional practice evaluations.

A review of staff pathologists' caseloads from April 2017 to June 2017, and April 2019 to June 2019 was completed. The pathologists' April 2017 through June 2017 [ongoing professional practice evaluations](#) (OPPEs) were reviewed to determine compliance with VHA and facility requirements.

The OIG reviewed, for adverse clinical outcomes, the EHRs of 12 patients whom facility staff identified as having been misdiagnosed by the subject pathologist. Within the context of this report, the OIG considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level care. The OIG recognizes that in addition to the potential for adverse clinical outcomes, avoidable delays and cancellations associated with the deficiencies discussed in this report may impact the convenience and quality of care received by veterans. This report focuses on patient harm in terms of adverse clinical outcomes.⁹

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).

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, § 7, 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

⁸ Facility Policy 11-40, *Medical Executive Board*, September 10, 2015. Facility documents refer to the medical executive committee and the medical executive board interchangeably. VHA documents use the term executive committee of the medical staff to refer to medical executive committees and boards. For the purpose of this report, the OIG refers to this entity as the medical executive board.

⁹ VHA describes certain instances of patient harm as adverse events that require disclosure. The OIG uses the term adverse event when discussing VHA policy related to disclosure.

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.

Patient Case Summary

The subject patient was a veteran in their 50s with an elevated [prostate-specific antigen](#) (PSA) level, seen in consultation by the facility Urology Service in the fall 2015.¹⁰ Facility urologists performed a [transrectal ultrasound-guided prostate biopsy](#) in February 2016. The subject pathologist interpreted the biopsy to be “negative for malignancy,” and a surgical resident informed the patient of the findings 13 days later.

During an internal quality review of tissue specimens, in November 2017, the P&LMS Chief determined that the patient’s 2016 prostate biopsy contained a “focus of [adenocarcinoma](#) not previously reported.” In November 2017, the P&LMS Chief entered a supplemental pathology report to the original report of February 2016. In February 2018, the P&LMS and Urology Chiefs made an institutional disclosure to the patient and a family member informing them that the initial prostate tissue interpretation was incorrect, and that timely follow-up care had not been provided. In addition, the patient and family were advised that the abnormality subsequently found in the original tissue samples, the basis for the disclosure, was corroborated by a non-VA pathology group.¹¹

In spring 2018, clinical assessment revealed a normal PSA level and a pelvic [magnetic resonance imaging \(MRI\)](#) to be negative for suspicion of high-grade cancer. The following month, the Urology Chief noted that based on test results, including a review by a non-VA pathologist, the patient had low-risk cancer of the prostate. Several treatment options were presented for the patient’s consideration including [expectant management](#), [radiation therapy](#), and [radical prostatectomy](#).¹² Although the patient initially elected to proceed with surgery, the patient changed their mind and indicated that they “no longer [want a] prostatectomy.” Upon further discussion with the Urology Chief, the patient indicated a desire to wait six months to “see what happens,” and opted for active surveillance. The Urology Chief considered the patient’s decision to delay any surgery to be “not an unreasonable strategy” given the lack of progression from the time of the original prostate biopsy and a “decrease in PSA and negative MRI.”

¹⁰ The OIG uses the singular form of their (they) in this instance for privacy purposes.

¹¹ VHA Handbook 1004.08.

¹² Masood Kahn and Alan Partin, “Expectant Management of Prostate Cancer,” *Reviews in Urology* 5, no. 4, 2003: 247-249. “Expectant management, also known as watchful waiting or deferred therapy,” is an alternative to active treatment in prostate cancer. “If progression of disease becomes apparent [during] follow-up, active treatment [can] then [be] initiated.”

In summer 2018, the patient presented to a non-VA emergency department complaining of chest pain. Within an hour of arriving, the patient became unresponsive, experienced cardiac arrest, was refractory to [advanced cardiac life support](#) protocols, and was pronounced dead.

Inspection Results

1. Misdiagnoses and Facility Leaders' Response

In September 2017, the P&LMS Chief initiated a routine 10 percent quality review of pathology cases from June 16, 2017, through June 30, 2017, and found that the subject pathologist had misdiagnosed a prostate needle biopsy. The P&LMS Chief reported the misdiagnosis to the Chief of Staff as required by VHA policy in October 2017.¹³ The OIG found that facility leaders ensured the completion of the required comprehensive clinical care reviews of the subject pathologist's nonmalignant prostate biopsy cases, which resulted in the identification of 10 additional prostate biopsy misdiagnoses.¹⁴ The OIG learned that within the retrospective review time frame, the subject pathologist had also misdiagnosed a skin biopsy (see appendix A).

VHA and facility policy require the P&LMS Chief to ensure the completion of a random 10 percent quality review of all [surgical pathology](#), [fine needle aspirates](#), [Mohs surgery](#), and [cytopathology](#) cases each quarter.¹⁵ VHA policy requires that the P&LMS Chief notifies the Chief of Staff and the patient's provider when there is significant change in diagnosis that affects treatment.¹⁶ Facility bylaws provide that the Chief of Staff may require a comprehensive clinical care review if there is sufficient evidence of substandard care, professional misconduct, or incompetence.¹⁷

Additionally, VHA policy requires that a secondary pathologist review and document all cases with an "unexpected diagnos[i]s of clinical significance" or a "malignancy not previously established" in the final report.¹⁸ Facility policy further requires that a secondary pathologist review all primary malignancies except certain skin cancers, discrepancies in findings, and all cases where a diagnosis is in doubt.¹⁹ VHA and facility policy require staff pathologists to conduct secondary reviews. In cases where there is disagreement, the P&LMS Chief must obtain

¹³ VHA Handbook 1106.01.

¹⁴ VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. Facility Policy 11-38, *Organizational Bylaws and Rules and Regulations of the Professional Staff*, October 14, 2015.

¹⁵ VHA Handbook 1106.01. Facility Policy 116909.463, *Interdepartmental Anatomic Pathology Consultations*, March 29, 2016.

¹⁶ VHA Handbook 1106.01.

¹⁷ Facility Policy 11-38.

¹⁸ VHA Handbook 1106.01.

¹⁹ Facility Policy 116909.463

a third opinion, from local consultants, such as pathologists at an affiliated medical school, or from the Joint Pathology Center.²⁰

The P&LMS Chief followed VHA policy and ensured the completion of the required 10 percent quality review of the surgical pathology cases, subsequently reporting the misdiagnosis to the Chief of Staff.²¹ Two days after the P&LMS Chief report the misdiagnoses to the Chief of Staff, the P&LMS Chief directed a senior staff pathologist to perform a retrospective review of the subject pathologist's nonmalignant prostate biopsy readings within the previous 400 days. The P&LMS Chief did not include other specimens given a personal opinion that prostate needle core biopsies can be a challenge to read, and facility leaders had no evidence that the subject pathologist had any other interpretation issues beyond the prostate needle core biopsies at that time. Five days after the P&LMS Chief directed the retrospective review, the P&LMS Chief reported seven additional misdiagnoses to the Chief of Staff.²²

Per the P&LMS Chief, the Chief of Staff then requested a comprehensive clinical care review per facility bylaws to cover an additional year.²³ The P&LMS Chief asked the same senior staff pathologist to perform the second retrospective review of the expanded dates, which included an additional 323 days. This review resulted in the finding of two additional misdiagnoses (see table 1).

Table 1. Clinical Case Review of Subject Pathologist

Retrospective Review	Dates Included in Review	Nonmalignant Cases Reviewed	Misdiagnoses Found
First	9/15/2016–10/20/2017	66	8*
Second	10/27/2015–9/14/2016	58	2

Source: OIG analysis of the retrospective reviews of subject pathologist

**Includes the subject patient*

The OIG also learned that the Dermatology Chief contacted the P&LMS Chief with a concern about a reading that occurred during the time frame of the first retrospective review in which the subject pathologist incorrectly identified the [margins](#) of a skin biopsy (dermatology case) (see appendix A).

Following the first and second retrospective reviews, the OIG determined that the P&LMS Chief followed VHA policy by reportedly asking three pathologists at an outside university to perform

²⁰ VHA Handbook 1106.01. Facility Policy 116909.463

²¹ VHA Handbook 1106.01.

²² One additional patient was identified in this retrospective review but was not included in the notification to the Chief of Staff.

²³ Facility Policy 11-38.

secondary reviews of the 11 misdiagnosed prostate biopsy cases.²⁴ The P&LMS Chief reported conducting a secondary review of the dermatology case. The OIG examined the external secondary review process and found that the P&LMS Chief documented and retained personal notations of the external review results.

Documentation of Findings in Patients' EHRs

The OIG learned that, following the discovery of the 12 misdiagnoses (the 11 prostate biopsy cases and the one dermatology case), the P&LMS Chief documented the new diagnoses in the patients' EHRs. If a modification to the final pathology report is clinically significant, VHA policy requires that pathologists correct pathology reports through documentation of a supplemental report and notification of the patient's provider. Facility policy further requires that any change in diagnosis is documented through a supplemental report.²⁵

The OIG determined that for all 12 misdiagnosed patients, the P&LMS Chief completed supplemental reports and documented a verbal notification to the clinical service chief and each patient's care provider on the same day of the supplemental report.

Communication of Actionable Test Results

Following the P&LMS Chief's documentation of the supplemental reports, the OIG learned that the Urology Chief did not notify 2 of 11 prostate biopsy patients of their new diagnoses.²⁶ The OIG found no documentation that facility providers notified the dermatology patient of the new diagnosis.²⁷

When there is a previously undiagnosed malignancy, VHA requires the pathologist to verbally communicate test results to the patient's provider as soon as possible, ideally within one working day of the new diagnosis.²⁸ Additionally, VHA requires that the provider communicate actionable test results to the patient no later than seven calendar days from the date that the results are available.²⁹

The OIG found that the P&LMS Chief communicated the new biopsy diagnoses to the patients' providers at the same time as entering the supplemental reports. Additionally, the OIG found that

²⁴ VHA Handbook 1106.01.

²⁵ VHA Handbook 1106.01. Facility Policy 116909.462.

²⁶ *Urology Basics—What You Should Know*. <https://www.urologyhealth.org/educational-materials/urology-basics-what-you-should-know> (The website was accessed on November 12, 2019.) “Urology is a branch of medicine that deals with health problems of the male and female urinary systems, and the male reproductive system,” including the prostate.

²⁷ The dermatology patient received treatment for the right ear lesion beginning in July 2017. The P&LMS Chief learned of the misdiagnosis in November 2017, facility providers did not report this misdiagnosis from the October 2016 pathology report to the patient.

²⁸ VHA Handbook 1106.01.

²⁹ VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015.

a facility provider notified 6 of the 12 patients within seven days of the supplemental report. However, facility providers notified 3 of the 12 patients after seven days, and the OIG found no documentation that the remaining three patients were notified of their new diagnoses.

The OIG determined that the P&LMS Chief followed VHA policy to verbally communicate test results to the patient's provider within one day of the new diagnoses and that facility providers notified 6 of the 12 patients within seven days. Facility providers failed to meet VHA requirements to notify the remaining six patients within seven days.

Clinical Event Reporting Processes

In October 2017, the P&LMS Chief notified the Chief of Staff and the Urology Chief that the external secondary reviewers from an outside university concurred with the eight misdiagnoses identified in the first retrospective review of the subject pathologist's work and that another patient misdiagnosis had been identified in the 10 percent quarterly review of the subject pathologist's work.

VHA and local policy require disclosures of adverse events if they are expected to impact the patient, cause a change in care, or pose a clinically significant risk of health consequences.³⁰ VHA requires documentation of a clinical disclosure in the EHR if the "harm is more than minor." VHA requires facility leaders, in conjunction with clinicians and other appropriate individuals, to initiate an institutional disclosure for an adverse event, regardless of whether the adverse event was the result of an error.³¹

Per VHA policy, the P&LMS Chief or designee must ensure that the appropriate designee immediately communicates errors to the provider caring for the patient, and that the errors are corrected in the EHR.³² VHA also requires that adverse events are reported to the facility's patient safety manager and all "laboratory-related adverse events" are reported to the VA Pathology Regional Commissioner.³³ Additionally, VHA requires facility leaders to submit an [issue brief](#) to VISN and VHA leaders when there are [sentinel events](#) or "significant clinical incidents/outcomes negatively affecting a group or cohort of Veterans."³⁴

³⁰ VHA Handbook 1004.08. Facility Policy 161-6, *Disclosure of Adverse Events to Patients*, December 29, 2015.

³¹ VHA Handbook 1004.08.

³² VHA Handbook 1106.01.

³³ VHA Handbook 1106.01. VA Pathology Regional Commissioners provide oversight and enforcement of the policies defined in VHA Handbook 1106.01 "and related directives under the direction of the P&LMS National Enforcement Officer and the National Director." VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

³⁴ Deputy Under Secretary for Health for Operations and Management, *10N Guide to VHA Issue Briefs*, June 26, 2017.

The OIG reviewed EHRs of the 11 prostate biopsy patients and one dermatology patient, and also interviewed facility staff, to determine if facility providers completed the required disclosures and notifications (see appendix A). Of the 12 patients,

- Facility staff and leaders did not initiate a disclosure for the patient who experienced an adverse outcome;
- Facility staff and leaders did not report the misdiagnoses of the 12 patients as adverse events to the Patient Safety Manager;
- The P&LMS Chief did not report the misdiagnoses of the 12 patients as adverse events to the VA Pathology Regional Commissioner, because of an unawareness of the requirement to do so; and
- Facility leaders reported the initial misdiagnosis and the diagnoses discovered in the first retrospective review to the VISN in a [heads-up](#) notification, but did not report the 12 misdiagnoses in an issue brief to the VISN.

The OIG team found that 1 of the 12 patients experienced an adverse clinical outcome—a worsening prognosis and a need for a higher level of care. The dermatology patient experienced the progression of a malignant process ultimately requiring ear reconstruction surgery 14 months after the original biopsy. The OIG determined that the P&LMS Chief followed VHA and facility policy by reporting the initial misdiagnosis to the Chief of Staff and initiating the retrospective clinical reviews. However, clinical leaders did not disclose a misdiagnosis to a patient who experienced an adverse clinical outcome.

Summary Suspension and Removal of Subject Pathologist

In October 2017, the former Facility Director notified the subject pathologist that the subject pathologist's clinical privileges would be summarily suspended for failure to appropriately identify malignancies, and a comprehensive case review would be conducted. In January 2018, the Chief of Staff renewed the summary suspension until March 2018, to allow for additional review time, and did not document an expected completion date. In May 2018, the Chief of Staff issued a proposed removal and revocation of clinical privileges based on the charge of failure to identify malignant tissue (with 11 specifications). Two weeks later, the former Facility Director issued a letter sustaining the charges against the subject pathologist, and removed the subject pathologist from federal employment.

Per VHA and facility policy, a facility director can summarily suspend a provider's clinical privileges pending the outcome of a comprehensive review and due process procedures when it is in the best interest of patient care due to potential imminent harm.³⁵ According to VHA policy, the comprehensive review should be accomplished within 30 days, and if it is not, the

³⁵ VHA Handbook 1100.19. Facility Policy 11-38. Facility Policy 11-39, *Credentialing and Privileging of Licensed Independent Practitioners (LIP's) and Non-LIP's Under a Scope of Practice*, December 29, 2015.

circumstances should be documented with an expected completion date. Once the comprehensive review is complete, facility policy requires that the reviewers report the results to the MEB within 14 days for review and recommendation to the facility director, who then has five days to make a final decision.³⁶ The MEB must document in meeting minutes activities such as conclusions and recommendations to track medical management decisions.³⁷

The OIG found that facility leaders followed VHA and facility requirements to summarily suspend the subject pathologist while conducting a comprehensive case review of the subject pathologist's nonmalignant prostate biopsy readings, which the P&LMS Chief reported was concluded within a month of the initial misdiagnosis discovery.³⁸ However, the OIG found there was no documentation renewing the summary suspension between March 2018 and May 2018, when the Chief of Staff proposed the removal and revocation of the subject pathologist's privileges.³⁹

Additionally, the OIG reviewed the facility's MEB meeting minutes between September 2017 and May 2019 and determined that the MEB did not document a review of the subject pathologist's comprehensive case review or the recommendation to revoke the subject pathologist's privileges.⁴⁰

2. Reinstatement of the Subject Pathologist and Facility Leaders' Response

The subject pathologist filed an appeal to the DAB in May 2018.⁴¹ In January 2019, the DAB partially sustained the charge of *Failure to Identify Malignant Tissue* and recommended the Acting Principal Deputy Under Secretary for Health (PDUSH) overturn the subject pathologist's removal from federal employment. In February 2019, the acting PDUSH instructed the Facility Director to overturn the subject pathologist's removal and return the pathologist to duty within 30 days. The current Facility Director approved the subject pathologist's privileges for reinstatement in March 2019.

³⁶ Facility Policy 11-38. Facility Policy 11-39.

³⁷ Facility Policy 11-40.

³⁸ VHA Handbook 1100.19. Facility Policy 11-38. Facility Policy 11-40.

³⁹ VHA Handbook 1100.19. Facility Policy 11-38. Footnote55

⁴⁰ The OIG team did not make a recommendation regarding this issue as the sufficiency of MEB documentation was already addressed in a recommendation in VA Office of Inspector General, *Comprehensive Healthcare Inspection of the Hunter Holmes McGuire VA Medical Center, Richmond, Virginia*. Report No. 18-04679-239, September 27, 2019. The recommendation was closed.

⁴¹ 38 U.S.C. § 7461. The VHA Disciplinary Appeals Board hears certain appeals regarding adverse personnel action(s). VA Directive 5021, *Employee/Management Relations*, April 15, 2002. *VA Directive 5021/1, Employee/Management Relations*, March 5, 2004.

Facility Leaders Did Not Comply with VHA's Privileging Processes

Privileging is the process through which facility leaders grant [licensed independent practitioners](#) permission to practice independently. VHA requires that practitioners be privileged prior to a new appointment or reappointment. The privileging process begins with the service chief's evaluation of the practitioner's request for privileges. The service chief then makes a recommendation to the facility's MEB. The MEB evaluates the practitioner's credentials along with the service chief's recommendation and determines if the practitioner's clinical competence supports a recommendation to grant privileges.⁴²

VHA policy states that the MEB minutes must reflect the documents reviewed and the reasoning for the privileging recommendation. The MEB then forwards the recommendation to the facility director for a final decision.⁴³ Although VHA assigns the MEB the responsibility of making privileging recommendations to the facility director, facility policy assigns this responsibility to the MPSC, which then reports to the MEB.⁴⁴

The OIG found that the current Facility Director approved the subject pathologist's privileges in March 2019. The approval was eight days prior to the MPSC's March 2019 meeting, during which a decision was made to recommend approval of the provider's privileges. The MPSC reported a summary of its recommendations to the MEB in March 2019. The MEB did not make a recommendation to the Facility Director. The OIG found that facility leaders did not comply with VHA's mandated privileging processes. Specifically, the Facility Director approved the pathologist's privileges prior to a formal recommendation from the MPSC or MEB.

Facility Leaders Did Not Comply with VHA's Professional Practice Evaluation Processes

In March 2019, the P&LMS Chief initiated a [focused professional practice evaluation](#) (FPPE) that concluded in June 2019. VHA policy requires initiation of an FPPE for practitioners returning after a lapse in privileges.⁴⁵ Per VHA policy, the service chief must include FPPE criteria upon the practitioner's privileging recommendation to the MEB. The MEB reviews the recommended criteria and once approved, forwards the recommendation to the facility director for final approval. The practitioner must accept the FPPE criteria or privileges will not be granted. Additionally, results of FPPEs must be reported to the MEB for consideration in making recommendations, such as transitioning the practitioner to an OPPE.⁴⁶

⁴² VHA Handbook 1100.19.

⁴³ VHA Handbook 1100.19.

⁴⁴ Facility Policy 011-015, *Medical Professional Standards Committee*, July 5, 2018. Facility Policy 011-040, *Medical Executive Council*, September 7, 2018.

⁴⁵ VHA Handbook 1100.19.

⁴⁶ VHA Handbook 1100.19.

The OIG reviewed the subject pathologist's privileging and FPPE documents that were initiated in March 2019, and found that facility leaders did not follow VHA policy regarding establishment of FPPE criteria. Specifically, the P&LMS Chief, the MPSC, and the MEB did not recommend, nor did the Facility Director approve, FPPE criteria for the subject pathologist prior to the FPPE's initiation in March 2019.

The P&LMS Chief told the OIG about informing the subject pathologist of an FPPE focusing on prostate cases. According to the P&LMS Chief, the Chief of Staff directed the P&LMS Chief to expand the FPPE to include a 100 percent review of the subject pathologist's cases. The P&LMS Chief could not state with certainty that the subject pathologist was informed of the expanded FPPE evaluation criteria. The subject pathologist told the OIG about being informed the work that was being reviewed was based on a recommendation from the DAB and the Chief of Staff. The subject pathologist also stated being aware that the prostate biopsy cases were being reviewed, but later learned that all of the subject pathologist's cases were being reviewed, not just prostate biopsies. The subject pathologist stated not seeing the FPPE in advance and not signing or accepting the FPPE.

The OIG also learned that in June 2019, the P&LMS Chief advanced the subject pathologist to an OPPE prior to the MEB's review of the FPPE results. In September 2019, the MPSC reviewed the subject pathologist's FPPE and recommended a continued FPPE due to the subject pathologist's failure to meet thresholds in turnaround times for surgical pathology readings.

The OIG found that facility leaders did not comply with VHA FPPE policies. The failure to develop FPPE criteria prior to granting privileges and the failure to present the FPPE results to the MPSC and MEB, in addition to the subject pathologist not accepting the FPPE criteria, represent vulnerabilities in the process of monitoring practitioner competence to perform privileges.

3. Other Finding: SLB Reporting Processes

The former Facility Director notified the subject pathologist of the summary suspension of clinical privileges in October 2017. In May 2018, the Chief of Staff issued a proposed removal and revocation of clinical privileges. Subsequently, in a May 2018 letter, the former Facility Director notified the subject pathologist of the decision to remove and revoke privileges for "failure to identify malignant tissue." Each notification stated that a report to the SLB would be considered.

The subject pathologist was reinstated in March 2019, and the current Facility Director approved the subject pathologist's clinical privileges. In May 2019, the current Facility Director sent a letter to the subject pathologist's SLB indicating that a provider in their jurisdiction "has been involved in egregious performance," and that an accelerated review of the pathologist was being conducted with the results to be sent to the SLB.

VHA requires a facility director or designee to report any licensed healthcare practitioner whose clinical practice or behavior “so substantially failed to meet generally-accepted standards of clinical practice as to raise a reasonable concern for the safety of patients” to their respective SLBs.⁴⁷ There are two review phases for an SLB review: an initial review and a comprehensive review. If an initial review of a practitioner’s conduct determines there may be substantial evidence that the individual’s practice meets the reporting criteria, the facility director initiates a comprehensive review to assess whether substantial evidence does exist.⁴⁸ The facility director must ensure the initiation of the SLB Reporting Program review (SLB review) within seven calendar days of a practitioner’s separation from VA employment or upon receipt of information suggesting that a practitioner’s clinical practice may have met the reporting standard. Once the comprehensive review is complete, the facility director must document, on a decision memorandum, a decision regarding reporting a provider to the SLB.⁴⁹

VHA also requires an expedited review for egregious performance, which includes a letter sent to SLBs within five days of the determination of egregious performance. Egregious performance is defined as conduct that prompts a facility director to summarily remove a licensed healthcare practitioner “from clinical duties because of an immediate and urgent concern for the safety of patients.”⁵⁰ In February 2018, VHA released an amendment to the SLB reporting requirement stating that “VA medical facility Directors have ultimate authority in deciding whether to report a licensed health care [practitioner] to their respective SLB(s).”⁵¹

The OIG reviewed facility documentation and interviewed former and current facility leaders to determine if leaders followed the SLB review process.⁵² The OIG found that facility leaders were unaware of who was responsible for an SLB review. The former Facility Director told the OIG team that the Chief of Staff was responsible for performing the SLB review and was not aware of a requirement for the facility director to conduct an initial SLB review within seven days of a licensed independent practitioner’s termination. In interviews with the OIG, the Chief of Staff denied being part of the SLB reporting process, and the Human Resources Chief stated that the Facility Director has the responsibility to make SLB reporting decisions.

The OIG found that neither the Chief of Staff nor the former Facility Director completed all elements of a VHA-required SLB review upon discovery of the subject pathologist’s “egregious performance.”⁵³ Specifically, through interviews and document reviews, the OIG determined that the Chief of Staff and the former Facility Director failed to

⁴⁷ VHA Handbook 1100.18. VHA Notice 2018-05.

⁴⁸ VHA Handbook 1100.18.

⁴⁹ VHA Handbook 1100.18. VHA Notice 2018-05.

⁵⁰ VHA Handbook 1100.18.

⁵¹ VHA Notice 2018-05.

⁵² VHA Handbook 1100.18. VHA Notice 2018-05.

⁵³ VHA Handbook 1100.18.

- Initiate an SLB review upon receipt of information suggesting that a practitioner's clinical practice may have met the reporting standard,
- Notify the SLB within five days of a finding of egregious performance,
- Document the decision to report or not report in a memorandum, and
- Complete the required Provider Exit Review Form within seven calendar days of the subject pathologist's termination.

The Chief of Staff's and the former Facility Director's noncompliance with VHA policy represented a failure to meet the "obligation to alert those entities charged with licensing health care professionals when there is serious concern with regard to a licensed health care [practitioner's] clinical practice."⁵⁴

4. Other Finding: P&LMS Quality Reviews and OPPE Processes

Quality Reviews of Subject Pathologist's Cases

The P&LMS Chief told the OIG that the P&LMS Chief ensures retrospective reviews are performed on 10 percent of all pathology cases. The P&LMS Chief further stated that the reviews capture 10 percent of each pathologist's work and that the data are used to complete each pathologist's OPPE.

VHA and facility policy require the P&LMS Chief to ensure that a random 10 percent quality review of all [surgical pathology](#), [fine needle aspirates](#), [Mohs surgery](#), and [cytopathology](#) cases is performed each quarter.⁵⁵ Facility policy further requires the P&LMS Chief to ensure a 10 percent review of each pathologist's cases, tracked monthly.⁵⁶ Although VHA policy does not require a specific number of cases reviewed for OPPEs, facility policy states, "Data included in OPPEs will be determined by the individual department or service."⁵⁷

The OIG identified through VHA Corporate Data Warehouse (CDW) data that the subject pathologist completed 554 cases from April through June 2017. The OIG reviewed the data to determine if the P&LMS Chief performed the required quality review of the subject pathologist. The OIG found that of the 554 cases, the P&LMS Chief and other staff pathologists reviewed 52 cases (9.4 percent), slightly below the facility's 10 percent requirement.⁵⁸

⁵⁴ VHA Handbook 1100.18.

⁵⁵ VHA Handbook 1106.01. Facility Policy 116909.463.

⁵⁶ Facility Policy 116909.458.

⁵⁷ Facility Policy 11-38.

⁵⁸ The OIG team pulled data from VHA's Corporate Data Warehouse on November 21, 2019. The original misdiagnosis that prompted the Comprehensive Review occurred during April 1, 2017, through June 30, 2017. Therefore, the OIG analyzed data from April 1, 2017, through June 30, 2017. Additionally, the team reviewed a comparable period of April 1, 2019, through June 30, 2019. Facility Policy 116909.458.

Quality Reviews of P&LMS Staff Pathologists

2017 Data

The OIG identified through CDW data that facility P&LMS staff pathologists performed 2,050 cases between April 1, 2017, and June 30, 2017. The OIG compared the total number of P&LMS cases that the P&LMS Chief identified as the data reviewed for the quality reviews and for each pathologist's OPPE. Of 2,050 cases, the P&LMS Chief and other staff pathologists reviewed 227 cases (11.1 percent) (see table 2).⁵⁹

Table 2. Comparison of Cases Reviewed from April 2017 to June 2017

Pathologist	Total Number of Cases Identified in CDW	Total Number of Cases Reviewed by P&LMS Chief in Quarterly Quality Reviews/OPPE	Percentage Reviewed
1 (subject)	554	52	9.4
2	472	48	10.2
3	444	50	11.3
4	336	48	14.3
5	244	29	11.9
Total	2,050	227	11.1

Source: Comparison of facility staff pathologists' OPPEs to completed cases

2019 Data

The OIG identified through CDW data that facility P&LMS staff pathologists performed 1,949 cases between April 1, 2019, and June 30, 2019. The OIG compared the total number of P&LMS cases that the P&LMS Chief identified as the data for the quality reviews and for each pathologist's OPPE. Of 1,949 cases, the P&LMS Chief reviewed 204 cases (10.5 percent) (see table 3).

Table 3. Comparison of Cases Reviewed from April 2019 to June 2019

Pathologist	Total Number of Cases Identified in CDW	Total Number of Cases Reviewed in Quarterly Quality Reviews/OPPE	Percentage Reviewed
1 (subject)	366	38	10.4
2	364	37	10.2
3	368	40	10.9
4	271	34	12.5

⁵⁹ This analysis reflects staff pathologists only and does not reflect those cases assigned for first reading by the P&LMS Chief; the OIG was told that those cases were reviewed through a different process.

Pathologist	Total Number of Cases Identified in CDW	Total Number of Cases Reviewed in Quarterly Quality Reviews/OPPE	Percentage Reviewed
5	277	26	9.4
6	303	29	9.6
Total	1,949	204	10.5

Source: Comparison of Facility Staff Pathologists' OPPEs to Completed Cases

The OIG determined that the quarterly retrospective reviews and OPPEs for P&LMS exceeded the required 10 percent standard collectively; however, the OIG found that the P&LMS Chief and other staff pathologists did not consistently review 10 percent of each pathologist's cases for the two reporting periods examined.

Conclusion

The OIG found that the P&LMS Chief followed VHA policy and performed a quality review of surgical pathology cases, subsequently reporting the subject pathologist's initial misdiagnosis to the Chief of Staff. Facility leaders ensured the required comprehensive clinical care reviews were conducted of the subject pathologist's nonmalignant prostate biopsy cases, which resulted in the identification of additional prostate biopsy misdiagnoses. The OIG also learned that within the time frame of the reviews, the subject pathologist had also misdiagnosed a skin biopsy.

Following the reviews, the OIG determined that the P&LMS Chief followed VHA policy. The P&LMS Chief reported asking three pathologists at an outside university to perform secondary reviews of the 11 misdiagnosed prostate biopsy cases, and the P&LMS Chief reported reviewing the dermatology case.

The OIG determined that for all 12 misdiagnosed patients, the P&LMS Chief completed supplemental reports and documented a verbal notification to the clinical service chief and each patient's care provider on the same day the supplemental reports were completed. The OIG found that a facility provider notified 6 of the 12 patients within seven days of the supplemental report. However, facility providers notified 3 of the 12 patients after seven days and the OIG found no documentation that the remaining three patients were notified of their new diagnoses.

Additionally, the OIG found that of the 12 patients, one patient who experienced an adverse clinical outcome did not have documented disclosures and facility staff and leaders did not report any of the 12 patient misdiagnoses as adverse events to the patient safety manager; nor did the P&LMS Chief report the 12 patients' misdiagnoses as adverse events to the VA Pathology Regional Commissioner. Although facility leaders reported the initial missed diagnosis and the diagnoses discovered in the first retrospective review to the VISN in a "heads-up" notification, they did not complete an issue brief.

Facility leaders summarily suspended the subject pathologist while conducting a comprehensive case review of the subject pathologist's nonmalignant prostate biopsy readings. However, the OIG found no documentation renewing the summary suspension between March 2018 and May 2018, as required by VA handbook 1100.19, when the Chief of Staff proposed the removal and revocation of the subject pathologist's privileges.

The MEB did not document a review of the subject pathologist's comprehensive case review or the recommendation to revoke the subject pathologist's privileges.⁶⁰

Facility leaders did not comply with VHA's mandated privileging processes. Specifically, the Facility Director approved the pathologist's privileges prior to a formal recommendation from the MPSC or MEB; facility leaders did not develop FPPE criteria prior to granting privileges to the subject pathologist; the P&LMS Chief failed to present FPPE results to the MPSC and MEB; and the subject pathologist did not accept the FPPE criteria prior to its initiation.

Facility leaders were unaware of who was responsible for an SLB review and neither the former Facility Director nor the Chief of Staff completed all elements of a VHA-required SLB review upon discovery of the subject pathologist's "egregious performance."

From April to June 2017, the P&LMS Chief and other staff pathologists reviewed 9.4 percent of the subject pathologist's cases, which is slightly below VHA and the facility's 10 percent requirement.

The quarterly retrospective reviews and OPPEs for P&LMS exceeded the required 10 percent standard collectively; however, the OIG found that the P&LMS Chief and other staff pathologists did not consistently review 10 percent of each pathologist's cases for the two reporting periods examined.

Recommendations 1–10

1. The Hunter Holmes McGuire VA Medical Center Director ensures that the Pathology and Laboratory Medicine Services actionable supplemental test results are communicated timely in accordance with Veterans Health Administration policy.
2. The Hunter Holmes McGuire VA Medical Center Director ensures that facility leaders adhere to Veterans Health Administration policy that outlines the processes for the disclosure of adverse events, including clinical and institutional disclosures.

⁶⁰ The OIG team did not make a recommendation regarding this issue as the sufficiency of MEB documentation was already addressed in a recommendation in VA Office of Inspector General, *Comprehensive Healthcare Inspection of the Hunter Holmes McGuire VA Medical Center, Richmond, Virginia*, Report No. 18-04679-239, September 27, 2019. As of March 4, 2020, this recommendation remains open.

3. The Hunter Holmes McGuire VA Medical Center Director reviews the treatment course for the identified dermatology patient who experienced an adverse clinical outcome and takes action, including disclosures, if appropriate.
4. The Hunter Holmes McGuire VA Medical Center Director ensures staff compliance with Veterans Health Administration policies related to reporting of all adverse events to the patient safety manager.
5. The Hunter Holmes McGuire VA Medical Center Director ensures staff compliance with Veterans Health Administration policies related to reporting adverse events to the VA Pathology Regional Commissioner.
6. The Hunter Holmes McGuire VA Medical Center Director ensures staff compliance with Veterans Health Administration policies related to issue briefs.
7. The Hunter Holmes McGuire VA Medical Center Director ensures that facility leaders adhere to Veterans Health Administration policy that outlines the summary suspension process for licensed independent practitioners.
8. The Hunter Holmes McGuire VA Medical Center Director verifies that facility leaders adhere to Veterans Health Administration policy that outlines the credentialing and privileging process as related to the subject pathologist.
9. The Hunter Holmes McGuire VA Medical Center Director and facility leaders meet all Veterans Health Administration requirements for state licensing board reporting.
10. The Hunter Holmes McGuire VA Medical Center Director ensures that the Pathology and Laboratory Medicine Service Chief ensures the required Veterans Health Administration and facility quality reviews of the Pathology and Laboratory Medicine Services' pathologists are performed.

Appendix A: Patient List

Facility quality reviews found 12 misdiagnoses in the subject pathologist's cases:

- The P&LMS Chief identified subject patient (Patient 1) during a routine 10 percent quality review of pathology cases from June 16, 2017, through June 30, 2017.
- A senior staff pathologist identified Patients 2–11 through two retrospective reviews conducted for the periods from October 27, 2015, through September 14, 2016, and from September 15, 2016, through October 20, 2017.
- The Dermatology Chief contacted the P&LMS Chief with a concern about a reading that the subject pathologist incorrectly identified the margins of a skin biopsy (Patient 12).

The OIG team reviewed the EHRs of the 12 identified patients to evaluate for

- Date of first reading,
- Date of supplemental report,
- Performance and date of disclosure, and
- Adverse clinical outcomes.

Table A.1. Patient Summaries and OIG Determination of Adverse Clinical Outcomes

Patient	First Reading Date	Supplemental Report Date	Disclosure Type	Disclosure Date	Adverse Clinical Outcome
1	July 2017	October 2017	Clinical	October 2017	No
2	December 2016	October 2017	Clinical	December 2017	No
3	April 2017	October 2017	None*	n/a	No
4	April 2017	October 2017	Clinical	November 2017	No
5	April 2017	October 2017	None*	n/a	No
6	April 2017	October 2017	Clinical	November 2017	No
7	July 2017	October 2017	Clinical	October 2017	No
8	July 2017	October 2017	Clinical	November 2017	No
9	September 2017	October 2017	Clinical	November 2017	No
10	February 2016	November 2017	Institutional	February 2018	No
11	December 2015	November 2017	Clinical	December 2017	No
12	September 2016	December 2017	None	n/a	Yes

Source: OIG analysis of EHRs and determination of adverse clinical outcomes

** The OIG team determined that no disclosure was required for this episode of care.*

Appendix B: Timeline of Events

Table B.1. Timeline of Events Related to the Employment of the Subject Pathologist and the Facility Leaders' Responses to the Subject Pathologist's Misdiagnoses

Date	Event
December 2015	MPSC renewed the subject pathologist's clinical privileges
September 2017	P&LMS Chief initiated a routine 10 percent quality review of surgical pathology cases from June 16, 2017 through June 30, 2017
October 2017	P&LMS Chief notified Chief of Staff of a finding of subject pathologist's misdiagnosis of a prostate adenocarcinoma
October 2017	A senior staff pathologist initiated a retrospective review of the subject pathologist's nonmalignant prostate biopsy readings within the previous 400 days and identifies eight cases as malignant
Fall 2017*	P&LMS Chief reported sending cases to pathologists at an outside university pathologists for review and receives concurrence for all cases
October 2017	Subject pathologist notified of summary suspension of privileges
October 2017	Chief of Urology provided case analysis to the P&LMS Chief and Chief of Staff and begins notifying patients
Fall 2017*	A senior staff pathologist performed retrospective review of the subject pathologist's nonmalignant prostate biopsy readings for an additional 323 days and identifies two additional cases as malignant
November 2017	P&LMS Chief recommended disapproval of the subject pathologist's clinical privileges for "excessive diagnostic error rate in anatomic pathology"
November 2017	Subject pathologist responded to suspension of privileges
November 2017	MPSC denied subject pathologist's routine renewal of clinical privileges "pending the outcome of the due process procedure"
November 2017	The Chief of Staff alerted VISN and VA leaders of the missed diagnoses in the first retrospective review through a heads-up notification
November 2017	P&LMS Chief documented OPPE for subject pathologist as "met or exceeded" OPPE parameters and identified no major discrepancies"
January 2018	Chief of Staff informed subject pathologist of summary suspension extension to March 2018
May 2018	Chief of Staff issued a proposed removal and revocation of clinical privileges of subject pathologist charging "Failure to Identify Malignant Tissue"
May 2018	Subject pathologist submitted a written reply to proposed action
May 2018	Former Facility Director sustained charge, issued notice of removal and revocation of privileges, and informed subject pathologist of effective termination date
May 2018	DAB received appeal from subject pathologist
August 2018	DAB hears testimony from the subject pathologist and facility staff

Facility Oversight and Leaders' Responses Related to the Deficient Practice
of a Pathologist at the Hunter Holmes McGuire VA Medical Center in Richmond, Virginia

Date	Event
February 2019	Acting PDUSH notified facility and subject pathologist of DAB outcome to partially sustain the charge of "Failure to Identify Malignant Tissue" and reverse the removal
March 2019	Current Facility Director started
March 2019	Subject pathologist reinstated
March 2019	Current Facility Director approved subject pathologist's clinical privileges
March 2019	Subject pathologist placed on a FPPE
March 2019	MPSC and MEB recommend approval of subject pathologist privileges
May 2019	Current Facility Director advised the SLB regarding subject pathologist's "egregious performance" and stated a "review is being conducted"
May 2019	Current Facility Director notified the subject pathologist of the concerns being reviewed about the subject pathologist's clinical practice and may report to the SLB
June 2019	Subject pathologist responded to current Facility Director's letter regarding SLB
June 2019	P&LMS Chief reported placing subject pathologist on an OPPE
August 2019	P&LMS Chief provided rebuttal to subject pathologist's response letter
September 2019	MPSC placed subject pathologist on an extended FPPE due to the subject pathologist's failure to meet turnaround time thresholds for surgical pathology readings
September 2019	MPSC reported all actions to the MEB; subject pathologist continued on FPPE for an additional 90 days

Source: OIG analysis of facility documents, interviews with VHA employees, and review of documentation related to the VHA DAB

** The P&LMS Chief was unable to provide an exact date.*

Appendix C: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: June 17, 2020

From: Network Director, VA Mid-Atlantic Health Care Network (10N6)

Subj: Healthcare Inspection—Facility Oversight and Leaders' Responses Related to the Deficient Practice of a Pathologist at the Hunter Holmes McGuire VA Medical Center, Richmond, Virginia

To: Director, Office of Healthcare Inspections (54HL07)
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. The attached subject report is forwarded for your review and further action. I reviewed the response of the Hunter Homes McGuire VA Medical Center, Richmond, Virginia, and concur with the facility's recommendations.
2. If you have further questions, please contact Dana Ballard, QMO, VISN 6.

(Original signed by:)

Deanne M. Seekins, MBA, VHA-CM

VA Mid-Atlantic Health Care Network Director, VISN 6

Appendix D: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: May 29, 2020

From: Executive Director, Central Virginia VA Health Care System (CVHCS) (652/00)

Subj: Healthcare Inspection—Facility Oversight and Leaders' Responses Related to the Deficient Practice of a Pathologist at the Hunter Holmes McGuire VA Medical Center, Richmond, Virginia

To: Director, VA Mid-Atlantic Health Care Network (10N6)

1. The Executive Director, CVHCS, reviewed the draft of the subject report and concurs with the findings.
2. A plan for corrective actions to include a timeline for completion and sustainment of improvements has been implemented.

(Original signed by:)

J. Ronald Johnson, MHA, FACHE

Comments to OIG's Report

Recommendation 1

The Hunter Holmes McGuire VA Medical Center Director ensures that the Pathology and Laboratory Medicine Services actionable supplemental test results are communicated timely in accordance with Veterans Health Administration policy.

Concur.

Target date for completion: December 1, 2020.

Director Comments

The Chief, Pathology and Laboratory Medicine Services (P&LMS) will ensure compliance with VHA Directive 1106.01 by reviewing the requirements with all staff pathologists. All actionable supplemental reports will be reviewed by the Chief, P&LMS and will be documented in the monthly P&LMS Quality Assurance and Improvement Committee (QAIC) minutes.

Recommendation 2

The Hunter Holmes McGuire VA Medical Center Director ensures that facility leaders adhere to Veterans Health Administration policy that outlines the processes for the disclosure of adverse events, including clinical and institutional disclosures.

Concur.

Target date for completion: December 1, 2020.

Director Comments

The Chief of Staff will review VHA Directive 1004.08, Disclosure of Adverse Event to Patients, with clinical service chiefs and require that they reeducate their providers. The reporting of adverse events is captured through the Joint Patient Safety Reporting (JPSR) System, which is VHA's means of reporting an adverse event. All JPSR events are reviewed every business day by the senior leadership team during morning report for potential disclosures of adverse events.

Recommendation 3

The Hunter Holmes McGuire VA Medical Center Director reviews the treatment course for the identified dermatology patient who experienced an adverse clinical outcome and takes action, including disclosures, if appropriate.

Concur.

Target date for completion: Completed. Patient seen by Dermatology and had surgery.

Director Comments

The Chief of Staff reviewed the treatment course for the identified dermatology patient with the appropriate clinical service chiefs. Appropriate clinical treatment was provided for the patient; thus, disclosure was not necessary for this case.

OIG Comments

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

Recommendation 4

The Hunter Holmes McGuire VA Medical Center Director ensures staff compliance with Veterans Health Administration policies related to reporting of all adverse events to the patient safety manager.

Concur.

Target date for completion: Completed.

Director Comments

Medical Center staff are continuously educated on what and how to report adverse events. For example, education regarding the reporting of adverse events is an ongoing process that occurs during New Employee Orientation (NEO), in-services during Patient Safety Week, Quality, Safety and Value (QSV) newsletters, Environment of Care (EoC) rounds, and just-in-time training when events occur that have not been reported. As mentioned above, staff are trained to report adverse events through JPSR, and all JPSR events are reviewed every business day by the senior leadership team during morning report. Also, a JPSR trend analysis is completed on a monthly basis during the Patient Safety Advisory Committee (PSAC).

OIG Comments

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

Recommendation 5

The Hunter Holmes McGuire VA Medical Center Director ensures staff compliance with Veterans Health Administration policies related to reporting adverse events to the VA Pathology Regional Commissioner.

Concur.

Target date for completion: December 1, 2020.

Director Comments

The Chief of Staff and the Chief, P&LMS reviewed the requirements of VHA Handbook 1106.01 regarding reporting adverse events to the VA Pathology Regional Commissioner. Laboratory and Pathology adverse events will be documented in the monthly P&LMS QAIC minutes. After an adverse event is discovered in anatomic pathology, the Chief of P&LMS will notify the VA Pathology Regional Commissioner through an encrypted email.

Recommendation 6

The Hunter Holmes McGuire VA Medical Center Director ensures staff compliance with Veterans Health Administration policies related to issue briefs.

Concur.

Target date for completion: December 1, 2020.

Director Comments

The Director ensures compliance with the 10N Guide to Veterans Health Administration Issue Briefs to provide information to facility, VISN, and VHA leadership about unusual incidents, deaths, disasters, or other significant events that generate media interest or impact care. The health care system will submit Issue Briefs for all notification triggers to VISN leadership for review and submission to the automated Issue Tracker. All facility EDMS [Electronic Document Management System] Education Development Management System] staff along with Senior Leadership Executive Assistants will attend the next three monthly VHA Issue Brief training calls to ensure compliance.

Recommendation 7

The Hunter Holmes McGuire VA Medical Center Director ensures that facility leaders adhere to Veterans Health Administration policy that outlines the summary suspension process for licensed independent practitioners.

Concur.

Target date for completion: December 1, 2020.

Director Comments

The Director will ensure that facility leaders adhere to VHA policy that outlines the summary suspension process for licensed independent practitioners. The Chief of Staff will review VHA Handbook 1100.19, Credentialing and Privileging, with Medical Executive Council (MEC) members and clinical service chiefs. A tracking tool will be developed to aid in meeting the deadlines and actions outlined in VHA Handbook 1100.19.

Recommendation 8

The Hunter Holmes McGuire VA Medical Center Director verifies that facility leaders adhere to Veterans Health Administration policy that outlines the credentialing and privileging process as related to the subject pathologist.

Concur.

Target date for completion: Completed, May 18, 2020.

Director Comments

The subject Pathologist was placed on a new for-cause Focused Professional Practice Evaluation (FPPE) on May 18, 2020 by the Chief, P&LMS, which was signed by the subject pathologist. All FPPE results are presented and approved monthly to the Medical Professional Standards Committee (MPSC) by the clinical service chiefs.

OIG Comments

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

Recommendation 9

The Hunter Holmes McGuire VA Medical Center Director and facility leaders meet all Veterans Health Administration requirements of state licensing board reporting.

Concur.

Target date for completion: December 1, 2020.

Director Comments

Facility leaders will meet all VHA requirements for their respective disciplines for state licensing board reporting and VHA Handbook 1100.18, Reporting and Responding to State Licensing Boards. All disciplines are monitored through the Credentialing and Privileging Department utilizing the VetPro system. A tracking tool will be developed to aid in meeting the deadlines and actions outlined in VHA Handbook 1100.19

Recommendation 10

The Hunter Holmes McGuire VA Medical Center Director ensures that the Pathology and Laboratory Medicine Service Chief ensures the required Veterans Health Administration and facility quality reviews of the Pathology and Laboratory Medicine Services' pathologists are performed.

Concur.

Target date for completion: Completed.

Director Comments

The Chief, P&LMS will continue to monitor quality reviews for pathology and laboratory providers. This action is monitored through the Focused/Ongoing Professional Practice Evaluation (F/OPPE) process and reported to the Medical Professional Standards Committee at the required intervals. The standard operating process has been updated with a minimal threshold being established.

OIG Comments

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

Glossary

adenocarcinoma. A cancerous tumor originating in glands.¹

advanced cardiac life support. A series of advanced interventions for patients in respiratory and cardiac arrest and includes basic life support as well as airway management and the use of medications.²

adverse events. Events connected with care or services delivered that result in harm or potential harm.³

biopsy. Diagnostic process of removing and examining cells, fluids or tissues from a living organism.⁴

clinical disclosure. A “process by which the patient’s clinician informs the patient or the patient’s personal representative, as part of routine clinical care, that a harmful or potentially harmful adverse event has occurred during the patient’s care.”⁵

cytopathology. A branch of pathology that deals with manifestations of disease at the cellular level.⁶

expectant management. “Known as watchful waiting or deferred therapy,” an alternative to active treatment in prostate cancer. “If progression of disease becomes apparent [during] follow-up, active treatment [can] then [be] initiated.”⁷

fine needle aspirates. The process of obtaining a sample of cells and bits of tissue for examination by applying suction through a fine needle attached to a syringe.⁸

focused professional practice evaluations. A tool used by managers to further evaluate the performance of practitioners who are newly privileged, lack documented competencies or whose

¹ <https://www.merriam-webster.com/dictionary/adenocarcinoma>. (The website was accessed on December 6, 2019).

² Nurse.org, *Everything Nurses Need to Know About ACLS, BLS & PALS Certifications 2019*. <https://nurse.org/articles/everything-nurses-need-to-know-about-acls-bls-pals/>. (The website was accessed on November 6, 2019.)

³ VHA Handbook 1004.08.

⁴ <https://www.merriam-webster.com/dictionary/biopsy>. (The website was accessed on December 6, 2019.)

⁵ VHA Handbook 1004.08.

⁶ <https://www.merriam-webster.com/dictionary/cytopathology>. (The website was accessed on December 6, 2019)

⁷ Masood Kahn, Alan Partin, “Expectant Management of Prostate Cancer,” *Reviews in Urology*, Vol. 5 No. 4, 2003, 247-249.

⁸ <https://www.merriam-webster.com/medical/fine%20needle%20aspiration>. (The website was accessed on December 6, 2019.)

practice raises questions as to the “practitioner’s ability to provide safe, high quality patient care.”⁹

heads-up. “A notification designed to allow facility and VISN leadership to provide a brief synopsis of the issue while facts are being gathered to be submitted as an issue brief.”¹⁰

institutional disclosure. “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.”¹¹

issue brief. A tool used to provide information to leadership within the organization, regarding a situation, event or issue.¹²

licensed independent practitioners. “Any individual permitted by law...and the facility to provide patient care services independently...within the scope of the individual’s license, and in accordance with individually-granted clinical privileges.”¹³

magnetic resonance imaging (MRI). A noninvasive tool used to look at organs, tissue and skeletal systems and to produce detailed computer-generated images of the body using magnetic fields.¹⁴

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.¹⁵

Mohs surgery. A surgical technique for the removal of skin cancers (such as basal cell carcinoma and squamous cell carcinoma).¹⁶

⁹ The Joint Commission, Focused Professional Practice Evaluation (FPPE) – Understanding the Requirements. <https://www.jointcommission.org/en/standards/standard-faqs/hospital-and-hospital-clinics/medical-staff-ms/000001485/> (The website was accessed on February 12, 2020.)

¹⁰ Deputy Under Secretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs*, June 26, 2017.

¹¹ VHA Handbook 1004.08.

¹² Deputy Under Secretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs*, June 26, 2017.

¹³ VHA Handbook 1100.19.

¹⁴ Mayo Clinic, *MRI*. <https://www.mayoclinic.org/tests-procedures/mri/about/pac-20384768>. (The website was accessed on November 6, 2019.)

¹⁵ Aim at Melanoma Foundation, *An Example of a Melanoma Pathology Report*. <https://www.aimatmelanoma.org/diagnosing-melanoma/pathology/example-melanoma-pathology-report/>. (The website was accessed on January 14, 2020.)

¹⁶ <https://www.merriam-webster.com/medical/Mohs%20surgery>. (This website was accessed on December 6, 2019.)

needle biopsy. A procedure to extract a sample of cells from tissue to diagnose a medical condition. Fine needle aspiration and core needle biopsies are common examples.¹⁷

ongoing professional practice evaluations. A tool used by managers to evaluate the performance clinical competence of privileged practitioners; also used to make decisions regarding continuance of privileges.¹⁸

pathology. A branch of medicine that studies the diseases of tissue.¹⁹

prostate. A small gland in men that produces the fluid that supports and transports sperm.²⁰

prostate-specific antigen. A protein which is made by the prostate gland and is often elevated in prostate cancer but can also be elevated in several benign conditions.²¹

radiation therapy. Treatment which targets and damages cancer cells by applying x-ray beams or other types of energy.²²

radical prostatectomy. “Partial or complete removal of the prostate” by surgical incision.²³

sentinel event. “A patient safety event that reaches a patient and results in... death, permanent harm, [or] severe temporary harm and intervention required to sustain life.”²⁴

surgical pathology. “The study of tissues removed from living patients during surgery to help diagnose a disease and determine a treatment plan.”²⁵

¹⁷ Mayo Clinic, *Needle Biopsy*. <https://www.mayoclinic.org/tests-procedures/needle-biopsy/about/pac-20394749>. (The website was accessed November 20, 2019.)

¹⁸ The Joint Commission, Ongoing Professional Practice Evaluation (OPPE)- Understanding the Requirements, <https://www.jointcommission.org/en/standards/standard-faqs/critical-access-hospital/medical-staff-ms/000001500/>. (The website was accessed on February 12, 2020.)

¹⁹ Lexico, US Dictionary, *Pathology*. <https://www.lexico.com/en/definition/pathology> (The website was accessed on February 12, 2020.)

²⁰ Mayo Clinic, *Prostate Cancer*. <https://www.mayoclinic.org/diseases-conditions/prostate-cancer/symptoms-causes/syc-20353087>. (The website was accessed on November 20, 2019.)

²¹ National Cancer Institute. <https://www.cancer.gov/types/prostate/psa-fact-sheet#what-is-the-psa-test>. (The website was accessed on November 6, 2019.)

²² Mayo Clinic, *Radiation therapy*. <https://www.mayoclinic.org/tests-procedures/radiation-therapy/about/pac-20385162>. (The website was accessed on November 5, 2019.)

²³ Johns Hopkins Medicine, *Radical Prostatectomy*. <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/radical-prostatectomy>. (The website was accessed on November 5, 2019.)

²⁴ Deputy Under Secretary for Health for Operations and Management (10N), *10N Guide to VHA Issue Briefs*, June 26, 2017.

²⁵ John Hopkins Medicine, *Surgical Pathology*. <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/surgical-pathology>. (This website was accessed on December 6, 2019.)

transrectal ultrasound-guided prostate biopsy. A procedure which involves the insertion of an ultrasound probe into the rectum and, using sound waves to create images of the prostate, allows select areas of tissue to be sampled by needle biopsy for analysis.²⁶

²⁶ Cedars-Sinai, *Ultrasound-Guided Prostate Biopsy*. <https://www.cedars-sinai.edu/Patients/Programs-and-Services/Imaging-Center/For-Patients/Exams-by-Procedure/Ultrasound/Ultrasound-Guided-Prostate-Biopsy.aspx>. (The website was accessed on November 5, 2019.)

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