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VETERANS HEALTH ADMINISTRATION

Mismanaged Surgical Privileging Actions and Deficient Surgical Service Quality Management Processes at the Hampton VA Medical Center in Virginia

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to review surgical service and quality management concerns at the Hampton VA Medical Center (facility) in Virginia.

The OIG received a complaint in October 2022 alleging that a surgeon (surgeon A) provided poor surgical care to a patient. After reviewing the patient case and finding that the assistant chief of surgery rather than surgeon A provided the care, the OIG notified facility leaders in November 2022, with no response required. In December 2022, the OIG received a complaint, which included 5 patient case examples (5 cases), that the assistant chief of surgery provided poor surgical care and that the Chief of Staff was aware of the concerns but did not address them. Upon request from the OIG for additional information, the Veterans Integrated Service Network (VISN) responded that the facility conducted a focused clinical care review (FCCR) of 15 cases performed by the assistant chief of surgery and found that 6 cases did not meet the standard of care (6 substandard care cases).[1] After review of the response and documentation, the OIG had concerns related to the overall surgical service and quality review processes, including ongoing professional practice evaluations (OPPEs) and focused professional practice evaluations (FPPEs), peer review processes, and institutional disclosures. The OIG opened the hotline inspection in May 2023.[2]

During this review, the OIG identified widespread failures and deficiencies related to facility leaders' responses to clinical care concerns and subsequent privileging actions involving the assistant chief of surgery; professional practice evaluations of surgeons; surgical service quality management; and institutional disclosures. The findings identified through this inspection highlight not only failures of facility leaders to ensure that the required processes were appropriately implemented, but also a lack of leaders' basic understanding of the processes that support delivery of safe health care.

[1] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. The 15 cases included the 5 cases and an additional 10 cases; The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

[2] Another OIG inspection team previously conducted a separate inspection at the facility and found that leaders failed to document all required elements in an institutional disclosure. Specifically, facility leaders failed to provide information about potential compensation.

Mismanagement of Clinical Care Concerns

The OIG found that facility leaders conducted three FCCRs of the assistant chief of surgery's cases but mismanaged these quality reviews and resulting administrative actions.[3]

According to Veterans Health Administration (VHA) policy, the FCCR report must be maintained in the Practitioner Profile.[4] Facility medical bylaws state that FCCR results will be reported to the Medical Executive Committee (MEC) within 14 calendar days after completion.[5] Facility leaders failed to document the results of the three FCCRs in the assistant chief of surgery's Practitioner Profile; failed to report the results of two of the FCCRs to the MEC; and delayed reporting the results of one FCCR to the MEC by almost six weeks. As a result, MEC members did not have all information when making decisions and recommendations to facility leaders regarding privileging actions for the assistant chief of surgery. During interviews, the Chief of Staff acknowledged relying on support staff to ensure tracking of necessary items for the MEC. Additionally, facility leaders did not follow VHA's guidance to use multiple reviewers for interrater reliability in any of the FCCRs to ensure the reviews were "fair and objective," as required by VHA. The Chief of Staff reported being unaware of VHA's guidance on how to conduct FCCRs.

Based on the patient safety concerns, facility leaders issued a summary suspension of privileges letter to the assistant chief of surgery in January 2023, and a partial summary suspension of privileges letter in February 2023. Per VHA policy, "[a] summary suspension may be viewed as a 'time out' to ensure patient safety while an investigation is conducted, generally a Focused Clinical Care Review (FCCR)."[6] The policy outlines a procedure and examples to issue a summary suspension. To ensure patient safety, the chief of staff recommends a summary suspension to the facility director, who issues the action to suspend clinical privileges.[7] If the

[3] According to the Chief of Staff, FCCR 1 was initiated in response to the chief of surgery's concerns about the assistant chief of surgery's care; FCCR 2 was conducted to get a "more in-depth review" and identified the 6 substandard care cases; and FCCR 3 was conducted based on a recommendation from the facility's Medical Executive Committee. Twenty-seven total cases were reviewed.

[4] VHA Medical Staff Affairs, Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance," Revision 3, January 2018.

[5] VA Medical Center, Hampton, Virginia, *Bylaws and Rules of the Medical Staff*, 2020.

[6] VHACO Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners," (Standard Operating Procedure – P9), July 14, 2021. Summary suspensions may be triggered by events such as findings from an "FPPE or OPPE, clinical team member reports, patient complaints, or findings from internal reviews such as [peer reviews]."

[7] VHACO Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners"; VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was in place during the time of some of the events discussed in this report. It was rescinded and replaced by VHA Directive 1100.21, *Privileging*, March 2, 2023, and subsequently VHA Directive 1100.21(1), *Privileging,* March 2, 2023, amended April 26, 2023. Unless otherwise specified, the April 2023 directive contains the same or similar language regarding privileging as the rescinded 2012 handbook and March 2023 directive.

suspension exceeds 30 days, a letter should be sent every 30 days to advise the provider of the ongoing investigation. If the suspension is rescinded, the notification should be made in writing by the facility director. The OIG found that the February 2023 partial summary suspension letter was issued without referencing rescission of the January 2023 full summary suspension letter, and found no evidence of subsequent letters extending the summary suspension or rescissions of the February 2023 suspension. The OIG also found conflicting and unclear information between the two suspension letters and the MEC minutes. The Chief of Staff, who chairs the MEC, told the OIG that the MEC minutes contained inaccuracies that misrepresented the actual discussions; however, a better mechanism for recording minutes was implemented. Additionally, the Chief of Staff stated the letters were drafted by the Chief of Staff's office, in consultation with human resources and the Office of General Counsel, and claimed having received incorrect guidance. The OIG found, however, that neither human resources nor the Office of General Counsel provided consultation related to the January or February letters.

Further, upon review of the FCCR 2 findings of the 6 substandard care cases, the MEC recommended reduction of the assistant chief of surgery's robotic surgery privileges and noted that "actions will be reported to SLB [State Licensing Board] and NPDB [National Practitioner Data Bank]."[8] The OIG found that facility leaders did not send the proposal and decision letters in proper order and did not include all elements in the proposal letter to provide the assistant chief of surgery the necessary due process, as required by VHA. Facility leaders once again cited having received incorrect guidance from human resources when describing the events. When requested by the OIG, facility leaders were unable to provide evidence of incorrect guidance from human resources. Ultimately, the failures in adhering to required processes caused facility leaders to rescind the proposed actions and restore the associate chief of surgery's clinical privileges. However, the assistant chief of surgery transferred to another VA facility in June 2023, preventing facility leaders from correcting the process and taking additional privileging actions.[9] The OIG also found facility leaders failed to report the standard of care deficiencies to the assistant chief of surgery's state licensing board (SLB) despite a recommendation from the

[8] VHA Handbook 1100.17, *National Practitioner Data Bank (NPDB) Reports*, December 28, 2009. The NPDB is a tool "that prevents practitioners from moving state to state without disclosure or discovery of previous damaging performance." VHA requires facility directors to report health care providers to the NPDB if there is a final adverse clinical privilege action in effect for longer than 30 days. The OIG learned that facility leaders initially reported the assistant chief of surgery to the NPDB in April 2023, but then rescinded the NPDB notification. The OIG learned through interviews and documentation that facility leaders did not provide the assistant chief of surgery the due process required for the NPDB report. The OIG determined that facility leaders correctly rescinded the NPDB notification; however, due to the assistant chief of surgery no longer being employed with clinical privileges at the facility, the MEC did not have the jurisdiction to make a recommendation for a privileging action, which may have provided a basis for reporting to the NPDB.

[9] The receiving VA medical facility, according to its Chief of Staff, does not offer, nor have the capability to perform, robotic-assisted surgery; VISN human resources specialists told the OIG that privileging letters are typically issued by the Credentialing and Privileging (C&P) office rather than human resources when there is no associated personnel action. The OIG found that the facility leaders did not recommend any personnel action.

MEC. According to VHA, facility directors have ultimate decision-making authority to determine whether clinical care provided to a patient "so significantly failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients or community, such that reporting to an SLB is warranted." The professional's supervisor must notify the Credentialing and Privileging (C&P) manager within seven business days of identification of substandard care so that the SLB reporting process can be initiated immediately.[10] In an interview, the Facility Director stated the C&P manager was tasked to make the report; however, the Facility Director was unable to validate the report was made. The Chief of Staff, who oversees the C&P manager, told the OIG of having directed the C&P manager to make the report and that the report was never made.[11] The Facility Director and the Chief of Staff provided statements to the OIG that indicated confusion about the reporting process. Failing to report licensed independent practitioners (LIPs) with identified substandard care to the SLB may impact patient safety if the LIP practices elsewhere in the state board's jurisdiction.[12]

Deficiencies in Professional Practice Evaluations

In response to the OIG's November 2022 referral of the complaint concerning surgeon A, facility leaders presented the matter to the MEC in January 2023. The MEC recommended a focused professional practice evaluation for cause (FPPE for cause) for surgeon A. The OIG found deficiencies related to the completion of the FPPE for cause.

According to VHA, an FPPE for cause is "a customized opportunity for a provider to demonstrate improvement or requisite knowledge and skill" and for facility leaders to determine whether any action should be taken on the provider's privileges.[13] An FPPE for cause is accepted by the provider who agrees with what is reviewed; and has clearly defined benchmarks or milestones, outcomes, and clinical care expectations.[14]

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[10] VHA Directive 1100.18, *Reporting and Responding to State Licensing Boards*, January 28, 2021. "A VA-initiated report to a SLB is only notice to the SLB that there is a question of a professional's clinical practice;" it does not indicate a VA action against the provider's license. Additionally, an SLB may or may not investigate, or take formal action against a provider's license, consistent with that state's SLB policies and procedures.

[11] The Chief of Staff was unable to provide evidence supporting direction to the C&P manager. The OIG was unable to interview the C&P manager, who was on extended leave for the duration of the inspection.

[12] After completion of the inspection, the OIG learned from the SLB where the assistant chief of surgery was licensed that a VISN official submitted a report in February 2024.

[13] VHA Medical Staff Affairs, Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance"; VHA Directive 1100.21, *Privileging,* March 2, 2023; VHA Directive 1100.21(1), *Privileging,* March 2, 2023, amended April 26, 2023. The amended directive provided an updated list of requirements for FPPE for cause; however, due to the review period, the OIG is using the VHA Medical Staff Affairs 2018 guidebook. Unless otherwise specified, the amended directive contains the same or similar language regarding FPPE for cause as the VHA Medical Staff Affairs 2018 guidebook.

[14] VHA Medical Staff Affairs, Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance."

The OIG found that facility leaders delayed initiating an FPPE for cause for surgeon A, did not document required elements, and did not report results back to the MEC. Although recommended by the MEC in January 2023, an FPPE for cause for surgeon A was not initiated until April 2023 and not completed until July 2023, six months later. The Chief of Staff acknowledged these deficiencies and stated that the recommendation was not tracked in MEC minutes and that C&P staff have changed how the minutes were being documented and recorded.

Additionally, the OIG reviewed documentation of when surgeon A successfully completed an initial FPPE in March 2022. VHA guidance specifies that the FPPE is to be reviewed with the LIP, and that successful completion of an FPPE is reported to the MEC and then the LIP is transitioned to a semi-annual OPPE.[15] The OIG found that the chief of surgery delayed notifying surgeon A of the FPPE and subsequent transition to an OPPE until 11 months later.[16] The chief of surgery cited that the delay in reviewing the successful initial FPPE with surgeon A was due to holidays and leave.

The OIG also reviewed the OPPEs of three general surgeons and found that the chief of surgery failed to complete the outcome and conclusion sections on the OPPE forms. According to the chief of surgery, "my error is that I did not indicate on the forms that I verbally communicated these points to the providers."

Deficiencies in Surgical Service Quality Management Processes

The OIG found deficiencies within surgical service quality management processes. Surgical Service clinical staff failed to complete required patient safety reports. Facility policy requires all adverse events and close calls "be reported, as soon as the event is discovered, through the Joint Patient Safety Reporting (JPSR) system," and clarifies "When in doubt, fill out a . . . report via JPSR."[17] The OIG determined 4 of 6 substandard care cases cited in FCCR 2 lacked a JPSR report and that, in one of the cases, the JPSR report was entered over one month after the injury occurred. During interviews, surgical staff reported lack of knowledge of how to report JPSRs, lack of formal JPSR training, being unclear about the responsibilities for reporting, fearing retaliation or retribution, and viewing the process as punitive. The assistant chief of surgery reported lack of awareness about facility policy for addressing patient safety reporting, and not using JPSRs due to favoring morbidity and mortality (M&M) conferences and peer reviews, adding that reports were made to supervisory and quality assurance staff. When surgery staff do

[15] VHA Medical Staff Affairs, Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance."

[16] According to VHA, an LIP is transitioned to a semi-annual OPPE after successful completion of an FPPE is reported to the MEC. VHA Medical Staff Affairs, Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance."

[17] Facility Memorandum No. 11-28, *Patient Safety Improvement Program,* April 30, 2020.

not report patient safety concerns, this impedes process improvement and increases risk to patients.

The OIG determined surgical leaders held M&M conferences in a manner that potentially compromised the formal peer review process and resulted in negative staff experiences. Inconsistent with VHA policy, the facility's standard operating procedure referred to M&M conferences as "surgical M&M peer review[s]."[18] VHA's peer review policy was revised in 2018 and removed the allowance for facility group peer reviews. Interviews with facility surgeons revealed that M&M conferences were problematic citing the utilization of a rating system, similar to the peer review process, but involving non-clinical staff and non-specialty matched peers that voted to determine whether a case undergo a formal peer review. The surgeon who facilitated M&M conferences explained that this process was in place during the previous chief of surgery's leadership period and no substantial changes had been made to the process. The facilitator also described VHA guidance about M&M conferences as vague. The Director of the Office of Medical-Legal Risk Management explained to the OIG during an interview that multiple reviews could have a "chilling effect" on "[people's] perceptions of peer review" and negatively impact the integrity of the facility's peer review program.

The OIG also found deficiencies within the formal peer review process. VHA policy states unplanned injuries, including lacerations, tears or punctures, that occur during an invasive procedure "should be considered for peer review for quality management" and places responsibility for this identification with clinical service chiefs.[19] Through OIG's review of peer review-related documentation, the OIG found that facility leaders, rather than the chief of surgery, recognized the need for peer review of 3 substandard cases, which included lacerations, tears, or punctures that occurred during the surgeries. The chief of surgery told the OIG that only cases reviewed in M&M conferences that resulted in a level 2 or 3 rating would be referred to peer review and there was no process for bringing cases forward in any other manner.[20] VHA policy indicates that the chief of surgery ensures cases that should be considered for peer review are identified and communicated to the appropriate facility staff. Lack of an effective peer review process can affect short- and long-term improvement in patient care for clinicians, thus inhibiting organizational improvement and optimal patient outcomes.

[18] Facility Standard Operating Procedure (SOP) 112-09, *Surgical Service Mortality and Morbidity (M&M) Review,* July 1, 2020. This standard operating procedure did not indicate a governing document; however, the OIG found references to M&M conferences in two VHA policies: VHA Directive 1320, *Quality Management and Patient Safety Activities That Can Generate Confidential Records and Documents*, July 10, 2020, and VHA Directive 1102.01(2), *National Surgery Office*, April 24, 2019, amended April 19, 2022.

[19] VHA Directive 1190.

[20] Facility SOP 112-09. Level 2 categorization is defined as "Most experienced, competent practitioners MIGHT have managed the case DIFFERENTLY in one or more of the aspects." Level 3 categorization is defined as "Most experienced, competent practitioners WOULD HAVE managed the case DIFFERENTLY in one or more aspects."

In addition, the VISN Chief Medical Officer (CMO) and facility chief of quality, safety, and value failed to prevent a management review from including 2 cases that were being peer reviewed concurrently. VHA's policy states that a peer review and a management review for the same episode of care "must not occur concurrently," and "if the need for a management review can be anticipated, it is preferable to postpone the 38 U.S.C. § 5705-protected activity [peer review] until the management review is completed or cancel the protected activity."[21] The OIG found that while an FCCR was conducted between January and February 2023, and 15 cases were reviewed, 2 of these cases were also peer reviewed from December 2022 through June 2023. The Chief of Staff reported no awareness of how cases were identified for the FCCR. The VISN CMO told the OIG of recommending the facility include the 5 cases to determine whether the FCCR results would "confirm or refute" initial concerns. The VISN CMO told the OIG that "I was aware in general that peer reviews were completed or being conducted on the five concerning cases. . . [but] did not know the status or the details." The OIG would have expected leaders to either stop the peer reviews or not include the 2 cases in the FCCR. Concurrent peer reviews and management reviews combine protected and non-protected information, blurring the lines between protected peer reviews used for quality improvement and potentially adverse privileging or disciplinary actions.

Deficiencies in Institutional Disclosure Processes

The OIG determined that facility leaders generally did not communicate and document required institutional disclosure elements. Nine of 10 facility-wide institutional disclosures completed by facility leaders from July 2022 through May 2023 did not include "advisement about potential compensation" as required by VHA directive.[22] A risk manager explained to the OIG having misunderstood the VHA directive, interpreting the requirement to advise patients or their personal representatives of compensation only if they "specifically ask[ed] for it." None of the institutional disclosures conducted by the facility included the requirement of notifying the patient or family of the option to obtain outside medical or legal advice. The risk manager reported using the required electronic health record template and acknowledged not knowing how to proceed when the template did not contain all the elements as required by the VHA directive. The risk manager retroactively provided compensation information to patients who were not advised during institutional disclosures of a specified time frame; however, the OIG determined that the time frame was insufficient and potentially would not capture all affected institutional disclosures needing correction. Additionally, 9 institutional disclosures were conducted by telephone but did not indicate a reason why they were completed by telephone rather than in person, which is required by VHA policy. The risk manager, who co-conducted the institutional disclosures with the Chief of Staff, cited that the institutional disclosure note

[21] VHA Directive 1190.

[22] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients,* October 31, 2018.

template in the electronic health record lacks a specific field to enter a reason. The Chief of Staff's response was that the risk manager scheduled the meetings.

The OIG made one recommendation to the VISN Director regarding concurrent management reviews and peer reviews. Eleven recommendations were made to the Facility Director related to FCCRs, summary suspensions, proposed reduction or revocation of privileges, SLB reporting, FPPEs and OPPEs, patient safety reporting, M&M conferences, identification of cases for peer review, and institutional disclosures.

VA Comments and OIG Response

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

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Contents

Abbreviations

C&P	Credentialing and Privileging
CMO	Chief Medical Officer
EHR	electronic health record
FCCR	focused clinical care review
FPPE	focused professional practice evaluation
LIP	licensed independent practitioner
MEC	Medical Executive Committee
M&M	morbidity and mortality
NPDB	National Practitioner Data Bank
OGC	Office of General Counsel
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
SLB	state licensing board
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to review surgical service and quality management concerns at the Hampton VA Medical Center (facility) in Virginia.

Background

The facility, part of Veterans Integrated Service Network (VISN) 6, serves southeastern Virginia and northeastern North Carolina and provides an array of services including inpatient care, surgery, and primary and specialty outpatient care. From October 1, 2021, through September 30, 2022, the facility served 66,537 patients.[1]

The facility's surgical complexity is categorized as "inpatient intermediate."[2] The facility offers surgical specialties including cardiac, ear, nose, and throat, general, ophthalmology, orthopedic, plastic, podiatry, urology, and vascular surgery. From January 1, 2022, through December 31, 2022, the facility completed 2,023 surgical procedures, including 231 robotic-assisted surgical procedures.[3]

Within the facility's Surgical Service, four licensed independent practitioners (LIPs), including the chief of surgery, assistant chief of surgery, and two general surgeons, were privileged as of November 2021 to perform robotic-assisted surgical procedures.[4] In February 2023, the Chief of Staff detailed the chief of surgery out of the leadership position and into the role of general surgeon after receiving allegations of clinical oversight concerns in the Surgical Service. The

[1] The facility is designated as a level 1c facility, which has "medium-high volume, medium risk patients, some complex clinical programs, and medium sized research and teaching programs." VHA Office of Productivity, Efficiency, and Staffing, "Facility Complexity Model Fact Sheet," January 28, 2021. The VHA Facility Complexity Model categorizes medical facilities as levels 1a, 1b, 1c, 2, or 3, with level 1a being the most complex and level 3 being the least complex.

[2] VHA Directive 1220(1), *Facility Procedure Complexity Designation Requirements to Perform Invasive Procedures in any Clinical Setting*, May 13, 2019, amended February 11, 2020. "Inpatient intermediate invasive procedures require an ICU [Intensive Care Unit] with a dedicated intensivist to make daily rounds and provide consultative services; the capability to monitor recovering patients on the ward; medical specialists and services available to care for anticipated complications and co-morbid conditions associated with intracavitary procedures and patients receiving these procedures including nephrology and dialysis, infectious disease, hematology/oncology, pulmonary, cardiology, interventional cardiology and interventional radiology; and immediately available clinicians privileged in thoracic and vascular surgery to respond to foreseeable complications."

[3] Robotic-assisted laparoscopic surgery is a minimally invasive surgical technique that combines the use of robotic systems and laparoscopic instruments. It allows surgeons to perform complex procedures with enhanced precision, dexterity, and control. Evalyn I. George et al., "Origins of Robotic Surgery: From Skepticism to Standard of Care," Journal of The Society of Laparoscopic & Robotic Surgeons, no. 22 (October – December 2018), https://doi:10.4293/JSLS.2018.00039.

[4] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

Chief of Staff moved the chief of surgery's detail offsite in March after receiving allegations of a hostile work environment.

Beginning in February 2023, the Chief of Staff served dually as Chief of Staff and as the acting chief of surgery. The Chief of Staff reported managing administrative-related matters since March while in the chief of surgery role, and clinical-related matters were assigned to the assistant chief of surgery.[5] In early June 2023, the assistant chief of surgery transferred to another VA medical facility, and approximately one month later, a facility ophthalmologist assumed the assistant chief of surgery clinical oversight duties. The Chief of Staff reinstated the previously-detailed chief of surgery back into the leadership role on September 7, 2023.

VHA Quality and Safety Programs

Veterans Health Administration (VHA) Quality and Patient Safety programs support a "framework promoting safe, timely, effective, efficient, and equitable patient-centered healthcare services."[6] Quality management programs ensure VHA is "hiring the right providers . . . screening for deviations from standards of care, and keeping our facilities in a continuous state of readiness and compliance with industry standards."[7]

Prior OIG Reports

In a September 2023 report, the OIG found that facility leaders failed to document all required elements in an institutional disclosure. Specifically, facility leaders failed to provide information about potential compensation "because the family member did not ask about it." The OIG made seven recommendations, including one recommendation related to institutional disclosure for a patient. As of February 2024, the recommendation regarding institutional disclosure was closed and six recommendations remain open.[8]

In a June 2022 report, the OIG determined that facility leaders did not initiate peer reviews for quality management as required by VHA policy, and facility staff did not submit patient safety reports as required by facility policy.[9] The OIG made seven recommendations, including staff

[5] The Chief of Staff is a hospitalist, did not report any surgical training to the OIG, and was not board certified in any surgical specialty during the inspection period.

[6] VHA Quality and Patient Safety, accessed September 27, 2023, https://vaww.qps.med.va.gov/default.aspx. (This website is not publicly accessible.)

[7] VHA Quality and Patient Safety, accessed September 27, 2023.

[8] VA OIG, *Delay in Diagnosis and Treatment for a Patient with a New Lung Mass at the Hampton VA Medical Center in Virginia*, Report No. 22-02800-225, September 29, 2023.

[9] For this report, a peer review for quality management is referred to as a peer review.

submission of patient safety reports and initiation of timely quality reviews. As of December 2023, all recommendations have been closed.[10]

In December 2021, the OIG published a comprehensive healthcare inspection report, which included opportunities for improvement in several areas. The OIG made six recommendations, one related to Surgical Workgroup meeting attendance; all recommendations have been closed.[11]

Allegations and Related Concerns

In October 2022, the OIG received a complaint alleging that a surgeon (surgeon A), while assisting the assistant chief of surgery, provided poor surgical care to a patient. The complaint included a patient case example. The OIG reviewed the patient case in the electronic health record (EHR) and, after finding surgeon A did not provide the care, sent the concern to facility leaders on November 7, with no response required from facility leaders.[12]

In December 2022, the OIG received a complaint alleging that the assistant chief of surgery provided poor surgical care and that the Chief of Staff was aware of the concerns but did not address them. The complaint included 5 patient cases (5 cases) as examples.[13] The OIG reviewed the allegations and the 5 cases and, in January 2023, sent a request to the VISN for further review and response. The OIG received a response in March and, after review, requested additional information from the VISN in April. According to the response, the VISN sent the review request to the facility. The Facility Director requested a focused clinical care review (FCCR) of 15 patient cases performed by the assistant chief of surgery, which included the 5 cases and an additional 10 randomly-selected robotic-assisted surgery cases.[14] The reviewer determined that 6 of the 15 cases did not meet the standard of care (6 substandard care cases); furthermore, 4 of the 15 cases reviewed had intraoperative complications.[15] Specifically,

- A patient underwent robotic-assisted laparoscopic surgery to place a diverting colostomy due to a diagnosis of rectal cancer. The FCCR reviewer noted concerns with choice of surgical procedure and with timing of surgery in close proximity to chemoradiation therapy.
- A patient with Crohn's disease underwent robotic-assisted laparoscopic surgery, which was converted to an open procedure after "several hours," to remove a fistula between the

[10] VA OIG, *Multiple Failures in Test Results Follow-up for a Patient Diagnosed with Prostate Cancer at the Hampton VA Medical Center in Virginia,* Report No. 21-03349-186, June 28, 2022.

[11] VA OIG, *Comprehensive Healthcare Inspection of the Hampton VA Medical Center in Virginia,* Report No. 21-00278-23, December 14, 2021.

[12] The assistant chief of surgery provided the care.

[13] The 5 cases included the patient case example from the October 2022 complaint.

[14] This FCCR is later discussed as FCCR 2 under Inspection Results.

[15] VHA Directive 1190. The FCCR reviewer determined 3 of the 5 cases did not meet standard of care and 3 of the additional 10 cases did not meet standard of care.

small bowel and bladder and repair the bladder and the bowel. The FCCR reviewer had concerns with the choice of anastomosis and noted that the surgery should have been converted to an open procedure sooner.

- A patient experienced laceration of the liver during placement of the initial trocar during a robotic-assisted surgery that was planned to remove part of the colon due to a diagnosis of cancer in a colon polyp. Surgeons worked to control the bleeding, anesthesia stabilized the patient, and the surgical procedure was aborted. The patient subsequently chose to transfer care to a surgeon in the community to remove the cancerous part of the colon. The FCCR reviewer noted concerns regarding the choice of trocar insertion point in the right upper quadrant of the abdomen.
- A patient underwent a robotic-assisted laparoscopic sigmoid colectomy for recurrent diverticulitis with findings of an abdominal wall abscess. The postoperative course was complicated by anastomotic leak, abscess, and colocutaneous fistula. The FCCR reviewer had concerns with the decision to continue the procedure robotically rather than converting to an open procedure due to the severity of inflammation and infection.
- A patient underwent a robotic-assisted laparoscopic sigmoid colectomy for diverticulitis. The surgery was complicated by injury to the liver and gallbladder during placement of the trocar resulting in bile leakage requiring a second surgery to remove the gallbladder. The FCCR reviewer had concerns regarding the trocar injury.
- A patient with chronic obstructive pulmonary disease underwent robotic-assisted transanal surgery to remove a rectal cancer. The FCCR reviewer's concerns were related to the choice to perform the surgery robotically resulting in a longer time under anesthesia given the patient's pulmonary condition.

Additionally, the response included that, according to the facility's Chief of Staff, there were no clinical concerns raised about the assistant chief of surgery until November 2022.

After review of the responses, the OIG opened the hotline inspection in May 2023 to assess surgical service and quality review processes, including ongoing professional practice evaluations (OPPEs) and focused professional practice evaluations (FPPEs), morbidity and mortality (M&M) conferences, peer review processes, and institutional disclosures. During the inspection, the OIG identified additional concerns with facility leaders' responses to clinical care concerns involving the assistant chief of surgery and subsequent privileging actions, and patient safety reporting.

Scope and Methodology

The OIG initiated the inspection on May 4, 2023, performed an on-site visit the week of June 27, 2023, and conducted virtual interviews through January 16, 2024.

The OIG interviewed facility executive leaders, Surgical Service leaders, a quality management leader, a risk manager, a patient safety manager, physicians, a nurse leader, a surgical quality nurse, a Credentialing and Privileging (C&P) specialist, and a surgical nurse; VISN Chief Medical Officer, C&P officer, and human resources specialists; and VHA leaders from the Office of C&P, the National Surgery Office, the Office of Medical-Legal Risk Management, and the National Center for Patient Safety. In addition, the OIG interviewed an Office of General Counsel staff attorney.

The OIG reviewed facility medical bylaws; committee charters, minutes, and attendance; administrative reviews and reports; LIP privileging documents; and reports in response to quality management issues. The OIG reviewed relevant EHRs, including the 5 cases. The OIG also reviewed relevant VHA and facility policies and procedures related to surgery and quality management processes.

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, as amended, 5 U.S.C. §§ 401–424. 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.

Inspection Results

The OIG found widespread failures and deficiencies with facility processes related to the privileging actions and professional practice evaluations of surgeons, surgical service quality management, and institutional disclosures.

1. Mismanagement of Clinical Care Concerns

The OIG learned through document review and interviews that facility leaders reviewed the assistant chief of surgery's clinical performance and took privileging actions after becoming aware of clinical care concerns. The OIG identified failures and deficiencies with these actions.

VHA has defined procedures for the clinical privileging of LIPs.[16] VHA describes "the intent of the privileging process is to ensure that LIP[s] have privileges that define their approved clinical duties, and that those privileges are based on current competence within the scope of the mission of the VA medical facility, and other relevant privileging criteria defined within the Medical Staff Bylaws."[17] The Medical Executive Committee (MEC), chaired by the Chief of Staff, is responsible for reviewing LIPs' privileges through processes such as OPPEs, FPPEs, focused professional practice evaluations for cause (FPPEs for cause), and FCCRs.[18] The chief of staff proposes privileging recommendations to the facility director who can take actions such as granting, denying, summary suspension, reduction, or revocation of privileges.[19] Some of these privileging actions necessitate reporting to a state licensing board (SLB) or the National Practitioner Data Bank (NPDB).[20]

Failures in Focused Clinical Care Reviews

The OIG determined that facility leaders failed to document the results of three FCCRs in the assistant chief of surgery's Practitioner Profile. Additionally, facility leaders failed to report the results of two of the three FCCRs and delayed reporting the results of one FCCR to the MEC.

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[16] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was in place during the time of some of the events discussed in this report. It was rescinded and replaced by VHA Directive 1100.21, *Privileging*, March 2, 2023, and subsequently VHA Directive 1100.21(1), *Privileging,* March 2, 2023, amended April 26, 2023. Unless otherwise specified, the April 2023 directive contains the same or similar language regarding privileging as the rescinded 2012 handbook and March 2023 directive.

[17] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).

[18] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1); VHA Medical Staff Affairs, Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance," Revision 3, January 2018; VHACO Medical Staff Affairs, "Medical Staff Leadership Structure," (Standard Operating Procedure – P1), Version 2, November 16, 2020.

[19] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).

[20] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1); VHA Directive 1100.18, *Reporting and Responding to State Licensing Boards*, January 28, 2021; VHA Handbook 1100.17, *National Practitioner Data Bank (NPDB) Reports*, December 28, 2009.

The OIG found that facility leaders did not follow VHA's guidance for any of the three FCCRs to ensure interrater reliability.

According to VHA, an FCCR is "an objective, fact finding process" involving a comprehensive clinical review of a provider's practice when a clinical concern has been identified.[21] An FCCR can result in privileging actions or reporting an LIP to the SLB.[22] The FCCR report must be maintained in the Practitioner Profile.[23] According to facility medical bylaws, FCCR results will be reported to the MEC within 14 calendar days after completion.[24]

The OIG found facility leaders conducted three FCCRs of the assistant chief of surgery's cases, totaling 27 cases reviewed, in response to clinical care concerns (see table 1).[25] Six substandard care cases were identified through FCCR 2.

[21] VHA Directive 1100.21; VHA Directive 1100.21(1). An FCCR is initiated by the Chief of Staff after either a clinical service chief brings forward concerns or "when a clinical performance concern has been triggered such as, but not limited to, not meeting FPPE or OPPE criteria for success, Level 3 peer review findings, concerns raised by treatment team members, sentinel events, or an unexpected patient care outcome." An FCCR "is typically completed through a retrospective file review but may also be completed through direct observation."

[22] VHA Directive 1100.21(1).

[23] VHA Medical Staff Affairs, Quality, Safety, and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance."

[24] VA Medical Center, Hampton, Virginia, *Bylaws and Rules of the Medical Staff*, 2020.

[25] According to the Chief of Staff, FCCR 1 was initiated in response to the chief of surgery's concerns about the assistant chief of surgery's care; FCCR 2 was conducted to get a "more in-depth review" of 15 robotic cases; and FCCR 3 was conducted based on the MEC's recommendation for a review of open cases.

Table 1. Summary of FCCRs for the Assistant Chief of Surgery

FCCR	Number of Reviewers	Total Number of Cases Reviewed or Observed	Review Completion Date	FCCR Results
1	1	5 robotic cases by direct observation	January 4–6, 2023	Assistant chief of surgery is "competent."*
2	1	15 robotic cases‡	February 14, 2023	6 substandard care cases
3	2	9 cases§ (Reviewer A: 4 cases; Reviewer B: 5 cases)	April 26, 2023	0 substandard care cases
		27 Total Cases		

Source: OIG analysis of completed case reviews.
**The FCCR 1 reviewer told the OIG that facility leaders requested observation to determine whether the assistant chief of surgery was "unsafe," and found the assistant chief of surgery to be a "a competent surgeon, and competent robotic surgeon" who is "at times unsure [of abilities]." The reviewer recommended that the assistant chief of surgery "resume all operative procedures," that a surgical assistant be available for all procedures to decrease surgical length, that two general surgeons operate "on the more complex surgical procedures," and suggested that "the four general surgeons rotate assisting each other rather than having separate teams. This will foster teamwork among the group, as it seems very divided."*
‡Five of the 15 cases were included in the OIG hotline complaint.
§Two of the 9 cases were included in FCCR 2 and found to be substandard care. One of the 2 cases was included in the OIG hotline complaint.

The OIG reviewed the assistant chief of surgery's Practitioner Profile and found no documentation of the results for any of the three FCCRs.

The OIG reviewed MEC minutes from February through July 2023 and found no documentation that the results of FCCR 1 or FCCR 3 were provided to the MEC. The results of FCCR 2 were presented to the MEC on March 27, 2023, almost six weeks after completion of the report, thus not meeting the facility's 14-day requirement.[26] During an interview, the Chief of Staff reported relying on support staff to ensure tracking of necessary items for the MEC and being unaware of VHA's guidance on how to conduct FCCRs. Because the MEC did not receive the results of FCCR 1 and FCCR 3, and the results of FCCR 2 were delayed, MEC members did not have all of the information available to them when making recommendations to facility leaders regarding privileging actions for the assistant chief of surgery.

Additionally, the OIG found that facility leaders utilized less than three reviewers to evaluate cases when conducting each of the three FCCRs. According to VHA, an FCCR "must be fair and objective," "should ideally be performed by three objective reviewers of similar

[26] The MEC recommended reduction of robotic privileges and an FPPE for cause with an external review of open surgeries since January 2022. Facility, *Bylaws and Rules of the Medical Staff*, 2020.

practice/specialty and clinical privileges," and "can be split between the three reviewers with each reviewer given the same 2–3 cases for interrater reliability evaluation."[27] When interviewed, the Chief of Staff was unaware of VHA guidance recommending multiple reviewers for FCCRs.

The OIG concluded facility leaders failed to follow VHA guidance related to FCCRs. The OIG found that the results of the three FCCRs were not included in the Practitioner Profile, which includes specific clinical practice data and supports the privileging process. Additionally, two of the three FCCR results were not provided to the MEC, and the FCCR that was reported to the MEC was not reviewed within the time frame required by facility policy. As such, this limited the MEC's knowledge of all reviews, which could have fully informed MEC members' decisions and recommendations about privileging actions regarding the assistant chief of surgery. Further, facility leaders' use of one reviewer in the evaluation of FCCR cases does not meet the intent of VHA guidance to ensure interrater reliability, and the OIG questions whether the three FCCRs met the requirement of a fair and objective review of the assistant chief of surgery's clinical care.

Summary Suspension

The OIG found facility leaders did not follow VHA policy or recommended guidance for issuing a summary suspension of privileges to the assistant chief of surgery. During the review of the assistant chief of surgery's summary suspension, the OIG found several inconsistencies in the process related to letters outlining the suspension, documentation in meeting minutes, and actions taken by the Facility Director. Specifically,

- a January 2023 summary suspension letter and a February 2023 summary suspension letter did not utilize the templated language recommended in the VHA standard operating procedure,
- the two letters were inconsistent as to whether the provider's clinical privileges were fully or partially suspended,
- the information documented in February MEC minutes about the summary suspension conflicted with the February summary suspension letter, and
- the Facility Director did not issue additional suspension letters after February and did not rescind the suspension.

Per VHA policy, a summary suspension is an action taken by a facility director to suspend clinical privileges when "the failure to take such action may result in an imminent danger to the

[27] VHA Medical Staff Affairs, Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance"; VHA Medical Staff Affairs, Quality, Safety, and Value, "Focused Clinical Care Reviews" (flow chart), "Three reviewers are ideal - one reviewer may not be reliable, two reviewers may disagree, three reviewers ensures there is a 'tie breaker.'"

health and safety of any individual."[28] The chief of staff recommends a summary suspension to the facility director to ensure patient safety.[29] "A summary suspension may be viewed as a 'time out' to ensure patient safety while an investigation is conducted, generally a Focused Clinical Care Review (FCCR)."[30] VHA policy outlines a procedure to issue a summary suspension and provides templated examples for the summary suspension letter and the extension to the summary suspension letter.[31]

Summary suspensions should be reported to the MEC; however, because "the purpose of a summary suspension is to quickly address imminent concerns of safety," a facility director should not wait to convene a committee meeting for discussion to summarily suspend a privileged practitioner's privileges.[32] If the suspension lasts longer than 30 days, a letter should be sent every 30 days to advise the provider of the ongoing investigation. If the investigation leads to a privileging action, "the summary suspension should remain in place until the privileging action and associated human resource actions are finalized."[33] If a summary suspension is rescinded, the notification should be made in writing by the facility director.

On January 9, 2023, the Facility Director sent the assistant chief of surgery a summary suspension letter stating:

> your clinical privileges are summarily suspended effective immediately. This action is being taken upon the recommendation of the Chief of Staff as concerns have been raised to suggest concerns of your clinical practice. This suspension is in effect pending a comprehensive investigation of these concerns.

A second letter was issued on February 2, 2023, by the interim Facility Director, informing the assistant chief of surgery of a partial summary suspension of privileges without referencing a rescission of the full summary suspension issued the month before:

> as of February 9, 2023, your clinical privileges for robotic procedures will remain summarily suspended for an additional 30 days (March 10, 2023). This suspension remains in effect while we await the receipt of the comprehensive review of the allegations under investigation.[34]

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[28] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).

[29] VHACO Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners," (Standard Operating Procedure – P9*),* July 14, 2021.

[30] VHACO Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners." Summary suspensions may be triggered by events such as findings from an "FPPE or OPPE, clinical team member reports, patient complaints, or findings from internal reviews such as [peer reviews]."

[31] VHACO Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners."

[32] VHACO Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners."

[33] VHACO Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners."

[34] The Chief of Staff was acting as the interim Facility Director.

The OIG determined that neither the January 9 nor February 2, 2023, letters conformed to recommended language provided by VHA guidance, including that aspects of the assistant chief of surgery's clinical practice did not meet the "accepted standards of practice" and "potentially constitute an imminent threat to patient welfare." In addition, there was no explanation of "the specific event which triggered the concern."[35]

The OIG found the summary suspension letters were inconsistent regarding which privileges had been suspended, as the January letter indicated "clinical privileges" and the February letter indicated "clinical privileges for robotics." The Chief of Staff stated the letters were drafted by the Chief of Staff's office, in consultation with human resources and the Office of General Counsel (OGC), and claimed having received incorrect guidance. The OIG found, however, that neither human resources nor OGC provided consultation related to the January or February letters.

The OIG reviewed MEC minutes and found the summary suspension was presented to the MEC by the Chief of Staff in February and March 2023. The OIG noted a discrepancy between the February 2023 MEC minutes that stated, "the summary suspension will be in place on ALL privileges performed in the operating room" and the language in the February 2 letter issued to the assistant chief of surgery that only referenced suspending robotic privileges.[36] The March 2023 MEC minutes also reflected the summary suspension pertained to all privileges. Due to the conflicting language—suspension of all privileges or suspension of robotic privileges—the OIG was unable to determine the extent of the assistant chief of surgery's loss of privileges. According to the Chief of Staff, "in re-reviewing these [MEC] minutes . . . there are things that are not accurate, that do not reflect what was actually communicated during the course of the meeting."

Facility leaders, when asked by the OIG, were unable to provide a letter extending the February 2 summary suspension of privileges, which should have been issued on or around March 10, 2023. The Chief of Staff acknowledged, "there should have been additional letters." In addition, the OIG found the Acting Chief of Staff, rather than the Facility Director, signed a letter dated May 23, 2023, clarifying that there were no limitations on the assistant chief of surgery's clinical privileges.[37]

The OIG found several inconsistencies in letters, documentation, and actions taken by the Facility Director related to the summary suspension of the assistant chief of surgery. In addition, the Facility Director did not follow VHA policy or guidance for issuing a summary suspension. Due to these inconsistencies, the OIG was unable to determine which clinical privileges the

[35] VHACO Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners."

[36] The OIG found the assistant chief of surgery did not perform any surgical procedures not permitted during the time frame privileges were suspended from January 9–May 23, 2023.

[37] The Acting Chief of Staff provided short-term coverage for the Chief of Staff.

assistant chief of surgery maintained throughout this process as some documentation referred to "all" privileges and other documentation stated "clinical privileges for robotic procedures" were suspended. These inconsistencies had the potential to affect patient care as the assistant chief of surgery was not made aware of which privileges were suspended, affecting the level of services available for patients. Additionally, failure to correctly follow VHA process procedures related to summary suspension is unfair to LIPs who are entitled to accurate notice consistent with due process.

Failed Attempt to Reduce Privileges

The OIG determined that facility leaders failed to follow VHA policy when reducing the assistant chief of surgery's privileges. Specifically, facility leaders sent the proposal and decision letters out of order and did not include all required elements in the proposal letter to provide the assistant chief of surgery the necessary due process.

When evidence supports "substandard care, professional misconduct, or professional incompetence performed by a privileged LIP," facility leaders can propose two types of privileging adverse actions (adverse privileging actions): a *reduction* of privileges or a *revocation* of privileges.[38]

VHA and facility policy require that when the MEC recommends reducing an LIP's privileges, the recommendation is forwarded to the facility director for review and tasked to the Chief of Staff for appropriate administrative action.[39] The Chief of Staff provides written notice to the LIP of the proposed adverse privileging action, potential reporting to the NPDB, and an opportunity for the LIP to request evidence and respond within 10 business days to the proposed adverse action in writing.[40] The facility director makes a final determination.[41]

According to the MEC minutes dated March 27, 2023, the committee recommended to reduce the assistant chief of surgery's robotic privileges following a review of the FCCR 2 results.[42] In a letter dated April 13 (reduction of privileges letter), the Facility Director informed the assistant chief of surgery that the MEC recommended an involuntary reduction of the LIP's robotic privileges and that "This Involuntary Reduction of your clinical privileges for concerns of

[38] VHA Handbook 1100.19; VHA Directive 1100.21, *Privileging,* March 2, 2023; VHA Directive 1100.21(1), *Privileging,* March 2, 2023, amended April 26, 2023.

[39] VHA Handbook 1100.19; VHA Office of Quality and Patient Safety, "Reduction of Privileges: Supplemental Reference to VHA Handbook 1100.19," https://vaww.qps.med.va.gov/divisions/qm/msa/AdverseActions/aaLanding.aspx. (This website is not publicly accessible.); Facility, *Bylaws and Rules of the Medical Staff*, 2020.

[40] VHA, "Reduction of Privileges: Supplemental Reference to VHA Handbook 1100.19."

[41] VHA Handbook 1100.19; VHA 1100.21, *Privileging,* March 2, 2023; VHA Directive 1100.21(1), *Privileging,* March 2, 2023, amended April 26, 2023.

[42] The Chief of Staff signed the MEC minutes on April 27 and the Facility Director signed May 1.

Clinical competency is reportable to the National Practitioner Data Bank (NPDB)," and "If you disagree with the decision . . . you may request a hearing." The assistant chief of surgery requested, in a letter dated April 24 to the Facility Director, the "evidence considered by the MEC in rendering its determination" and a hearing. In a letter dated May 8 (written notice of proposal), the Chief of Staff advised the assistant chief of surgery of the proposal to reduce clinical privileges for robotic surgery. The following day, on May 9, the Chief of Staff issued another letter to the assistant chief of surgery rescinding the Facility Director's April 13 letter. The Acting Chief of Staff signed a letter dated May 23, clarifying that both the April 13 and May 8 letters were rescinded and that there were no limitations on the assistant chief of surgery's clinical privileges. On June 4, the assistant chief of surgery transferred to another VA medical facility.[43]

The OIG found that the Facility Director's April 13, 2023, reduction of privileges letter failed to provide adequate notice to the assistant chief of surgery of the proposal to reduce privileges, and was sent out of order with the Chief of Staff's May 8 written notice of proposal. The OIG also found the Chief of Staff's May 8 proposal letter failed to include notification of potential reporting to NPDB.

In response to why the April 13, 2023, reduction of privileges decision letter was issued before the May 8 written notice of proposal, the Facility Director told the OIG that leaders did not receive the "appropriate feedback from the [human resources]," however acknowledged, "we didn't catch it either."[44] The Chief of Staff acknowledged that the proposal letter did not contain the required elements due to incorrect guidance from human resources and, therefore, had it rescinded.[45] When requested by the OIG, facility leaders were unable to provide evidence of incorrect guidance from human resources.[46] The Chief of Staff reported the intention to recommence the adverse privileging action but the process was halted when the assistant chief of surgery transferred to another facility.

The OIG concluded that facility leaders failed to follow adverse privileging action requirements, which resulted in facility leaders rescinding proposed actions and restoring the associate chief of surgery's clinical privileges. The assistant chief of surgery's transfer to another VA health care facility in early June 2023 precluded facility leaders from correcting the process, including initiating additional actions.

[43] The receiving VA medical facility, according to its Chief of Staff, does not offer, nor have the capability to perform, robotic-assisted surgery.

[44] VISN human resources specialists told the OIG that privileging letters are typically issued by the C&P office rather than human resources when there is no associated personnel action. The OIG found that the facility leaders did not recommend any personnel action.

[45] According to the Chief of Staff, letters were drafted by staff within the Office of Chief of Staff.

[46] Other documented consultation with VISN human resources and OGC occurred in May 2023.

Related Concern: Misuse of Adverse Privileging Action Terminology

Upon review of the documents related to the assistant chief of surgery's adverse privileging action, the OIG found multiple examples of facility leaders' misuse of the term *revocatio*n of privileges instead of *reduction* of privileges in

- MEC meeting minutes on April 6,
- a sentence in the letter dated April 13 stating, "If you disagree with the decision that this reduction in privileges constitutes a revocation of your Robotic Surgery clinical privileges, you may request a hearing," and
- information recorded in VetPro.[47]

The Chief of Staff voiced understanding of the differences between the two adverse privileging actions; however, although the March and April MEC minutes were signed by the Chief of Staff, there was no awareness of the improper use of *revocation*, when the intended term was *reduction* of privileges. The OIG concluded that the manner in which both terms were used caused confusion with the privileging process.

Failure to Report Surgeon to State Licensing Board

The OIG determined facility leaders did not report identified standard of care deficiencies to the assistant chief of surgery's SLB.

VHA has broad authority to report appointed or separated VHA-licensed healthcare professionals to each SLB where the professional holds a license when substantial evidence indicates that the professional's clinical practice significantly failed to meet generally accepted standards.[48] VHA policy states that facility directors have ultimate decision-making authority to determine whether clinical care provided to a patient "so significantly failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients or community, such that reporting to an SLB is warranted."[49] In such cases, the professional's supervisor must notify the C&P manager within seven business days of identification of

[47] VHA Directive 1100.21; VHA Directive 1100.21(1); VHA requires VetPro be used for the credentialing process.
[48] VHA Directive 1100.18.
[49] VHA Directive 1100.18.

substandard care so that the SLB reporting process can be initiated immediately.[50] Facility C&P managers are "responsible for reporting licensed providers to respective state licensing boards."[51]

The OIG found facility leaders did not report the assistant chief of surgery to the SLB. On March 27, 2023, the MEC recommended reduction of the assistant chief of surgery's robotic surgery privileges based on the FCCR 2 findings of 6 substandard care cases and noted "actions will be reported to SLB and NPDB."[52]

During an interview with the OIG in July 2023, the Facility Director stated that, according to the Chief of Staff, the assistant chief of surgery was reported to the SLB. In a follow-up interview, the Facility Director stated the C&P manager was tasked to make the report; however, the Facility Director was unable to validate the report was made. The Chief of Staff, who oversees the C&P manager and is the Chair of the MEC, told the OIG of having directed the C&P manager to make the report to the SLB and that the report was never made.[53] In late-September, the OIG team conveyed preliminary findings to the Facility Director, who made statements that confounded the reporting to the NPDB with the SLB. In mid-October, the OIG received an unsolicited email from the Chief of Staff, stating that the SLB report was made at the time the NPDB report was completed,

> I am informed that in completing this form there is a button that clicks and sends to SLB. However after the direction from OGC to rescind the reporting for both NPDB and SLB, the record for the provide [provider] was expunged. Additionally corrections were made to Vetpro to remove entry.[54]

VHA policy on SLB reporting provides specific procedures on how to make an SLB report, which does not involve reporting to an SLB through a "button." Furthermore, the OIG queried

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[50] VHA Directive 1100.18. "A VA-initiated report to a SLB is only notice to the SLB that there is a question of a professional's clinical practice;" it does not indicate a VA action against the provider's license. Additionally, an SLB may or may not investigate, or take formal action against a provider's license, consistent with that state's SLB policies and procedures; Beginning in February 2023, the Chief of Staff served as the acting chief of surgery for administrative-related matters.

[51] VHA Directive 1100.18.

[52] VHA Handbook 1100.17. The NPDB is a tool "that prevents practitioners from moving state to state without disclosure or discovery of previous damaging performance." VHA requires facility directors to report health care providers to the NPDB if there is a final adverse clinical privilege action in effect for longer than 30 days. The OIG learned that facility leaders initially reported the assistant chief of surgery to the NPDB in April 2023, but then rescinded the NPDB notification. The OIG learned through interviews and documentation that facility leaders did not provide the assistant chief of surgery the due process required for the NPDB report. The OIG determined that facility leaders correctly rescinded the NPDB notification; however, due to the assistant chief of surgery no longer being employed with clinical privileges at the facility, the MEC did not have the jurisdiction to make a recommendation for a privileging action, which may have provided a basis for reporting to the NPDB.

[53] The Chief of Staff was unable to provide evidence supporting direction to the C&P manager. The OIG was unable to interview the C&P manager, who was on extended leave for the duration of the inspection.

[54] After completion of the inspection, the OIG learned from the SLB where the assistant chief of surgery was licensed that a VISN official submitted a report in February 2024.

the OGC attorney, who stated, "I was never asked for guidance on SLB reporting concerning this case."

The OIG determined FCCR 2, which identified 6 substandard care cases, should have triggered the Facility Director to make a report to the SLB where the assistant chief of surgery was licensed. Reporting to the SLB avoids the appearance of VA "sheltering or protecting its professionals from reasonable reporting standards which apply in the non-VA health care community."[55]

The OIG found that facility leaders conducted FCCRs in a manner that did not provide objective reviews of the assistant chief of surgery's clinical care, and not all of the results of those reviews were shared with the MEC, which limited awareness of all information prior to making decisions and recommendations. The resulting summary suspension letters and adverse privileging actions were not completed in accordance with VHA policy. Additionally, the Facility Director did not report the assistant chief of surgery to the SLB. In summary, these deficiencies in privileging actions not only impact the LIP's due process, but also raise patient safety concerns. Failing to report LIPs with identified substandard care to the SLB may impact patient safety if the LIP practices elsewhere in the state board's jurisdiction.

2. Deficiencies in Professional Practice Evaluations

Focused Professional Practice Evaluation for Cause

The OIG determined that facility leaders delayed initiating an FPPE for cause for surgeon A, documentation did not contain all required elements, and results were not reported back to the MEC. The Chief of Staff told the OIG of becoming aware of concerns regarding surgeon A's clinical care after receiving the OIG referral sent on November 7, 2022, and two peer reviews. The OIG found the MEC recommended an FPPE for cause for surgeon A in January 2023.

According to VHA, an FPPE for cause is "a customized opportunity for a provider to demonstrate improvement or requisite knowledge and skill" and for facility leaders to determine whether any action should be taken on the provider's privileges.[56] An FPPE for cause is time-limited; accepted by the provider who agrees with what is reviewed; and has clearly defined

[55] VHA Directive 1100.18.

[56] VHA Medical Staff Affairs, Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance"; VHA Directive 1100.21; VHA Directive 1100.21(1). The amended directive provided an updated list of requirements for FPPE for cause; however, due to the review period, the OIG is using the VHA Medical Staff Affairs 2018 guidebook. Unless otherwise specified, the amended directive contains the same or similar language regarding FPPE for cause as the VHA Medical Staff Affairs 2018 guidebook.

benchmarks or milestones, outcomes, and clinical care expectations.[57] The FPPE for cause should be reported to the MEC when completed.[58]

The OIG found that, although recommended by the MEC in January 2023, an FPPE for cause for surgeon A was not initiated until April 2023 and not completed until July 2023.[59] The OIG also found that the FPPE for cause documentation did not include clearly defined benchmarks or milestones, outcomes, and clinical care expectations, as well as an indication that the provider agreed with the review.

After the MEC recommended the FPPE for cause in January 2023, the OIG found no further discussion or oversight of the matter, or that the FPPE for cause was completed, in subsequent minutes.[60] When asked, the Chief of Staff acknowledged that the recommendation for an FPPE for cause for surgeon A was not tracked to ensure the initiation or completion. The Chief of Staff explained that these concerns were discovered during reviews with the VISN C&P officer, who also suggested a better mechanism for recording minutes, and suggestions have been implemented. During interviews, the Chief of Staff acknowledged these deficiencies and explained that C&P staff have changed how the minutes were being documented and recorded.

The OIG concluded that facility leaders' delay initiating the FPPE for cause for surgeon A contributed to a final decision regarding surgeon A's practice concerns approximately six months later that may have created a concern for patient safety. Additionally, the FPPE for cause documentation did not include all required elements and the results were not reported back to the MEC. Although VHA does not stipulate a time frame to start an FPPE for cause after the MEC makes a recommendation, the OIG would have expected leaders to have initiated the FPPE for cause prior to April 2023. A standard of care issue had been identified in January 2023 and an FPPE for cause is an opportunity for the provider to demonstrate improvement.

Focused Professional Practice Evaluation

The OIG determined that the chief of surgery delayed notifying surgeon A of a successful initial FPPE and subsequent transition to an OPPE.

[57] VHA Medical Staff Affairs, Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance."

[58] VHA Medical Staff Affairs, Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance."

[59] The January 2023 MEC minutes recorded discussions regarding surgeon A's "FPPE for cause for lack of documentation, and outstanding alerts, and unsigned notes" rather than any concerns about clinical care provided.

[60] The OIG reviewed January through July 2023 MEC minutes.

VHA policy requires results of an FPPE be reported to the MEC.[61] According to VHA guidance, successful completion of an FPPE is reported to the MEC and then the LIP is transitioned to a semi-annual OPPE. VHA guidance specifies that the FPPE is to be reviewed with the LIP.[62]

The OIG reviewed documentation and found the initial FPPE for surgeon A was successfully completed on March 1, 2022, and reported to the MEC, but the chief of surgery did not communicate the subsequent transition to an OPPE to surgeon A until February 3, 2023.

The chief of surgery told the OIG the delay in reviewing the successful initial FPPE with surgeon A was due to holidays and leave. When asked by the OIG, the Chief of Staff was unaware of the 11-month delay. The Chief of Staff stated, "my expectation [for reviewing the FPPE with surgeon A]. . . would [have] been within a week of them getting it back from MEC." In addition, the Chief of Staff concurred with the OIG that providers are supposed to "know when they're successfully completed and when they're able to transition to an OPPE."

The OIG found that the chief of surgery delayed communicating surgeon A's successful initial FPPE by 11 months. The OIG concluded that the delayed communication of a successful FPPE to surgeon A demonstrated a lack of attention to detail and understanding of processes integral to surgical privileges.

Ongoing Professional Practice Evaluation

The OIG determined that the chief of surgery failed to complete items on OPPE forms related to outcome and conclusion of the evaluation.

According to VHA, the chief of surgery is responsible for implementing OPPE requirements within the Surgical Service.[63]

[61] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).

[62] VHA Medical Staff Affairs, Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance."

[63] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).

The OIG reviewed the OPPEs of three general surgeons, conducted by the chief of surgery, for care provided from April 1, 2022, through September 30, 2022.[64] The OPPEs were signed by the chief of surgery and the respective surgeons. The OIG found that the same two items were not completed on any of the three OPPE forms. The items addressed whether clinical privileges should be continued, modified, limited, or revoked; and whether an action plan needed to be deployed.

3. DECISION: Based on review of data, clinical privileges should be: *1. Continued 2. Modified 3. Limited 4. Revoked*

4. DEPLOYMENT: Action Plan: *No Actions Indicated__ Continue to monitor for trends.__ Education/Provider feedback__ Refer to MEC__*

Figure 1. *Illustration of the two items as they appear on the OPPE forms.*
Source: OIG replication of applicable portion of the facility OPPE form.

The chief of surgery confirmed this was a responsibility of the role and that "my error is that I did not indicate on the forms that I verbally communicated these points to the providers." When the OIG requested further explanation, the chief of surgery did not provide additional information.

The OIG concluded that the chief of surgery consistently failed to document an outcome and conclusion in the general surgeons' OPPEs. The practice of not documenting such critical information in OPPEs prevents transparency in the provider evaluation process and may impose a barrier for leaders to take necessary action to ensure the quality and safety of patient care.

VHA outlines privileging processes allowing clinical leaders to identify concerns regarding LIPs' professional practice. When these processes are not followed or completed thoroughly, the quality of care may be impacted. The OPPE and FPPE process findings are not conducive to facility leaders ensuring LIPs are providing quality clinical care.

3. Deficiencies in Surgical Service Quality Management Processes

The OIG identified deficiencies in surgical service quality management processes.

Patient Safety Reporting

The OIG found that Surgical Service clinical staff failed to complete patient safety reports as required for 5 of the 6 substandard care cases cited in FCCR 2.[65]

VHA recognizes the importance of having an atmosphere where staff members are encouraged to report safety-related concerns. For this to occur, staff need to be able to trust that the focus will be on improvements rather than retribution.[66] The VHA Patient Safety Handbook requires

[64] Three general surgeons included the assistant chief of surgery and surgeon A.

[65] FCCR 2 determined that standard of care was not met.

[66] VHA Journey to High Reliability, "HRO Just Culture Fact Sheet," December 29, 2021.

staff "report, as per local policy, any unsafe conditions of which they are aware, even though the conditions have not yet resulted in an adverse event or close call."[67] Facility policy requires all adverse events and close calls "be reported, as soon as the event is discovered, through the Joint Patient Safety Reporting (JPSR) system," and clarifies "When in doubt, fill out a . . . report via JPSR."[68]

The OIG found 5 of the 6 substandard care cases failed patient safety reporting requirements.[69] Specifically, 4 cases lacked a JPSR report. In review of the fifth case, the OIG found the assistant chief of surgery documented in the patient's EHR that the patient sustained an iatrogenic injury during surgery on November 1, 2022. However, the OIG did not find surgical staff reported the injury through a JPSR. Instead, a non-surgical staff member entered a JPSR report on December 7.

According to the assistant chief of surgery, reasons for not completing JPSR reports included

- not being aware of facility policy addressing patient safety reporting,
- not using JPSR reporting due to favoring M&M conference and peer reviews, and
- having reported the events to supervisory and quality assurance staff.[70]

Surgical Service clinical staff reported to the OIG

- not knowing how to report through JPSR;
- lacking formal training on reporting through JPSR;
- being unclear about their responsibility in reporting, especially if they were not present for the event;
- fearing retaliation or retribution; and
- viewing the process as punitive.

Facility and patient safety leaders opined that possible barriers to JPSR reporting included surgery staff believing that an event was not required to be reported through JPSR if it was identified on an informed consent as a possible complication. However, the Chief of Staff

[67] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. The handbook was in effect during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The 2023 directive contains the same definitions for adverse events and close calls as the rescinded 2011 handbook but does not include language on reporting any unsafe conditions.

[68] Facility Memorandum No. 11-28, *Patient Safety Improvement Program,* April 30, 2020. Reports can be made anonymously.

[69] The OIG found a JPSR was submitted timely for the sixth case. The facility identified 2 of the 5 substandard care cases that failed patient safety reporting requirements as adverse events.

[70] The assistant chief of surgery informed the Chief of Staff, chief of surgery, and surgical quality nurse.

clarified the expectation would be for Surgical Service clinical staff to complete a JPSR report for all complications, including possible known complications, and reported addressing the misperception through training.

The OIG concluded that clinical staff failed to follow reporting requirements for 5 surgical cases identified as receiving substandard care. Given that facility policy requires JPSR reporting "as soon as the event is discovered," the OIG would expect a JPSR report to be completed by Surgical Service clinical staff aware of the injury.[71] When surgery staff do not report patient safety concerns, this impedes process improvement and increases risk to patients.[72]

Surgical Morbidity and Mortality Conferences

The OIG found that surgical leaders conducted M&M conferences in a manner similar to peer review rather than as intended by VHA.

VHA defines M&M conferences as "discussions among clinicians of the care provided to individual patients who died or experienced complications," used for improving quality of health care in VA medical facilities.[73] According to literature, historically M&M conferences have been educational.[74] The OIG received further clarification from two national program offices that M&M conferences were educational in nature, provided opportunities for quality and safety improvement, and were not a part of the peer review process.[75] VHA policy provides limited guidance regarding M&M conferences, without any specific requirements for frequency, the types of cases selected, or specific formats for the conferences.

A peer review is a confidential, non-punitive process for evaluating health care provided by an individual, designed to promote patient safety, organizational improvements, and optimal patient outcomes. After reviewing relevant documentation to the case, an initial peer reviewer assigns a

[71] Facility Memorandum No. 11-28, *Patient Safety Improvement Program,* April 30, 2020.

[72] VHA Directive 1050.01.

[73] VHA Directive 1320, *Quality Management and Patient Safety Activities That Can Generate Confidential Records and Documents*, July 10, 2020. "Records and documents created by the Department of Veterans Affairs (VA) as part of a medical quality-assurance program are confidential and privileged and must not be disclosed to any person or entity except under limited circumstances as authorized by 38 U.S.C. § 5705 and its implementing regulations."

[74] Molly Kobritz, Zhenni Xie, Anthony Antonacci, Vihas Patel, "Surgical Quality at the Intersection Between Education and Accountability – Overview for Trainees and Surgeons in Practice," American College of Surgeons, accessed August 1, 2023, https://www.facs.org/for-medical-professionals/news-publications/journals/rise/articles/surgical-quality-at-the-intersection-between-education-and-accountability/.

[75] VHA's Medical-Legal Risk Management Program provides "policy guidance on issues related to preventing malpractice and reducing harm," to include but not limited to peer review. "Medical-Legal Risk Management" (website), VHA's Office of Quality and Patient Safety, https://vaww.qps.med.va.gov/divisions/qm/mlrm/mlrmDefault.aspx. (This website is not publicly accessible.); The OIG interviewed VHA National Surgery Office and VHA Office of Medical-Legal Risk Management leaders.

level of care reflecting the reviewer's evaluation of the standard of care provided.[76] The Peer Review Committee evaluates and discusses the initial review and then provides a final level assignment.[77]

Inconsistent with VHA policy, the OIG found that a facility standard operating procedure refers to M&M conferences as "surgical M&M peer review[s]."[78] The standard operating procedure further provides multiple examples of M&M screening criteria requiring peer review.[79] Upon review of VHA policy, the OIG found that VHA's peer review policy was revised in 2018 and removed the allowance for facility group peer reviews; this was confirmed by leaders from VHA's Office of Medical-Legal Risk Management.

During interviews, several surgeons reported that M&M conferences were problematic, citing the utilization of a rating system, similar to the peer review process, but involving non-clinical staff and non-specialty matched peers that voted to determine whether a case undergo a formal peer review. One surgeon provided an example of a case that was reviewed in M&M and found to be a level 1, which would not require further review, yet was later sent to peer review for additional review.[80] Another surgeon described the M&M process as a "circus" where "anyone. . . . can chime in and rate people based on what they think is right or wrong."

The surgical quality nurse confirmed that M&M conferences also used the same initial rating form used in the peer review process and M&M conference participants anonymously voted upon a rating for each M&M case presented. The surgeon who facilitated M&M conferences explained that this process was in place during the previous chief of surgery's leadership period and no substantial changes had been made to the process. The facilitator also described VHA guidance about M&M conferences as vague. The Director of the Office of Medical-Legal Risk Management further explained that multiple reviews could have a "chilling effect" on "[people's] perceptions of peer review" and negatively impact the integrity of the facility's peer review program.

[76] Facility Standard Operating Procedure (SOP) 112-09, *Surgical Service Mortality and Morbidity (M&M) Review,* July 1, 2020.

[77] VHA Directive 1190. "Level 1 is the level at which most experienced and competent clinicians would have managed the case in a similar manner. Level 2 is the level at which most experienced and competent clinicians might have managed the case differently, but it remains within the standard of care. Level 3 is the level at which most experienced and competent clinicians would have managed the case differently."

[78] Facility SOP 112-09. This standard operating procedure did not indicate a governing document; however, the OIG found references to M&M conferences in two VHA policies: VHA Directive 1320 and VHA Directive 1102.01(2), *National Surgery Office*, April 24, 2019, amended April 19, 2022.

[79] Facility SOP 112-09.

[80] Facility SOP 112-09. Level 1 categorization is defined as "most experienced, competent practitioners WOULD HAVE managed the case SIMILARLY in all aspects listed."

The OIG learned that facility leaders were aware of surgical staff's concerns about the M&M conferences through an email with the chief of quality, safety, and value and the Chief of Staff in February 2023, and an April 2023 administrative fact finding with M&M recommendations.

The OIG concluded that the facility's surgical M&M conferences and standard operating procedure do not align with VHA policy, the National Surgery Office, and VHA Medical-Legal Risk Management, potentially compromising the peer review process and resulting in negative experiences for staff.

Peer Review Processes

Identification of Potential Cases for Peer Review

The OIG found that the chief of surgery should have identified 3 cases in which injuries occurred during invasive procedures and communicated with the appropriate facility staff to ensure the cases were considered for the formal peer review process.

Although events for peer review may be discovered through a variety of means including occurrence screens, executive notification, and concerns from other facility committees, VHA policy states unplanned injuries, including lacerations, tears or punctures, that occur during an invasive procedure "should be considered for peer review for quality management."[81] VHA further indicates "clinical service chiefs . . . are responsible for ensuring that occurrences that may be considered for, or that require, Peer Review for Quality Management are identified and communicated to responsible program staff."[82]

The OIG reviewed peer review-related documentation and found that of the 5 cases, 3 met VHA criteria for consideration for peer review as they included lacerations, tears, or punctures that occurred during an invasive procedure. Documentation indicated that the 3 cases were identified by facility leaders, rather than the chief of surgery, and communicated to the risk manager.

When asked how surgical cases were selected for peer review, the chief of surgery indicated that only cases reviewed in M&M conferences and rated a level 2 or 3 would be referred to peer review, and there was no process to bring cases forward in any other manner.[83] In addition, the chief of quality, safety, and value told the OIG that during a conversation with the chief of surgery, it was discovered that the chief of surgery was aware of several "nicks" that occurred during invasive procedures and that information was not relayed to quality management or risk management staff. The OIG determined that the chief of surgery was aware of these 3 cases and

[81] VHA Directive 1190.

[82] VHA Directive 1190. According to the chief of quality, safety, and value, a risk manager is responsible for leading the peer review process.

[83] Facility SOP 112-09. Level 2 categorization is defined as "Most experienced, competent practitioners MIGHT have managed the case DIFFERENTLY in one or more of the aspects." Level 3 categorization is defined as "Most experienced, competent practitioners WOULD HAVE managed the case DIFFERENTLY in one or more aspects."

did not discuss them with the chief of quality, safety, and value, who supervised the risk management staff, until after the referral was sent by the OIG in November 2022.[84] VHA policy requires that the chief of surgery ensures cases that should be considered for peer review are identified and communicated to the appropriate facility staff.[85]

The OIG concluded that the chief of surgery did not ensure consideration of peer review for 3 cases in which patients sustained injuries during invasive procedures. Lack of an effective peer review process can affect short- and long-term improvement in patient care for clinicians, thus inhibiting organizational improvement and optimal patient outcomes.

Management Review and Peer Reviews for the Same Incident of Care

The OIG determined that the VISN Chief Medical Officer (CMO) and the chief of quality, safety, and value failed to prevent 2 cases from being reviewed concurrently in peer review and a management review (FCCR 2).

VHA's peer review policy states that a peer review and a management review for the same episode of care "must not occur concurrently."[86] Peer reviews can generate confidential documents protected under 38 U.S.C. § 5705.[87] Management reviews, including FCCRs, are not confidential or privileged under 38 U.S.C. § 5705 and can be used for personnel action.[88] "If the need for a management review can be anticipated, it is preferable to postpone the 38 U.S.C. § 5705-protected activity [peer review] until the management review is completed or cancel the protected activity."[89] VHA provides guidance that a facility Chief of Staff will contact the VISN CMO for assistance in selecting reviewers for an FCCR.[90] Additionally, the VISN CMO provides clinical leadership and direction in the implementation of the peer review policy within assigned VA medical facilities.[91]

While FCCR 2 was conducted between January and February 2023, and 15 cases were reviewed, the OIG found that 2 of these cases were also peer reviewed from December 2022 through June 2023.[92] The Chief of Staff told the OIG the VISN's assistance was requested for FCCR 2; however, the Chief of Staff reported no awareness of how cases were identified for the review. In

[84] The 3 cases occurred on September 13–20, 2022; October 18, 2022; and November 1, 2022; and the peer reviews were initiated on December 7, 2022; and December 9, 2022.

[85] VHA Directive 1190.

[86] VHA Directive 1190.

[87] VHA Directive 1190.

[88] VHA Directive 1190.

[89] VHA Directive 1190.

[90] VHA Office of Quality, Safety and Value, "Provider Competency And Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance."

[91] VHA Directive 1190.

[92] The 2 peer review cases were completed on June 5, 2023.

review of email correspondence and through interviews, the OIG learned that the chief of quality, safety, and value provided the VISN CMO with the 15 cases to be reviewed in FCCR 2. The VISN CMO told the OIG of recommending the facility include the 5 cases to determine whether the FCCR 2 results would "confirm or refute" initial concerns. The VISN CMO told the OIG that "I was aware in general that peer reviews were completed or being conducted on the five concerning cases . . . [but] did not know the status or the details." Per VHA policy, VISN and facility leaders should have either postponed or canceled the 2 peer reviews while FCCR 2 was being conducted.[93]

The OIG concluded that the VISN CMO and the chief of quality, safety, and value allowed a concurrent management review on 2 cases being peer reviewed. The OIG would have expected leaders to either stop the peer reviews or not include the 2 cases in FCCR 2. Concurrent peer reviews and management reviews combine protected and non-protected information, blurring the lines between protected peer reviews used for quality improvement and potentially adverse privileging or disciplinary actions.

The OIG found that clinical staff did not follow facility policy regarding entering JPSRs for 5 substandard surgical cases; when staff do not report patient safety concerns, opportunities are missed to improve processes, which increases risk to patients. Surgical M&M conferences and facility standard operating procedures were not in alignment with VHA policy or the National Surgery Office and VHA Medical-Legal Risk Management office's expectations, resulting in potential compromise to the peer review process and negative experiences for staff. In addition, the chief of surgery did not recognize 3 cases in which patients sustained injuries during invasive procedures as potential cases for peer review, which is another component of quality management and patient safety processes.

4. Deficiencies in Institutional Disclosure Processes

The OIG determined that facility leaders generally did not communicate and document required institutional disclosure elements. Additionally, although the risk manager made efforts to retroactively correct the deficient institutional disclosures of a specified time frame, the OIG determined that the time frame was insufficient and potentially would not capture all affected institutional disclosures needing correction.

VHA defines an institutional disclosure as a formal process where facility leaders inform a patient or their personal representative that an adverse event that "resulted in, or is reasonably expected to result in, death or serious injury" has occurred, "to maintain trust between patients and VA healthcare professionals."[94] VHA requires that facility leaders provide "specific information about the patient's right and recourse" to include information about potential

[93] VHA Directive 1190.

[94] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients,* October 31, 2018.

compensation from the Veterans Benefits Administration and under the Federal Tort Claims Act, and the option of obtaining outside medical or legal advice for further guidance.[95] VHA includes that institutional disclosures need "to take place in a suitable environment . . . in order to provide adequate time to ensure that the patient's questions and concerns can be addressed."[96] Unless impossible or impractical, VHA prefers facility leaders to complete institutional disclosures in person; however, if completed by telephone, the reason why must be documented.[97] When institutional disclosures are not completed as required, patients and their personal representatives may inadvertently be denied their rights.[98]

The OIG reviewed 10 facility-wide institutional disclosures completed by facility leaders from July 1, 2022, through May 31, 2023.[99] The OIG found that, of the 10 institutional disclosures, 9 institutional disclosures did not include "advisement about potential compensation." During an interview, a risk manager recalled having misunderstood the VHA directive, interpreting the requirement to advise patients or their personal representatives of compensation only if they "specifically ask[ed] for it."[100] The risk manager reported seeking clarification from a VISN subject matter expert in March 2023, following a prior OIG inspection related to an institutional disclosure, when learning to include the compensation information in all institutional disclosures.[101]

The OIG found the risk manager and OGC provided two different time frames for completion of retroactive work. The risk manager told the OIG of receiving guidance from OGC to review previously completed institutional disclosures beginning October 1, 2020, and provide patients or their personal representatives with compensation information. OGC, however, sent an email to the OIG explaining that although they had not provided direct advice on interpretation of the disclosure policy, based on the time frame of the federal tort claim act statute of limitations of

[95] VHA Directive 1004.08.

[96] VHA Directive 1004.08.

[97] VHA Directive 1004.08.

[98] VHA Directive 1004.08.

[99] Facility leaders included the Chief of Staff and a risk manager; VHA Directive 1004.08. VHA requires a national note template for EHR documentation of completed institutional disclosures; The risk manager completed the associated EHR documentation. These 10 institutional disclosures are inclusive of the one disclosure referenced in VA OIG, *Delay in Diagnosis and Treatment for a Patient with a New Lung Mass at the Hampton VA Medical Center in Virginia*; the 10 institutional disclosures are also inclusive of a patient's same episode of care disclosed to two different individuals.

[100] The risk manager documented "[patient] has already filed a tort claim" for one patient.

[101] VA OIG, *Delay in Diagnosis and Treatment for a Patient with a New Lung Mass at the Hampton VA Medical Center in Virginia*. The prior OIG report included an institutional disclosure recommendation specific to a single patient.

two years, that period of time for a lookback might be too "narrow." The risk manager, however, interpreted OGC's advice to retroactively review work starting from October 1, 2020.[102]

None of the institutional disclosures conducted by the facility included the requirement of notifying the patient or family of the option to obtain outside medical or legal advice. The OIG found the EHR institutional disclosure note template does not include a field for each of the required elements, including notification of the option to obtain outside medical or legal advice. The risk manager told the OIG of not having received guidance on how to proceed when the template did not contain all the elements as required by the VHA directive.

Nine institutional disclosures were conducted by telephone and none of the nine included the reason why they were completed by telephone rather than in person. When asked why the reason was not documented, the risk manager, who co-conducted the institutional disclosures with the Chief of Staff, cited that the institutional disclosure note template in the EHR lacks a specific field to enter a reason. When asked why the institutional disclosures were conducted by telephone, the Chief of Staff stated the risk manager scheduled the meetings.

The OIG concluded that facility leaders failed to complete institutional disclosures as required. Although the risk manager retroactively provided compensation information to patients who were not advised during institutional disclosures that occurred from October 1, 2020, through May 31, 2023, the OIG is concerned, based on information received from OGC, that the time frame may be too narrow. These deficiencies could result in patients or their personal representatives being unaware of their rights and options for recourse to an adverse event and are not conducive toward building trust with patients.

Conclusion

The OIG reviewed surgical service and quality management concerns and identified widespread failures and deficiencies related to facility leaders' responses to clinical care concerns and subsequent privileging actions involving the assistant chief of surgery; professional practice evaluations of surgeons; surgical service quality management; and institutional disclosures. The OIG determined that the findings identified through this inspection highlight not only failures of facility leaders to ensure that the required processes were appropriately implemented, but also a lack of leaders' basic understanding of the processes that support delivery of safe health care.

Facility leaders made numerous process errors when taking privileging actions concerning the assistant chief of surgery. Facility leaders completed three FCCRs of the assistant chief of

[102] The risk manager noted that as of March 2024, one patient who received the compensation information during the retroactive work filed a tort claim. The OIG reviewed all facility institutional disclosures from October 1, 2020, through May 31, 2023 (24 total), and verified the risk manager's completion of retroactively providing compensation information. This was inclusive of the 10 institutional disclosures completed from July 1, 2022, through May 31, 2023.

surgery's clinical care but failed to document any of the FCCR results in the Practitioner Profile, failed to provide the results of two of the FCCRs to the MEC, and delayed reporting the results of one FCCR to the MEC. These errors limited the MEC's knowledge of all reviews, which could have fully informed MEC members' decisions and recommendations about privileging actions regarding the assistant chief of surgery. Further, the three FCCRs were not completed by multiple reviewers to ensure interrater reliability and an objective evaluation of the assistant chief of surgery's clinical care.

Several inconsistencies related to issuing a summary suspension of privileges to the assistant chief of surgery were identified, including the suspension letters, MEC meeting minutes, and actions taken by the Facility Director. These inconsistencies had the potential to affect patient care as the assistant chief of surgery was not aware of which privileges were suspended, affecting the level of services available for patients. Failure to correctly follow summary suspension procedures is unfair to LIPs who are entitled to accurate notice in order to ensure due process.

In an attempt to reduce the assistant chief of surgery's privileges, facility leaders did not send letters in the correct order and did not include all required elements in the proposal letter to provide the assistant chief of surgery the necessary due process. Due to these failures, facility leaders rescinded the proposed actions and restored the associate chief of surgery's clinical privileges. When the assistant chief of surgery transferred to another VA facility, facility leaders were unable to redress the process and take additional privileging actions. In multiple instances, facility leaders misused the term *revocation* of privileges instead of *reduction* in privileges in documents related to the assistant chief of surgery's adverse privileging action, adding further confusion to any actions taken. Facility leaders failed to report the assistant chief of surgery to the SLB. Failing to report LIPs with identified substandard care to the SLB may impact patient safety if the LIP practices elsewhere in the state board's jurisdiction.

Facility leaders delayed initiating the FPPE for cause for surgeon A, documentation did not contain all required elements, and results were not reported back to the MEC. Facility leaders also delayed notifying surgeon A of a successful initial FPPE and subsequent transition to an OPPE. Additionally, the chief of surgery failed to complete items on OPPE forms related to outcome and conclusion of the evaluation. OPPE and FPPE processes allow clinical leaders to identify concerns regarding LIPs' professional practice. When these processes are not followed or completed thoroughly, the quality of patient care may be impacted.

Surgical Service clinical staff failed to complete patient safety reports as required for 5 substandard care cases, which impedes process improvement and increases risk to patients. Surgical leaders conducted M&M conferences in a manner similar to peer review that is inconsistent with VHA policy, the National Surgery Office, and VHA Medical-Legal Risk Management, potentially compromising the peer review process and resulting in negative experiences for staff. The chief of surgery should have identified 3 cases in which injuries

occurred during invasive procedures and communicated with the appropriate facility staff to ensure the cases were considered for peer review. Lack of an effective peer review process can affect short- and long-term improvement in patient care for clinicians, thus inhibiting organizational improvement and optimal patient outcomes. The VISN CMO and the chief of quality, safety, and value failed to prevent 2 cases from being reviewed concurrently in peer review and a management review. Concurrent peer reviews and management reviews combine protected and non-protected information, which confuses the intent of the separate processes, blurring the lines between protected peer reviews and potentially adverse actions.

Facility leaders generally did not communicate and document institutional disclosure elements, which could result in patients or their personal representatives being unaware of their rights and options for recourse, and are not conducive toward building trust with patients. The risk manager made efforts to retroactively correct deficient institutional disclosures of a specified time frame; however, the time frame was insufficient to potentially capture all affected institutional disclosures.

Recommendations 1–12

1. The Hampton VA Medical Center Director conducts focused clinical care reviews in accordance with Veterans Health Administration requirements, and monitors for compliance.

2. The Hampton VA Medical Center Director ensures that summary suspensions are conducted in accordance with Veterans Health Administration policy, and monitors for compliance.

3. The Hampton VA Medical Center Director confirms that proposed reduction or revocation of privileges complies with Veterans Health Administration policies and procedures, and monitors for compliance.

4. The Hampton VA Medical Center Director complies with Veterans Health Administration requirements when reporting licensed independent practitioners to state licensing boards.

5. The Hampton VA Medical Center Director completes a review of Medical Executive Committee meeting minutes and ensures recommendations made for focused professional practice evaluations for cause for licensed independent practitioners have been completed according to Veterans Health Administration requirements.

6. The Hampton VA Medical Center Director ensures that, when providers are transitioned from an initial focused professional practice evaluation to an ongoing professional practice evaluation, the transition is reported and documented as required by Veterans Health Administration policy, and monitors for compliance.

7. The Hampton VA Medical Center Director ensures that ongoing professional practice evaluations include documentation of all conclusionary outcomes required by Veterans Health Administration policy.

8. The Hampton VA Medical Center Director ensures surgical staff have an understanding of Veterans Health Administration Joint Patient Safety Reporting submissions and tracks submissions specific to Surgical Service, and monitors for compliance.

9. The Hampton VA Medical Center Director completes a comprehensive review of surgical morbidity and mortality conferences and ensures facility policy and practice is in alignment with Veterans Health Administration policy and, as necessary, consults with Veterans Health Administration's National Surgery Office and Veterans Integrated Service Network leaders, and monitors for compliance.

10. The Hampton VA Medical Center Director ensures that the chief of surgery has a process to identify potential cases for peer review and communicates those cases to the appropriate program staff.

11. The Mid-Atlantic Veterans Integrated Service Network Director confirms the Hampton VA Medical Center Director ensures that management reviews and peer reviews, if both indicated for the same incident of care, are conducted in accordance with Veterans Health Administration policy, and are not conducted concurrently.

12. The Hampton VA Medical Center Director considers seeking guidance from the Office of General Counsel to determine the appropriate time frame for ensuring all required elements for previously completed institutional disclosures have been met.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: June 18, 2024

From: VA Mid-Atlantic Health Care Network Director, VISN 6 (15N6)

Subj: Healthcare Inspection—Mismanaged Surgical Privileging Actions and Deficient Surgical Service Quality Management Processes at the Hampton VA Medical Center in Virginia

To: Director, Office of Healthcare Inspections (54HL04)
Executive Director, Office of Integrity and Compliance (10OIC)

1. Thank you for the opportunity to review the draft report of the Healthcare Inspection related to Mismanaged Surgical Privileging Actions and Deficient Surgical Service Quality Management Processes at the Hampton VA Medical Center in Virginia.

2. I have reviewed and concur with the OIG recommendations and the action plans submitted by the Hampton VA Medical Center. As we remain committed to ensuring our Veterans receive exceptional care, VISN 6 Leadership will ensure the actions to correct the findings are completed and sustained as described in their responses.

3. I would like to thank the Office of Inspector General for their thorough review and if there are any questions regarding responses or additional information required, please contact VISN 6 Quality Management Officer.

(*Original signed by:*)

Paul S. Crews, MPH, FACHE

[OIG comment: The OIG received the above memorandum from VHA on July 5, 2024.]

VISN Director Response

Recommendation 11

The Mid-Atlantic Veterans Integrated Service Network Director confirms the Hampton VA Medical Center Director ensures that management reviews and peer reviews, if both indicated for the same incident of care, are conducted in accordance with Veterans Health Administration policy, and are not conducted concurrently.

_X _Concur

____Nonconcur

Target date for completion: September 30, 2024

Director Comments

The Mid-Atlantic Veterans Integrated Network Director will confirm compliance through a cross-reference of cases for peer review and management reviews. The facility will submit the cross-reference information to the VISN monthly and the VISN Risk Management Officer (RMO) will perform the cross-reference check. The VISN RMO will provide a summary report to the VISN Executive Leadership Team and Quality & Patient Safety Committee for 6 months with a goal of 100% compliance of no concurrent peer and management reviews.

In addition to the oversight review, re-education will be provided to the Mid Atlantic Integrated Services Network senior leadership teams at each of the respective facilities including quality management, risk management, and peer review coordinators on Directive 1190 Peer Review for Quality Management.

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: May 21, 2024

From: Director, Hampton VA Medical Center (590/00)

Subj: Healthcare Inspection—Mismanaged Surgical Privileging Actions and Deficient Surgical Service Quality Management Processes at the Hampton VA Medical Center in Virginia

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

1. Thank you for the opportunity to review and respond to the draft report, *Mismanaged Surgical Privileging Actions and Deficient Surgical Service Quality Management Processes at the Hampton VA Medical Center in Virginia.*

2. I have reviewed the draft report and concur with the recommendations. The findings outlined in the Office of Inspector General report reflect a thorough evaluation.

3. If you have any questions regarding the information provided, please contact the Chief, Quality & Patient Safety.

(*Original signed by*:)

Taquisa K Simmons, Ph.D., LCSW
Director, Hampton VA Medical Center

[OIG comment: The OIG received the above memorandum from VHA on July 5, 2024.]

Facility Director Response

Recommendation 1

The Hampton VA Medical Center Director conducts focused clinical care reviews in accordance with Veterans Health Administration requirements, and monitors for compliance.

_X _Concur

____Nonconcur

Target date for completion: December 31, 2024

Director Comments

The Chief of Staff, Medical Executive Council (MEC) members, and the Credentialing and Privileging (C&P) staff will be re-educated on the Medical Bylaws and the process for focused clinical care reviews in alignment with VHA guidance. The C&P manager/designee will develop a reporting tool to monitor all focused clinical care reviews. Compliance for focused clinical care reviews will be reported to MEC as a standing agenda item by the C&P manager /designee and action taken if the need is indicated by the monitoring results.

Recommendation 2

The Hampton VA Medical Center Director ensures that summary suspensions are conducted in accordance with Veterans Health Administration policy, and monitors for compliance.

_X _Concur

____Nonconcur

Target date for completion: December 31, 2024

Director Comments

The Chief of Staff, Medical Executive Council (MEC) members, and the Credentialing and Privileging (C&P) staff will be re-educated on the Medical Bylaws and the process for summary suspensions in alignment with VHA guidance. The C&P manager/designee will develop a reporting tool to monitor all summary suspensions. Compliance for summary suspensions will be reported to MEC as a standing agenda item by the C&P manager/designee and action taken if the need is indicated by the monitoring results.

Recommendation 3

The Hampton VA Medical Center Director confirms that proposed reduction or revocation of privileges complies with Veterans Health Administration policies and procedures, and monitors for compliance.

_X _Concur

____Nonconcur

Target date for completion: December 31, 2024

Director Comments

The Chief of Staff, Medical Executive Council (MEC), and the Credentialing and Privileging (C&P) staff will be re-educated on the Medical Bylaws and the process for the reduction and revocation of privileges in alignment with VHA guidance. The C&P manager/designee will develop a reporting tool to monitor all proposed reduction and revocation of privileges. Compliance for the reduction and revocation of privileges will be reported to MEC as a standing agenda item by the C&P manager/designee and action taken if the need is indicated by the monitoring results.

Recommendation 4

The Hampton VA Medical Center Director complies with Veterans Health Administration requirements when reporting licensed independent practitioners to state licensing boards.

_X _Concur

____Nonconcur

Target date for completion: December 31, 2024

Director Comments

The Chief of Staff, Medical Executive Council (MEC), and the Credentialing and Privileging (C&P) staff will be re-educated on the Medical Bylaws and the process for reporting licensed independent practitioners (LIPs) to state licensing boards in alignment with VHA guidance. The C&P manager/designee will develop a reporting tool to monitor the reporting of LIPs to the state licensing board. Compliance for the reporting of licensed independent practitioners to the state licensing boards will be reported to MEC as a standing agenda item by the C&P manager/designee and action taken if the need is indicated by the monitoring results.

Recommendation 5

The Hampton VA Medical Center Director completes a review of Medical Executive Committee meeting minutes and ensures recommendations made for focused professional practice

evaluations for cause for licensed independent practitioners have been completed according to Veterans Health Administration requirements.

_X _Concur

____Nonconcur

Target date for completion: June 30, 2024

Director Comments

The Medical Center Director has conducted a look back review of all Medical Executive Council (MEC) minutes from October 22, 2022, to present, to ensure that all recommendations made for focused professional practice evaluations for cause, have been completed. The Director will report findings and the expectations to the MEC for closure in the next reporting period.

OIG Comments

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

Recommendation 6

The Hampton VA Medical Center Director ensures that, when providers are transitioned from an initial focused professional practice evaluation to an ongoing professional practice evaluation, the transition is reported and documented as required by Veterans Health Administration policy, and monitors for compliance.

_X _Concur

____Nonconcur

Target date for completion: December 31, 2024

Director Comments

The Chief of Staff, Medical Executive Council (MEC), and the Credentialing and Privileging (C&P) staff will be re-educated on the Medical Bylaws and the process for an initial focused professional practice evaluation to an ongoing professional practice evaluation in alignment with VHA directive. The C&P manager/designee will develop a reporting tool to monitor all OPPEs and FPPEs per VHA guidance. Compliance for the reporting and documenting of OPPEs and FPPEs will be reported to MEC as a standing agenda item by the C&P manager/designee and action taken if the need is indicated by the monitoring results.

Recommendation 7

The Hampton VA Medical Center Director ensures that ongoing professional practice evaluations include documentation of all conclusionary outcomes required by Veterans Health Administration policy.

_X _Concur

____Nonconcur

Target date for completion: December 31, 2024

Director Comments

By June 30, 2024, the Chief of Staff will review and validate that all ongoing professional practice evaluations summary forms have all the VHA required elements as required by VHA Directive 1100.20(1), and VHA Directive 1100.21(1). MEC members will be re-educated on the required documentation for the ongoing professional practice evaluations at the July 2024, MEC meeting. To ensure that all required conclusionary outcomes are documented, the C&P manager/designee will review all OPPE forms for completeness prior to submission and presentation to MEC. Compliance for the completed documentation of all conclusionary outcomes will be reported as a standing agenda item to MEC by the C&P manager/designee.

Recommendation 8

The Hampton VA Medical Center Director ensures surgical staff have an understanding of Veterans Health Administration Joint Patient Safety Reporting submissions and tracks submissions specific to Surgical Service, and monitors for compliance.

_X _Concur

____Nonconcur

Target date for completion: December 31, 2024

Director Comments

On June 5, 2024, the Patient Safety Managers conducted a surgical specific patient safety training at the Surgery Service staff meeting. Surgery Leadership instructed all surgical staff to complete the Patient Safety Talent Management System (TMS) course #4626643. As of June 17, 2024, 97% of the surgical staff has completed this training. The facility meets twice a week, with patient safety stakeholders to review detected incidents and trends and will supplement the processes of that review by ensure that related documentation is cross referenced and surgical events are completed as required in policy. Compliance will be reported by the Patient Safety Manager to the Quality and Patient Safety Council and action taken if the need is indicated by the monitoring results.

Recommendation 9

The Hampton VA Medical Center Director completes a comprehensive review of surgical morbidity and mortality conferences and ensures facility policy and practice is in alignment with Veterans Health Administration policy and, as necessary, consults with Veterans Health Administration's National Surgery Office and Veterans Integrated Service Network leaders, and monitors for compliance.

_X _Concur

____Nonconcur

Target date for completion: Completed, recommend closure

Director Comments

The Medical Center Director and the Chief of Staff requested a consultative site visit from the VISN 6 Chief Medical Officer (CMO) to assist with a review of the surgical services management practices to ensure coordinated oversight and leadership. An onsite visit was conducted by the CMO on August 17 and 18, 2023. The CMO attended the surgical Morbidity and Mortality (M&M) conference and made recommendations to the facility to pause the M&M conference immediately. The site leaders were directed to restructure the meetings in alignment with VHA Directive 1320, *Quality Management and Patient Safety Activities That Generate Confidential Records and Documents* and VHA Directive 1102.01(2) *National Surgery Office*. On December 18, 2023, the Chief of Surgery created the new Surgical Service M&M SOP, 112-09. This SOP was reviewed and approved by the VISN 6 CMO. The newly restructured M&M conference resumed January 2024. To ensure all cases were presented to M&M, two M&M conferences were held twice a month. As of May 22, 2024, there have been nine (9) M&M conferences in alignment with VHA guidance and the new Hampton SOP. Facility requests closure of this recommendation based on evidence provided.

OIG Comments

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

Recommendation 10

The Hampton VA Medical Center Director ensures that the chief of surgery has a process to identify potential cases for peer review and communicates those cases to the appropriate program staff.

_X _Concur

____Nonconcur

Target date for completion: July 31, 2024

Director Comments

By the end of June 2024, the Chief of Surgery and the Surgical Quality Nurse will be provided education from the Risk Manager and the Chief of Staff on the peer review process. The Chief of Surgery and the Surgical Quality Nurse, in collaboration with the Chief of Staff will create a process to identify and report cases for peer review in addition to those already identified through usual processes. The Surgical Quality Nurse will attend weekly meetings with the Risk Manager to communicate cases for peer review evaluation to Quality and Patient Safety for review. This updated process will be added as a required training for the Chief of Surgery and the Surgical Quality Nurse positions in surgical service.

Recommendation 12

The Hampton VA Medical Center Director considers seeking guidance from the Office of General Counsel to determine the appropriate time frame for ensuring all required elements for previously completed institutional disclosures have been met.

_X _Concur

____Nonconcur

Target date for completion: Completed, recommend closure.

Director Comments

On May 21, 2024, the VISN 6 Risk Manager, Chief of Staff, Chief, Quality and Patient Safety, Risk Manager, and the Accreditation Specialist met with the Office of General Counsel (OGC), to discuss the appropriate time frame for ensuring that all required elements for previously completed institutional disclosures were met. The OGC determined all required elements for the previous completed institutional disclosures have been met, as they met the two-year statute of limitations from the time of disclosure. The OGC also stated there was no statute of limitations for any of the Veterans from filing a VBA claim. Facility requests closure of this recommendation based on evidence above.

OIG Comments

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

Glossary

To go back, press "alt" and "left arrow" keys.

abscess. "A localized collection of pus surrounded by inflamed tissue."[103]

adverse event. "Untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm directly associated with care or services delivered by VA providers."[104]

anastomotic. An adjective used to describe "the surgical union of parts and especially hollow tubular parts."[105]

bile. "A digestive fluid produced by the liver and stored in the gallbladder. "[106]

chemoradiation. A treatment for cancer using chemotherapy and radiation.[107]

clinical privileging. "The process by which a VA facility authorizes a LIP to independently (i.e., without supervision or restriction) provide healthcare services on a facility-specific basis."[108]

close call. "An event or situation that could have resulted in an adverse event but did not, either by change or through timely intervention."[109]

colectomy. "A surgical procedure to remove all or part of [the] colon."[110]

colocutaneous fistula. A passage or tunnel between the colon and the skin.[111]

colon polyp. "A small clump of cells that forms on the lining of the colon" and over time may develop into colon cancer.[112]

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[103] *Merriam-Webster.com Dictionary*, "abscess," accessed February 21, 2024, https://www.merriam-webster.com/dictionary/abscess.

[104] VHA Handbook 1050.01; VHA Directive 1050.01.

[105] *Merriam-Webster.com Dictionary*, "anastomotic," accessed February 21, 2024, https://www.merriam-webster.com/dictionary/anastomotic.

[106] Mayo Clinic, "*Bile reflux,"* accessed February 21, 2024, https://www.mayoclinic.org/diseases-conditions/bile-reflux/symptoms-causes/syc-20370115.

[107] Mayo Clinic, "*Cancer Treatment,"* accessed February 26, 2024, https://www.mayoclinic.org/tests-procedures/cancer-treatment/about/pac-20393344.

[108] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).

[109] VHA Handbook 1050.01; VHA Directive 1050.01.

[110] Mayo Clinic, "*Colectomy,"* accessed February 21, 2024, https://www.mayoclinic.org/tests-procedures/colectomy/about/pac-20384631.

[111] Alexandros Charalabopoulos, Evangelos Misiakos, and Anastasios Macheras, "Colocutaneous fistula complicating sigmoid diverticulitis," *International Journal of Surgery Case Reports,* (Elsevier, 2011), 68–70.

[112] Mayo Clinic, "*Colon polyps,*" accessed February 21, 2024, https://www.mayoclinic.org/diseases-conditions/colon-polyps/symptoms-causes/syc-20352875.

credentialing. "The process of obtaining, verifying, and assessing the qualifications of a health care provider to provide care or services in or for the VA health care system."[113]

Crohn's disease. A type of inflammatory bowel disease that causes swelling of the tissues in the "digestive tract, which can lead to abdominal pain, severe diarrhea, fatigue, weight loss and malnutrition."[114]

diverticulitis. When diverticula (small, bulging pouches that can form within the digestive system lining) are inflamed or infected.[115]

diverting colostomy. A temporary procedure where a surgeon pulls a loop of bowel through the abdominal wall to divert or keep feces out of a certain section of the colon that needs to rest and heal.[116]

due process. "A course of formal proceedings (such as legal proceedings) carried out regularly and in accordance with established rules and principles."[117]

fistula. "An abnormal connection between two body parts" that is usually the result of an injury, surgery, infection, or inflammation.[118]

focused clinical care review. "An objective retrospective review of a LIP's clinical practice in one or more areas if a clinical care concern has been triggered."[119]

focused professional practice evaluation. "An oversight process within a defined period of evaluation whereby the respective clinical service chief and the [MEC] evaluates the privilege-specific competence of a LIP who does not yet have documented evidence of competently performing the requested privileges at the VA medical facility."[120]

focused professional practice evaluation for cause. "A time-limited period during which the clinical service chief assesses the health care LIP's performance to determine if any action should be taken on the LIP's privileges after a clinical concern has been triggered and a FCCR

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[113] VHA Directive 1100.20.

[114] Mayo Clinic, "*Crohn's disease,"* accessed February 21, 2024, https://www.mayoclinic.org/diseases-conditions/crohns-disease/symptoms-causes/syc-20353304.

[115] Mayo Clinic," *Diverticulitis,"* accessed February 21, 2024, https://www.mayoclinic.org/diseases-conditions/diverticulitis/symptoms-causes/syc-20371758.

[116] Cleveland Clinic, "*Loop Colostomy: Procedure, Recovery, Risk & Benefits,"* accessed February 21, 2024, https://my.clevelandclinic.org/health/treatments/24589-loop-colostomy.

[117] *Merriam-Webster.com Dictionary,* "due process," accessed October 4, 2023, https://www.merriam-webster.com/dictionary/due%20process.

[118] National Institutes of Health/National Library of Medicine-MedlinePlus, "*Fistula,"* accessed February 21, 2024, https://medlineplus.gov/ency/article/002365.htm.

[119] VHA Directive 1100.21; VHA Directive 1100.21(1).

[120] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).

has been conducted. It is not a restriction or limitation on the ability to practice independently, but rather an oversight process to be employed by the clinical service chief when there is a concern regarding a LIP's clinical competence to continue providing some aspect of care."[121]

iatrogenic. "Induced unintentionally by a physician or surgeon."[122]

interrater reliability. "The extent to which 2 or more independent raters or observers consistently obtain the same result when using the same assessment tool." [123]

Joint Patient Safety Reporting. "The recognized enterprise-wide patient safety reporting system used in VHA to report safety events."[124]

laceration. "A torn and ragged wound."[125]

laparoscopic. A minimally invasive surgical technique for abdominal diagnosis and treatment.[126]

licensed independent practitioner. "An individual permitted by law and the VA medical facility, through its Medical Staff Bylaws to provide patient care services independently, without supervision or direction, within the scope of the individual's license and in accordance with privileges granted by the facility."[127]

management review. A non-protected review that "must be used if the purposes is: to provide a basis for an action that may affect personnel status or clinical privileges."[128]

Medical Executive Committee. "A group of individuals, the majority of whom are licensed physician members of the medical staff practicing in the VA medical facility, that is selected or elected and removed according to the process contained in the Medical Staff Bylaws. This group is responsible for making specific recommendations directly to the organization's governing

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[121] VHA Directive 1100.21; VHA Directive 1100.21(1).

[122] *Merriam-Webster.com Dictionary,* "iatrogenic," accessed September 7, 2023, https://www.merriam-webster.com/dictionary/iatrogenic.

[123] "42 U.S. Code § 9832 – Definitions" (web page), Cornell Law School, accessed October 5, 2023, https://www.law.cornell.edu/uscode/text/42/9832#:~:text=(14)%20The%20term%20%E2%80%9C%20interrater%20reliability%20%E2%80%9D%20means,same%20result%20when%20using%20the%20same%20assessment%20tool.

[124] VA, "HRO JPSR Fact Sheet," accessed August 7, 2023, https://dvagov.sharepoint.com/sites/vhahrojourney/SitePages/About_HRO_Home.aspx#just-culture. (This site is not publicly accessible).

[125] *Merriam-Webster.com Dictionary*, "laceration," accessed February 21, 2024, https://www.merriam-webster.com/dictionary/laceration.

[126] *Merriam-Webster.com Dictionary,* "laparoscopic," accessed February 22, 2024, https://www.merriam-webster.com/dictionary/laparoscopic; Mayo Clinic, *"Minimally invasive surgery*," accessed April 3, 2024, https://www.mayoclinic.org/tests-procedures/minimally-invasive-surgery/about/pac-20384771.

[127] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).

[128] VHA Directive 1190.

body for approval, as well as receiving and acting on reports and recommendations from medical staff committees, clinical departments or services, and assigned activity groups."[129]

Medical Staff Bylaws. "A governance framework that establishes the roles and responsibilities of a body and its members. The organized medical staff at a VA medical facility creates a written set of documents that describes its organizational structure and the rules for its self-governance. These documents create a system of rights, responsibilities, and accountabilities between the organized medical staff and the VA medical facility Director as the governing body, and between the organized medical staff and its members."[130]

National Practitioner Data Bank. "A web-based repository of reports containing information on medical malpractice payments and certain adverse actions related to LIPs."[131]

occurrence screens. "The evaluation of episodes of care against a list of specified criteria. Cases that involve one or more of the occurrences are reviewed to identify possible problems in patient care. Cases meeting the criteria may be entered into an ongoing occurrence screening database to be reviewed and analyzed regularly to identify patterns that may be problematic."[132]

ongoing professional practice evaluation. "The ongoing monitoring of privileged LIPs to identify clinical practice trends that may impact the quality and safety of care."[133]

Practitioner Profile. "A LIP-specific file containing only information LIP-specific clinical practice data and relevant administrative information which supports the privileging process. This file is maintained by the clinical service chief and presented to the [MEC], and the VA medical facility Director to support privileging decisions. Information contained within the Practitioner Profile includes the LIP's FPPE, […] FPPE for Cause, and Focused Clinical Care Reviews."[134]

reduction of privileges. "May include restricting or prohibiting a LIP's performance of selected specific procedures."[135]

revocation of privileges. "The permanent loss of all clinical privileges."[136]

sigmoid. A section of the colon right above the rectum.[137]

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[129] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).
[130] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).
[131] VHA Directive 1100.21; VHA Directive 1100.21(1).
[132] VHA Directive 1320.
[133] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).
[134] VHA Directive 1100.21; VHA Directive 1100.21(1).
[135] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).
[136] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).
[137] *Merriam-Webster.com Dictionary,* "sigmoid colon," accessed February 26, 2024, https://www.merriam-webster.com/dictionary/sigmoid%20colon.

standard of care. "A diagnostic and/or treatment process that a clinician should follow for a certain type of patient, illness, or clinical circumstance. It is how similarly qualified clinicians would have managed the patient's care under the same or similar circumstances."[138]

state licensing board. "In the context of health care means the agency of a State that is primarily responsible for the licensing of the physician or LIP to furnish health care services."[139]

summary suspension. "an action taken by the VA medical facility Director to suspend clinical privileges when the failure to take such action may result in an imminent danger to the health and safety of any individual. Summary suspension may be applied to one or more selected privileges or all privileges depending upon the circumstances and clinical concern."[140]

transanal. A surgical approach using a specialized type of scope inserted through the anus to remove very small rectal cancers.[141]

trocar. A sharp-pointed surgical instrument.[142]

VetPro. "VHA's mandatory credentialing software platform to document the credentialing of VHA LIPs. This system facilitates completion of a uniform, accurate, and complete credentials file."[143]

[138] VHA Directive 1190.

[139] VHA Directive 1100.21; VHA Directive 1100.21(1).

[140] VHA Handbook 1100.19; VHA Directive 1100.21; VHA Directive 1100.21(1).

[141] Mayo Clinic, "*Rectal cancer*," accessed February 22, 2024, https://www.mayoclinic.org/diseases-conditions/rectal-cancer/diagnosis-treatment/drc-20352889.

[142] *Merriam-Webster.com Dictionary*, "trocar," accessed February 21, 2024, https://www.merriam-webster.com/dictionary/trocar.

[143] VHA Directive 1100.21; VHA Directive 1100.21(1).

OIG Contact and Staff Acknowledgments

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