US DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficiencies in Facility Leaders' Summary Suspension of a Provider and Patient Safety Reporting Concerns at the VA Black Hills Health Care System in Fort Meade, South Dakota

Healthcare Inspection | **23-01502-234** | **August 29, 2024**

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the VA Black Hills Health Care System (facility) in Fort Meade, South Dakota, to evaluate facility leaders' response to an alleged impairment of a general surgeon (subject provider) and assess concerns with patient safety event reporting. The complainant reported that in early November 2022, a surgical staff member witnessed an empty alcohol bottle fall out of the subject provider's scrub jacket in the facility's surgical locker room and reported the event to the acting Chief of Staff (COS) the next day. Following this event, the acting COS removed the subject provider from direct patient care. Facility leaders conducted a factfinding into the allegation, which concluded in early December 2022, and "confirmed the presence of an empty alcohol bottle" but could not determine actual impairment.

In late November 2022, the OIG Office of Investigations also received a report of the subject provider's alleged impairment. After completing an investigation of the allegation, the OIG Office of Investigations referred the concern to the OIG Office of Healthcare Inspections in late February 2023. Prior to the inspection, the OIG Office of Healthcare Inspections team learned that facility leaders completed a second factfinding in late July 2023, and after reviewing the results, the OIG Office of Healthcare Inspections team identified additional concerns regarding the facility leaders' response to the allegation and patient safety event reporting. A healthcare inspection was initiated on August 29, 2023, to evaluate the concerns.

Failure to Issue a Timely Summary Suspension

Veterans Health Administration (VHA) policy specifies, "if the concern for safety reaches the level of removing a Privileged Practitioner from care, [the concern] has also reached the level of issuing the summary suspension."[1] A summary suspension is the process facility leaders use to remove a practitioner from clinical care duties when the failure to take action may result in an imminent danger to any individual if the provider continues to engage in clinical practice.[2]

The OIG learned that in November 2022, the acting COS issued a detail letter reassigning the subject provider to the facility's Care in the Community Department with instructions to refrain

[1] VHA Central Office Medical Staff Affairs, "Standard Operating Procedure, Summary Suspensions of Privileged Practitioners," July 14, 2021.

[2] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was in effect at the time of the events discussed in this report until it was rescinded and replaced by VHA Directive 1100.21 (1), *Privileging*, March 2, 2023, amended April 26, 2023. The two handbooks contain the same or similar language related to summary suspension of privileges; VHA Central Office Medical Staff Affairs, "Standard Operating Procedure, Summary Suspensions of Privileged Practitioners," July 14, 2021; Facility Bylaws, Rules, and Regulations of the Medical Staff approved September 20, 2021, amended March 9, 2023. Facility Bylaws, Rules, and Regulations of the Medical Staff approved September 11, 2023. Unless otherwise specified, the September 2023 bylaws contains the same or similar language as the March 2023 bylaws.

from direct patient care.[3] However, in January 2023, the facility leaders learned that the subject provider directly contacted a surgical patient. The acting COS reassigned the subject provider to the facility's travel department and issued a new detail letter with instructions to refrain from any direct or indirect patient care. The OIG determined that because the concern for patient safety reached the level of removing the subject provider from patient care, the Facility Director, per VHA requirements, was obligated to issue a summary suspension when the concerns were identified in early November 2022.[4]

According to the second factfinding report that was completed in late July, patient care concerns were substantiated and as a result, the COS decided to pursue revoking the provider's privileges. Facility leaders and staff sought consultation from VHA program office leaders and consultants regarding the privileging process, including how to proceed with notifying the subject provider of the proposed revocation of privileges.

As a result of these discussions, the OIG learned the interim Facility Director issued a summary suspension letter to the subject provider in mid-October 2023.[5] In late November 2023, the COS issued a proposed removal from federal service to the subject provider. Despite the intent of leaders to remove the subject provider from patient care through the detail process, facility leaders did not summarily suspend the subject provider until 11 months after learning of the alleged impairment. The OIG was concerned that the COS allowed the subject provider to engage in patient care by not suspending privileges when detailed, potentially placing patients at risk of harm.

The OIG identified factors that may have contributed to facility leaders' delay in issuing a summary suspension to include a misunderstanding of VHA and facility policy regarding summary suspensions; an initial presumption that the subject provider's actions were conduct related and that privileging actions were not indicated; and facility leaders were waiting for upcoming changes to VHA's privileging policy for privileging actions.

Failure to Complete Focused Clinical Care Review

A Focused Clinical Care Review (FCCR) is a comprehensive review of a provider's practice for which there is an identified concern or issue and is typically initiated by a summary suspension.

[3] A detail is a "temporary assignment of an employee to a different position for a specified period, with the employee returning to his or her regular duties at the end of the detail."

[4] VHA Handbook 1100.19; VHA Directive 1100.21(1); VHA Central Office Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners"; Facility Medical Staff Bylaws and Rules.

[5] During an interview, the associate director reported assuming the role of the interim Facility Director on October 8, 2023.

Per facility bylaws, the COS initiates an FCCR when evidence finds a practitioner may have demonstrated substandard care that would impact safe patient care.[6]

The OIG determined that facility leaders failed to complete an FCCR when the provider was removed from patient care in November 2022 and again when clinical care concerns were identified after the first factfinding.

Although the COS reported completing a review of the clinical care provided to three patients by the subject provider, the review did not meet VHA requirements for an FCCR by failing to include objective reviewers with a similar specialty and practice as the subject provider.[7] The COS acknowledged being concerned about not being in the same specialty (as a surgeon) stating, "I kind of dropped the ball" and "haven't gotten external reviews."[8] Because facility leaders did not conduct a comprehensive review of the care provided by the subject provider, there were limited opportunities to identify additional incidents of potential clinical care concerns and to assess for harm.[9]

Deficiencies in Patient Safety Event Reporting

Per VHA, a tenet of a High Reliability Organization is fostering a just culture to emphasize a system of learning from adverse events and close calls and avoiding punitive action after a patient safety event.[10] Additionally, staff have an ethical duty to report patient safety events and follow VHA procedures for reporting adverse events in the Joint Patient Safety Reporting (JPSR) system.[11]

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[6] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018; Facility Medical Staff Bylaws and Rules. The immediate supervisor, in this case the COS, typically would conduct a preliminary review of the clinical concerns, "to determine whether a comprehensive focused clinical care review or other administrative review is warranted."

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

[8] VHA Medical Staff Affairs Quality, Safety, and Value "Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance,' January 2018. If a clinical concern is identified, an external review may be indicated to avoid any potential bias.

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

[10] VHA National Center for Patient Safety, *Guidebook for JPSR Business Rules and Guidance*, November 2021. November 2021."Why is Just Culture important to a High Reliability Organization (HRO)?" "Just Culture is an atmosphere of trust in which people are encouraged (even rewarded) for providing essential safety-related information."

[11] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011, rescinded and replaced by VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The new directive contains similar language regarding patient safety as the rescinded handbook.

The OIG identified that facility surgical staff did not consistently report patient safety events in the JPSR system.[12]

During interviews, multiple facility surgical staff stated not reporting patient safety events due to apprehensions over potential retaliation, retribution, and a perceived lack of accountability when events were reported. Additionally, facility surgical staff did not report potential patient safety events due to confusion regarding when and how to use the JPSR system and being unclear about the responsibility to report.

When asked by the OIG about completion of training in reporting adverse events, close calls, and near misses using the JPSR system, several facility surgical staff denied or could not recall being offered or receiving JPSR training. However, the OIG found through document review that the interviewed facility surgical staff completed annual JPSR training.

Despite completing the required JPSR training, facility surgical staff failed to follow reporting processes and did not enter patient safety events in the JPSR system when indicated. The OIG is concerned that the failure to report patient safety events diminishes the ability of facility leaders and quality management staff to identify and remediate unsafe conditions.

The OIG made two recommendations to the Facility Director related to VHA policy for summary suspensions, privileging actions, and conducting FCCRs; and one recommendation to the Facility Director in conjunction with the National Center for Patient Safety related to patient safety reporting processes.

VA Comments

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

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Assistant Inspector General
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[12] VHA Handbook 1050.01.

Contents

Abbreviations

COS	Chief of Staff
FCCR	Focused Clinical Care Review
JPSR	Joint Patient Safety Reporting
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the VA Black Hills Health Care System (facility) in Fort Meade, South Dakota, to evaluate facility leaders' response to an alleged impairment of a general surgeon (subject provider) and assess concerns with patient safety event reporting.

Background

The facility is part of Veterans Integrated Service Network (VISN) 23, comprising two campuses located in Fort Meade and Hot Springs, South Dakota, and nine community-based outpatient clinics.[1] The facility provides extended nursing home, inpatient psychiatric services, residential rehabilitation treatment, and medical and surgical services. From October 1, 2022, through September 30, 2023, the facility served 20,187 unique patients. The facility has 249 operating beds, including 44 hospital operating beds, 72 domiciliary operating beds, 104 community living center beds, and 29 compensated work therapy/transitional residence operating beds. The Veterans Health Administration (VHA) classifies the facility as a level 3, low complexity facility.[2]

Prior OIG Reports

In a May 2023 report, the OIG found that a former Facility Director failed to share administrative investigation board findings with other senior leaders, resulting in a lapse of understanding and follow-up of the administrative investigation board's recommendations.[3] Both recommendations were closed as of December 22, 2023.

In a March 2024 report, the OIG identified medical staff privileging concerns and made two recommendations related to completion and review of Ongoing Professional Practice Evaluations data and documents. In addition, the OIG made one Environment of Care and one Mental Health related recommendation. All four of the recommendations remain open.[4]

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[1] The facility provides outpatient services in Nebraska: Gordon and Scottsbluff; North Dakota: Fort Yates; South Dakota: Eagle Butte, Pierre, Pine Ridge, Rapid City, and Winner; and Wyoming: Newcastle.

[2] VHA Office of Productivity, Efficiency and Staffing, "Facility Complexity Model Fact Sheet," approved January 28, 2021, categorizes medical facilities based on patient population, clinical services offered, educational, and research missions. "The model rates facilities as 1a, 1b, 1c, 2, or 3, with facilities rating 1a being the most complex and those rated 3 the least complex." A level 3 facility has "low volume, low risk patients, few or no complex clinical programs, and small or no research and teaching programs."

[3] VA OIG, *Issues Related to an Administrative Investigation Board at the VA Black Hills Health Care System in Fort Meade and Hot Springs, South Dakota*, Report No. 22-00540-107, May 2, 2023.

[4] VA OIG, *Comprehensive Healthcare Inspection of the VA Black Hills Health Care System in Fort Meade, South Dakota*, Report No. 23-00097-113, March 26, 2024.

Allegation and Related Concern

In early November 2022, a surgical staff member reported to the acting Chief of Staff (COS) that an empty alcohol bottle fell out of the subject provider's scrub jacket at the facility. Following this event, the acting COS, removed the subject provider from direct patient care.[5] In mid-November, the state licensing board received an anonymous complaint concerning an allegation that the subject provider was impaired at work and while on call. In late November 2022, the allegation regarding the subject provider's alleged impairment was also reported to the OIG Office of Investigations. Specifically, a facility staff member reported to facility leaders witnessing an empty alcohol bottle fall out of the subject provider's scrub jacket in the facility's surgical locker room. Facility leaders conducted a factfinding into the allegation, which concluded in early December 2022, and "confirmed the presence of an empty alcohol bottle" but could not determine actual impairment.[6]

The OIG Office of Investigations, after completing an investigation of the allegation, referred the concern to the OIG Office of Healthcare Inspections in late February 2023. An OIG congressional relations specialist contacted VISN 23 leaders to request additional information about the allegation in late March 2023 and received a reply in late June 2023. The OIG reviewed the VISN leaders' June response and learned that a second factfinding to review patient care concerns identified in the prior factfinding was expected to be completed. In late July 2023, the second factfinding was completed. The OIG Office of Healthcare Inspections team reviewed the second factfinding report and identified concerns regarding facility leaders' response to the allegation and patient safety event reporting. A healthcare inspection was initiated on August 29, 2023, to evaluate the concerns.

Scope and Methodology

The OIG conducted an on-site visit from October 31 through November 2, 2023. Virtual interviews were conducted from September 18, 2023, through April 3, 2024. The OIG interviewed VHA program office leaders, VISN and facility leaders, and relevant VISN and facility staff.

[5] During an interview, the former associate COS for acute specialty medicine reported being in the role of acting COS at the time of the event.

[6] VA Directive 0700, *Administrative Investigation Boards and Factfindings*, August 10, 2021; VA Handbook 0700, *Administrative Investigation Boards and Factfindings*, August 17, 2021. Per VHA, a factfinding is a less formal administrative investigation used by facility leaders to determine if more extensive investigations may be required. Results of a factfinding may direct actions meant to correct the problem investigated or indicate the need to conduct a formal administrative investigation.

The OIG reviewed applicable VHA directives and handbooks, facility policies related to credentialing and privileging and patient safety, facility committee meeting minutes, quality and management review documents, and other relevant documents.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, as amended, 5 U.S.C. §§ 401–424. The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Timeline of Events

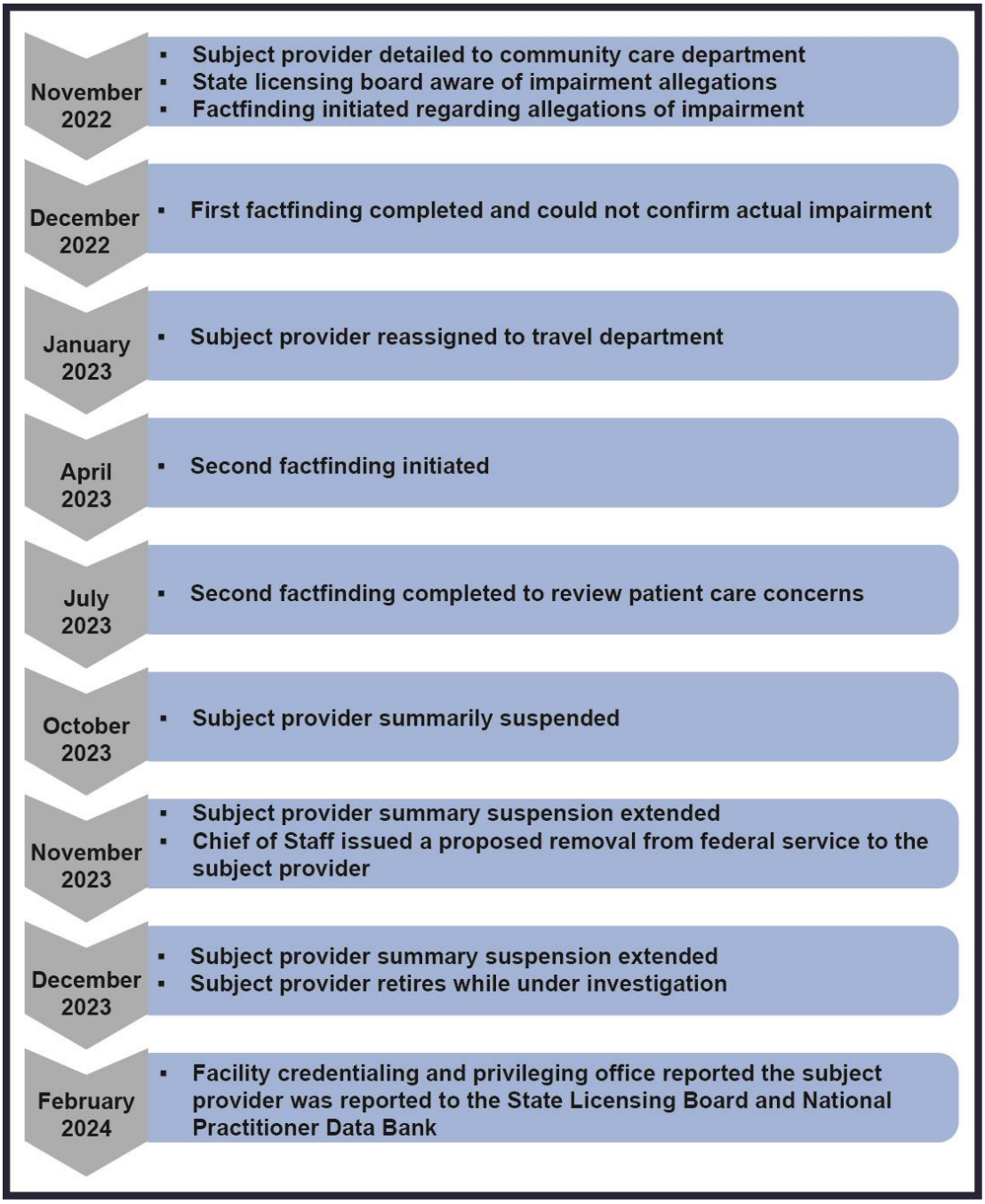

Figure 1. *List of events pertinent to the subject provider from November 2022 through February 2024. Source: OIG review of facility documents.*

Inspection Results

1. Deficiencies in Facility Leaders' Response to the Subject Provider's Alleged Impairment

In response to the allegation concerning the subject provider being impaired, facility leaders conducted two factfindings and a clinical review, and proposed removing the provider from federal service. However, the OIG determined that when patient care concerns were initially identified in November 2022, facility leaders failed to suspend the provider's privileges and failed to conduct a focused clinical care review (FCCR) as required.

VHA requires that the Facility Director, on the recommendation of the COS, issue a summary suspension to remove a practitioner from clinical care duties when the failure to take such action may result in an imminent danger to the health and safety of any individual if the provider continues to engage in clinical practice.[7] Further, "if the concern for safety reaches the level of removing a Privileged Practitioner from care, [the concern] has also reached the level of issuing the summary suspension."[8]

According to VHA, an FCCR is a comprehensive retrospective review of a provider's practice for which there is an identified clinical concern or issue, and is typically initiated by a summary suspension or after completion of a factfinding.[9] "Initiation of a summary suspension triggers the obligation to conduct a Focused Clinical Care Review of the LIP's [Licensed Independent Practitioner] practice."[10] Facility bylaws specify that the COS initiate an FCCR when sufficient evidence exists based on preliminary factfinding that a practitioner may have demonstrated substandard care that impacts the ability to provide safe patient care.[11] "The focus and number of case reviews should be reflective of current clinical practice and patient population. The cases

[7] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was in effect at the time of the events discussed in this report until it was rescinded and replaced by VHA Directive 1100.21(1), *Privileging*, March 2, 2023, amended April 26, 2023. The two handbooks contain the same or similar language related to summary suspension of privileges; VHA Central Office Medical Staff Affairs, "Standard Operating Procedure, Summary Suspensions of Privileged Practitioners," July 14, 2021; Facility Bylaws, Rules, and Regulations of the Medical Staff approved September 20, 2021, amended March 9, 2023. Facility Bylaws, Rules, and Regulations of the Medical Staff approved September 11, 2023. Unless otherwise specified, the September 2023 bylaws contains the same or similar language as the March 2023 bylaws.

[8] VHA Central Office Medical Staff Affairs, "Standard Operating Procedure, Summary Suspensions of Privileged Practitioners," July 14, 2021.

[9] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

[10] VHA Medical Staff Affairs Quality, Safety, and Value, "Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE [Focused Professional Practice Evaluation] for Cause Guidance," January 2018; VHA Directive 1100.21(1).

[11] Facility Medical Staff Bylaws and Rules. The immediate supervisor, in this case the COS, typically would conduct a preliminary review of the clinical concerns, "to determine whether a comprehensive focused clinical care review or other administrative review is warranted."

must be randomly selected and cannot be intentionally selected to only include cases of concern."[12] VHA suggests the FCCR be "performed by three objective reviewers of similar specialty [and] practice."[13]

Failure to Issue a Timely Summary Suspension

The OIG found facility leaders summarily suspended the subject provider's privileges in mid-October 2023, 11 months after learning of the alleged impairment. The OIG determined that facility leaders failed to issue a summary suspension of the subject provider's privileges when removing the provider from patient care in early November 2022 due to concerns for patient safety.

Due to the allegation of impairment, in early November 2022, the acting COS sent an email to the subject provider with instructions to abstain from direct patient care pending investigation. Two days later, the acting COS issued a detail letter reassigning the subject provider to the facility's Care in the Community Department with instructions to refrain from entering the surgery suite, ambulatory care, or inpatient areas.[14]

During an interview with the OIG, the COS reported that detailing the subject provider to the Care in the Community Department was appropriate at the time, as there was a need to have an individual with medical knowledge review consults. The COS informed the OIG that the subject provider's role during the detail consisted of placing medication orders for traveling veterans who did not have a primary care provider. The COS opined that prescribing medications was not considered patient care. The OIG learned that as a result of the subject provider contacting a surgical patient in mid-December 2022, the acting COS reassigned the subject provider in early January 2023 to the facility's travel department and issued a new detail letter with instructions "to refrain from direct or indirect patient care and to refrain from entering inpatient or

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

[13] VHA Medical Staff Affairs Quality, Safety, and Value, "Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance." January 2018; VHA Directive 1190. The Facility Chief of Staff has the responsibility to "coordination of arrangements for initial reviews to be conducted at another facility or VISN when there is no qualified peer at the facility or if there is a conflict of interest to complete locally."

[14] "Chapter 35. Glossary of Terms Used in Processing Personnel Actions," Office of Personnel Management, accessed June 12, 2024. A detail is the "temporary assignment of an employee to a different position for a specified period, with the employee returning to his or her regular duties at the end of the detail."; "Request and Coordinate Care," VA Community Care, accessed March 15, 2024, https://www.va.gov/COMMUNITYCARE/providers/Care-Coordination.asp#RFS; In the VA Community Care program, " strong care coordination between VA and community provider ensures Veterans receives timely and high-quality care."; VHA Office of Integrated Veteran Care (IVC) Community Care, "Care Coordination," chap. 3 in *IVC Field Guidebook.* "Care coordination is defined as a system-wide approach to the deliberate organization of all Veteran care activities between two or more participants or systems to facilitate the appropriate delivery of health care services."

ambulatory care areas."

The OIG determined that the subject provider continued to provide direct patient care by prescribing medications until the reassignment to the travel department in early January 2023.

Because the concern for patient safety reached the level of removing the subject provider from direct and indirect patient care, the Facility Director was obligated to issue a summary suspension per VHA policy rather than a detail assignment.[15]

The OIG identified three factors that may have contributed to the facility leaders' failure:

- The COS misunderstood VHA and facility policy regarding summary suspensions.
- Facility staff and leaders presumed the subject provider's actions were based on the subject provider's conduct and that privileging actions were not indicated.
- Facility leaders waited for upcoming changes to VHA's privileging policy for privileging actions.[16]

During an interview, the COS reported originally thinking that removing the provider from clinical care was the same as summarily suspending the provider's privileges; however, in a separate interview, the COS acknowledged misinterpreting the two actions. The COS reported being unfamiliar with the rules for summary suspension, the resulting clinical reviews, and the reporting requirements. The COS described having the concern that by summarily suspending the subject provider's privileges, the facility would be required to report the subject provider to the National Practitioner Data Bank after 30 days, and the facility would be at risk if there was no impairment. During the same interview, the COS subsequently acknowledged this interpretation was "wrong," as according to VHA policy, summary suspensions may be extended every 30 days, and reporting adverse actions to the National Practitioner Data Bank does not occur until actions are finalized.[17]

Additionally, current and former facility staff and leaders reported that a summary suspension was not completed because the understanding was that the allegation was related to conduct as opposed to the quality of care provided, and that there was no evidence to support any findings of impairment when the allegation was reported.[18] Specifically, a former facility credentialing and privileging manager reported providing guidance to both the acting COS and the former

[15] VHA Handbook 1100.19; VHA Directive 1100.21(1); VHA Central Office Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners"; Facility Medical Staff Bylaws and Rules.

[16] VHA Directive 1100.21(1); VHA Central Office Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners." The OIG learned through interviews that facility leaders waited for upcoming changes to policy.

[17] VHA Directive 1100.21(1); VHA Central Office Medical Staff Affairs, "Summary Suspensions of Privileged Practitioners"; VHA Central Office Medical Staff Affairs, "Standard Operating Procedure, Summary Suspensions of Privileged Practitioners," July 14, 2021.

[18] VHA Handbook 1100.19. VHA privileging policy allows for a summary suspension of privileges based on professional conduct.

Facility Director, that "there was no evidence that [the subject provider had] seen a patient or treat[ed] a patient so it wasn't a quality of care concern at the time, it was a conduct issue." However, the OIG found through document review that the subject provider participated in one surgical procedure on the day of the alleged impairment.

In late April 2023, facility leaders initiated a second factfinding to review patient care concerns that were identified in the initial factfinding. According to the second factfinding report, the patient care concerns were substantiated. During an interview, the COS reported deciding, in early September, to pursue revoking the provider's privileges based on the factfinding report.

Subsequently, the Office of General Counsel notified facility staff and leaders through email correspondence in mid-September 2023, of imminent changes to the process for removal or modification of a provider's privileges. The email stated that the new policy guidance would be published in the upcoming week; however, in the meantime, if a facility had a pending privileging action, the recommendation was to contact VHA Credentialing and Privileging Workforce Management Consultant group to request a privileged provider consult.[19]

The OIG found through document review, following the Office of General Counsel's notification, facility leaders and staff waited for upcoming changes to policy to take privileging actions against the subject provider. Additionally, facility leaders and staff sought consultation from VHA program office leaders regarding the privileging process, including how to proceed with notifying the subject provider of the proposed revocation of privileges. As a result of these discussions, the interim Facility Director issued a letter to the subject provider in mid-October 2023, stating that privileges would be summarily suspended.[20] The OIG learned that in late November 2023, the COS issued a proposed removal from federal service to the subject provider.

The OIG learned that the subject provider resigned during the summary suspension, and after the proposed removal from federal service was issued. The current facility credentialing and privileging manager reported that facility leaders filed a report regarding the subject provider to the National Practitioner Data Bank and sent a copy to the state licensing board as required by VHA policy.[21]

The OIG determined that the COS allowed the subject provider to engage in patient care when detailed, and delayed summarily suspending privileges, potentially placing patients at risk of

[19] A privileged provider consult is a consultation with VHA subject matter experts that provides guidance to facility staff and leaders regarding privileging actions.

[20] During an interview, the OIG learned that the former Facility Director left facility employment on October 8, 2023, and the associate director assumed the role of the interim Facility Director.

[21] VHA Directive 1100.18; VHA Central Office Medical Staff Affairs, "Standard Operating Procedure, Summary Suspensions of Privileged Practitioners," July 14, 2021; VHA Handbook 1100.17, *National Practitioner Data Bank (NPDB) Reports*, December 28, 2009. Facility leaders are required to report to the NPDB a physician or dentist who resigns "while under investigation by the facility for "possible incompetence or improper professional conduct."

harm. The OIG concluded that the COS lacked a working knowledge of applicable VHA policy, and based on the lack of knowledge, the COS did not make a recommendation to the Facility Director to summarily suspend the subject provider's privileges when removed from patient care in early November 2022.[22]

Failure to Complete Focused Clinical Care Review

The OIG determined that facility leaders failed to complete an FCCR when the provider was removed from patient care in November 2022 and when clinical care concerns were identified after the first factfinding (December 2022), as required by VHA policy.[23]

During an interview, the COS, whose specialties are internal medicine, geriatrics, and rheumatology, recalled conducting a clinical review of three patient cases reported by surgical staff and identified through the factfindings. Further, the COS confirmed that no FCCR had been completed to evaluate the subject provider's clinical care. Although the COS reported completing a clinical review, the review did not have objective reviewers with similar specialty and practice as the subject provider, as required.[24] The COS acknowledged being concerned about not being in the same specialty (as a surgeon) stating, "I kind of dropped the ball" and "haven't gotten external reviews."[25] The OIG determined that although the COS completed a review of the clinical care provided to three patients by the subject provider, the review was not the required FCCR.

The OIG concluded that facility leaders failed to follow VHA and facility requirements to complete an FCCR when a concern about the subject provider's ability to provide safe patient care was identified.[26] The OIG was concerned that because facility leaders did not conduct a comprehensive review of the care provided by the subject provider, opportunities to identify additional incidents of clinical care concerns and to assess for harm were limited.[27]

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[22] VHA Central Office Medical Staff Affairs, "Standard Operating Procedure, Summary Suspensions of Privileged Practitioners," July 14, 2021.

[23] VHA Directive 1190; VHA Medical Staff Affairs Quality, Safety, and Value, "Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance," January 2018.

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

[25] VHA Medical Staff Affairs Quality, Safety, and Value, "Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance," January 2018. If a clinical concern is identified, an external review may be indicated to avoid any potential bias.

[26] VHA Directive 1190; VHA Medical Staff Affairs Quality, Safety, and Value, "Provider Competency and Clinical Care Concerns Including: Focused Clinical Care Review and FPPE for Cause Guidance," January 2018; Facility Medical Staff Bylaws and Rules.

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

2. Deficiencies in Patient Safety Event Reporting

The OIG determined that facility surgical staff did not report patient safety events due to apprehensions over potential retaliation, confusion regarding when and how to enter a patient safety event in the Joint Patient Safety Reporting (JPSR) system, and being unclear about the responsibility to report.[28]

VHA's National Center for Patient Safety recognizes that a tenet of a High Reliability Organization is fostering a just culture that emphasizes a system of learning from adverse events and close calls, and avoiding punitive action after a patient safety event.[29] VHA further states that high reliability requires an environment where "employees at every level of our organization are empowered to speak up for safety and effect positive change."[30] Staff have an ethical duty to report patient safety events and follow VHA procedures for reporting adverse events in the JPSR system. VHA also requires staff "report, as per local policy, any unsafe conditions of which they are aware, even though the conditions have not yet resulted in an adverse event or close call."[31] Further, facility policy requires staff to report adverse events and close calls within 24 hours.[32]

During interviews, facility surgical staff told the OIG of patient safety concerns related to the clinical care performed by the subject provider. Specifically, surgical staff recalled the subject provider

- had a patient who experienced unusual bleeding during a gallbladder removal,
- asked a nurse for the proper placement of a mesh patch during an inguinal hernia repair surgery,
- missed multiple colon polyps during a patient's colonoscopy, and

[28] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011, rescinded and replaced by VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023. The new directive contains similar language regarding patient safety as the rescinded handbook. "JPSR System is a mandated web-based system used by VHA employees to report patient safety events."

[29] VHA National Center for Patient Safety, *Guidebook for JPSR Business Rules and Guidance*, November 2021."Why is Just Culture important to a High Reliability Organization (HRO)?" "Just Culture is an atmosphere of trust in which people are encouraged (even rewarded) for providing essential safety-related information."

[30] VA, Veterans Health Administration, *VHA High Reliability Organization (HRO) Reference Guide—Pre-Decisional Deliberative Document*, April 2023. "High reliability means evidence-based, exceptional care is consistently delivered for every patient, every time, at any facility across VHA."

[31] VHA Handbook 1050.01. VHA defines adverse events as any harm or incident caused to a patient during the course of care or services. A close call is described as an event or situation that could have caused harm.

[32] Facility Medical Center Policy, ORG-002 *Patient Safety Program*, April 12, 2022.

- performed a hemorrhoidectomy in a treatment room without sedation.[33]

The OIG requested JPSR records related to the subject provider's clinical care from February 1, 2021, through November 1, 2022, to determine whether patient safety concerns were reported, and a facility staff member provided one JPSR record.[34] Given the concerns reported to the OIG by facility surgical staff regarding the subject provider's provision of clinical care, the OIG would have expected multiple reports of patient safety events in the JPSR system.

When asked by the OIG why patient safety concerns were not consistently reported through the JPSR system, multiple facility surgical staff responded that apprehensions over potential retaliation, retribution, and a perceived lack of accountability when events were reported, as reasons that kept staff from reporting. During an interview with the OIG, the COS noted concern regarding the lack of a culture of safety and acknowledged staff's apprehension of patient safety reporting due to staff's mistrust.

The OIG also learned that some facility surgical staff did not report potential patient safety events due to confusion regarding when and how to use the JPSR system and being unclear about the responsibility to report. Further, one surgical staff member reported being aware of the JPSR system but acknowledged not knowing much about it.

When asked by the OIG about completion of training in reporting adverse events, close calls, and near misses using the JPSR system, several facility surgical staff denied or could not recall being offered or receiving JPSR training. However, the OIG found, through document review, that the interviewed facility surgical staff completed annual JPSR training. Through email correspondence, the patient safety officer reported that facility staff receive JPSR training at new employee orientation, annually through the electronic VA training system, and upon request as refresher training.[35] The OIG concluded that facility surgical staff, despite completing the required JPSR training, failed to follow reporting processes and did not enter patient safety

[33] "Gallstones," Mayo Clinic, accessed January 16, 2024, https://www.mayoclinic.org/diseases-conditions/gallstones/symptoms-causes/syc-20354214. A gallbladder is a small organ on the right side of the abdomen that stores a digestive fluid that is released into the small intestine; "Inguinal hernia," Mayo Clinic, accessed January 16, 2024, https://www.mayoclinic.org/diseases-conditions/inguinal-hernia/symptoms-causes/syc-20351547. "Occurs when tissue, such as part of the intestine, protrudes through a weak spot in the abdominal muscles."; "Colon Polyps," Cleveland Clinic, accessed January 16, 2024, https://my.clevelandclinic.org/health/diseases/15370-colon-polyps. "Growths, like tiny bumps, that form on the inside lining of your colon or rectum. They're usually harmless, but some types can turn into colon cancer after many years. Healthcare providers remove colon polyps when they find them during a routine colonoscopy."; "Colonoscopy," Mayo Clinic, accessed January 16, 2024, https://www.mayoclinic.org/tests-procedures/colonoscopy/about/pac-20393569. "An exam used to look for changes – such as swollen, irritated tissues, polyps, or cancer – in the large intestine (colon) and rectum."; "Hemorrhoids," Mayo Clinic, accessed January 16, 2024, https://www.mayoclinic.org/diseases-conditions/hemorrhoids/diagnosis-treatment/drc-20360280. A hemorrhoidectomy is the surgical removal of a hemorrhoid.

[34] For the purpose of this report, the OIG team determined the end of JPSR review period to be the subject provider's last day of patient care on November 1, 2022.

[35] VA Directive 0004, *Education and Learning Delivery System*, April 20, 2012. The Talent Management System (TMS) is a web-based application that provides a record of training and education of VA employees.

events in the JPSR system when indicated. The OIG is concerned that the failure to report patient safety events diminishes the ability of facility leaders and quality management staff to identify and remediate unsafe conditions.

Conclusion

The OIG found facility leaders failed to issue a summary suspension of the subject provider's privileges when removing the provider from patient care in early November 2022. Factors that may have contributed to facility leaders' failure to issue a summary suspension included misunderstandings of VHA and facility policy regarding summary suspensions, an initial presumption that the subject provider's actions were conduct related and that privileging actions were not indicated; and facility leaders waiting for upcoming changes to VHA's privileging policy for privileging actions. Ultimately, facility leaders summarily suspended the subject provider's privileges in mid-October 2023, 11 months after learning of the alleged impairment. The OIG is concerned that the COS's misunderstanding of summary suspension policies and failure to suspend privileges allowed the subject provider to engage in patient care when detailed, potentially placing patients at risk of harm.

The OIG determined that facility leaders failed to complete an FCCR both when the provider was removed from patient care in November 2022, and when clinical care concerns were identified after the first factfinding. Despite the COS conducting a clinical review of patient care concerns regarding the subject provider, which were identified during a factfinding and reported by surgical staff, the COS failed to include reviewers with similar specialty and practice as the subject provider and the review did not meet the requirements of an FCCR. The OIG is concerned that because facility leaders did not conduct a comprehensive review of the care delivered by the subject provider, opportunities to identify additional incidents of clinical care concern and to assess for harm were limited.

Facility surgical staff, despite completing the required JPSR training, failed to follow reporting processes and did not enter patient safety events in the JPSR system when indicated.

Recommendations 1–3

1. The VA Black Hills Health Care System Director ensures that summary suspensions and related privileging actions are conducted in accordance with Veterans Health Administration policy, and monitors for compliance.

2. The VA Black Hills Health Care System Director in conjunction with facility leaders and surgical service leaders, ensures a focused clinical care review is completed of the care provided by the subject provider according to Veterans Health Administration policy, and takes action as warranted.

3. The VA Black Hills Health Care System Director, in conjunction with the National Center for Patient Safety, evaluates the patient safety event reporting processes, identifies deficiencies, and takes action as warranted to ensure compliance with entering adverse events or close calls into the Joint Patient Safety Reporting system.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: July 5, 2024

From: Director, VA Midwest Healthcare Network (10N23)

Subj: Healthcare Inspection—Deficiencies in Facility Leaders' Summary Suspension of a Provider and Patient Safety Reporting Concerns at the VA Black Hills Health Care System in Fort Meade, South Dakota

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

1. Thank you for the opportunity to review and comment on OIG's draft report for the Healthcare Inspection—Deficiencies in Facility Leaders' Summary Suspension of a Provider and Patient Safety Reporting Concerns at the VA Black Hills Health Care System in Fort Meade, South Dakota.

2. I concur with the recommendations and action plan provided within the facility response to this report.

3. If you have further questions or concerns, please contact VA Black Hills Director of Quality and Patient Safety.

(*Original signed by:*)

Robert P. McDivitt, FACHE
Executive Director
VA Midwest Health Care Network (VISN 23)

[OIG comment: The OIG received the above memorandum from VHA on July 24, 2024.]

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: July 5, 2024

From: Director, VA Black Hills Healthcare System Fort Meade (568)

Subj: Healthcare Inspection—Deficiencies in Facility Leaders' Summary Suspension of a Provider and Patient Safety Reporting Concerns at the VA Black Hills Health Care System in Fort Meade, South Dakota

To: Director, VA Midwest Healthcare Network (10N23)

1. Thank you for the opportunity to review and comment on OIG's draft report for the Healthcare Inspection—Deficiencies in Facility Leaders' Summary Suspension of a Provider and Patient Safety Reporting Concerns at the VA Black Hills Health Care System in Fort Meade, South Dakota.

2. I concur with the recommendations and action plan provided within the facility response to this report.

3. If you have further questions or concerns, please contact VA Black Hills Director of Quality and Patient Safety.

(*Original signed by*:)

Spencer Mion, MHA, MBA, FACHE, CPO
Medical Center Director

[OIG comment: The OIG received the above memorandum from VHA on July 24, 2024.]

Facility Director Response

Recommendation 1

The VA Black Hills Health Care System Director ensures that summary suspensions and related privileging actions are conducted in accordance with Veterans Health Administration policy and monitors for compliance.

_X _Concur

____Nonconcur

Target date for completion: August 2024

Director Comments

The Executive Committee of the Medical Staff (ECMS) will receive training related to the summary suspension process including roles and responsibilities when there is concern related to provision of care by a privileged provider which raises imminent concern of patient care during the August 2024 ECMS meeting. This will be documented in the meeting minutes and include the attendance roster. In addition, training related to the summary suspension process will be included in the orientation for new members effective immediately. The Medical Center Director will ensure that a Summary Suspension memorandum will be issued when privileged providers are removed from patient care due to concerns of imminent safety of a patient per the VHA Directive 1100.21(1) Privileging, Standard Operating Procedure SOP-P09 Summary Suspensions of Privileged Practitioners Version 2.

OIG Comments

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

Recommendation 2

The VA Black Hills Health Care System Director in conjunction with facility leaders and surgical service leaders, ensures a focused clinical care review is completed of care provided by the subject provider according to VHA policy, and takes action as warranted.

_X _Concur

____Nonconcur

Target date for completion: December 2024

Director Comments

The VA Black Hills Health Care System Director will ensure policy is followed per VHA Directive 1100.21 (1) and take appropriate action as warranted. The focused clinical care review action and process will be tracked and monitored through the Credentialing and Privileging Office. The results from the Focused Clinical Care Review will be reviewed by the ECMS with a recommended action to the medical facility Director per the VHA Directive 1100.21(1), Privileging, SOP-P27 Fair Hearing Process for Privileging Actions Version 2.

Recommendation 3

The VA Black Hills Health Care System Director, in conjunction with the National Center for Patient Safety, evaluates the patient safety event reporting processes, identifies deficiencies, and take action as warranted to ensure compliance with entering adverse events or close calls into the Joint Patient Safety Reporting System.

_X _Concur

____Nonconcur

Target date for completion: July 2025

Director Comments

VA Black Hills Healthcare System will evaluate current Joint Patient Safety Reporting System Reporting Processes and the facility Culture of Safety, identify gaps, and develop an action plan in collaboration with the Veterans Integrated Service Network and the National Center Patient Safety to address the gaps and incorporate OIG recommendations. The plan will include specific actions, an implementation timeline, and monitoring process.

OIG Contact and Staff Acknowledgments

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