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VETERANS HEALTH ADMINISTRATION

Facility Leaders' Oversight and Quality Management Processes at the Gulf Coast VA Health Care System Biloxi, Mississippi

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to an allegation that a thoracic surgeon (surgeon) provided poor quality of care to five patients at the Gulf Coast Veterans Health Care System (facility) in Biloxi, Mississippi. The OIG received three allegations in 2017. Two of the allegations were addressed in a prior OIG report, *Inadequate Intensivist Coverage and Surgery Service Concerns* at the Gulf Coast Veterans Health Care System.¹ The OIG's Office of Healthcare Inspections deferred review of the third allegation related to the surgeon's quality of care until the OIG's Office of Investigations reviewed concerns under its jurisdiction for potential criminal actions. The OIG resumed its evaluation of the allegation related to the surgeon's quality of care.

When the OIG team re-visited the facility in April 2018, the team found the facility had verified concerns related to the surgeon's quality of care for two of the five patients.³ The OIG agreed with the facility's findings. To ensure proper corrective action had been taken and sustained, and to help prevent such recurrences, the OIG team focused on facility leaders' actions after learning about the deficiencies in care, including their oversight of overall quality management processes.

Among the issues the OIG team reviewed during this inspection was leaders' knowledge of credentialing and privileging deficiencies associated with the surgeon. Veterans Health Administration (VHA) policy specifies credentialing and privileging requirements for all healthcare professionals who provide patient care services at a medical facility.⁴ The OIG determined that facility leaders did not follow policy requirements related to the credentialing process, evaluation of performance for privileging, the reporting of quality of care concerns to the National Practitioner Data Bank and state licensing boards, and the inactivation of the surgeon's file in VHA's credentialing system for all licensed healthcare personnel (VetPro).⁵

¹ The prior report (Report No. 17-03399-150) was issued by the OIG on March 29, 2018.

² From this point forward, the "OIG team" is used to refer to OIG's Office of Healthcare Inspections team, not the Office of Investigations team.

³ The surgeon is no longer employed by Veterans Health Administration.

⁴ VHA Handbook 1100.19, Credentialing and Privileging, October 15, 2012.

⁵ The National Practitioner Data Bank is a web-based repository of reports containing information on medical malpractice payments and certain adverse actions related to health care, providers, and suppliers. <u>https://www.npdb.hrsa.gov/topNavigation/aboutUs.jsp</u>. (The website was accessed on April 27, 2019.)

Surgeon Credentialing and Privileging

The OIG team reviewed the surgeon's credentialing and privileging files and determined that before hiring the surgeon in August 2013, facility leaders were aware of licensure and malpractice issues, including the relinquishing of a state medical license in October 2006 to prevent continued prosecution in a disciplinary case. Despite this, the Credentialing Committee recommended—and the Facility Director approved—the surgeon's medical staff appointment. Unfortunately, none of the current facility staff interviewed by the OIG knew the reason for the recommendation or approval and there was no documentation related to the basis for the recommendation or approval. VHA and facility policy required the Veterans Integrated Service Network (VISN) Chief Medical Officer's approval prior to the surgeon's appointment due to the relinquished medical license.⁶ The OIG requested documentation demonstrating that the required approval had been obtained, but facility leaders were unable to produce it.

The OIG team determined that facility leaders did not complete components of the surgeon's evaluations required by VHA policy to grant provider-specific privileges including an initial focused professional practice evaluation (FPPE), subsequent FPPEs, and routine ongoing professional practice evaluations (OPPEs).⁷ In addition, the OIG team found that facility leaders were deficient in granting and continuing the surgeon's clinical privileges without required evidence of competency.

When interviewed, facility leaders did not have a clear understanding of the requirements for reviewing the surgeon's care provided.⁸ Facility leaders also removed the surgeon in October 2017 from the clinical care setting without following required processes, including notifications to external reporting agencies.⁹ As a result, facility leaders were unable to report the surgeon to the National Practitioner Data Bank and were delayed in reporting to state licensing boards.¹⁰

⁹ VHA Handbook 1100.19.

⁶ VHA Handbook 1100.19; Gulf Coast Veterans Health Care System, Memorandum No. 11-58-12, *Credentialing and Privileging and Reporting to the National Practitioner Data Bank*, June 25, 2012.

⁷ VHA Handbook 1100.19. FPPEs and OPPEs, part of a facility's oversight process, allow assessment of a provider's privilege-specific competence. FPPE occurs with initial medical staff appointments or the granting of new privileges. It may also be used when a question arises regarding a currently privileged practitioner's ability to provide safe, high-quality patient care. OPPE allows assessment of continued competency, and may include a review of certifications, direct observation, clinical discussions, and clinical pertinence reviews. Data must be practitioner-specific, reliable, easily retrievable, timely, justifiable, comparable, and risk adjusted where appropriate.

⁸ Interviewees included an acting medical center director, acting chief of staff, and newly installed chief of staff; not all interviewees were in the roles when some of the oversight deficiencies occurred.

¹⁰ At the time the facility took action related to reporting to state licensing boards in 2017, the surgeon was licensed in two states. The facility took steps to report the surgeon to one state board in September 2018, but did not initiate action to report the surgeon to the second state board until April 2019.

During the April 2018 site visit, the OIG team found that although the surgeon resigned from VHA on December 12, 2017, the Chief of Surgery did not provide credentialing and privileging staff justification related to an exit-interview statement–"failed to meet generally accepted standards of practice"–until mid-June 2018. The justification was needed to take the appropriate steps to inactivate the surgeon's VetPro file.¹¹ Facility leaders did not comprehend that the failure to take appropriate steps to close the VetPro file impacted quality of care processes.

Due to concerns for patient safety and potential effects of oversight failures, the OIG team expanded the scope of the review from the surgeon-related oversight processes to include a facility-wide oversight process review.

Systemic Deficiencies in Credentialing and Privileging

The OIG team identified concerns related to the facility's credentialing and privileging processes, particularly the lack of FPPE and OPPE documentation. In order to evaluate these concerns, the OIG team reviewed service file documentation for 50 facility providers who were newly appointed to the medical staff from October 2016 through December 2017 (study period). The following reflected deficiencies in facility oversight responsibilities:

- Fourteen of the 50 service files lacked documentation of a defined or completed FPPE.
- Three of four providers who requested and were granted a new privilege or change in privilege did not have an FPPE to evaluate provider-specific competency.
- Three of seven FPPEs completed due to concerns related to a provider's quality of care were not discussed at the oversight committee.
- Six instances in 18 provider service files with an OPPE were found where facility leaders did not include reviews of appropriateness of care, patient safety, and/or desired outcomes.

Quality Management Processes

The OIG also reviewed several quality management processes including relevant committee and reporting activities (including documentation), institutional disclosures, and administrative investigative boards (AIBs).¹² Among the weaknesses identified were the following:

¹¹ VHA Handbook 1100.19.

¹² VA Handbook 0700, Transmittal Sheet, *Administrative Investigations*, July 31, 2002. An AIB is a VA standard procedure used for collecting and analyzing evidence, ascertaining facts, and documenting complete and accurate information including significant misconduct by employees, mismanagement of funds, or reports of unsafe conditions.

- An oversight committee's poor documentation and follow-up action, including reports of poor compliance with cardiac life support certification, made it difficult for leaders to ensure policy requirements were met.¹³
- The facility's Health Information Management Section experienced leadership challenges which affected oversight related to the administrative closing of electronic health record notes.¹⁴
- Confidential Veterans Affairs Surgical Quality Improvement Program (VASQIP) data were improperly posted in a working group's minutes on the facility's internal website accessible to all VHA staff.¹⁵
- Meeting minutes revealed that over a 12-month period, 3 of 15 patients who died within 30 days of a surgical procedure did not have their care presented to the appropriate group for review, resulting in the patient safety manager lacking assurance that all adverse patient events were reported in accordance with facility procedures.
- Although staff providing direct patient care must have appropriate life-saving certifications, a high number of compliance reports (15 of 23 basic life support and all six advanced cardiac life support) did not document completion. The Nursing Service did not submit required reports to its oversight committee for 5 of the 10 months reviewed. Reasons for noncompliance were not provided.
- Although the Patient Safety Committee met as required, the meeting minutes lacked enough detail for required action steps related to patient safety adverse event reports and proactive risk assessments.¹⁶
- Of the 22 peer reviews in which the reviewer would have taken different action or believed the care provider's action was incorrect, the OIG team found 12 adverse actions

¹³ Gulf Coast Veterans Health Care System Memorandum No. 00-67-16, *Councils, Boards, and Committees,* August 18, 2016; Gulf Coast Veterans Health Care System Memorandum No. 11-42-13, *Executive Committee of the Medical Staff,* April 24, 2013. "Activities will be recorded in sufficient detail to track medical management decisions and problem solving. Minutes will reflect conclusions, recommendations, actions, and follow-up plans, as appropriate."

¹⁴ Gulf Coast Veterans Health Care System Memorandum No. 136-01-15, July 7, 2015, was rescinded and replaced by Gulf Coast Veterans Health Care System Memorandum No. 136-01-16, *Consolidated Health Records Policy*, May 10, 2016, which contains same or similar language related to administrative closure of electronic documentation.

¹⁵ VHA Directive 2008-077, Quality Management (QM) and Patient Safety Activities that can Generate Confidential Documents, November 7, 2008. VHA Handbook 1102.01, National Surgery Office, January 30, 2013.

¹⁶ Gulf Coast Veterans Health Care System Memorandum No. 00-67-16, Attachment D, outlines the facility's required elements (including status of action items and target dates for completion).

associated with care or services provided; yet, based on the facility processes used, eight events did not appear to be reported to the patient safety manager as required.¹⁷

- The patient safety manager did not complete the required 18-month proactive risk assessment (completed for the purpose of helping to prevent adverse patient events) for The Joint Commission accredited programs.¹⁸
- Although facility leaders had processes for determining if institutional disclosures were warranted in appropriate cases, the OIG identified eight events (based on a review of relevant root cause analyses and peer reviews) in which the facility was unable to provide evidence that an institutional disclosure was considered.¹⁹
- Of the three AIB reviews related to alleged employee misconduct or unsafe conditions that the facility initiated during the study period, facility leaders did not make certain that extensions were approved when reviews exceeded the 45-calendar day timeframe for completion.²⁰

Due to changes in leadership and facility leaders' multiple instances of quality management failures that appeared to be due to a lack of knowledge or understanding of VHA policies, the OIG recommended that the VISN Director oversee implementation of facility recommendations.

The OIG made 18 recommendations to the Facility Director related to professional practice evaluation processes, National Practitioner Data Bank and state licensing board reporting, documenting sufficient detail in committee meeting minutes to reflect decision-making and protecting certain confidential information. Recommendations also centered on reporting events to the Patient Safety Committee, reporting surgery patients' deaths as required, completing proactive risk assessments, and institutional disclosure and AIB review processes.

¹⁷ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010, describes peer review levels as Level 1 which indicates that most experienced, competent providers would have managed the patient's care similarly; Level 2 indicates that most providers might have handled the patient's care differently; and Level 3 indicates that most providers would have handled the patient's care differently. This directive was rescinded and replaced by VHA Directive 1190, *Peer Review for Quality Management*, November 28, 2018, which contained a revised definition for Level 2; VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 04, 2011; GCVHCS 00F-09-15, *Patient Safety Improvement Program*, July 17, 2015. At the facility, the first employee who noted unsafe conditions had a duty to complete a report that was submitted to the patient safety manager.

¹⁸ VHA Handbook 1050.01. Completion of an annual Proactive Risk Assessment is required as a way of assessing "a product or process to identify system weaknesses, and associated corrective actions, before an adverse event happens." The proactive risk assessment frequency was modified to 18 months in a memorandum dated September 20, 2012, from the VHA Chief Safety and Risk Awareness Officer.

¹⁹ VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012, corrected copy October 12, 2012.

²⁰ VA Handbook 0700, Transmittal Sheet, Administrative Investigations, July 31, 2002.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided an acceptable action plan (see appendixes B and C, pages 27-40 for the Directors' comments). The OIG considers all recommendations open and will follow up on the planned and recently implemented actions to ensure they have been effective and sustained.

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Abbreviations

ACLS	advanced cardiovascular life support	
AIB	administrative investigation board	
BLS	basic life support	
COS	Chief of Staff	
ECMS	Executive Committee of the Medical Staff	
EHR	electronic health record	
FPPE	focused professional practice evaluation	
FY	fiscal year	
NPDB	National Practitioner Data Bank	
OIG	Office of Inspector General	
OPPE	ongoing professional practice evaluation	
SLB	state licensing board	
VASQIP	Veterans Affairs Surgical Quality Improvement Program	
VHA	Veterans Health Administration	
VISN	Veterans Integrated Service Network	



Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to an allegation that a thoracic surgeon (surgeon) provided poor quality of care to five patients at the Gulf Coast Veterans Health Care System (facility), Biloxi, Mississippi. The OIG received three allegations in 2017. Two of the allegations were addressed in the OIG report, *Inadequate Intensivist Coverage and Surgery Service Concerns*, Gulf Coast Veterans Health Care System, Biloxi, Mississippi, Report No. 17-03399-150, March 29, 2018. The OIG's Office of Healthcare Inspections deferred review of the third allegation related to the surgeon's quality of care until the OIG's Office of Investigations reviewed concerns under its jurisdiction for potential criminal actions. The OIG Office of Healthcare Inspections resumed its evaluation of the allegation related to the surgeon's quality of care after the Office of Investigations closed its review on November 13, 2017, without proceeding further.

When the OIG healthcare team visited the facility in April 2018, inspectors found the facility had taken actions and verified concerns related to the surgeon's quality of care for two of the five patients.²¹ The OIG agreed with the facility's findings. To ensure proper corrective action had been taken and sustained, and to help prevent such recurrences, the OIG healthcare team focused on facility leaders' actions after learning about the deficiencies in care, including their oversight of overall quality management processes.

About the Facility

The facility, along with its associated community based outpatient clinics, served 71,013 veterans in fiscal year (FY) 2018 and operated 245 beds, including 72 inpatient beds, 72 domiciliary beds, and 101 community living center beds.²² It has a Facility Complexity Model Level designation of 1c and provides primary care, medicine, surgery, psychiatry, psychology, neurology, oncology, dentistry, geriatrics, extended care, and physical medicine and rehabilitation services. The facility has affiliations with Keesler Air Force Base, Louisiana State University, Tulane University, and the University of South Alabama.

²¹ The surgeon is no longer employed by Veterans Health Administration.

²² The facility, part of Veterans Integrated Service Network (VISN) 16, includes a tertiary care medical facility located in Biloxi, Mississippi, and four community based outpatient clinics located in Mobile, Alabama; and Pensacola, Eglin Air Force Base (Valparaiso), and Panama City, Florida.

Credentialing and Privileging

VHA has defined procedures for the credentialing and privileging of all healthcare professionals who are permitted by law and the medical facility to practice independently within the scope of the individual's license, and in accordance with individually-granted clinical privileges.²³

Credentialing refers to the systematic process of screening and evaluating qualifications. The applicant must have the requisite education, training, experience, as well as the mental health, physical health, and skills to fulfill the requirements of the position and support the requested clinical privileges.²⁴

Privileging is the process by which a provider is permitted by law and the medical facility to provide medical care services within the scope of the individual's license. Privileges need to be specific, based on the individual's clinical competence, recommended by service chiefs and the Executive Committee of the Medical Executive Council, and approved by the facility director. Privileges are granted for a period not to exceed two years; providers must undergo re-privileging prior to the expiration of the held privileges (see appendix A for more detailed information about the facility's credentialing and privileging process).²⁵

Surgeon

The surgeon began working at the facility on August 25, 2013. Prior to the initial appointment, the facility's Credentialing Committee reviewed and approved the surgeon's practice history. According to Credentialing Committee meeting minutes, facility leaders were aware of a past negative professional history, including four adverse actions with medical boards, one adverse action resulting in the revocation of privileges, and three cases of alleged malpractice.

In February 2014, approximately five months after the surgeon started at the facility, the Chief of Staff (COS) requested a review of a patient's care provided by the surgeon through a Professional Standards Board.²⁶ The surgeon's privileges were summarily suspended while the Professional Standards Board conducted a review. The Professional Standards Board determined

²³ VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was due for recertification October 31, 2017, but has not been recertified.

²⁴ VHA Handbook 1100.19.

²⁵ VHA Handbook 1100.19.

²⁶A Professional Standards Board is convened on an ad hoc basis to address concerns of the medical staff. Through the COS, service chiefs can request a Professional Standards Board to address provider performance concerns. The Professional Standards Board will investigate the charges and draft a report with a recommended action to the Executive Committee of the Medical Staff (ECMS) which reviews the report and decides to accept, reject, or modify the recommendation made by the Professional Standards Board. If the ECMS acts to reduce or revoke the privileges of a licensed independent practitioner, the licensed independent practitioner is entitled to due process to include hearings, attorney representation, and appeals.

all alleged deficiencies "to be without merit" and the surgeon resumed surgical activities on April 7, 2014.

As part of a facility's quality management process, provider performance is evaluated using a confidential and non-punitive process known as peer review. VHA policy identifies clinical events requiring consideration of peer review.²⁷ After evaluating a case, peer reviewers assign a peer review level to the actions and decisions made by the provider under review (see appendix A for more detailed information related to the peer review process).²⁸

Peer reviews conducted by the facility did not identify concerns after the 2013 Professional Standards Board review related to the surgeon's quality of care until 2017. On October 31, 2017, facility leaders placed the surgeon on a "surgical pause".²⁹ During interviews, the OIG team learned that facility leaders pursued an external proctorship for the surgeon; however, the surgeon resigned prior to further professional evaluations or proctoring.³⁰ According to facility leaders, after staff identified a discrepancy in the malpractice history reported on the surgeon's original application and leaders brought the issue to the attention of the surgeon, the surgeon resigned effective December 12, 2017.

Concerns

The OIG issued a report in 2018 that addressed two of three allegations received in 2017 related to surgical services.³¹ After OIG's Office of Investigations completed a review of concerns under its jurisdiction without proceeding further in November 2017, OIG's Office of Healthcare Inspections resumed its evaluation of the third remaining allegation related to the surgeon's

²⁷ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. This directive expired June 30, 2015 and was replaced by VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. Triggering events include lack of adequate documentation of a patient's deterioration during the 48 hours preceding death; death during or within 30 days of a surgical procedure; and signs of a patient's deteriorating condition that should have been noted and/or communicated to the physician, but were not.

²⁸ VHA Directive 2010-025. A peer reviewer is a healthcare professional who can assess the provider's actions relative to the episode of care under review. Level 1 indicates that most experienced, competent providers would have managed the patient's care similarly. Level 2 indicates that providers might have handled the patient's care differently. Level 3 indicates that providers would have handled the patient's care differently.

²⁹ The OIG team noted that the term "surgical pause" is not an action per VHA directive; the correct action would have been a summary suspension of privileges.

³⁰ In a proctorship, a provider is assigned to observe the practice of another provider performing specified activities. The surveying provider, the proctor, will report observations as required. The proctor must have the specific clinical privileges to perform the activity, however the proctor must not be directly involved in the care the observed provider is delivering.

³¹ VA Office of Inspector General, Healthcare Inspection, Inadequate Intensivist Coverage and Surgery Service Concerns, Gulf Coast Veterans Health Care System, Biloxi, Mississippi. Report No. 17-03399-150, March 29, 2018.

quality of care.³² The OIG team found the facility had verified specific quality of care concerns for two of the five identified patients.³³ The OIG agreed with the facility's findings and the team focused this inspection on facility leaders' actions after confirming surgeon-related poor quality of care and their oversight of quality management processes.

During the inspection, the OIG team identified deficiencies in the facility's credentialing and privileging process. After identifying the deficiencies, the OIG expanded the scope of the inspection to review several quality management processes including relevant committee and reporting activities (including documentation), institutional disclosures, and administrative investigative boards (AIBs).³⁴

Scope and Methodology

The OIG team initiated the inspection in December 2017 and conducted a site visit April 10–12, 2018. The OIG team interviewed staff including the prior acting Facility Director and current Facility Director, prior acting and current COS, Acting Chief of Medicine Service, Chief of Quality and Performance Management, Risk Manager, and the Patient Safety Manager.³⁵ The OIG team consulted with a representative from the National Surgery Office as well as the VHA Director of Medical Staff Affairs. The OIG team met with staff from the U.S. Government Accountability Office and the OIG Comprehensive Healthcare Inspection Program who were concurrently conducting inspections at the facility. Despite several attempts by telephone, mail, and electronic mail, the OIG was unable to arrange an interview with the surgeon.

The review of facility processes focused on the timeframe October 2016 through December 2017 (study period). The OIG reviewed patient electronic health records (EHRs), facility and VHA policies, patient safety documents, credentialing and privileging files, quality of care review records, provider training records, and other documents relevant to the inspection. OIG staff reviewed data obtained during the study period from VHA Corporate Data Warehouse about patient deaths occurring within 30 days of a surgical procedure.³⁶ The OIG team evaluated

³² From this point forward, the term "OIG team" refers to the Office of Healthcare Inspections team rather than the Office of Investigations team.

³³ The surgeon is no longer employed by Veterans Health Administration.

³⁴ VA Handbook 0700, Transmittal Sheet, *Administrative Investigations*, July 31, 2002. An AIB is a standard procedure used for collecting and analyzing evidence, ascertaining facts, and documenting complete and accurate information including significant misconduct by employees, mismanagement of funds, or reports of unsafe conditions.

³⁵ Other interviewees included credentialing and privileging staff, human resources representatives, facility administrative staff, Veterans Affairs Surgical Quality Improvement Program (VASQIP) staff, prior and current facility committee chairpersons, and facility providers and staff knowledgeable about surgical service clinical operations.

³⁶ Corporate Data Warehouse is a centralized data repository that contains VHA clinical, administrative, and financial data.

facility Executive Committee of the Medical Staff (ECMS) and subordinate committee activities, processes, and records.

Additionally, the OIG team reviewed more than 7,000 email messages and attachments obtained from Clearwell (VHA-authorized software program) to determine if there was additional insight into Veterans Integrated Service Network (VISN) and facility leaders and other staff knowledge or communication of concerns related to the surgeon.

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.

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

In response to the original allegation regarding poor quality of care by the surgeon, the OIG team reviewed the surgeon's documented performance history at the facility, from the time of initial appointment to resignation. In addition, the OIG team reviewed EHR documentation of the five patients identified by the complainant in 2017. The team noted that facility leaders reviewed the quality of care provided to the five named patients, confirmed deficiencies in two of the five patients' care that were addressed through the peer review process.

Due to concerns for patient safety and potential effects of oversight failures, the OIG team expanded the scope of the review from the surgeon-related oversight processes to include a facility-wide oversight process review. The OIG team identified deficiencies in the facility's quality management oversight processes.

1. Deficiencies in Facility Leaders' Oversight

Surgeon's Credentialing and Privileging

VHA policy specifies the credentialing and privileging requirements for all healthcare professionals who provide patient care services at the facility (see appendix A for additional information related to credentialing and privileging processes).³⁷ The OIG team determined that for the surgeon, facility leaders did not follow required policy related to the credentialing process, evaluating performance for privileging, reporting quality of care concerns to the National Practitioner Data Bank (NPDB) and state licensing boards (SLBs), or inactivating the VetPro file.³⁸

Credentialing

The OIG team determined that facility leaders knew, prior to hiring the surgeon, of previous medical licensure and malpractice issues. However, facility leaders were unable to produce documentation reflecting the required VISN Chief Medical Officer's approval prior to the surgeon's medical staff appointment.

³⁷ VHA Handbook 1100.19.

³⁸ The NPDB is a web-based repository of reports containing information on medical malpractice payments and certain adverse actions related to health care, providers, and suppliers. It is a workforce tool that prevents providers from moving state-to-state without disclosure or discovery of previous damaging performance. <u>https://www.npdb.hrsa.gov/topNavigation/aboutUs.jsp</u>. (The website was accessed on April 27, 2019.) VetPro is VHA's credentialing system for all licensed healthcare personnel.

According to VHA and facility policy, VISN Chief Medical Officer approval is required when a new applicant has had previous action against or voluntarily relinquished a medical license to avoid potential action, or a history of specific instances of alleged malpractice.³⁹

On June 24, 2013, VetPro documentation reflected that the former Chief of Surgery approved the surgeon for full-time employment as a vascular/thoracic surgeon at the facility. VetPro documentation included excerpts from Credentialing Committee meeting minutes reflecting that the surgeon had five reports in the Federation of State Medical Boards and NPDB; four adverse actions with medical boards, and one adverse action resulting in revocation of privileges.⁴⁰ In addition, the surgeon had three cases of alleged malpractice; two were dismissed and one resulted in a payout. The OIG team confirmed that the surgeon voluntarily relinquished a state medical licenses to prevent continued prosecution in a disciplinary case.

Due to changes in leadership and staff, the OIG was unable to discuss initial credentialing and privileging issues with employees who were knowledgeable about decision-making that occurred in 2013. The OIG relied on documentation to discover the details noted above. While a review of one of the surgeon's patients was conducted in early 2014, the OIG did not identify other documentation or concerns related to quality of care issues with the surgeon's practice until 2017 as discussed in the privileging section.

Privileging

The OIG team determined that facility leaders did not complete the surgeon's initial focused professional practice evaluation (FPPE) and subsequent FPPEs and ongoing professional practice evaluations (OPPEs) in accordance with VHA policy. In addition, the OIG team found that facility leaders granted and continued the surgeon's privileges without required evidence of competency.

According to VHA policy, an FPPE must be completed when a provider is granted new or additional clinical privileges.⁴¹ Specifically, the policy requires the results of an FPPE to be documented in the provider's service file and reported to the oversight committee (ECMS for the facility) for consideration in making recommendations for clinical privileges. VHA policy further

³⁹ VHA Handbook 1100.19. Gulf Coast Veterans Health Care System, Memorandum No. 11-58-12, *Credentialing and Privileging and Reporting to the National Practitioner Data Bank*, June 25, 2012, was rescinded and replaced by Gulf Coast Veterans Health Care System, Memorandum No. 11-58-15, *Credentialing and Privileging and Reporting to the National Practitioner Data Bank*, July 24, 2015, which contains the same or similar language related to VISN Chief Medical Officer approval of specified credentialing and privileging processes.

⁴⁰ The Federation of State Medical Boards is a national nonprofit organization representing the 70 medical and osteopathic boards of the United States and its territories. The ultimate objective is to promote excellence in medical practice, licensure, and regulation as the national resource and voice on behalf of state medical boards in their protection of the public. <u>https://www.fsmb.org/about-fsmb/</u>. (The website was accessed on November 21, 2018.) ⁴¹ VHA Handbook 1100.19.

requires that non-anesthesia providers who utilize moderate sedation must complete a period of FPPE or OPPE specific to moderate sedation care prior to approval of clinical privileges.⁴² In addition, facility policy requires that all completed FPPEs and OPPEs be maintained by the provider's service.⁴³

At the time of initial appointment, facility leaders approved the surgeon's requested thoracic surgery privileges and placed the surgeon on an initial 90-day FPPE beginning August 25, 2013. The OIG team found that the surgeon's first OPPE began on October 1, prior to the completion of the initial FPPE. The completed, initial FPPE was not approved until December 16, which was 76 days after the start of the surgeon's OPPE.

On October 21, 2013, facility leaders granted the surgeon additional clinical privileges in moderate sedation. The Credentialing Committee documented in the meeting minutes that the surgeon was required to undergo a 90-day FPPE for the newly requested clinical privilege; however, the OIG team found no documentation of a completed FPPE for moderate sedation. On June 19, 2015, the Facility Director approved the surgeon's requested additional clinical privileges for endobronchial ultrasound; however, the OIG team found no documentation that leaders completed an FPPE as required.⁴⁴

National Practitioner Data Bank and State Licensing Board Reporting

The OIG team determined that facility leaders removed the surgeon from providing clinical care without following required processes including notifications to external reporting agencies and quality of care reviews. As a result, facility leaders were unable to report the surgeon to the NPDB and were delayed in reporting to SLBs.⁴⁵

⁴² VHA Directive 1073, *Moderate Sedation by Non-Anesthesia Providers*, December 30, 2014; Moderate sedation is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands. Cardiovascular function is usually maintained.

⁴³Gulf Coast Veterans Health Care System, Memorandum No. 11-58-12, *Credentialing and Privileging and Reporting to the National Practitioner Data Bank*, June 25, 2012, was in place at the time the surgeon initially received clinical privileges. The 2012 memorandum was rescinded and replaced by Gulf Coast Veterans Health Care System, Memorandum No. 11-58-15, *Credentialing and Privileging and Reporting to the National Practitioner Data Bank*, July 24, 2015, which contains the same or similar language related to FPPE and OPPE documentation.

⁴⁴ An endobronchial ultrasound is a minimally invasive procedure to diagnose lung cancer, infections, and other diseases causing enlarged lymph nodes in the chest.

https://health.ucsd.edu/specialties/pulmonary/procedures/Pages/endobronchial.aspx. (The website was accessed on June 04, 2018.)

⁴⁵ An SLB is a state agency with primary responsibility for physician or provider licensing to furnish health care services. 42 U.S.C. § 11151.

http://uscode.house.gov/view.xhtml?req=(title:42%20section:11151%20edition:prelim). (The website was accessed on June 20, 2018).

VHA policy and facility bylaws state that when a provider is removed from clinical care, an official notification in the form of a letter of summary suspension is required.⁴⁶ The letter must include information regarding the requirement to report the individual to the NPDB, if indicated. VHA policy further states that the provider will be reported to the NPDB if a provider under review leaves prior to the conclusion of the investigation prompted by the summary suspension.⁴⁷ VHA policy also requires a review of the provider's clinical practice be initiated within seven calendar days of the provider leaving VA employment, or receipt of information that the provider's practice may be reportable to the SLB.⁴⁸ Specifically, SLB reporting is required when a provider "substantially failed to meet generally accepted standards of clinical practice as to raise reasonable concern for the safety of patients."⁴⁹

On October 31, 2017, facility leaders placed the surgeon on a "surgical pause".⁵⁰ Facility leaders told the OIG that while the surgeon was under the "surgical pause," they pursued an external proctorship for the surgeon.

Through interviews and data review, the OIG team confirmed that the surgeon did not perform surgeries from the initiation of the "surgical pause" through the time of resignation on December 12, 2017. The OIG determined that the surgeon was not provided an official summary suspension of privileges notification letter. Therefore, according to VHA policy and as confirmed by the VHA Director of Medical Staff Affairs, facility leaders were unable to report the surgeon to the NPDB.

To further evaluate facility leaders' reporting, the OIG team reviewed documentation of six facility providers who had been reported to the NPDB during the study period. Five were reported due to medical malpractice settlements and one was reported due to resigning while under a malpractice settlement agreement. The OIG team determined that each of these reports met the qualification for initial reporting and facility leaders had taken the proper steps to notify the providers and subsequently report them to the NPDB.

⁴⁶ VHA Handbook 1100.19; Bylaws and Rules of the Medical Staff of Veterans Health Administration (VHA), VA Gulf Coast Veterans Health Care System, 2015 was in place during the time of the review. The 2015 Bylaws were replaced by Bylaws and Rules of the Medical Staff of VHA, VA Gulf Coast Veterans Health Care System, 2017, that contains the same or similar language related to credentialing and clinical privileging.

⁴⁷ VHA Handbook 1100.19; VHA Handbook 1100.17, *National Practitioner Data Bank (NPDB) Reports*, December 28, 2009. This directive was scheduled for recertification on or before the last working day of December 2014 and has not been recertified.

⁴⁸ VHA Handbook 1100.18, *Reporting and Responding to State Licensing Boards,* December 22, 2005. This handbook was scheduled for recertification on or before the last working day of December 2010 and has not been recertified.

⁴⁹ VHA Handbook 1100.18.

⁵⁰ The OIG team noted that the term "surgical pause" is not an action per the VHA directive; the correct action would have been a summary suspension of privileges.

The OIG also identified that facility leaders did not initiate a review of the surgeon's clinical practice within seven calendar days of leaving VA employment, or upon leaders' notification that the provider's practice may be reportable to SLBs. Facility leaders should report and monitor adverse provider data, such as conduct and competence, to SLBs.⁵¹ Timely and accurate data assist organizations in making well-informed employment, credentialing, and medical licensing decisions.

Facility leaders were initially aware on October 17, 2017, that peer review triggers were met to indicate concerns related to the surgeon's clinical practice. While conducting on-site interviews in April 2018, and continuing throughout the OIG inspection, the OIG team contacted facility leaders to determine the status of reporting to external agencies and the status of the surgeon's clinical privileges. On May 2, 2018, facility leaders told the OIG team that the surgeon's surgical cases were under review and depending on the outcome, information might be reportable to the SLB. On September 18, 2018, facility leaders reported the surgeon to one SLB (SLB 1).

However, the facility failed to recognize that the surgeon was also licensed in a second state. Upon questioning by the OIG, the facility recognized this failure in April 2019 and initiated steps to report the surgeon to the second SLB (SLB 2).

The delay in reporting prolonged the non-availability of surgeon quality of care information for SLB inquiries.

VetPro File Inactivation

During the site visit to the facility in April 2018, the OIG team found that although the surgeon resigned on December 12, 2017, the corresponding VetPro file had not been inactivated.⁵²

The OIG team conducted telephone and on-site interviews, and reviewed documents to determine what actions had been taken by facility leaders to inactivate the surgeon's VetPro file and to address the quality of care concerns. The OIG team found continued delays in the inactivation of the surgeon's VetPro file and facility leaders' response to the quality of care concerns. The delay of action indicated an unclear understanding of the significance of the quality of care issues and required subsequent actions. This was in addition to the areas outlined throughout this report detailing facility leaders' failures to follow required steps to address the identified quality of care concerns.

OIG Review of Other Facility Providers' FPPEs and OPPEs

To further evaluate the facility's FPPE and OPPE process, the OIG team reviewed FPPE and OPPE documentation and service files of 50 facility providers who were appointed to the

⁵¹ VHA Handbook 1100.19.

⁵² VHA Handbook 1100.19.

medical staff during the study period as well as 10 months of ECMS meeting minutes for the study period. The OIG identified deficiencies related to FPPE documentation, completion of an FPPE when a provider requested a new privilege, reporting of FPPE results to the oversight committee (specifically when a "for cause" FPPE was completed due to concerns about a provider's practice), and information included in OPPE reviews.⁵³ Table 1 illustrates the OIG team findings.

VHA and Facility Requirements ⁵⁴	OIG Findings
New facility providers undergo FPPE as defined at the time of privilege approval.	Fourteen of the 50 provider service files did not contain documentation of a defined or completed FPPE.
Providers undergo FPPE when there is a change or request for a new privilege.	Three of four providers who requested a change or new privilege did not have an FPPE.
The ECMS must consider all information, including reasons for renewal when criteria have not been met, such as a "for cause" FPPE and document deliberations in the meeting minutes.	Three of seven "for cause" FPPEs were not presented to the ECMS for consideration in making recommendations on clinical privileges.
OPPE reviews conducted by service chiefs must be comprised of activities with defined criteria that emphasize appropriateness of care, patient safety, and desired outcomes.	Six of 18 provider service files that contained an OPPE did not contain a review for appropriateness of care, patient safety, and/or desired outcomes.

 Table 1. Provider Privileging Requirements and OIG Findings

Source: VA OIG team analysis of VHA and facility policies and bylaws

2. Facility Quality Management Processes

Several committee activities and quality management processes were not in compliance with VHA and facility policies. VHA policy requires integration of an organizational structure that promotes the exchange and flow of quality management information and avoidance of organizational silos.⁵⁵

⁵³ Within the context of what the ECMS oversees, the facility's 2015 Bylaws state that "for cause" FPPEs are done when there is concern about competence and the care being rendered to patients. According to VHA Directive 2010-025, "FPPE may also be used when a question arises regarding a currently privileged practitioner or provider's ability to provide safe, high-quality patient care..."

⁵⁴ VHA Handbook 1100.19. Gulf Coast Veterans Health Care System, Memorandum No. 11-42-13, *Executive Committee of the Medical Staff*, April 24, 2013 was rescinded and replaced by Gulf Coast Veterans Health Care System, Memorandum No. 11-42-17, *Executive Committee of the Medical Staff*, October 10, 2017, that contains the same or similar language related to ECMS responsibilities and documentation.

⁵⁵ VHA Directive 1026, *VHA Enterprise Framework for Quality, Safety, and Value,* August 2, 2013. This VHA Directive was scheduled for recertification on or before the last working day of August 2018 but has not been recertified.

To help determine the effectiveness of the facility's committee structure and reporting, the OIG team reviewed selected elements of quality management processes, including required committee activities and meeting minutes.

Committee Structure and Reporting

The OIG team reviewed ECMS meeting minutes and subordinate committees/workgroup activities under the jurisdiction of the ECMS.⁵⁶ The subordinate committees and workgroup are required to submit reports and/or meeting minutes to ECMS for review.⁵⁷ The OIG team did not identify concerns related to the Credentialing Committee or the Peer Review Committee. However, the OIG team identified concerns related to the following subordinate committees and workgroup:

- Medical Records Committee
- Facility Surgical Workgroup
- Critical Care Committee

ECMS

The OIG team determined that ECMS meeting minutes reflected inconsistent discussion of findings and documented actions. Facility policy requires that the ECMS meets monthly to review and act on subordinate committee recommendations, and to document decisions and discussion "in sufficient detail to track medical management decisions and problem solving."⁵⁸

The OIG team reviewed ECMS meeting minutes for the study period and found that, although the ECMS met at the frequency required, ECMS meeting minutes did not clearly document careful consideration and review of information provided by subordinate committees. For example, the Critical Care Committee submitted reports to the ECMS with missing data and deficient basic life support (BLS) and advanced cardiac life support (ACLS) compliance rates for

⁵⁶ The ECMS was responsible for providing subordinate committee oversight. Only those committees under the jurisdiction of the ECMS that pertain to the concerns under review are addressed in this report.

⁵⁷ Gulf Coast Veterans Health Care System Memorandum No. 11-42-13, *Executive Committee of the Medical Staff*, April 24, 2013, was rescinded and replaced by Gulf Coast Veterans Health Care System Memorandum No. 11-42-17, *Executive Committee of the Medical Staff*, October 10, 2017, which contains same or similar language related to ECMS responsibilities and documentation.

⁵⁸ Gulf Coast Veterans Health Care System Memorandum No. 11-42-13. "Activities will be recorded in sufficient detail to track medical management decisions and problem solving. Minutes will reflect conclusions, recommendations, actions, and follow-up plans, as appropriate."

multiple services. In addition, ECMS and subordinate meeting minutes did not clearly reflect meeting discussions or actions.⁵⁹

Medical Records Committee

The OIG team found that the Medical Records Committee had standing monthly meetings; however, Medical Records Committee members were unable to complete processes and reporting during the absence of a facility Chief, Health Information Management Section.

Facility policy requires that the Medical Records Committee meet at least quarterly to provide oversight of the facility's ongoing EHR review process and report results to the ECMS.⁶⁰ The Medical Records Committee is responsible for identification of documentation problems or processes for which additional programming support or process redesign is needed. In addition, the Medical Records Committee is responsible for oversight of components and completeness of the EHR. An EHR is considered complete when all documentation is entered and signed by the author. According to facility policy, a record may be administratively closed if the author is no longer available; however, documentation must include an explanation of record activity and must be signed by the Chief, Health Information Management Section. The Chief, Health Information Management Section is required to provide a quarterly report of the number and nature of delinquent records to the Medical Records Committee, COS, and service chiefs.⁶¹

At each meeting, the Medical Records Committee reviewed facility data regarding delinquent Inpatient History and Physical Reports, Operative Reports, and Discharge Summary Reports. Once the Medical Records Committee reviewed the data, service chiefs were responsible for addressing service-related deficiencies in the documentation of EHRs. However, facility staff told the OIG team that the Medical Records Committee did not consistently receive Health Information Management Section data reports when the facility was without a Chief, Health Information Management Section. According to facility staff, an intern at the facility intermittently represented the Chief, Health Information Management Section during the two years the position was vacant. As evidenced in Medical Records Committee meeting minutes and in staff interviews, the Medical Records Committee had difficulty accomplishing processes and reports during that time. As of December 2017, the facility had a permanently assigned Chief, Health Information Management Section.

⁵⁹ Gulf Coast Veterans Health Care System Memorandum No. 00-67-16, *Councils, Boards, and Committees,* August 18, 2016.

⁶⁰ Gulf Coast Veterans Health Care System Memorandum No. 136-17-15, *Medical Records Committee*, December 28, 2015.

⁶¹ Gulf Coast Veterans Health Care System Memorandum No. 136-17-15. "A record is defined as delinquent if, at 30 days post patient discharge, the record is deficient in the presence or authentication of required documentation, including history and physical examination, discharge summary, and/or operative report."

Unsigned progress notes are generally not visible to other users who access patient EHRs. During the March 2017 Medical Records Committee meeting, members discussed the issue of "numerous unsigned notes" by providers who no longer worked at the facility. At that time, the Medical Records Committee agreed that closing EHR documentation should be included in the checkout process for a provider to officially separate from the facility.

At the April 2017 meeting, the Medical Records Committee agreed that Health Information Management Section staff could administratively close notes left unsigned by providers who no longer worked at the facility. The Medical Records Committee reported the decision to the ECMS and the ECMS approved the decision. In March 2018, the closing of EHR documentation had been added to the checkout process.

As of June 7, 2018, facility staff were unable to provide documentation of notes administratively closed by Health Information Management Section staff. Therefore, the OIG team was unable to validate that facility leaders adhered to VHA policy regarding the administrative closure of EHR notes. According to current facility staff, Health Information Management Section staff only administratively close a note after it has been brought to the Medical Records Committee for initial approval and the COS for final approval.

Facility Surgical Workgroup

The OIG team found that the Facility Surgical Workgroup meeting minutes were available on the facility's unsecured intranet site and contained protected Veterans Affairs Surgical Quality Improvement Program (VASQIP) data.

VHA policy states that VASQIP data are protected and required to be maintained on a secure intranet site.⁶² The Facility Surgical Workgroup supports the VISN 16 Surgical Work Group to integrate VASQIP, improve practice and patient safety, ensure communication at the facility level, and provide oversight of the Surgical Care Morbidity and Mortality Conference.⁶³ At each meeting, members review and analyze VASQIP data with a goal to improve surgical care within the facility. The Facility Surgical Workgroup meeting minutes, containing protected VASQIP data and were published on the facility's unsecured intranet site, accessible by all VHA and facility staff.

⁶² 38 United States Code §5705, "Confidentiality of medical quality-assurance records. Records and documents created by the Department as part of a medical quality-assurance program (other than reports submitted pursuant to section 7311(g) 1 of this title) are confidential and privileged and may not be disclosed to any person or entity except as provided in subsection (b) of this section." VHA Directive 2008-077, *Quality Management (QM) and Patient Safety Activities that can Generate Confidential Documents*, November 7, 2008. This directive expired November 30, 2013 and has not been recertified or replaced.

⁶³ Gulf Coast Veterans Health Care System Memorandum No. 112-03-14, *Facility Surgical Work Group* was rescinded and replaced by Gulf Coast Veterans Health Care System Memorandum No. 112-03-17, *Facility Surgical Work Group*, August 9, 2017, which contains the same or similar language related to functions of the Facility Surgical Workgroup Sub-Committee.

Surgical Care Morbidity and Mortality Conference

The Surgical Care Morbidity and Mortality Conference did not include the review of all patients whose death occurred within 30 days of a surgical procedure and did not include reporting of all adverse events to the patient safety manager as required.

Facility standard operating procedure requires that Surgical Care Morbidity and Mortality Conference members review patient deaths during surgery or within 30 days after a surgical procedure, and report adverse events to patient safety. The purpose of the Surgical Care Morbidity and Mortality Conference "is to ensure ongoing monitoring and evaluation of quality, appropriateness, and effectiveness of surgical patient care."⁶⁴

The OIG team reviewed Surgical Care Morbidity and Mortality Conference meeting minutes from FY 2017 through FY 2018, quarter 2, and found that 3 of 15 patients' care whose death occurred within 30 days of a surgical procedure were not presented to the Surgical Care Morbidity and Mortality Conference for review.⁶⁵ In addition, the OIG team determined that adverse events discussed at Surgical Care Morbidity and Mortality Conferences were not reported to the patient safety manager as defined by facility standard operating procedure.

Critical Care Committee

Facility staff BLS and ACLS certifications were not current and facility leaders did not address deficiencies reported by the Critical Care Committee.⁶⁶

Facility policy states that all clinically active staff who provide direct clinical care to patients are required to have evidence of current BLS certification.⁶⁷ Only specified providers are required to be ACLS certified; however, all ACLS certified staff must also maintain BLS certification. Facility policy further states that staff who do not maintain current certification will not be

⁶⁴ VA Gulf Coast Veterans Health Care System, Surgical Service Standard Operating Procedure for Morbidity and Mortality Occurrences, June 13, 2013.

⁶⁵ Although the study period was October 2016 through December 2017, the OIG reviewed information from quarter 2 of FY 2018 for this section of the report to capture patient deaths that occurred within 30 days of a surgery performed at the end of quarter 1 of FY 2018.

⁶⁶ BLS teaches the basic steps for treatment of a patient who is without a pulse or not breathing. BLS training reinforces knowledge of CPR, relieving choking, and using an automated external defibrillator. ACLS is an advanced course to enhance skills in the resuscitation of a pulseless patient, that includes CPR as well as related pharmacology, airway management, and management of stroke.

⁶⁷ Gulf Coast Veterans Health Care System Memorandum No. 11-43-12, *Cardiopulmonary Resuscitation: Basic and Advanced Cardiac Life Support Training and Certification,* June 21, 2012 was rescinded and replaced by Gulf Coast Veterans Health Care System Memorandum No. 11-43-18, *Cardiopulmonary Resuscitation: Basic and Advanced Cardiac Life Support Training and Certification,* March 19, 2018, which contains same or similar language related to the facility's ACLS and BLS requirements.

allowed to work unless a waiver has been obtained.⁶⁸ In addition, the policy outlines the supervisory responsibility to address the lapse in certification with progressive actions until certification is obtained or final disciplinary action is taken. Facility policy states that service chiefs are responsible for tracking staff compliance with BLS and ACLS certification requirements.

The Critical Care Committee meets monthly and submits a quarterly executive summary of performance improvement activities to the ECMS, including tracking reports related to BLS and ACLS.⁶⁹ The OIG team reviewed Critical Care Committee and ECMS meeting minutes from the study period and found that service compliance reports for BLS and ACLS certifications were not consistently tracked and/or reported to the ECMS. In addition, the OIG team found no evidence of actions taken to address certification deficiencies or obtain compliance data from non-reporting services.

The OIG team reviewed the service compliance reports used to track BLS and ACLS certifications submitted to the Critical Care Committee for the study period.⁷⁰ The OIG team determined that 15 of the 23 service compliance reports did not consistently reflect that required staff had current BLS certification. In addition, all six applicable service compliance reports did not consistently reflect that required staff had current ACLS certification. The OIG team also found that Nursing Service did not submit a BLS and ACLS compliance report for 5 of the 10 months reviewed.

To determine whether more recent reports reflected improved compliance, the OIG team requested BLS and ACLS compliance reports for FY 2018, quarter two. The OIG team found that 11 of 23 service compliance reports did not consistently reflect compliance with BLS and ACLS certifications.⁷¹

Patient Safety Program

The VHA National Patient Safety Improvement Handbook outlines patient safety processes designed to minimize the possibility of inadvertent harm to patients. Processes include the reporting of adverse events and close calls with an emphasis on prevention as the ideal method to

⁶⁸ Gulf Coast Veterans Health Care System Memorandum No. 11-43-12.

⁶⁹ Gulf Coast Veterans Health Care System Memorandum No. 111-11-13, *Critical Care Committee*, October 15, 2013 was rescinded and replaced by Gulf Coast Veterans Health Care System Memorandum No. 111-11-17, *Critical Care Committee*, May 19, 2017, which contains same or similar language related to Critical Care Committee requirements to meet and report to ECMS.

⁷⁰ Staff within these services are required to have up to date BLS and/or ACLS certifications. The study period was for 15 months; however, the OIG reviewed 12 months of Critical Care Committee meeting minutes (excluded Critical Care Committee meetings: December 2016; January 2017; November 2017).

⁷¹ The OIG team reviewed FY 2018, quarter 2 Critical Care Committee meeting minutes to determine if BLS and ACLS compliance had improved.

reduce adverse events. Identifying patient safety-related incidents, conducting proactive risk assessments, broadly evaluating the actual and potential contributory factors, and analyzing, trending, and reporting near misses and actual incidents are keys to preventing future occurrences of similar events.⁷²

The OIG team determined that several components of the patient safety program were not compliant with VHA and facility policies, and that adverse event reporting and disclosure were not being completed as warranted.

Patient Safety Committee

Facility policy defines the focus of the Patient Safety Committee, which is to improve patient safety by providing oversight of activities associated with safe healthcare delivery, recognizing potential patient harm, and ensuring process improvement occurs to prevent a repeat of adverse events.⁷³ Patient Safety Committee responsibilities include reporting of adverse events, tracking patient safety events and outcomes, identifying risk to patients, and compliance with National Patient Safety Goals. The Patient Safety Committee is required to meet 10 times per year.

The OIG team found that although the Patient Safety Committee met as required, the meeting minutes lacked sufficient detail. The meeting minutes reflected limited to no discussion of patient safety activities such as patient safety event reports and proactive risk assessments.

Adverse Event Reporting

VHA policy defines adverse events as occurrences of harm or potential harm directly associated with care or services provided by the facility.⁷⁴ Examples of adverse events include medication, diagnostic, or procedural errors; suicide attempts or gestures; or other events that could result in harm or injury to a patient. VHA policy requires all adverse events to be reported to the patient safety manager.⁷⁵

The OIG team found that the patient safety manager received 608 reports of adverse events for the study period. To ensure that the patient safety manager was made aware of adverse events, the OIG team reviewed 22 Level 2 and 3 peer review events to confirm adverse event reporting occurred when required. The OIG team found 12 of 22 peer reviews met criteria for adverse event reporting. Staff appropriately notified the patient safety manager of four adverse events;

⁷² VHA Handbook 1050.01.

 ⁷³ Gulf Coast Veterans Health Care System Memorandum No. 00F-02-15, *Patient Safety Committee*, July 31, 2015.
 ⁷⁴ VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012, corrected copy October 12, 2012.

⁷⁵ VHA Handbook 1050.01.

however, the OIG team identified eight instances where adverse event reports were not submitted to the patient safety manager as required by VHA policy.

Proactive Risk Assessments

The facility is required to complete at least one proactive risk assessment every 18 months for each of The Joint Commission accredited programs.⁷⁶ The facility is accredited by The Joint Commission in Behavioral Health Care, Home Care, and as a Hospital. The OIG team found no proactive risk assessment completed at the facility from FY 2015 through FY 2017 for The Joint Commission accredited programs.

Institutional Disclosures

The OIG team determined that the facility did not have processes in place to ensure consideration of institutional disclosure in appropriate cases.

VHA policy requires that patients, and when appropriate, their families, be informed of adverse events directly associated with VA medical care that result in serious injury or death.⁷⁷ The intent of institutional disclosure is to fully inform patients and their families about all clinically significant facts related to the harm caused by VA medical care and options to pursue for potential compensation.

The OIG team found that facility leaders completed three institutional disclosures in the study period. To further identify adverse events and determine whether additional institutional disclosures were considered or performed, the OIG team evaluated root cause analyses and Level 2 and 3 peer reviews completed during the study period.⁷⁸ Of the 26 events reviewed, the OIG team determined that eight events met criteria for consideration of an institutional disclosure; however, the facility was unable to provide evidence that an institutional disclosure was considered for any of these eight adverse events.⁷⁹

⁷⁶ VHA Handbook 1050.01. Completion of an annual proactive risk assessment is required as a way of assessing a product or process to identify system weaknesses, and associated corrective actions, before an adverse event happens. The proactive risk assessment frequency was modified to 18 months in a memorandum dated September 20, 2012, from the VHA Chief Safety and Risk Awareness Officer.

⁷⁷ VHA Directive 1004.08. Adverse events include events that resulted in, or reasonably expected to result in, death or serious injury; prolonged hospitalization; or life-sustaining intervention or intervention to prevent impairment or damage.

⁷⁸ Root cause analysis is a process to identify the factors related to an adverse event or close call.

⁷⁹ VHA Directive 1004.08. The eight additional events include the two patients identified in the 2017 complaint who had Level 3 peer review finding.

Administrative Investigation Boards

Facility leaders did not complete AIBs within the required timeframe and did not follow VA policy to document the reasons for granting an extension.

According to VA policy, an AIB is a standard procedure used for collecting and analyzing evidence, ascertaining facts, and documenting complete and accurate information including significant misconduct by employees, mismanagement of funds, or reports of unsafe conditions.⁸⁰ Policy requires AIBs to be completed within 45 calendar days of the date the AIB convened. The 45-calendar day timeframe may be extended when clearly written reasons for an extension are added to official AIB documents.⁸¹

Facility leaders initiated three AIBs during the study period. The OIG team determined that as of May 31, 2018, two of the three AIBs initiated in July and August 2017 remained open. The third AIB, initiated in October 2016, was not completed until March 2017. All three AIBs exceeded the 45-calendar day timeframe and did not include an amendment with the reasons for extension as required in VA policy.

Conclusion

Facility leaders knew, prior to hiring the surgeon, of previous medical licensure issues and were unable to produce documentation reflecting VISN Chief Medical Officer approval that is required for hiring a provider under such circumstances. The OIG team determined that the surgeon's initial and subsequent FPPEs and OPPEs were not completed in accordance with VHA policy. The initial FPPE was not completed before initiation of an OPPE. In addition, the OIG team found that facility leaders granted and continued the surgeon's privileges without the required evidence of all competencies.⁸²

To determine whether findings related to the surgeon's practice evaluations were isolated or more systemic, OIG inspectors evaluated documentation related to 50 facility providers with an initial appointment to the medical staff during the study period. Fourteen provider service files did not contain documentation of a defined or completed FPPE, three of four providers who requested modified or new privileges did not have an FPPE, three of seven "for cause" FPPEs were not presented to ECMS for approval, and 6 of 18 service files which contained OPPEs did not contain all required elements.

⁸⁰ VA Handbook 0700 Transmittal Sheet, *Administrative Investigations*, July 31, 2002 (Appendix A).

⁸¹ VA Handbook 0700 states, "The reasons for extensions shall be summarized in an amendment to the Charge Letter, in the Preliminary Statement of the Investigative Report, or in the Completion Certificate."

⁸² The OIG team found no documentation of FPPEs for ensuring competency in the use moderate sedation or endobronchial ultrasonography.

The surgeon was removed from clinical care without facility leaders following required processes including notifications and quality of care reviews. As a result, the provider could not be reported to the NPDB and reporting to SLBs was delayed. The surgeon was reported to SLB 1 in 2018 but steps to report the surgeon to SLB 2 were not initiated until April 2019. A review of facility reporting of other providers to the NPDB revealed that the facility had properly taken steps to report.

During a site visit to the facility in April 2018, the OIG team found that although the surgeon resigned on December 12, 2017, the corresponding VetPro file had not been inactivated. The inactivation of the surgeon's VetPro file and facility leaders' responses to the quality of care concerns indicated an unclear understanding of the significance of the quality of care issues and required subsequent actions.

ECMS meeting minutes reflected inconsistent discussion of findings and documented actions. Patient Safety Committee meeting minutes also lacked sufficient detail. The meeting minutes reflected limited to no discussion on items such as patient safety adverse event reports and proactive risk assessments.

The facility did not complete the required proactive risk assessments for all The Joint Commission accredited programs.

Facility staff were unable to provide documentation of notes administratively closed by the Health Information Management Section; therefore, the OIG team was unable to validate that facility leaders adhered to VHA policy regarding the administrative closure of notes.

Other identified deficiencies included the posting of protected VASQIP data on the facility's intranet site, which resulted in unauthorized access to all VA staff, a failure to document the presentation of all patients whose death occurred within 30 days of a surgical procedure to the Surgical Care Morbidity and Mortality Conference, and the lack of reporting adverse events discussed at the Surgical Care Morbidity and Mortality Conference to the patient safety manager.

The OIG team reviewed the compliance reports used to tracked BLS and ACLS certifications. The team determined that 15 of the 23 service compliance reports did not consistently reflect that required staff had current BLS certification. In addition, all six applicable service compliance reports did not reflect that required staff had current ACLS certification. The OIG team also found that Nursing Service did not submit a BLS and ACLS compliance report for five out of the 10 months reviewed.

OIG inspectors found 12 instances which met criteria for adverse event reporting. The patient safety manager was appropriately notified of four adverse events; however, the OIG team identified eight instances where adverse event reports were not submitted to the patient safety manager as required by VHA policy.

The OIG team determined that the facility process to identify and consider adverse events requiring an institutional disclosure did not ensure all adverse events were evaluated. Facility

leaders completed three institutional disclosures in the study period. Of the 26 root cause analyses and peer reviews completed during the study period, the OIG team determined that eight additional events met criteria for consideration of an institutional disclosure; however, the facility was unable to provide evidence that an institutional disclosure was considered for any of these eight adverse events.

Three AIBs initiated during the study period exceeded the 45-calendar day timeframe without a documented approved extension as required by VHA policy.

Due to changes in leadership and facility leaders' multiple instances of quality management failures that appeared to be due to a lack of knowledge or understanding of VHA policies, the OIG recommended that the VISN Director oversee implementation of facility recommendations.

Recommendations 1–19

- 1. The Veterans Integrated Service Network 16 Director oversees implementation of recommendations directed to the Gulf Coast VA Health Care System Director.
- 2. The Gulf Coast VA Health Care System Director ensures that providers with previous licensure issues or malpractice cases meeting the Veterans Health Administration indicated threshold for Veterans Integrated Service Network Chief Medical Officer review, are approved by the Veterans Integrated Service Network Chief Medical Officer prior to appointment of the provider to the medical staff as required by Veterans Health Administration policy and monitors compliance.
- 3. The Gulf Coast VA Health Care System Director ensures that Focused and Ongoing Professional Practice Evaluations are completed in accordance with Veterans Health Administration policy and monitors compliance.
- 4. The Gulf Coast VA Health Care System Director ensures that actions are taken to ensure processes are followed to review and report providers, when indicated, to the National Practitioner Data Bank and state licensing boards in the timeframe required by Veterans Health Administration policy and monitors compliance.
- 5. The Gulf Coast VA Health Care System Director reviews the circumstances surrounding the failure to report the surgeon to all licensing boards in states where the surgeon held active licenses in December 2017 and takes action, if necessary.
- 6. The Gulf Coast VA Health Care System Director ensures that the Executive Committee of the Medical Staff's meeting minutes provide sufficient detail to allow tracking of medical management decisions and problem solving and monitors compliance.
- 7. The Gulf Coast VA Health Care System Director determines the scope of previously administratively closed incomplete notes in patient electronic health records that have been administratively closed to ensure compliance with Veterans Health Administration policy and monitors compliance.
- 8. The Gulf Coast VA Health Care System Director tracks and monitors the process used to administratively close incomplete electronic health record notes by providers who no longer work at the Gulf Coast VA Health Care System.
- 9. The Gulf Coast VA Health Care System Director ensures and monitors that protected information contained in the Facility Surgical Workgroup minutes is maintained on a secure intranet site in alignment with Veterans Health Administration policy.
- 10. The Gulf Coast VA Health Care System Director confirms that patients' care whose death occurred within 30 days of a surgical procedure are reviewed and monitors compliance.

- 11. The Gulf Coast VA Health Care System Director ensures that required staff maintain basic life support and advanced cardiac life support certification as required by Veterans Health Administration policy and monitors compliance.
- 12. The Gulf Coast VA Health Care System Director makes sure that required Gulf Coast Health Care System services submit monthly basic life support and advanced cardiac life support compliance reports to the Critical Care Committee.
- 13. The Gulf Coast VA Health Care System Director verifies that monthly basic life support and advanced cardiac life support compliance reports are provided to the Executive Committee of the Medical Staff as required by Gulf Coast VA Health Care System policy and monitors for compliance.
- 14. The Gulf Coast VA Health Care System Director makes sure that Patient Safety Committee meeting minutes reflect a discussion of patient safety activities as required by Gulf Coast VA Health Care System policy and monitors compliance.
- 15. The Gulf Coast VA Health Care System Director makes certain that past and future adverse events are reported to the patient safety manager as defined in Gulf Coast Health Care System policy and monitors compliance.
- 16. The Gulf Coast VA Health Care System Director ensures that at least one proactive risk assessment is completed every 18 months for The Joint Commission accredited programs as required by Veterans Health Administration policy and monitors compliance.
- 17. The Gulf Coast VA Health Care System Director makes certain that an effective process is in place to identify and review cases where an institutional disclosure may be indicated and monitors compliance.
- 18. The Gulf Coast VA Health Care System Director reviews the eight identified events that met criteria for consideration of an institutional disclosure as required by Veterans Health Administration policy and takes action as warranted.
- 19. The Gulf Coast VA Health Care System Director ensures that Administrative Investigation Boards are completed within the 45-calendar day timeframe required by Veterans Health Administration policy and monitors compliance.

Appendix A: Additional Background Information

Credentialing and Privileging

Credentialing Committee members review applications and credentialing documents for providers seeking appointment to the facility's medical staff. The COS and service chiefs conduct the initial review of providers' credentialing documents and requested clinical privileges and refer the providers' supporting documentation to the Credentialing Committee for consideration prior to appointment. At initial appointment, and continuing at each re-privileging cycle, Credentialing Committee members review the status and appropriateness of clinical privileges.⁸³ Credentialing Committee members are also required to evaluate FPPE and OPPE results (see descriptions below) and to determine the appropriateness of the continuation of clinical privileges.

Credentialing

Credentialing is a component of the hiring process and refers to the steps used to screen and evaluate qualifications and other provider credentials including, but not limited to: licensure, education, training, experience, current competence, and health status. During the credentialing process, providers are expected to submit information about their professional backgrounds including evidence of professional licenses and details surrounding malpractice claims, if applicable. This information is collected through both paper and electronic processes with similar questions being asked in multiple locations.

Credentialing documents are collected by facility Human Resources and Credentialing Office staff. Upon notification from Human Resources, credentialing staff enroll provider information into VetPro.⁸⁴ This includes issuing the provider a password and access into VetPro to populate licensure, education, and other relevant background information.

The provider submits documents and responds to questions that are cross-referenced through multiple specialized data bases and personal references. After initial screening, the information is presented to the COS and service chief for review and verification. The provider's credentialing information is presented to the Credentialing Committee for discussion and a determination whether to recommend approval. If recommended for approval, the provider's file is sent to the

⁸³ Bylaws and Rules of the Medical Staff of Veterans Health Administration (VHA), VA Gulf Coast Veterans Health Care System, 2015, was in place during the time of the review. The 2015 Bylaws were replaced by Bylaws and Rules of the Medical Staff of VHA, VA Gulf Coast Veterans Health Care System, 2017, which contains the same or similar language related to credentialing and clinical privileging.

⁸⁴ VetPro is VHA's credentialing system for all licensed healthcare personnel.

facility director for final approval and signature prior to appointment to the medical staff and before providing care at the facility.⁸⁵

Privileging

Privileging is defined as the process by which a licensed provider is permitted by law and a facility to practice independently.⁸⁶ Clinical privileges specify the approved medical or other patient care services the provider can perform. Clinical privileges are to be limited within the scope of the provider's license and based on the clinical competence as determined by peer references, professional experience, health status, education, training, and licensure. Clinical privileges must be facility-specific, provider-specific, and within the available resources at the facility. Providers must be re-privileged every two years to include an evaluation of their professional performance, judgment, and clinical and/or technical competence. The facility's COS is responsible for maintaining the credentialing and privileging for the facility. To obtain and maintain clinical privileges, VHA policy requires facility service chiefs ensure credentialed providers undergo FPPE when indicated.⁸⁷ Facility service chiefs must also conduct OPPE regularly to ensure that providers maintain their clinical skills.

FPPE

An FPPE is a time-limited oversight period allowing the credentialed provider to independently practice during the performance evaluation of the granted clinical privileges.⁸⁸ FPPE occurs when a provider is new to the facility or an existing provider requests a new clinical privilege. In addition, an FPPE is initiated in cases of a "for cause" event where there is concern regarding a provider's competence and the care being rendered to patients.⁸⁹ Results of an FPPE must be documented in the provider's file and reported to the ECMS for consideration in making recommendations on clinical privileges and other considerations.⁹⁰

⁸⁵ Gulf Coast Veterans Health Care System Memorandum No, 11-58-15, Credentialing and Privileging and Reporting to the National Practitioner Data Base, July 24, 2015.

⁸⁶ VHA Handbook 1100.19.

⁸⁷ VHA Handbook 1100.19.

⁸⁸ VHA Handbook 1100.19. Credentials include a combination of the provider's licensure, education, training, experience, competence, and health status.

⁸⁹ Bylaws and Rules of the Medical Staff of Veterans Health Administration (VHA), VA Gulf Coast Veterans Health Care System, 2015, was in place during the time of the review. The 2015 Bylaws were replaced by Bylaws and Rules of the Medical Staff of VHA, VA Gulf Coast Veterans Health Care System, 2017, which contains the same or similar language related to credentialing and clinical privileging.

⁹⁰ VHA Handbook 1100.19.

OPPE

An OPPE is dependent upon the successful completion of the FPPE. In order to determine the provider's level of competence and evaluate the outcomes of care, facility service chiefs must collect and maintain relevant provider-specific data. The provider re-privileging process includes consideration of such factors as the number of procedures performed or major diagnoses treated; rates of complications compared with those of others doing similar procedures; and adverse results indicating patterns or trends in a provider's clinical practice. VHA policy requires the timeframe for OPPE to be defined locally, and at a minimum, service chiefs must be able to demonstrate that relevant provider OPPE data is reviewed regularly (for example, at a minimum of every six months).⁹¹

Peer Review

Provider performance is evaluated using a confidential and non-punitive process known as peer review. Peer review contributes to quality management efforts in the delivery of patient care to ensure issues are identified and acted upon proactively to produce optimal patient outcomes. VHA policy identifies clinical events requiring consideration of peer review, including, but not limited to: lack of adequate documentation of a patient's deterioration during the 48 hours preceding death; death during or within 30 days of a surgical procedure; and signs of a patient's deteriorating condition that should have been noted and/or communicated to the physician, but were not.⁹² After evaluating a case, peer reviewers assign a peer review level to the actions and decisions made by the provider under review.^{93,} The Peer Review Committee is responsible to provide a final peer review level assignment to each reviewed provider and to ensure that the final review of each case is completed within 120 days. The supervisor of the provider being reviewed is responsible for implementing appropriate non-disciplinary, non-punitive action, and for providing feedback to the Peer Review Committee of action taken. In addition, VHA policy requires each facility to establish specific peer review triggers, such as two Level 3 peer review ratings in a six-month period, that generate a focused review of a provider's clinical care.⁹⁴

⁹¹ VHA Handbook 1100.19.

⁹² VHA Directive 2010-025.

⁹³ A peer reviewer is a healthcare professional who can assess the provider's actions relative to the episode of care under review. Factors considered when selecting a peer reviewer include whether the individual has similar training, experience, clinical privileges, or scope of practice. VHA Directive 2010-025 describes peer review levels as Level 1 which indicates that most experienced, competent providers would have managed the patient's care similarly; Level 2 indicates that most providers might have handled the patient's care differently; and Level 3 indicates that most providers would have handled the patient's care differently.

⁹⁴ VHA Directive 2010-025.

Appendix B: VISN 16 Director Comments

Department of Veterans Affairs Memorandum

Date: July 12, 2019

- From: Director, South Central VA Health Care Network (VISN 16)
- Subj: Healthcare Inspection—Facility Leaders' Oversight and Quality Management Processes at the Gulf Coast VA HCS, Biloxi, Mississippi
- To: Director, Office of Healthcare Inspections (54HL03)

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

1. The South Central VA Health Care Network has reviewed and concurs with the findings and recommendations in the OIG healthcare inspection report entitled, "Facility Leaders' Oversight and Quality Management Processes at the Gulf Coast VA Health Care System, Biloxi, Mississippi."

2. For questions or additional information requests, please call 601-206-7022.

(Original signed by:)

Skye McDougall, PhD Director, South Central VA Health Care Network

Comments to OIG's Report

Recommendation 1

The Veterans Integrated Service Network 16 Director oversees implementation of recommendations directed to the Gulf Coast VA Health Care System Director.

Concur.

Target date for completion: September 1, 2019

Director Comments

The VISN Director has reviewed the eighteen recommendations included in the report and will ensure a process is in place to monitor actions taken at the facility level to ensure they are implemented and sustained.

Appendix C: Gulf Coast VA Health Care System Director Comments

Department of Veterans Affairs Memorandum

Date: July 12, 2019

From: Director, Gulf Coast Veterans Health Care System (520/00)

- Subj: Healthcare Inspection—Facility Leaders' Oversight and Quality Management Processes at the Gulf Coast VA HCS, Biloxi, Mississippi
- To: Director, South Central VA Health Care Network, (VISN 16)

1. Gulf Coast Veterans Health Care System has reviewed and concur with this Health Inspection report.

2. We recognize opportunities for improvements in our practice and corrective actions are being fully implemented to address the recommendations.

(Original signed by:)

Bryan C. Matthews, MBA Director, Gulf Coast Veterans Health Care System

Comments to OIG's Report

Recommendation 2

The Gulf Coast VA Health Care System Director ensures that providers with previous licensure issues or malpractice cases meeting the Veterans Health Administration indicated threshold for Veterans Integrated Service Network Chief Medical Officer review, are approved by the Veterans Integrated Service Network Chief Medical Officer prior to appointment of the provider to the medical staff as required by Veterans Health Administration policy and monitors compliance.

Concur.

Target date for completion: September 30, 2019

Director Comments

The Professional Credentials Office for Gulf Coast Veterans Health Care System (GCVHCS) has established an internal tracking tool of the Documentation of Review of Licensure/ Certification/ Registration Actions for licensed providers with previous licensure actions, new licensure actions, or malpractice cases. The tool will assist in ensuring that the steps in the processes for the national requirements for documentation of the mandated reviews at the facility-level and VISN-level, which includes that the disposition is logged into the respective provider's VetPro electronic credentialing file utilizing the VHA Documentation of Review of Licensure/ Certification/ Registration Actions form. Outcomes are recorded in the Committee minutes for future reference as needed. Target for compliance is 100 percent, with monthly audits of the tracking tool's appropriate utilization for three consecutive months.

Recommendation 3

The Gulf Coast VA Health Care System Director ensures that Focused and Ongoing Professional Practice Evaluations are completed in accordance with Veterans Health Administration policy and monitors compliance.

Concur.

Target date for completion: December 31, 2019

Director Comments

All privileged providers who are placed on a Focused Professional Practice Evaluation (FPPE) are tracked via an internal tracking system within the Professional Credentials Office. This tracking system documents (1) the nature of the FPPE, e.g., initial FPPE or FPPE for clinical concern; (2) the date FPPE reporting is due; (3) any request for a change in the due date for the

FPPE approved by the Credentialing Committee of GCVHCS; (4) the date of the final reporting for the FPPE; and, (5) the disposition of the final reporting of the FPPE, i.e., pass or fail. Monthly performance of the tracking will be reported at the Credentialing Committee of GCVHCS. Target for compliance is 90 percent, with monthly audits of occurring with 90 percent compliance for three consecutive months.

All privileged providers on an Ongoing Professional Practice Evaluation (OPPE) are tracked via an internal tracking system by the Professional Credentials Office at GCVHCS. This tracking system documents (1) the date OPPE reporting is due; (2) the date the OPPE is signed by the provider and supervisor; and (3) documentation of successful OPPE or any concerns in the OPPE, e.g., failure of a metric requiring a for-cause FPPE for documented deficiency. Random, service-level audits of providers have been initiated by the Professional Credentials Office. Biannual performance of the tracking outcomes for the timely completion of OPPE (each OPPE period is 6 months) will be reported at the Credentialing Committee of GCVHCS. Target for compliance is 90 percent compliance for a bi-annual reporting period.

Recommendation 4

The Gulf Coast VA Health Care System Director ensures that actions are taken to ensure processes are followed to review and report providers, when indicated, to the National Practitioner Data Bank and state licensing boards in the timeframe required by Veterans Health Administration policy and monitors compliance.

Concur.

Target date for completion: September 30, 2019

Director Comments

The Professional Credentials Office utilizes an internal tracking system to map the flow of reporting of patient safety issues to the National Practitioner Data Bank (NPDB) and relevant state licensing boards (SLBs) for licensed providers whose clinical care has been substantiated as substandard. This tracking system documents (1) the date the clinical care concern was communicated to the Office of the Chief of Staff; (2) the clinical care area in which the provider renders service, e.g., inpatient medicine, outpatient behavioral health, Community Living Center; (3) the date the substandard care concern is substantiated or not substantiated; and (4) the dates the substandard care concern is reported to NPDB and relevant SLBs as required. Monthly audits of this tracking system will review performance. Target for compliance is 100 percent, with monthly audits of the tracking log functions and outcomes for three consecutive months.

Recommendation 5

The Gulf Coast VA Health Care System Director reviews the circumstances surrounding the failure to report the surgeon to all licensing boards in states where the surgeon held active licenses in December 2017 and takes action, if necessary.

Concur.

Target date for completion: September 30, 2019

Director Comments

The Professional Credentials Office at GCVHCS has implemented a process where at the time of initial appointment for a physician, the Professional Credentials Office will request and receive an American Medical Association (AMA) Physician Profile in addition to all other documents routinely requested to credential a provider. This AMA Physician Profile report will be utilized to ensure that the provider has disclosed all state licenses, active or inactive, into his/her VetPro electronic credentialing file.

When a physician is re-credentialed, the Professional Credentials Office will request and receive a Federation of State Medicals Boards (FSMB) report, which lists all active and inactive licenses held by a physician at the time of last update by FSMB. This FSMB report will be utilized to ensure that a provider has disclosed all state licenses, active or inactive, into his/her VetPro electronic credentialing file.

To examine compliance of credentialed physicians who are not in the process of initial credentialing or re-credentialing, the Professional Credentials Office has developed an internal tracking system where a sample of physicians who are currently credentialed are pulled for review. An FSMB report will be requested and received and compared to the licenses, active or inactive, disclosed by a physician in his/her VetPro electronic credentialing file.

Recommendation 6

The Gulf Coast VA Health Care System Director ensures that the Executive Committee of the Medical Staff's meeting minutes provide sufficient detail to allow tracking of medical management decisions and problem solving and monitors compliance.

Concur.

Target date for completion: September 30, 2019

Director Comments

In March 2019, the Professional Credentials Office amended the comprehensive summary submitted to Executive Committee of the Medical Staff (ECMS) to include a detailed list of the documents reviewed regarding providers who are being recommended for privileges. A further

enhancement was made to include a more detailed provider specific report concerning decisions and/or privileging actions taken by the Committee concerning current staff and/or those being considered for privileging that need to be reported up to ECMS. To ensure all information is captured accurately, ECMS minutes are then reviewed for accuracy by a member of the Professional Credentials Office and/or Quality Management. A monthly audit of compliance will be utilized to determine compliance with this change in practice. Target for compliance is 100 percent of communications captured in Committee minutes with a request for closure occurring with three consecutive months of successful performance.

Recommendation 7

The Gulf Coast VA Health Care System Director determines the scope of previously administratively closed incomplete notes in patient electronic health records that have been administratively closed to ensure compliance with Veterans Health Administration policy and monitors compliance.

Concur.

Target date for completion: October 31, 2019

Director Comments

GCVHCS has filled the vacant Chief of Health Information Management System position for the health care system. In addition, the Medical Records Committee has been assigned a new Chair to assist in remedying deficiencies identified by the Inspector General's Office during this review. New oversight of this Committee is tasked with ensuring that the matter of incomplete notes that require administrative closure are being addressed timely and thoroughly. A review of the current state, as well as the previous way of operating with regards to the management of previously administratively closed incomplete notes, has been initiated which will identify the scope and depth of the identified issue with a resulting plan of action. To address the reporting deficiency, during the monthly Medical Records Committee a standing report of administratively closed incomplete notes are now being presented for review. A list of outstanding notes will be shared with the Chief of Staff's office, with notifications being sent to the Service Chiefs on a monthly basis for action of their identified providers. Target for compliance is 90 percent with a request for closure occurring with three consecutive months of successful performance.

Recommendation 8

The Gulf Coast VA Health Care System Director tracks and monitors the process used to administratively close incomplete electronic health record notes by providers who no longer work at the Gulf Coast VA Health Care System.

Concur.

Target date for completion: October 31, 2019

Director Comments

To address the reporting deficiency as it relates to administratively closed incomplete notes, during the monthly Medical Records Committee a standing report of such notes are now being presented for review. With new leadership of the Committee, a sustainable process has been implemented to ensure a lapse in reporting and timely resolution does not reoccur. As part of the process, a list of outstanding notes will be shared with the Chief of Staff's office, with notifications being sent to the Service Chiefs on a monthly basis for action of their identified providers. Target for compliance is 90 percent with a request for closure occurring with three consecutive months of successful performance.

Recommendation 9

The Gulf Coast VA Health Care System Director ensures and monitors that protected information contained in the Facility Surgical Workgroup minutes is maintained on a secure intranet site in alignment with Veterans Health Administration policy.

Concur.

Target date for completion: June 30, 2019

Director Comments

Surgery Service has established a new secure SharePoint site entitled "GCVHCS-Surgical Service-Secure Site". This site is now used as a repository for such items as morbidity and mortality minutes/cases, shared peer review documents, and workgroup minutes. Access to the SharePoint site has been restricted to only staff with a need-to-know for these minutes and documents. Based on the actions already taken and implemented, the facility respectfully request closure for this recommendation.

OIG Comments

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

Recommendation 10

The Gulf Coast VA Health Care System Director confirms that patients' care whose death occurred within 30 days of a surgical procedure are reviewed and monitors compliance.

Concur.

Target date for completion: September 30, 2019

Director Comments

The GCVHCS Surgical Quality Improvement Nurse has implemented a process to ensure deaths that occurred within 30 days of a surgical procedure are reviewed by the appropriate committee. The Morbidity & Mortality Committee agenda and minutes have been modified to include a standing/recurring section that focuses solely on this matter. Cases will be identified in this section of the agenda and discussions will be captured in Committee minutes. If additional actions are warranted, this will be reflected in the minutes. Target for compliance is 100 percent capture of cases with a request for closure occurring with three consecutive months of successful performance.

Recommendation 11

The Gulf Coast VA Health Care System Director ensures that required staff maintain basic life support and advanced cardiac life support certification as required by Veterans Health Administration policy and monitors compliance.

Concur.

Target date for completion: September 30, 2019

Director Comments

GCVHCS has an established policy that outlines the requirements that staff engaged in clinical activities (e.g., Nurses, Dentists, Surgeons, Psychologists, etc.) are to maintain basic life support and advanced cardiac life support as required by their position, role and/or function. Existing policy adherence was addressed with all clinical Service Chiefs during the Critical Care Committee meeting in April 2019 and actions have been implemented to ensure compliance with national and local policy. An established reporting process is in place through the Critical Care Committee. Service level compliance reports are tracked. To ensure consistent reporting and compliance by all required services, a comprehensive tracking grid has been established noting all required services that are to be report, current compliance rates, service outliers, and if a plan of action is in place to address outliers. Target for compliance is that 100 percent of required staff will maintain the required training or have a waiver in place in accordance with national and local policy. A request for closure will occur with three consecutive months of successful performance.

Recommendation 12

The Gulf Coast VA Health Care System Director makes sure that required Gulf Coast Health Care System services submit monthly basic life support and advanced cardiac life support compliance reports to the Critical Care Committee.

Concur.

Target date for completion: September 30, 2019

Director Comments

GCVHCS has an established policy that outlines the requirements that staff engaged in clinical activities (e.g., Nurses, Dentists, Surgeons, Psychologists, etc.) are to maintain basic life support and advanced cardiac life support as required by their position, role and/or function. Existing policy adherence was addressed with all clinical Service Chiefs during the Critical Care Committee meeting in April 2019 and actions have been implemented to ensure compliance with national and local policy. An established reporting process is in place through the Critical Care Committee. Service level compliance reports are tracked. To ensure consistent reporting by all required services, a comprehensive tracking grid has been established noting all required services that are to report, current compliance rate, service outliers, and if a plan of action is in place to address outliers. Target for compliance is that 100 percent of required services will report on BLS/ACLS compliance in Critical Care Committee monthly. A request for closure will occur with three consecutive months of successful performance.

Recommendation 13

The Gulf Coast VA Health Care System Director verifies that monthly basic life support and advanced cardiac life support compliance reports are provided to the Executive Committee of the Medical Staff as required by Gulf Coast VA Health Care System policy and monitors for compliance.

Concur.

Target date for completion: September 30, 2019

Director Comments

BLS/ACLS compliance data is included in the Critical Care Committee's summary to the Executive Committee of the Medical Staff (ECMS). This summary was being sent forward on a quarterly basis instead of monthly. Starting with the July 2019 meeting of ECMS, a monthly summary of Critical Care Committee minutes will be sent forward for members to review. This monthly summary will include ACLS/BLS compliance reporting. Target for compliance is that 100 percent of monthly ECMS minutes will include BLS/ACLS compliance data from the Critical Care Committee. A request for closure will occur with three consecutive months of successful performance.

Recommendation 14

The Gulf Coast VA Health Care System Director makes sure that Patient Safety Committee meeting minutes reflect a discussion of patient safety activities as required by Gulf Coast VA Health Care System policy and monitors compliance.

Concur.

Target date for completion: August 31, 2019

Director Comments

Following the implementation of the Joint Patient Safety Reporting tool for improved incident reporting, the Patient Safety Office now receives a more robust accounting of all reported incidents in the health care system. A change in capturing and reporting of this patient safety information in committee minutes has been implemented by the Patient Safety Office. Aggregated data and trend reports are now reviewed by the committee with appropriate discussion regarding cases as needed reflected in the minutes. Target for compliance is 100 percent of patient safety committee minutes will reflect full discussion and consideration of patient safety activities. A request for closure will occur with three consecutive months of successful performance.

Recommendation 15

The Gulf Coast VA Health Care System Director makes certain that past and future adverse events are reported to the patient safety manager as defined in Gulf Coast Health Care System policy and monitors compliance.

Concur.

Target date for completion: August 31, 2019

Director Comments

The Patient Safety Manager meets regularly (weekly) with the Risk Manager to discuss cases. These sessions will continue to ensure information exchange as appropriate within the guidelines of confidentiality of the peer review process. Regarding incident reporting, since the OIG visit occurred, the Joint Patient Safety Reporting (JPSR) tool has been fully implemented with a resulting increase in the variety and number of reported incidents compared to the previous Veterans Health Information Systems and Technology Architecture based system. Subsequent to the OIG visit, additional education and promotion was provided to all employees during Patient Safety Week targeting incident reporting and the new JPSR tool. Along with extensive email messages, website items, rounding, and fliers, presentations were provided by the Patient Safety Manager to multiple staff meetings including the Surgical Staff Meeting in March 2019. Also following the OIG visit, the 2018 Patient Safety Culture Survey occurred in September 2018. The Executive Summary results revealed participation tripled, 12 of 15 dimensions scored above overall VA averages, scores overall were the best since 2000, and 85 percent of respondents acknowledged understanding of reporting patient safety issues. A monitor has been established to facilitate the tracking of reporting of events to the Patient Safety Office. The target for compliance is 100 percent of patient safety events will be reported to the Patient Safety Office

and reportedly monthly in committee minutes. A request for closure will occur with three consecutive months of successful performance.

Recommendation 16

The Gulf Coast VA Health Care System Director ensures that at least one proactive risk assessment is completed every 18 months for The Joint Commission accredited programs as required by Veterans Health Administration policy and monitors compliance.

Concur.

Target date for completion: August 31, 2019

Director Comments

Proactive Risk Assessments are being completed within 18-month time intervals. The Patient Safety Office completed a project in May 2015 and in FY2016 and were submitted to the National Center for Patient Safety reporting portal in September 2016. The next risk assessment was completed in February-March 2018. An additional risk assessment is underway related to suicide risk assessment across all campuses and will be completed by September and within the 18-month requirement as well. GCVHCS is in compliance with this recommendation and requests closure.

OIG Comments

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

Recommendation 17

The Gulf Coast VA Health Care System Director makes certain that an effective process is in place to identify and review cases where an institutional disclosure may be indicated and monitors compliance.

Concur.

Target date for completion: September 30, 2019

Director Comments

A comprehensive screening tool and tracking sheet has been developed by the Risk Manager, the Patient Safety Manager and the facility Surgical Quality Nurse. This new tool will aid in the identification of events that have occurred in the agency that may warrant an institutional disclosure. This group of professionals are meeting weekly to review reported/received events to ensure continuous monitoring. If any events are identified for possible disclosure, those cases are elevated to the Chief of Staff's Office for further discussion with the Director as needed. The

target for compliance is 100 percent of events are identified and captured on the tracking tool. Reporting of the outcomes will be made to the Executive Committee of the Medical Staff by the facility Risk Manager. A request for closure will occur with three consecutive months of successful performance.

Recommendation 18

The Gulf Coast VA Health Care System Director reviews the eight identified events that met criteria for consideration of an institutional disclosure as required by Veterans Health Administration policy and takes action as warranted.

Concur.

Target date for completion: August 31, 2019

Director Comments

A comprehensive review of Peer Review and Root Cause Analysis cases for the identified study period has been initiated to determine whether additional institutional disclosures are warranted. This review is to be completed by the Patient Safety Office and the Risk Management Office and is expected to take no longer than 45 days. For cases that are identified as requiring an institutional disclosure, appropriate action will be taken.

Recommendation 19

The Gulf Coast VA Health Care System Director ensures that Administrative Investigation Boards are completed within the 45-calendar day timeframe required by Veterans Health Administration policy and monitors compliance.

Concur.

Target date for completion: July 15, 2019

Director Comments

The Risk Manager has implemented a process to improve tracking of Administrative Investigation Boards. Once a Board is established, the initiated date is logged in and tracked by Quality & Performance Management through Quality, Safety & Value Committee. A 45-calendar day target date is established with reminders sent to the Risk Manager and Board Chair to ensure the Board is on-track to be completed within the established timeframe. In accordance with Veterans Health Administration policy, if an extension of the deadline is required by the Convening Authority due to an urgent or unforeseen matter, the reasons for extensions shall be summarized in an amendment to the Charge Letter, in the Preliminary Statement of the Investigative Report, or in the Completion Certificate. Currently, GCVHCS has one open Board. This Board was established on May 31, 2019. A target date of July 15, 2019, has been set for completion, which is within the 45-calendar day timeframe.

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