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VETERANS HEALTH ADMINISTRATION

Chief Of Staff's Provision of Care Without Privileges, Quality of Care Deficiencies, and Leaders' Failures at the Montana VA Health Care System In Helena

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate allegations regarding the Chief of Staff (COS) at the Montana VA Health Care System in Helena (facility).[1] The OIG reviewed allegations related to the COS's provision of pregnancy care outside of approved privileges and deficient quality of care to a pregnant patient (Patient 1), deficiencies in the quality of gynecologic surgery and post-operative care provided for a patient (Patient 2), and deficiencies in the facility's process for privileging the COS.[2] Additionally, the OIG evaluated facility leaders' responses to identified concerns.

COS Provided Pregnancy Care Without Privileges

The OIG substantiated that the COS practiced without privileges and outside of Veterans Health Administration (VHA) policy when providing pregnancy care for Patient 1 during her second and third trimesters of pregnancy. The COS, who completed residency training in obstetrics and gynecology in 2009, held privileges for clinical practice at the facility to diagnose, treat, and manage patients' "gynecological problems" and to perform delineated gynecologic surgeries and procedures.[3] The COS was not privileged to provide obstetric or pregnancy care.

Privileging is the process facility leaders use to grant a provider permission to perform clinical services. Generally, providers are only to perform clinical services for which they are privileged.[4] The process protects patients by ensuring that a provider's privileges are within the scope of the provider's license and competence and are consistent with a facility's resources.

VHA policy specifies that pregnancy care is typically provided by authorized healthcare professionals in the community.[5] VHA providers are responsible for referring pregnant patients

[1] The COS, who also provided direct patient care as a facility gynecologist in the surgical service, was appointed June 12, 2019, and resigned from the facility during the OIG's inspection effective August 27, 2022.

[2] For the purposes of this report, the OIG uses the term *pregnancy care* to refer to prenatal and *obstetric care* for the management of pregnancy.

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

[4] During emergencies, providers are permitted to perform clinical care without privileges.

[5] VHA Directive 1330.03, *Maternity Health Care and Coordination*, November 3, 2020. The VHA Chief Officer, Women's Health, advised that pregnancy care is very rarely provided at VA beyond standard first trimester care while a patient is establishing care with a community obstetrician-gynecologist. In those rare instances, the care was authorized under a waiver that was provided due to special arrangements with affiliated community partners, which provided resources not standardly found within VHA facilities.

to an authorized community provider "as early as possible after the pregnancy is diagnosed."[6] Facility policy requires a community care maternity consult be placed when a patient has a positive pregnancy test and chooses to use VA benefits for coverage.[7] The policy does not include an option to receive pregnancy care at the facility.[8]

Through electronic health record (EHR) review, the OIG found that the COS provided pregnancy care without privileges to Patient 1. Patient 1 was diagnosed with pregnancy by the COS in Spring 2021. The COS appropriately referred Patient 1 to a community obstetrician-gynecologist (OB/GYN) for maternity care as soon as pregnancy was diagnosed. However, the community OB/GYN relocated outside the local area early in Patient 1's second trimester of pregnancy. The COS documented an intent to continue monitoring the progress of Patient 1's pregnancy, per the patient's request, until she re-established care with the community OB/GYN after the relocation. The COS documented the COS's continuing pregnancy care after Patient 1 re-established care with the community OB/GYN. The COS's continued care included seven office visits with the COS in the second and third trimesters of Patient 1's pregnancy; two of these visits were to assess for potential severe pregnancy-related complications.

When asked about being privileged to provide pregnancy care during an interview with the OIG, the COS described being "privileged for continuity of care of all the patients that are assigned to me."[9] When asked again specifically about privileges to provide pregnancy care, the COS reported being "privileged to take care of women regardless of their situation." However, the OIG noted a distinction between gynecology privileges and obstetrics privileges. Based on correspondence from the Veterans Integrated Service Network (VISN) Chief Medical Officer regarding privileging, as well as an interview with the VHA Director of Reproductive Health, the OIG confirmed that the facility does not privilege providers for pregnancy care after the first trimester of pregnancy, as the facility lacks the necessary infrastructure to provide pregnancy care.

[6] VHA Directive 1330.03. The first trimester (week 1–week 12 of pregnancy) is the period when pregnancy is usually diagnosed. Pregnancy care during the first trimester may be provided by VHA gynecologists or primary care providers, who may manage early pregnancy care while a patient is establishing care with a qualified obstetric provider in the community; Facility Standard Operating Procedure (SOP) 11-24-01, "Maternity Management," January 16, 2019. Facility policy requires a community care maternity consult be placed when a patient has a positive pregnancy test and chooses to use VA benefits for coverage, and does not include an option to receive pregnancy care at the facility.

[7] Facility SOP 11-24-01, "Maternity Management," January 16, 2019. VA/Department of Defense (DoD), *VA/DoD Clinical Practice Guideline for the Management of Pregnancy*, Version 3.0, March 2018.

[8] Facility SOP 11-24-01. A service agreement between primary care and gynecology services at the facility states that pregnancy care is not provided by the gynecologic surgical service and that all pregnancy care should be referred to community care. The COS's clinical privileges for gynecology fell under the facility's surgical service.

[9] The COS refused to voluntarily appear for an interview after resigning from VHA. As a result, the OIG used its testimonial subpoena authority to compel the COS to testify.

A management review, conducted by VHA's Director of Reproductive Health, also concluded that the COS provided pregnancy care during Patient 1's second and third trimesters without privileges and noted that the facility did not have the infrastructure to provide pregnancy care after the first trimester of pregnancy. Practicing outside of approved privileges posed a direct risk to patient safety. Furthermore, the COS, as the Chairperson of the Clinical Executive Board, was responsible for maintaining the facility's privileging process and ensuring that facility providers abided by the medical staff bylaws, rules, and regulations, which include provisions requiring that providers practice within the scope of their approved privileges.[10]

COS Failed to Follow Evidence-Based Clinical Standards for Care

The OIG substantiated allegations that the COS provided substandard care to Patient 1 and Patient 2, a gynecologic patient for whom the COS performed endometrial ablation in Spring 2021 and urgent laparoscopy in Summer 2021 for suspected ovarian torsion. The OIG found that the COS failed to follow evidence-based clinical standards for care, specifically identifying deficiencies in the COS's quality of care for

- Patient 1, who the COS evaluated for two potentially severe pregnancy complications;
- Patient 2, whose post-operative treatment included an inadequate antibiotic and delayed consultation; and
- Patient 2, for whom the COS performed endometrial ablation without completing expected preoperative testing.

Deficiencies in the COS's quality of care were also found during management reviews initiated by the facility and the VISN.[11]

During two of the visits occurring within Patient 1's third trimester of pregnancy, the COS evaluated Patient 1 to assess for potential severe pregnancy-related complications—hemolysis, elevated liver enzymes, and low platelet count (HELLP) syndrome and preterm prelabor rupture of membranes (PROM).[12] Potential pregnancy-related complications should have been referred

[10] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was in place during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1100.21(1), *Privileging*, March 2, 2023. The 2023 directive, amended April 26, 2023, contains the same or similar language regarding privileging as the rescinded 2021 handbook. The credentialing portion of VHA Handbook 1100.19 was superseded by VHA Directive 1100.20, *Credentialing of Health Care Providers*, September 15, 2021.

[11] Deficiencies in quality of care were identified during a management review of the COS's provision of care for Patient 1. Deficiencies were also identified during a broader retrospective management review of the COS's clinical practice, which was conducted following the COS's resignation. The retrospective review is further discussed in the Leaders' Failures in Oversight section of the report.

[12] The COS evaluated Patient 1 for possible hemolysis, elevated liver enzymes, and low platelet count at approximately 31 weeks of pregnancy, and for possible preterm prelabor rupture of membranes at 34 4/7 weeks of pregnancy.

to community care for evaluation and treatment. During an interview with the OIG, the COS acknowledged ordering laboratory tests to evaluate for HELLP and scheduling an examination appointment to check the patient's blood pressure, but reported having considered HELLP syndrome as "unlikely." The COS also acknowledged that HELLP syndrome is considered an urgent or emergent condition in pregnancy, and patients whose pregnancy had reached viability may be admitted to a hospital to consider delivery. When asked why he evaluated Patient 1 for preterm PROM, a condition he agreed was an urgency of pregnancy, the COS stated she was put on his schedule by the Emergency Department staff and, therefore, he had to see the patient. However, he acknowledged that he "certainly" had control over the medical advice and examination he provided to the patient. He asserted that he adequately ruled out preterm PROM by completing a sterile speculum examination, a pH test of vaginal fluid, and an ultrasound. However, the OIG did not find documentation in the EHR of an emergency department visit or the pH test to rule out preterm PROM. Delaying the evaluation for HELLP syndrome and performing the evaluation for preterm PROM at the facility, which was not capable of providing pregnancy care, put Patient 1 and her fetus at risk for complications of pregnancy, including preterm delivery and death.

The COS was a signatory on the facility's policy for obstetric and gynecologic emergencies in the Emergency Department, which requires that patients who present to the facility's Emergency Department at 20 or more weeks of gestation "with illness, significant injury or pregnancy threatening symptoms. . . will be evaluated by the ED [Emergency Department] provider immediately and transferred emergently to a facility that can manage such cases." In addition, the policy states that "transfer for patients at or past viability (22–23 weeks) should be of maximal urgency" due to "the unavailability of fetal heart rate monitoring" at the facility. As such, the COS should have directed Patient 1 to a community facility equipped to evaluate and manage obstetric care rather than evaluating Patient 1 for potential severe pregnancy-related conditions at the facility.

In addition to the COS not having privileges to provide care at this point in the patient's pregnancy, a management review, conducted by VHA's Director of Reproductive Health, determined that the care provided was below the standard of care. Further, the facility did not have the necessary trained staff, equipment, and supplies to safely manage the potential complications. Provision of care outside the scope of services that can be safely supported by a facility's infrastructure increases risks of adverse outcomes for patients. The management review findings noted that HELLP syndrome and preterm PROM have potential for severe complications and indicated that the COS's failure to meet standard of care in the evaluation for these conditions placed Patient 1 and her fetus at risk.

The OIG did not substantiate that the COS provided substandard care for Patient 2 during gynecologic surgery resulting in a negative clinical outcome. Patient 2 experienced bowel perforation and an injury of the serosa (serosal injury) as a complication of laparoscopic surgery.

However, the OIG was unable to determine whether the COS's surgical technique contributed to the complication or whether Patient 2's bowel perforation could have been diagnosed sooner. The OIG identified opportunities for improvement in the COS's management of post-operative care for Patient 2.

The OIG determined that the antibiotic the COS ordered after Patient 2's surgical procedure was inadequate to empirically treat for intraabdominal infection or bowel perforation. When asked why he chose the antibiotic ordered, the COS stated, "It's a general broad coverage that we use preoperatively and post operatively." However, the OIG's review of the documentation in the EHR shows the COS ordered cefazolin, which is an antibiotic that does not have broad-spectrum activity against the multiple bacteria that cause intraabdominal abscesses. Further, the OIG determined that, had the COS formally consulted the facility hospitalist at the time of the patient's admission to the intensive care unit, appropriate broad-spectrum antibiotics may have been ordered sooner. The COS and facility physicians subsequently took appropriate action to transfer Patient 2 to another hospital to manage the bowel perforation as management of this condition was beyond the capabilities of the facility. While Patient 2 experienced a bowel perforation and serosal injury and the OIG identified concerns with aspects of the COS's management of post-operative care for Patient 2, the OIG was unable to determine whether alternate management strategies would have resulted in a different clinical outcome.

The OIG also found that the COS did not follow evidence-based clinical standards during another episode of care, four months prior to the laparoscopy, for Patient 2, failing to perform an endometrial biopsy to rule out endometrial cancer in advance of performing an endometrial ablation procedure. During interviews with facility staff, the OIG was told that the COS did not routinely perform endometrial biopsies in advance of endometrial ablation procedures.

The OIG performed a focused review of the 35 endometrial ablation procedures performed by the COS from July 2019 through August 2022 and found that in 32 of the 35 cases, the COS did not complete an endometrial biopsy to rule out endometrial cancer in advance of the endometrial ablation procedure.[13] According to the American College of Obstetricians and Gynecologists, endometrial biopsy should be performed in advance of an endometrial ablation procedure since endometrial ablation is contraindicated in patients with endometrial cancer and should be performed only "when the possibility of endometrial or uterine cancer has been reliably ruled

[13] The OIG performed a limited review of endometrial ablation procedures performed by the COS from July 2019 through August 2022. Patient EHRs were reviewed to determine if an endometrial biopsy had been completed and results reported prior to the endometrial ablation procedure. EHRs were also reviewed to determine the results of any endometrial sampling performed on the day of the ablation procedure to determine if any patients had a diagnosis of endometrial cancer. The OIG did not find any diagnosed cases of endometrial cancer in this review. The OIG did not assess the appropriateness of patient selection or indications for the endometrial ablation procedures.

out."[14] The COS told the OIG that "it's not necessary to do an endometrial biopsy prior to an ablation" and added "doing a biopsy prior to an ablation is not typically done." He further stated that endometrial biopsy was only indicated in cases of "abnormal heavy menstrual bleeding" and "thickened endometrium on a pelvic ultrasound." The COS's failure to perform an endometrial biopsy prior to ablation procedures placed patients at risk of a failure to detect endometrial cancer, which is a contraindication for endometrial ablation and should be ruled out prior to endometrial ablation procedures.

Leaders' Failures in Oversight

The OIG found deficiencies in leaders' oversight, resulting in failure to detect quality of care concerns and take action on known and substantiated concerns, which presented risks to patient safety.

The OIG found that the required ongoing monitoring of privileged independent practitioners was not completed for the COS.[15] VHA requires completion of ongoing professional practice evaluations at least every six months in order to provide continuing oversight of privileged providers' quality of care. The chief of surgery's failure to ensure completion of ongoing professional practice evaluations (OPPEs) resulted in failure to detect problems in the COS's quality of care and identify practice trends that may impact patient safety.[16] According to the VISN Chief Medical Officer and the Deputy Chief Medical Officer, challenges related to completing OPPEs requiring external reviewers, which is a requirement for the COS, are a nationally recognized issue. The VISN Chief and Deputy Chief Medical Officers reported having processes in place to assist facilities who required an external reviewer, with the VISN Deputy Chief Medical Officer clarifying "the ownership is on the facility to seek out those specialists when necessary." The VISN Credentialing and Privileging Officer also reported being unaware of any challenges the facility was experiencing with the OPPE process. The process facilitated by the VISN Chief Medical Officer to address this requirement did not effectively ensure the completion of facility OPPEs that required external reviewers.

The OIG substantiated that facility leaders did not follow additional required privileging processes for the COS. Failures in communication between the COS and chief of surgery

[14] The American College of Obstetricians and Gynecologists Committee on Gynecologic Practice, Committee, Opinion, "Management of Acute Abnormal Uterine Bleeding in Nonpregnant Reproductive-Aged Women," *Obstetrics & Gynecology* 121, no. 4, (April 2013): 891-896.

[15] VHA Handbook 1100.19; Facility MCM 11-22-02, *Credentialing and Privileging of Licensed Independent Providers*, June 20, 2019. Professional practice evaluation is a process for evaluating the privilege-specific competence of a provider. When a provider is granted new privileges, a time-limited focused professional practice evaluation is required to assess the provider's ability to perform the new privileges.

[16] Additionally, the failure in oversight to ensure completion of required OPPEs was concerning, as the COS served as the chair of the facility's Clinical Executive Board, and according to facility policy, was responsible for assurance that professional practice evaluations were conducted for all providers.

regarding approved privileges may have contributed to a lack of clarity regarding the COS's privileges. During an interview with the OIG, the COS reported not being provided a copy of his approved privileges as required and cited verbal communication with the chief of surgery as a basis for understanding of his approved privileges. The chief of surgery told the OIG that the COS performed cystoscopies without privileges. When asked what actions were taken, the chief of surgery told the OIG "I, uh, just let it go," and attributed the lack of action to concerns about existing conflicts in the working relationship with the COS, who was the chief of surgery's direct supervisor. The OIG found that the chief of surgery failed to address discrepancies in understanding of the COS's privileges and concerns regarding the COS's scope of practice.

Failure to provide documentation of approved privileges to a provider violates facility policy and may result in lack of clarity about a provider's approved privileges. However, given the COS's leadership role, the OIG would expect the COS to be aware of the scope of approved privileges prior to performing procedures and to be knowledgeable regarding how to obtain a copy of approved privileges if clarification was needed.[17]

The acting COS recommended, and the Facility Director approved, the COS's re-privileging in July 2021 without following established facility processes by including an addendum containing a list of procedures that was not presented to the credentialing committee. Although the Facility Director told the OIG that the addendum was for clarification of the COS's existing privileges, the OIG determined that the addendum contained unapproved procedures. When asked about the addendum, the Facility Director reported, "I would not know that they were new privileges because I'm not a physician." The addendum containing unapproved privileges was uploaded with the approved 2021 privileges to the facility shared drive that surgical staff used to confirm a provider's privileges when scheduling procedures. The OIG determined that the failure to follow established facility processes during the COS's re-privileging, and inclusion of an addendum that contained procedures that had not been reviewed or approved within the COS's privileging package, could lead to staff believing the COS was privileged to perform the procedures.[18]

The OIG did not substantiate the allegation that fear of reprisal resulted in a lack of follow-up on concerns regarding the provision of unprivileged pregnancy care by the COS. During interviews, the OIG found that, regardless of potential fear of reprisal, staff brought concerns about the COS's provision of pregnancy care to service level managers, who reported the concerns through the facility's quality management program. Quality management staff raised the concerns to

[17] The COS serves as the Chairperson of the Clinical Executive Board and is responsible for maintaining the facility's privileging process and ensuring adherence to the medical staff bylaws, which require that providers practice within the scope of their approved privileges.

[18] VHA Handbook 1100.19. "Copies of current clinical privileges must be available to medical facility staff on a need to-know basis in order to ensure practitioners are functioning within the scope of their clinical privileges. Operating rooms and intensive care units are examples of areas where staff must be aware of practitioner privileges." The facility's clinical shared drive can be used by surgical staff to look up and confirm a provider's privileges and credentialing, such as for confirmation when scheduling procedures.

leaders. Leaders initiated a management review of the COS's provision of pregnancy care for Patient 1 in January 2022.[19] However, the OIG determined that the Facility Director failed to follow VHA policy for state licensing board (SLB) reporting. The Facility Director did not initiate the process to report the COS to the SLB on two separate occasions and failed to complete SLB reporting timely on a third occasion. During an interview with the OIG, the Facility Director reported not being knowledgeable about the process and relying on facility credentialing and privileging staff to identify cases that required SLB reporting. The credentialing and privileging manager reported having the responsibility to initiate the steps required to report a provider to an SLB but stated in this case the VISN Chief Medical Officer and credentialing and privileging were responsible because the COS was a member of the executive leadership team. The VISN Credentialing and Privileging Officer explained to the OIG that the VISN has no role in reporting providers to SLBs, rather, that the responsibility lies with facility directors, consistent with VHA policy.[20]

According to VHA policy, the facility directors must ensure SLB reporting is "initiated as soon as there is substantial evidence of the provider significantly failing to meet the generally accepted standards of clinical practice."[21] The steps for SLB reporting "should be completed in less than 100-calendar days."[22]

The Facility Director failed to initiate the SLB reporting policy after the management review findings concluded the COS provided substandard care that was outside of the scope of privileges. The OIG found that although an exit review had been initiated and signed by the acting chief of surgery within seven business days of the COS's resignation, the form was incomplete. The exit review form referenced evidence of the COS practicing outside of approved privileges and again the Facility Director did not initiate SLB reporting processes. A retrospective review, initiated after the COS's resignation by the acting chief of surgery, determined that the COS "failed to meet generally accepted standards of clinical practice that

[19] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A management review is a review non-protected review conducted for purposes other than confidential quality assurance, such as to provide basis for an action affecting clinical privileges or personnel status. Management reviews include activities such as Focused Clinical Care reviews and Administrative Investigations.

[20] VHA Directive 1100.18, Reporting and Responding to State Licensing Boards, January 28, 2021.

[21] VHA Directive 1100.18.

[22] VHA Directive 1100.18. Following a review with findings of substantial evidence of failure to meet generally accepted standards of clinical practice, an evidence file must be prepared, a notice of intent to report must be sent to the provider, and the provider must be given an opportunity for response and rebuttal. Following a facility director's decision to report to the SLB, the relevant VISN conducts a privacy review. Following the privacy review, the facility director sends a reporting letter to the SLB.

raised reasonable concerns for the safety of patients."[23] However, the Facility Director failed to complete timely SLB reporting as specified by VHA policy.

Due to the facility's repeated failures to adhere to VHA's SLB reporting policy, the COS was not reported to the SLBs until November 14, 2023, and continued to provide care to patients outside of VHA without SLB notification of the deficiencies. The OIG made repeated requests to the facility for updates regarding SLB reporting.

The OIG made one recommendation to the Under Secretary for Health related to reviewing VHA maternity care directives to determine whether more specific guidance on the limitations of pregnancy care at VA facilities is necessary to ensure that pregnant patients receive maternity care according to evidence-based practice standards.

The OIG made three recommendations to the VISN Director related to ensuring processes are in place to support facilities' external reviews for OPPEs in cases requiring external review; ensuring a process is in place to monitor for timely completion of administrative actions for members of the facility executive leadership team when appropriate; and conducting a review of the state licensing board reporting processes at the facility to ensure compliance with VHA policy.

The OIG made six recommendations to the Facility Director related to ensuring that all providers practice within their approved privileges; ensuring adherence to VHA and facility policies for pregnancy care; ensuring a subject matter expert review of endometrial ablation procedures performed by the COS to determine whether standards of care were followed and taking action as indicated; ensuring adherence to VHA and facility policies pertaining to privileging and re-privileging of providers, including the COS; conducting a comprehensive review of the facility ongoing professional practice evaluation processes to ensure compliance with VHA and facility policy, and following up as indicated; and taking action on the findings from the retrospective review of care provided by the COS, and determining whether clinical or institutional disclosures or additional patient follow-up is indicated.

[23] The facility credentialing and privileging manager told the OIG "since there was a significant number of findings" during the retrospective review of the COS's care, "it was decided to review the remaining charts to complete a 100% review of procedures."

VA Comments and OIG Response

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

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Contents

Abbreviations

ACOG	American College of Obstetricians and Gynecologists
CLC	community living center
COS	Chief of Staff
DoD	Department of Defense
EHR	electronic health record
FPPE	focused professional practice evaluation
IUD	intrauterine device
OB/GYN	obstetrician-gynecologist
OPPE	ongoing professional practice evaluation
OIG	Office of Inspector General
SLB	state licensing board
SOP	standard operating procedure
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate allegations received regarding the Chief of Staff (COS) at the Montana VA Health Care System in Helena (facility).[1] The OIG reviewed allegations related to the COS's provision of pregnancy care outside of approved privileges and deficient quality of care provided to a pregnant patient (Patient 1), deficiencies in the quality of gynecologic surgery and post-operative care provided for a patient (Patient 2), and deficiencies in the facility's process for privileging the COS.[2] Additionally, the OIG evaluated leaders' responses to identified concerns.

Background

The Montana VA Health Care System is part of Veterans Integrated Service Network (VISN) 19, the Rocky Mountain Network, and has 18 sites of care statewide, including the facility, 13 community-based outpatient clinics, and a community living center (CLC). The Veterans Health Administration (VHA) classifies the facility as a complexity level 3, low complexity. The facility's surgical program invasive procedure complexity level is designated as inpatient standard.[3] The facility has 18 hospital beds, which includes 6 intensive care unit beds, 24 domiciliary beds, and 17 CLC beds. From October 1, 2021, through September 30, 2022, the facility served 39,854 patients, including over 3,500 women veterans.

Prior OIG Report

The OIG published a healthcare inspection report entitled *Mistreatment and Care Concerns for a Patient at the VA Montana Healthcare System in Miles City and Fort Harrison* on January 26, 2023.[4] Findings from the report included a determination that lack of oversight prevented consideration of staff disciplinary actions and a review for state licensing board (SLB) reporting, that facility leaders failed to provide oversight of a physician's care as required, and did not fully

[1] The COS, who also provided direct patient care as a facility gynecologist in the surgical service, was appointed June 12, 2019, and resigned from the facility during the OIG's inspection effective August 27, 2022.

[2] For the purposes of this report, the OIG uses the term *pregnancy care* to refer to prenatal and *obstetric care* for the management of pregnancy.

[3] VHA, *VHA Invasive Procedure Complexity for Surgical Programs*, accessed June 28, 2022, https://www.va.gov/health/surgery/. "VHA "invasive procedure complexity" establishes the infrastructure that is required at a VHA facility in relationship to the complexity of procedures being performed. This requirement ensures that the scope of the invasive procedure is within the capability of the facility. This requirement makes sure that invasive procedures are performed under the safest possible conditions. A facility infrastructure refers to: physicians, nursing, other medical personnel, space, equipment, supplies, sterile processing, and other support services related to an invasive procedure."

[4] VA OIG, *Mistreatment and Care Concerns for a Patient at the VA Montana Healthcare System in Miles City and Fort Harrison*, Report No. 22-01341-43, January 26, 2023.

assess the physician's performance and competence.[5] The OIG made one recommendation to the Rocky Mountain Network Director related to the review of facility staff's actions taken in response to the allegations and concerns related to the identified patient. The OIG made six recommendations to the Facility Director related to ensuring the rights of CLC patients, reviewing the nursing and physician care provided to the patient during CLC and hospital admissions, and reviewing the screening and admissions process for CLC patients. One of seven recommendations remains open.

Allegations and Related Concerns

From January 7, 2022, through June 22, 2022, the OIG received four complaints regarding the COS, which included the following allegations:

- The COS provided pregnancy care outside of approved privileges.
- The COS provided substandard advanced pregnancy care to a female patient (Patient 1).
- The COS provided substandard care during gynecologic surgery and post-operative care for another female patient (Patient 2), resulting in a negative clinical outcome.
- Appropriate credentialing and privileging processes were not followed for the COS.
- A report was filed regarding the COS providing pregnancy care outside the scope of the COS's privileges, but no follow-up occurred due to fear of reprisal.

The OIG referred complaints received in January and March 2022 regarding practice outside the scope of provider privileges and substandard pregnancy care to VISN leaders for a response. VISN leaders' response cited VHA's Director of Reproductive Health management review findings substantiating the allegations that the COS provided pregnancy care outside approved privileges and provided substandard pregnancy care to Patient 1. The OIG received additional complaints regarding privileging issues and quality of care provided by the COS. Given multiple complaints and to evaluate leaders' response to substantiated allegations, the OIG opened a healthcare inspection to assess the allegations of the COS's provision of care outside approved privileges and failure to follow accepted evidence-based clinical standards, the facility's failure to follow required credentialing and privileging processes, and to evaluate leaders' responses to substantiated concerns.[6]

[5] The COS served as a facility leader during the period of the oversight failures discussed within the report.

[6] The original allegations stated "substandard" care. The OIG interpreted the allegation to mean care that did not meet evidence-based clinical standards; the OIG made no opinion regarding the standard of care.

Scope and Methodology

The OIG initiated the inspection in June 2022. The OIG conducted a site visit from August 23–24, 2022. Virtual interviews were also conducted prior to, during, and following the site visit.

The OIG interviewed confidential complainants, VHA program office leaders (Chief Officer, Women's Health; Director, Women's Reproductive Health; and Director for Medical Staff Affairs), VISN 19 leaders (Network Director, Chief Medical Officer, Deputy Chief Medical Officer, Chief Surgical Consultant, Chief Human Resource Officers, Deputy Chief Human Resource Officer, Credentialing and Privileging Officer, and Quality Management Officer) and staff, facility leaders (Director, Associate Director, Associate Director Patient Care Services, associate chief of staff for inpatient medicine, associate chief of nursing services, chief of quality management, chief of credentialing and privileging, and chief of surgery), and relevant facility staff (maternity care coordinator; women veterans program manager; former credentialing and privileging staff; executive assistant to the COS; and clinical staff, including physicians and nurses from relevant services).

The OIG made multiple attempts to interview the COS, both before and after the COS terminated employment at the VA. After the COS's resignation on August 27, 2022, the OIG issued a subpoena to compel testimony and scheduled the interview in October 2022.[7] While the COS presented for the interview as specified in the subpoena, the attorney for the COS advised the OIG that the COS declined to answer questions. After the COS's attorney communicated to the OIG that the COS would not appear for an interview, the United States Attorney, District of Montana, filed a summary action for enforcement of the subpoena on December 7, 2022. Following the filing of briefs in support of enforcement by the United States, and in opposition by the COS's attorney, a United States District Court Magistrate Judge issued a decision and order dated April 26, 2023, requiring the COS to appear and testify.[8] The OIG interviewed the COS on June 8, 2023.[9]

The OIG reviewed relevant VHA and facility policies and procedures, electronic health records (EHRs), clinical practice guidelines, quality and management reviews, credentialing and privileging documents, committee meeting minutes, human resource and personnel documents,

[7] The *Strengthening Oversight for Veterans Act of 2021*, Pub. L. 117-136 (June 7, 2022) (codified at 38 U.S.C. § 312(d)) allows the OIG to subpoena the attendance and testimony of witnesses as necessary to enable the OIG to perform its authorized oversight functions.

[8] United States v. Maganito, No. MC 22-1-H-KLD, 2023 WL 3097197 (D. Mont. Apr. 26, 2023).

[9] Events that occurred during the COS's tenure at the facility were the primary focus of the OIG's inspection. Although the COS resigned in August 2022 and some information contained in the report is from an interview that occurred in June 2023, the report refers to the COS as COS. The same convention was utilized when referencing the chief of surgery, who was no longer employed in that position at the time of the OIG's interview.

and email correspondence. The OIG did not independently verify VHA data for accuracy or completeness.

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 documents 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 leadership on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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

Inspection Results

The OIG found deficiencies in the COS's clinical practice. Specifically, the COS provided pregnancy care without privileges and rendered care that failed to meet evidence-based clinical standards for Patient 1. The OIG did not substantiate that the COS provided substandard care but identified opportunities for improvement in the COS's management of post-operative care for Patient 2. The OIG identified additional quality of care concerns, finding that the COS did not follow evidence-based clinical standards of care for a gynecologic procedure during a prior treatment episode for Patient 2.

The OIG found deficiencies in leaders' oversight, resulting in failure to detect quality of care concerns and take action on known and substantiated concerns, which presented risks to patient safety. The OIG identified deficiencies in the facility's compliance with requirements for ongoing monitoring of providers' practice and substantiated deficiencies in the privileging processes for the COS. The OIG did not substantiate the allegation that fear of reprisal resulted in leaders' failure to follow up on concerns regarding the provision of pregnancy care by the COS. However, the OIG found that the Facility Director failed to follow VHA policy for SLB reporting.

COS Provided Pregnancy Care Without Privileges

The OIG substantiated that the COS provided pregnancy care without privileges.

Privileging is the process facility leaders use to grant a provider permission to perform clinical services. Generally, providers are only to perform clinical services for which they are privileged.[10] The process protects patient safety by ensuring that a provider's privileges are within the scope of the provider's license and competence, and are consistent with a facility's resources.[11] VHA providers must request privileges at least every two years and more often if modifications in privileges are desired.[12] VHA policy requires facility leaders to consider providers' training, experience, competence, and ability to perform the requested privileges. Additionally, before granting privileges, facility leaders must consider the availability of the resources necessary to support the requested privileges at the facility. The COS is responsible for maintaining the facility's privileging process and ensuring that all providers abide by the medical staff bylaws, rules, and regulations. The COS serves as the Chairperson of the Clinical Executive Board and is responsible for maintaining the facility's privileging process and ensuring that facility providers abide by the medical staff bylaws, rules, and regulations, which include provisions requiring that providers practice within the scope of their approved privileges.[13]

The OIG reviewed the COS's 2019 and 2021 credentialing and privileging documentation. The COS held privileges for clinical practice at the facility to diagnose, treat, and manage patients' "gynecological problems" and to perform delineated gynecologic surgeries and procedures. The chief of surgery told the OIG that the COS was granted basic gynecology privileges, included in the facility's standard delineation of privileges for a gynecologist, at the direction of the VISN's Chief Medical Officer.[14] The facility's standard delineation of privileges for a gynecologist did

[10] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. This handbook was in place during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1100.21(1), Privileging, March 2, 2023. The 2023 directive, amended April 26, 2023, contains the same or similar language regarding privileging as the rescinded 2021 handbook. The credentialing portion of VHA Handbook 1100.19 was superseded by VHA Directive 1100.20, *Credentialing of Health Care Providers*, September 15, 2021. During emergencies, providers are permitted to perform clinical care without privileges.

[11] VHA Handbook 1100.19.

[12] VHA Handbook 1100.19. Resources may include "adequate facilities, equipment, and the number and type of qualified support personnel.

[13] VHA Handbook 1100.19.

[14] Through review of the COS's credentialing record the OIG learned that the COS completed residency training in obstetrics and gynecology from June 2005 through June 2009. The credentialing record indicated the COS participated in a urogynecology fellowship from mid-2015 to early 2016 but did not complete the fellowship. American Urogynecologic Society, "What is a Urogynecologist," accessed on May 31, 2023, https://www.augs.org/patient-services/what-is-a-urogynecologist/. Urogynecology is a surgical specialty focusing on treatment of female pelvic floor disorders. "The pelvic floor is a set of muscles, ligaments, and connective tissue in the lowest part of the pelvis that provides support for a woman's internal organs, including the bowel, bladder, uterus, vagina and rectum;" The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

not include obstetric services. The COS was not privileged to provide obstetric or pregnancy care.

The COS provided pregnancy care without privileges and without the resources necessary for safe pregnancy care during Patient 1's second and third trimesters. Failure of the COS, a member of the facility's executive leadership team, to follow requirements put in place to safeguard patient safety is particularly concerning. One staff member described the influence of leaders, stating "I think people look at. . . particularly executive leadership, that you're supposed to know the rules. . . if you're doing this. . . I'm supposed to be allowing it, and so, I think particularly when you are in that role, I think you have to be held to even a higher standard."

VHA policy requires provision and coordination of maternity care for eligible veterans enrolled in VA's healthcare system.[15] All VA maternity care, whether furnished at a VA facility or through community care, "must follow accepted evidence-based clinical standards."[16]

The first trimester (week 1–12) of pregnancy is the period when pregnancy is usually diagnosed. Pregnancy care during the first trimester may be provided by VHA gynecologists or primary care providers, who may manage early pregnancy diagnosis and care while a patient is establishing care with a qualified obstetric provider in the community.

VHA policy specifies that pregnancy care is typically provided by authorized healthcare professionals in the community.[17] VHA providers are responsible for referring pregnant patients to an authorized community provider "as early as possible after the pregnancy is diagnosed."[18] Facility policy requires a community care maternity consult be placed when a patient has a positive pregnancy test and chooses to use VA benefits for coverage.[19] The policy does not include an option to receive pregnancy care at the facility.[20]

VHA's Chief Officer, Women's Health told the OIG that pregnant patients should be referred to a qualified obstetric provider in the community as soon as possible after the diagnosis of

[15] VHA Directive 1330.03, *Maternity Health Care and Coordination*, November 3, 2020.

[16] VHA Directive 1330.03.

[17] VHA Directive 1330.03. The VHA Chief Officer, Women's Health advised that pregnancy care is very rarely provided at VA beyond standard first trimester care while a patient is establishing care with a community OB/GYN. In those rare instances, the care was authorized under a waiver that was provided due to special arrangements with affiliated community partners, which provided resources not standardly found within VHA facilities.

[18] VHA Directive 1330.03.

[19] Facility SOP 11-24-01, "Maternity Management," January 16, 2019; VA/Department of Defense (DoD), *VA/DoD Clinical Practice Guideline for the Management of Pregnancy*, Version 3.0, March 2018.

[20] Facility SOP 11-24-01. A service agreement between primary care and gynecology services at the facility states that pregnancy care is not provided by the gynecologic surgical service and that all pregnancy care should be referred to community care. The COS clinical privileges for gynecology fell under the facility's surgical service.

pregnancy because, with rare exceptions, VA providers do not have the clinical privileges to provide pregnancy care.[21]

A facility women's health staff member confirmed that while pregnant patients might receive care at the facility early in pregnancy, during the first trimester, such as for laboratory tests to confirm pregnancy or early pregnancy ultrasound, pregnant patients are referred to a qualified obstetric provider in the community for their pregnancy care. Another facility women's health staff member also told the OIG that the facility does not provide pregnancy care and that all pregnant patients are referred to the community.

Through EHR review, the OIG found that the COS appropriately referred Patient 1 to a community obstetrician-gynecologist (OB/GYN) for maternity care as soon as pregnancy was diagnosed by the COS. However, Patient 1's community OB/GYN relocated outside the local area early in Patient 1's second trimester of pregnancy. An initial EHR entry regarding the community OB/GYN's relocation indicated that Patient 1 would need to find a new community provider. A later EHR entry documented Patient 1's preference to continue care with the established community OB/GYN despite the relocation. No referral to a new local community provider was initiated.[22] The COS documented an intent to continue monitoring the progress of the Patient 1's pregnancy, per the patient's request, until Patient 1 re-established care with the community OB/GYN after the relocation. The COS documented the COS's continuing pregnancy care after the patient re-established care with the community OB/GYN. According to Patient 1's EHR, the COS provided pregnancy care to Patient 1 during seven office visits in the second and third trimesters of Patient 1's pregnancy.[23] See appendix A for a case summary detailing the COS's provision of pregnancy care for Patient 1.

[21] VHA Directive 1330.01(4), *Health Care Services for Women Veterans,* February 15, 2017, amended January 8, 2021. Directive 1330.01(4) was amended to 1330.01(5) on August 25, 2022, which was amended to 1330.01(6) on September 9, 2022, which was amended to 1330.01(7) on May 14, 2023. The latter two versions of the directive include language that specifies "If sites are planning to enhance capacity and provide onsite prenatal care, they must submit a proposal to WHS [Women's Health Services] and the Office of Clinical Operations and Management (10NC) describing capacity and proposed onsite services for review."

[22] No EHR documentation was found indicating efforts were made to coordinate an alternate community provider in the local area to manage pregnancy care.

[23] Five of the seven office visits were for routine, scheduled prenatal care; two of the visits were to assess for potential severe pregnancy-related complications.

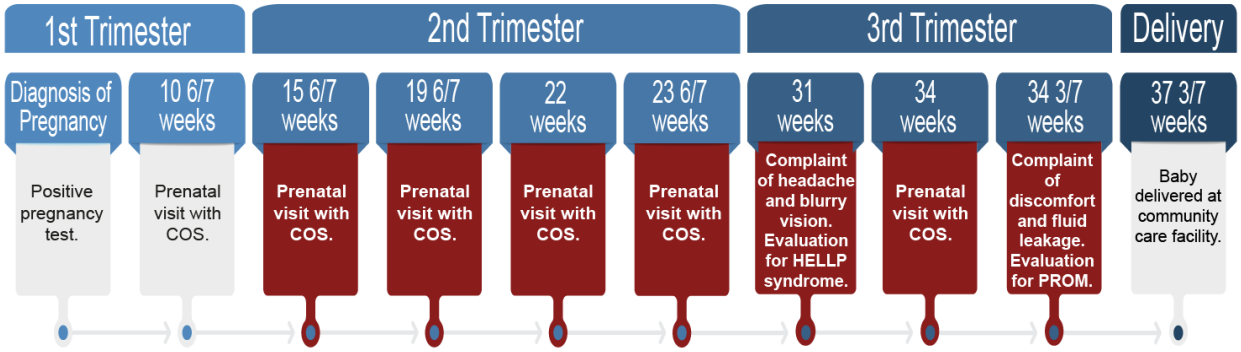

Figure 1. *Timeline of COS pregnancy care for Patient 1.*
Source: VA OIG review of Patient 1's EHR.
Note: Fractions in the figure reference partial weeks in days. For example, 34 3/7 weeks refers to 34 weeks and 3 days.

A management review conducted by the VHA Director of Reproductive Health concluded that the COS provided pregnancy care during the patient's second and third trimesters without privileges. VHA's Director of Reproductive Health told the OIG that the facility does not have the infrastructure to provide pregnancy care after the first trimester of pregnancy. In the management review, the Director of Reproductive Health also noted that the facility does not have the capability, equipment, providers, or staff to meet the recommended guidelines for facilities to provide basic maternal care per American College of Obstetricians and Gynecologists (ACOG) guidelines.[24]The COS was not privileged to perform pregnancy care beyond the early care management needed in the first trimester when a pregnancy is diagnosed and while the patient is establishing care with a qualified obstetric provider in the community.

When asked about being privileged to provide pregnancy care during an interview with the OIG, the COS described being "privileged for continuity of care of all the patients that are assigned to me." When asked again specifically about privileges to provide pregnancy care, the COS reported being "privileged to take care of women regardless of their situation." The OIG, however, notes the distinction between gynecology privileges and obstetrics privileges. Based on correspondence from the VISN Chief Medical Officer regarding privileging, as well as interview with the VHA Director of Reproductive Health, the OIG confirmed that the facility does not privilege providers for pregnancy care after the first trimester of pregnancy, as the facility lacks

[24] ACOG and the Society for Maternal Fetal Medicine, "Obstetric Care Consensus: Levels of Maternal Care," *Obstetrics & Gynecology*, 134, No. 2: e41-e55. To manage associated risks and reduce maternal morbidity and mortality, facilities providing basic pregnancy care should have the "ability to detect, stabilize, and initiate management of unanticipated maternal-fetal or neonatal problems that occur during the antepartum [before childbirth], intrapartum [during childbirth], or postpartum [after childbirth] period until the patient can be transferred to a facility at which specialty maternal care is available."

the necessary infrastructure to provide pregnancy care.[25] Practicing outside of approved privileges poses a direct risk to patient safety.

COS Failed to Follow Evidence-Based Clinical Standards for Care

The OIG substantiated that the COS failed to follow evidence-based clinical standards for care. Specifically, the OIG found deficiencies in the COS's quality of care for

- Patient 1, who the COS evaluated for two potentially severe pregnancy complications;
- Patient 2, whose post-operative treatment included an inadequate antibiotic and delayed consultation; and
- Patient 2, for whom the COS performed endometrial ablation without completing expected preoperative testing.

Although the OIG found deficiencies in the care received by Patient 2, the OIG did not substantiate that the COS's deficient care caused Patient 2 to experience a negative clinical outcome. Through management reviews, the facility also found deficiencies in the COS's quality of care.[26]

Deficiencies in COS's Quality of Pregnancy Care

The OIG found that the COS failed to direct Patient 1 to a community facility equipped to evaluate and manage obstetric care rather than evaluating Patient 1 for potential severe pregnancy-related conditions at the facility. Specifically, during two of the visits occurring within Patient 1's third trimester of pregnancy, the COS evaluated Patient 1 to assess for potential severe pregnancy-related complications—hemolysis, elevated liver enzymes, and low

[25] US Department of Health and Human Services, Office of Women's Health, "Stages of Pregnancy." "Pregnancy lasts about 40 weeks, counting from the first day of [the woman's] last normal period. The weeks are grouped into three trimesters;" VA/DoD, *VA/DoD Clinical Practice Guideline for the Management of Pregnancy*. Not all patients diagnosed with pregnancy will require pregnancy care, as the first trimester is also a time when miscarriages are more common, and some patients may choose to terminate pregnancy. VHA providers may manage early pregnancy care while a patient is establishing care with a qualified obstetric provider in the community.

[26] Deficiencies in quality of care were identified during the management review conducted by VHA's Director of Reproductive Health regarding the COS's provision of care for Patient 1, discussed below. Deficiencies were also identified during a broader retrospective management review of the COS's clinical practice, which was conducted following the COS's resignation. The retrospective review is further discussed in the Leaders' Failures in Oversight section.

platelet count (HELLP) and preterm prelabor rupture of membranes (PROM).[27]

According to the VHA Director of Reproductive Health and facility policy, potential pregnancy-related complications should have been referred to community care for evaluation and treatment. The facility's policy for obstetric and gynecologic emergencies in the Emergency Department (signed by the COS) requires that patients who present to the facility's Emergency Department at 20 or more weeks of gestation "with illness, significant injury or pregnancy threatening symptoms. . . will be evaluated by the ED [Emergency Department] provider immediately and transferred emergently to a facility that can manage such cases."[28] In addition, the policy states that "transfer for patients at or past viability (22–23 weeks) should be of maximal urgency" due to "the unavailability of fetal heart rate monitoring" at the facility.[29]

At the request of the VISN Chief Medical Officer, the VHA Director of Reproductive Health conducted a management review of the care COS to Patient 1 for evaluation of possible HELLP syndrome at approximately 31 weeks of pregnancy and for possible preterm PROM at 34 4/7 weeks of pregnancy. In addition to the COS not having privileges to provide care at this point in the patient's pregnancy, the VHA's Director of Reproductive Health determined that

- the care provided by the COS during these evaluations was below the standard of care;
- the facility did not have the necessary trained staff, equipment, and supplies to safely manage the potential complications; and[30]
- provision of care outside the scope of services that cannot be safely supported by a facility's infrastructure increases risks of adverse outcomes for patients.

[27] The COS evaluated Patient 1 for possible HELLP at approximately 31 weeks of pregnancy and for possible preterm PROM at 34 4/7 weeks of pregnancy. HELLP syndrome is a severe form of preeclampsia, a hypertensive disorder of pregnancy that increases risk of preterm delivery, maternal morbidity, and mortality. PROM is the leakage of amniotic fluid prior to the onset of labor. When this occurs prior to 37 weeks of gestation, the condition is referred to as preterm PROM. Complications of preterm PROM include intraamniotic infection in the amniotic sac and the risks to the newborn of premature birth to include difficulty breathing, bleeding in the brain, and life-threatening inflammation in the intestines.

[28] Facility SOP, "Treatment of Obstetric and Gynecology (OB/GYN) Emergencies in the Emergency Department," January 1, 2020; Facility Primary Care / Gynecology Surgery Provider Agreement. The facility's service agreement between primary care and gynecology services also specified that pregnancy care was "NOT provided by GYN Surgical Service" and that "ALL pregnancy care should be sent out through Care in the Community."

[29] Facility SOP, "Treatment of Obstetric and Gynecology (OB/GYN) Emergencies in the Emergency Department."

[30] The American College of Obstetricians and Gynecologists, ACOG Practice Bulletin, *Clinical Management Guidelines for Obstetrician-Gynecologists*, "Prelabor Rupture of Membranes," accessed July 6, 2022, https://journals.lww.com/greenjournal/Fulltext/2020/03000/Prelabor_Rupture_of_Membranes__ACOG_Practice.41.aspx. Clinical women's health staff members confirmed the facility did not have microscopes in the clinical setting necessary to check for ferning of amniotic fluid or commercially available tests for amniotic fluid proteins, which are typically used to confirm diagnosis of preterm premature rupture of membranes.

The management review findings noted that HELLP syndrome and preterm PROM have potential for severe complications and indicated that the COS's failure to meet standard of care in the evaluation for these conditions placed Patient 1 and her fetus at risk.

COS Failed to Refer Patient for Evaluation for HELLP Syndrome

HELLP syndrome is a severe form of preeclampsia that is associated with increased rates of maternal morbidity and mortality. Preeclampsia is a hypertensive disorder of pregnancy that typically occurs after 20 weeks of gestation. Preeclampsia increases risk of spontaneous or preterm delivery. ACOG lists severe preeclampsia as an example of a condition that should be managed at a hospital that can provide Level III maternal care.[31] ACOG notes that the clinical course of severe preeclampsia "is characterized by progressive deterioration of maternal and fetal condition."[32]

According to the patient's EHR, at 30 weeks and 5 days of pregnancy, Patient 1 reported symptoms of headache and blurry vision to the COS in an after-hours telephone communication. The COS documented the after-hours communication in the EHR the following morning. The COS noted that the patient's home blood pressure had been normal and documented having advised the patient to rest and to go to the hospital if symptoms worsened. The COS also instructed Patient 1 to inform the community OB/GYN, ordered lab tests to evaluate for HELLP syndrome, and scheduled Patient 1 to see the COS two days later. The COS did not document contacting Patient 1's community OB/GYN regarding Patient 1's symptoms and the COS's concern for possible HELLP syndrome.

The VHA Director of Reproductive Health told the OIG that the COS should have advised Patient 1 to go to a hospital capable of pregnancy care to be evaluated for possible HELLP syndrome at the time of the after-hours telephone communication. Given the risks of severe preeclampsia and HELLP syndrome, the OIG would have expected that the COS advise Patient 1 to immediately go to a hospital capable of evaluating and managing these conditions as soon as the COS considered HELLP syndrome as a possible cause of Patient 1's reported symptoms of headache and blurry vision.[33] Instead, the COS ordered laboratory tests to be completed the following day and scheduled Patient 1 for an appointment two days later. During an interview with the OIG, the COS acknowledged ordering laboratory tests to evaluate for HELLP and scheduling an examination appointment to check the patient's blood pressure, but reported

[31] The American College of Obstetricians and Gynecologists and the Society for Maternal Fetal Medicine, "Obstetric Care Consensus: Levels of Maternal Care." Level III maternal care facilities are capable of providing care for "more complex maternal medical conditions, obstetric complications, and fetal conditions."

[32] The American College of Obstetricians and Gynecologists, ACOG Practice Bulletin, *Clinical Management Guidelines for Obstetrician-Gynecologists*, "Gestational Hypertension and Preeclampsia," accessed September 5, 2022, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/06/gestational-hypertension-and-preeclampsia.

[33] Facility SOP, "Treatment of Obstetric and Gynecology (OB/GYN) Emergencies in the Emergency Department."

having considered HELLP syndrome as "unlikely." The COS also acknowledged that HELLP syndrome is considered an urgent or emergent condition in pregnancy, and patients whose pregnancy had reached viability may be admitted to a hospital to consider delivery. When asked why he evaluated Patient 1 for preterm PROM, a condition he agreed was urgent in pregnancy, the COS stated she was put on his schedule by the Emergency Department staff and, therefore, he had to see the patient. However, he acknowledged that he "certainly" had control over the medical advice and examination he provided to the patient. He asserted that he adequately ruled out preterm PROM by completing a sterile speculum examination, a pH test of vaginal fluid, and an ultrasound. However, the OIG did not find documentation in the EHR of an emergency department visit or the pH test to rule out preterm PROM. Delaying the evaluation for HELLP syndrome and performing the evaluation at the facility, which was not capable of providing pregnancy care, put Patient 1 and her fetus at risk for complications of pregnancy, including preterm delivery and death.

COS Improperly Evaluated Patient for Preterm PROM

Patient 1 reported symptoms of leakage of clear fluid from the vagina at 34 weeks and 3 days gestation. The COS examined Patient 1 at the facility to rule out preterm PROM. The COS conducted a sterile speculum exam. The COS did not document evaluating the vaginal fluid by pH test or for fern under a microscope. During interviews with clinical staff and review of facility procedures, the OIG learned that the facility did not have the necessary supplies and equipment to complete a thorough clinical assessment for, and management of, preterm PROM if diagnosed. Assessment needs include microscopes necessary to check for fern of amniotic fluid, commercially available tests for amniotic fluid proteins, and fetal heart rate monitoring capability.[34] The COS performed an ultrasound and documented an "intact membrane," although ACOG guidelines specify that an ultrasound is not sufficient to diagnose rupture of membranes.[35] Contrary to the ACOG guidelines, the COS also performed a digital exam of the cervix without documenting completion of definitive tests to rule out preterm PROM.

According to ACOG guidelines, to determine whether rupture of a pregnant patient's membranes has occurred, the physician performs a vaginal exam with a sterile speculum and visually inspects the cervix and vagina for the presence of amniotic fluid.[36] Next, the physician tests the

[34] Facility SOP, "Treatment of Obstetric and Gynecology (OB/GYN) Emergencies in the Emergency Department."

[35] The American College of Obstetricians and Gynecologists, ACOG Practice Bulletin, *Clinical Management Guidelines for Obstetrician-Gynecologists*, "Prelabor Rupture of Membranes," accessed July 6, 2022, https://journals.lww.com/greenjournal/Fulltext/2020/03000/Prelabor_Rupture_of_Membranes__ACOG_Practice.41.aspx.

[36] The American College of Obstetricians and Gynecologists, ACOG Practice Bulletin, *Clinical Management Guidelines for Obstetrician-Gynecologists*, "Prelabor Rupture of Membranes," accessed July 6, 2022, https://journals.lww.com/greenjournal/Fulltext/2020/03000/Prelabor_Rupture_of_Membranes__ACOG_Practice.41.aspx.

vaginal fluid for the presence of amniotic fluid with a pH test or by observing the dried vaginal fluid under a microscope for a pattern known as ferning.[37] While ultrasound examination may be conducted, it is not diagnostic for rupture of membranes.[38] ACOG recommends that a digital exam of the cervix in a patient suspected of having PROM should be avoided because a digital exam increases the risk of infection.[39] Pregnant patients diagnosed with preterm PROM should undergo monitoring of fetal heart rate and monitoring for uterine contractions. VA policy requires that providers adhere to evidence-based clinical standards.[40] The care that the COS provided to Patient 1 to evaluate for possible preterm PROM did not meet accepted guidelines. The COS's actions put Patient 1 and her fetus at risk of intraamniotic fluid infection and complications of premature birth.

COS's Gynecologic Surgical and Post-Operative Care of Patient

The OIG did not substantiate that the COS provided substandard care during gynecologic surgery resulting in a negative clinical outcome. The OIG was unable to determine whether the COS's surgical technique contributed to a complication experienced by Patient 2. The OIG identified opportunities for improvement in the COS's management of post-operative care for Patient 2, but was unable to determine whether alternate management strategies would have resulted in a different clinical outcome. Appendix B provides a full case summary for Patient 2.

[37] Providers conduct a visual exam of the vagina by inserting a speculum into the vagina. The speculum holds the walls of the vaginal open so that a provider can visually inspect the vagina and cervix.

[38] Other tests such as evaluation for the presence of fetal fibronectin or use of commercially available test for amniotic proteins are sensitive but not specific for the diagnosis of ruptured membranes. Finally, if the diagnosis is uncertain, blue dye may be instilled into the amniotic sac guided by ultrasound; passage of blue dye into the vagina indicates rupture of the amniotic sac.

[39] A provider performs a digital examination of the cervix by inserting one or two gloved fingers into the vagina. This type of examination may be performed during pregnancy to assess for signs of impending labor or delivery.

[40] VHA Directive 1330.03.

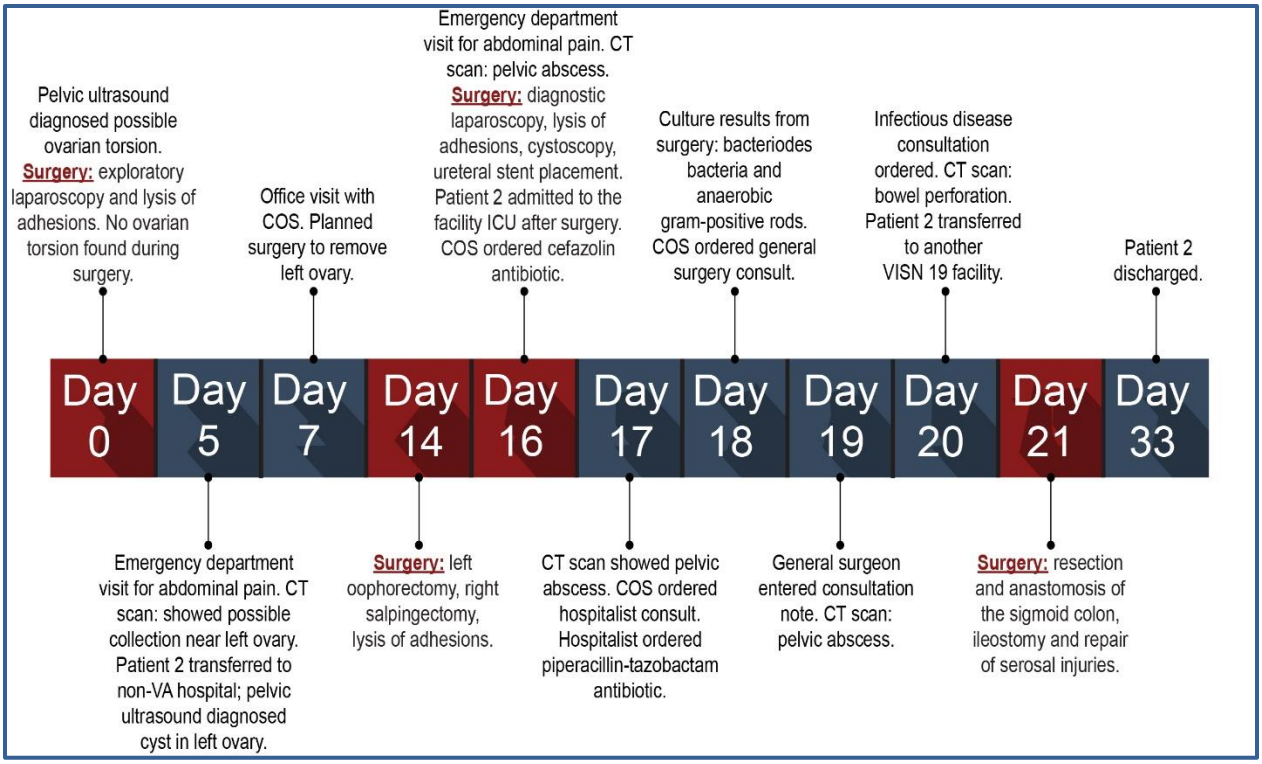

Figure 2. *Timeline of care for Patient 2.*
Source: VA OIG analysis of Patient 2's EHR.

The OIG found that Patient 2 experienced bowel perforation and a serosal injury as a complication of laparoscopic surgery. The OIG determined that the antibiotic ordered after Patient 2's surgical procedure in Fall 2021 (Day 16) was inadequate to empirically treat for intraabdominal infection or bowel perforation. The OIG was unable to determine whether Patient 2's bowel perforation could have been diagnosed sooner than Fall 2021 (Day 20). The OIG found that the COS and facility physicians took appropriate action to transfer Patient 2 to another hospital to manage the bowel perforation as management of this condition was beyond the capabilities of the facility.

Bowel injury, including serosal abrasion and bowel perforation, is a known complication of laparoscopic gynecologic surgery. Bowel injury has been found to occur in 0.13 percent of laparoscopic gynecologic surgeries.[41] Patients known to have adhesions from prior surgeries are at risk for bowel injury. Bowel injury may be detected during a surgical procedure at the time of injury or may be diagnosed during a patient's post-operative course. Post-operative diagnosis of bowel injury is associated with a higher morbidity and mortality than bowel injury diagnosed at the time of the surgical procedure.

[41] Natalia Llanera, Anup Shah, and Magdy Milad. 2015. "Bowel Injury in Gynecologic Laparoscopy: A Systematic Review," *Obstetrics & Gynecology* 125, no. 6 (June): 1407-1417.

Patient 2 had four CT scans of the abdomen and pelvis during admission to the facility before the bowel perforation was diagnosed. The first three CT scans did not diagnose bowel perforation, although they did show fluid collections consistent with abscess as well as free air in the abdomen. CT scans on the day of Patient 2's third surgery (Day 16) and on the day after admission (Day 17) showed a fluid collection, and a laboratory test showed elevated white blood cells, indicating infection.

Antibiotics should be initiated when an intraabdominal infection is diagnosed or considered likely. Post-operative intraabdominal abscesses usually contain multiple different bacteria and antibiotic treatment guidelines recommend broad-spectrum antibiotic coverage.

The COS did not order broad-spectrum antibiotic coverage after the third surgery. When asked why the COS chose the antibiotic ordered, the COS stated, "It's a general broad coverage that we use preoperatively and post operatively." However, OIG review of the EHR shows the COS ordered cefazolin, which is an antibiotic that does not have broad-spectrum activity against the multiple bacteria that cause intraabdominal abscesses. While Patient 2 received one dose of a broad-spectrum antibiotic in the Emergency Department prior to the third surgery, this antibiotic would have had to be administered every eight hours to remain effective. In interviews, facility physicians told the OIG that cefazolin was not adequate antibiotic coverage for the possibility of a perforated bowel. The OIG would have expected the COS to have ordered a broad-spectrum antibiotic when Patient 2 was admitted after the third surgery while awaiting results of cultures obtained during the surgical procedure. Once culture results were available, antibiotic therapy could then be tailored.[42]

The VHA Director of Reproductive Health told the OIG that general surgeons are experts on bowel injury. A facility general surgeon told the OIG that a surgeon should have a high level of suspicion for the possibility of iatrogenic bowel injury after multiple abdominal surgeries. The chief of surgery told the OIG that it is not normal for enteric bacteria to grow in pelvic fluid cultures and that if colon injury is suspected, surgery may be indicated. While the facility general surgeon reported being informally alerted by the COS of plans for the third surgery, the COS did not formally consult the facility general surgeon until two days after the patient's admission. The COS may have considered formally consulting the facility general surgeon sooner than two days after Patient 2's admission to assist in evaluating for a bowel perforation. However, the OIG could not determine whether consulting the facility general surgeon sooner would have resulted in an earlier diagnosis of bowel perforation.

When the COS consulted the facility hospitalist a day after Patient 2 was admitted to the hospital, the facility hospitalist recommended broadening antibiotic coverage and ordered piperacillin-tazobactam. The OIG determined that had the COS consulted the facility hospitalist

[42] The recommended antibiotics for empiric treatment of intraabdominal abscesses include piperacillin-tazobactam, ertapenem, moxifloxacin, or meropenem.

at the time of admission to the intensive care unit, appropriate broad-spectrum antibiotics may have been ordered sooner.

While Patient 2 experienced a bowel perforation and serosal injury and the OIG identified concerns with aspects of the COS's management of post-operative care for Patient 2, the OIG was unable to determine whether alternate management strategies would have resulted in a different clinical outcome.

COS Failed to Complete Expected Preoperative Testing

The OIG found that the COS did not follow evidence-based clinical standards when failing to perform an endometrial biopsy to rule out endometrial cancer in advance of an endometrial ablation procedure, which was completed during a previous episode of care for Patient 2.

Endometrial ablation is a procedure to cauterize the lining of the uterus and is a treatment for heavy menstrual bleeding that has failed conservative treatments such as oral contraceptive pills and a levonorgestrel intrauterine device (IUD).[43] Endometrial ablation is indicated only for premenopausal women who have completed childbearing. Endometrial biopsy should be performed in advance of an endometrial ablation procedure since endometrial ablation is contraindicated in patients with endometrial cancer and should be performed only "when the possibility of endometrial or uterine cancer has been reliably ruled out."[44] Premenopausal women with a history of polycystic ovary syndrome who experience abnormal uterine bleeding have a higher risk of endometrial cancer.

Patient 2 had a history of polycystic ovary syndrome and experienced heavy, painful vaginal bleeding and had not obtained relief of symptoms from oral contraceptive pills or a levonorgestrel IUD. The COS did not perform an endometrial biopsy in advance of the endometrial ablation procedure, and instead, performed the biopsy on the day of the endometrial ablation procedure. The COS did not have results of the biopsy before completing the endometrial ablation procedure. While the result of the biopsy completed on the day of the endometrial ablation procedure was benign and Patient 2 did not experience harm, the OIG is concerned that the COS did not follow accepted evidence-based clinical standards.

A VHA gynecologist told the OIG that the standard of care is to perform an endometrial biopsy ahead of an endometrial ablation procedure.[45] However, the OIG learned from facility staff that

[43] The American College of Obstetricians and Gynecologists, "Endometrial Ablation," accessed October 24, 2022, https://www.acog.org/womens-health/faqs/endometrial-ablation.

[44] The American College of Obstetricians and Gynecologists Committee on Gynecologic Practice, Committee Opinion, "Management of Acute Abnormal Uterine Bleeding in Nonpregnant Reproductive-Aged Women," *Obstetrics & Gynecology* 121, no. 4, (April 2013): 891-896.

[45] The American College of Obstetricians and Gynecologists Committee on Gynecologic Practice, Committee Opinion, "Management of Acute Abnormal Uterine Bleeding in Nonpregnant Reproductive-Aged Women," *Obstetrics & Gynecology* 121, no. 4, (April 2013): 891-896.

the COS did not "routinely" perform endometrial biopsies in advance of endometrial ablation procedures. The OIG found that the COS performed 35 endometrial ablation procedures from July 2019 through August 2022. The OIG performed a focused review of these procedures and found that in 32 of the 35 cases, the COS did not complete an endometrial biopsy to rule out endometrial cancer in advance of the endometrial ablation procedure.[46]

The COS told the OIG that "it's not necessary to do an endometrial biopsy prior to an ablation" and added "doing a biopsy prior to an ablation is not typically done." He further stated that endometrial biopsy was only indicated in cases of "abnormal heavy menstrual bleeding" and "thickened endometrium on a pelvic ultrasound."

The COS's failure to perform an endometrial biopsy prior to ablation procedures placed patients at risk of a failure to detect endometrial cancer, which is a contraindication for endometrial ablation, and should be ruled out prior to endometrial ablation procedures.

Leaders' Failures in Oversight

The OIG found deficiencies in leaders' oversight, resulting in failure to detect quality of care concerns and take action on known and substantiated concerns, which presented risks to patient safety. Specifically, ongoing professional practice evaluations (OPPEs) were not completed; privileging processes were not followed; and, when deficiencies in the COS's care were identified, the concerns were not reported to the SLB as required.[47]

Chief of Surgery Failed to Ensure Completion of the COS's OPPEs

The OIG found that the chief of surgery did not ensure completion of required OPPEs for the COS. Further, facility leaders misrepresented to VHA Medical Staff Affairs that OPPEs were completed for the COS. As a result, processes to detect problems in the COS's quality of care and identify practice trends that may impact patient safety were lacking.

Professional practice evaluation is a process for evaluating the privilege-specific competence of a provider. When a provider is granted new privileges, a time-limited focused professional practice evaluation (FPPE) is required to assess the provider's ability to perform the new privileges.[48]

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[46] The OIG performed a limited review of endometrial ablation procedures performed by the COS from July 2019 through August 2022. Patient EHRs were reviewed to determine if an endometrial biopsy had been completed and results reported prior to the endometrial ablation procedure. EHRs were also reviewed to determine the results of any endometrial sampling performed on the day of the ablation procedure to determine if any patients had a diagnosis of endometrial cancer. The OIG did not find any diagnosed cases of endometrial cancer in this review. The OIG did not assess the appropriateness of patient selection or indications for the endometrial ablation procedures.

[47] VHA Handbook 1100.19. Facility MCM 11-22-02, *Credentialing and Privileging of Licensed Independent Providers*, June 20, 2019.

[48] VHA Handbook 1100.19; Facility MCM 11-22-02.

Once the FPPE is successfully completed, an OPPE must be completed at least every six months.[49] OPPEs provide continuing oversight of privileged providers' quality of care.

Facility service chiefs are responsible for "monitoring and surveillance of the professional competency and performance of those who provide patient care services with delineated clinical privileges," which includes FPPEs and OPPEs.[50] Facility policy assigns responsibility to the COS to "assure that professional practice evaluations are conducted for all providers."[51] A provider external to the facility with similar privileges and training is required to complete the OPPE when the provider is (1) the COS of a facility, (2) a "solo provider," or (3) part of a "two-deep" service or specialty. The VISN Chief Medical Officer is responsible for development of a "VISN-wide process for external reviews of FPPE/OPPE by practitioners with similar training and privileges."[52]

Although an FPPE was completed in October 2019, after the COS's initial privileging, the OIG learned that OPPEs were not subsequently completed as required. When questioned why OPPEs were not completed for the COS, the chief of surgery stated, "It was difficult to get someone to agree to review GYN [gynecology]. There's so few GYN [gynecologic] surgeons out there that getting somebody to review [was difficult]" and added that it was "especially difficult" because the provider in question was the COS. The chief of surgery reported that difficulty getting reviews for some specialists was discussed within the VISN 19 surgical workgroup and that the VISN Chief Surgical Consultant facilitated communication between facilities to identify specialty providers to perform external reviews for OPPEs, but difficulties persisted.

The COS acknowledged responsibility for oversight of the OPPE process through the facility's credentialing committee; however, the COS reported having no involvement in facilitating the OPPE process, and described the COS's responsibility as being initiation of disciplinary actions as needed if a service chief failed to ensure OPPEs were completed. During an interview with the OIG, the COS initially reported no awareness of deficiencies in completion of OPPEs requiring external reviewers, but subsequently clarified that sometimes an extension would be requested when there was difficulty finding a reviewer for a particular subspecialty. The COS then reported awareness of recurrent deficiencies in completion of OPPEs in the surgical service, and also reported taking disciplinary action toward the chief of surgery.

During an interview with the facility credentialing and privileging manager, the OIG learned that the surgery service was consistently behind on OPPEs for surgeons. Another facility service

[49] VHA Handbook 1100.19; Facility MCM 11-22-02.

[50] VHA Handbook 1100.19.

[51] Facility MCM 11-22-02.

[52] Assistant Under Secretary for Health for Clinical Services/CMO (11), "Implementation of Enterprise-Wide Focused Professional Practice Evaluation (FPPE) and Ongoing Professional Practice Evaluation (OPPE) Specialty-Specific Clinical Indicators," May 18, 2021.

leader confirmed challenges related to completing OPPEs requiring external reviewers, and stated VISN support had been less than effective for resolving the recurrent difficulties.

The OIG found that the VISN Chief Medical Officer did not effectively facilitate a process to ensure completion of facility OPPEs that required external reviewers. The VISN Credentialing and Privileging Officer confirmed that the VISN could assist by finding an external reviewer if the facility requested assistance, but reported being unaware of any challenges the facility was experiencing with the OPPE process. The VISN Deputy Chief Medical Officer indicated that obtaining external reviews when a review is needed has been a nationally recognized issue. The VISN Deputy Chief Medical Officer noted working with facilities in 2019 to identify solo providers and their specialties and share that information across the VISN to facilitate inter-facility agreements for external reviews. The VISN Deputy Chief Medical Officer told the OIG that following that 2019 effort, the VISN would assist when requested and "put an ask out to the sites like 'we need a review done for 'X' specialty,' that type of thing," but clarified "the ownership is on the facility to seek out those specialists when necessary." The VISN Chief Medical Officer reported doing site visits at all facilities in the VISN and assessing OPPE and FPPE compliance during those visits, citing that the OPPE process at the facility was "actually pretty good." The VISN Chief Medical Officer indicated that plans to address reviews for solo specialty providers and chiefs of staff, which must be performed outside the local facility, are "coordinated via the local COS offices and the ICC [Integrated Clinical Communities] specialty HSS's [Health System Specialists]." [53] The VISN Chief Medical Officer indicated the VISN continued to facilitate development of agreements between facilities for external reviews and provided an updated spreadsheet from fiscal year 2022 of providers in the VISN who required external reviews to be coordinated between facilities. However, the VISN Chief Medical Officer also acknowledged challenges with external OPPEs as a national issue, and referenced a national work group that is trying to develop a system to automate the process of assigning required external reviews across facilities.[54]

During the inspection, the OIG also noted that the facility's annual credentialing and privileging program 2022 self-assessment to VHA Medical Staff Affairs attested that the COS's OPPEs

[53] VHA Directive 1159, *VHA Specialty Care Program Office and National Programs*, March 9, 2022. VHA Specialty Care Integrated Clinical Communities are "are a common, Veteran-centered operational clinical structure intended to drive a consistent Veteran experience and enable information to flow more rapidly across VHA. This enhanced communication structure is intended to enable VHA's leadership to communicate consistently between the field, through the Veterans Integrated Service Network (VISN) and VHA Central Office (VHACO)."

[54] The VHA Director of Medical Staff Affairs advised the OIG that the national office was requesting support to build an automated system level program, which would be coordinated at the VISN level, to support facilities when external reviewers were required for the professional practice evaluation process. A prototype was successfully piloted in VISN 8, and Medical Staff Affairs planned to request funding support to build out the program further in order to support all VISNs.

were reviewed and results sent to the applicable service chief (chief of surgery).[55] The OIG determined the attestation misrepresented facility leaders' compliance with this requirement, as no OPPEs had been completed for the COS.

The chief of surgery's failure to ensure completion of OPPEs resulted in failure to detect problems in the COS's quality of care and identify practice trends that may impact patient safety. Failure to complete OPPEs also meant objective data from evaluation of recent practice was not available to inform the credentialing committee's recommendation during a required bi-annual assessment for re-privileging of the COS's in July 2021.[56] The failure of leaders to ensure completion of required OPPEs, or to facilitate processes when barriers to completion of OPPEs were identified, was concerning, as the lack of oversight negated the effectiveness of processes intended to ensure patient safety.[57]

Facility Leaders Failed to Follow Privileging Processes

The OIG found that failures to follow and document privileging processes may have contributed to discrepancies in understandings of the COS's privileges for cystoscopies.

Deficiencies in Communications and Oversight Regarding Approved Privileges

The OIG found deficiencies in communications between the COS and chief of surgery regarding approved privileges, which may have contributed to a lack of clarity regarding the COS's privileging for cystoscopies. The OIG also found that the chief of surgery failed to address discrepancies in understanding of the COS's privileges for cystoscopies and concerns regarding the COS's scope of practice.

During inspection of allegations of provision of care outside approved privileges, the OIG found that the COS had performed 15 cystoscopies between March 2020 and August 2022, and noted

[55] The facility submitted annual credentialing and privileging program self-assessments to VHA Medical Staff Affairs in 2020, 2021, and 2022, which included audits of OPPEs. The 2022 self-assessment added a requirement for facility audits to include review of FPPEs and OPPEs for Chiefs of Staff. The facility reported compliance with this requirement, endorsing that the COS's OPPEs were reviewed and the results returned to the applicable service chief, with an attestation to that effect signed in January 2022. The attestation of the facility self-assessment was signed by the Associate Director, Patient Care Services on January 31, 2022, and cosigned by the COS, and Associate Director, in the capacity as acting Medical Center Director.

[56] At the time of re-privileging, OPPEs are utilized to confirm quality of care and identify practice trends that may impact patient safety, informing the Credentialing Committee's recommendations to continue a provider's existing privileges or to limit or revoke existing privileges. During re-privileging, the service chief reviews the OPPEs over the previous two years to confirm the provider's competency with the requested privileges. The chief of surgery acknowledged problems with completion of the COS's OPPEs, but indicated that the Credentialing Committee did not delay re-privileging based on overdue OPPEs.

[57] Assistant Under Secretary for Health for Clinical Services/CMO (11), "Implementation of Enterprise-Wide Focused Professional Practice Evaluation (FPPE) and Ongoing Professional Practice Evaluation (OPPE) Specialty-Specific Clinical Indicators," May 18, 2021; Facility MCM 11-22-02.

that cystoscopy was not included in the COS's credentialing file delineating approved gynecologic privileges. During an interview with the OIG, the COS also acknowledged that cystoscopy was not listed on the signed delineation of approved privileges. However, the COS reported understanding that approved privileges included cystoscopies, and noted cystoscopy was listed on an addendum that was submitted by the COS to facility credentialing and privileging staff with privileging requests in both 2019 and 2021. The COS further stated that approval of privileges for cystoscopy was "implied" within the signed delineation of approved privileges. The COS clarified "implied" to mean that cystoscopy was approved because the procedure was conducted as part of other procedures that were included in the approved privilege list, such as a cystocele or enterocele repair.

Privileges approved in 2019 were specified on the "Gynecology Clinical Privileges Delineation" form, and cystoscopy was not listed as an approved privilege. Review of the COS's VetPro credentialing file also showed that the COS's 2019 credentialing package did not include the addendum with the list of procedures that the COS had submitted to credentialing staff with the standard privilege delineation form. However, the OIG confirmed that an addendum containing a list of procedures, including cystoscopy, was submitted by the COS to facility credentialing and privileging staff with the privileging requests in 2019 and in 2021. The OIG's review of correspondence accompanying the 2019 addendum noted that the COS identified the addendum as "a comprehensive list of procedures for which I requested privileges in the past." The COS's correspondence requested assistance identifying which procedures fell within the facility's surgical complexity, noting the COS's intention to not request privileges outside the scope of the facility's complexity level.[58] The COS's 2021 credentialing file included the addendum, with a list of procedures nearly identical to those found in the 2019 addendum. However, as discussed further below, the addendum was not included in the scope of privileges approved during the COS's re-privileging in 2021.

The OIG consulted with the VHA National Surgery Office for a subject matter expert opinion. While the National Surgery Office opinion noted inability to determine intent for permission to perform cystoscopy as part of those procedures due to lack of documentation from the Clinical Executive Board meeting regarding this issue, the National Surgery Office advised that "not all gynecologists are trained to perform cystoscopy." The National Surgery Office noted that "cystoscopy is often listed as a separate procedure for gynecology privileging due to variation of training among gynecologists."

Facility policy specifies that service chiefs are responsible for "ensuring that each practitioner applying or renewing has a copy of his/her approved privileges."[59] During an interview with the OIG, the COS reported that no copy of approved privileges had been provided, but also cited

[58] The OIG confirmed that cystoscopies were within the facility's surgical complexity level.

[59] Facility MCM 11-22-02.

verbal communication with the chief of surgery as a basis for understanding that approved privileges included cystoscopy. However, during an interview with the OIG, the chief of surgery indicated understanding that cystoscopy was not one of the COS's approved privileges. The OIG reviewed privileging-related email correspondence and the COS's credentialing and privileging file. While unable to determine the issue definitively, the OIG found no documentation showing that the COS was provided a copy of the approved privileges following the COS's initial privileging in July 2019. Failure to provide documentation of approved privileges to a provider violates facility policy and may result in lack of clarity about a provider's approved privileges.[60] However, as previously discussed, the COS served as the Chairperson of the Clinical Executive Board and was responsible for maintaining the facility's privileging process and ensuring adherence to the medical staff bylaws, which require that providers practice within the scope of their approved privileges.[61] As such, the OIG would expect the COS to be aware of the scope of approved privileges prior to performing procedures and to be knowledgeable regarding how to obtain a copy of approved privileges if clarification was needed.

During an interview with the OIG, the chief of surgery acknowledged awareness of the COS performing cystoscopies. Despite the reported awareness of the COS performing these procedures and the chief of surgery's report that the COS was not privileged for cystoscopy, the chief of surgery acknowledged taking no corrective action on the issue.[62] The chief of surgery stated, "I, uh, just let it go," and attributed the lack of action to concerns about existing conflicts in the working relationship with the COS, who was the chief of surgery's direct supervisor.[63]

The OIG would have expected the chief of surgery to discuss the provision of care outside of the chief of surgery's understanding of the COS's approved privileges with the COS. Alternatively, if conflict in the working relationship prevented resolution directly with the COS, the OIG would have expected the chief of surgery to utilize the facility's established patient safety reporting mechanisms to address these concerns.

Deficiencies in the Re-Privileging Review Process and Documentation

The OIG found that facility leaders recommended, and the Facility Director approved, the COS's re-privileging in July 2021 without following established facility processes for review of requested privileges.

[60] Facility MCM 11-22-02.

[61] VHA Handbook 1100.19.

[62] The COS's privileges fell under the purview of the facility's surgical service, and the chief of surgery was administratively responsible for surgical service operations.

[63] Organizationally, the surgical service fell under the COS, and the chief of surgery reported to the COS.

VHA and facility policies require that review and renewal of provider privileges (re-privileging) must be conducted at least every two years, and the same re-privileging process is required for all providers, including the COS.[64]

According to the policies, the re-privileging request must be made by the provider and the re-privileging process must be completed prior to expiration of the provider's current privileges and must include a statement of the specific clinical privileges requested.[65] The service chief of the department for which the applicant is requesting clinical privileges is responsible for assessing information relevant to evaluating the provider's performance, judgment, and clinical skills and documenting the review and rationale for recommending approval, disapproval, or modification of the requested privileges in VetPro.[66] Once the service chief's assessment is completed, facility policy requires that the credentialing committee reviews the appraisal, including the provider's requested privileges, FPPE, OPPEs, and any identified concerns. The service chief provides a recommendation to the facility's Clinical Executive Board, which in turn makes a recommendation to the Facility Director regarding the approval, disapproval, or modification of the provider's requested privileges.[67] The Facility Director makes final privileging decisions.

Credentialing Committee meeting minutes from July 6, 2021, included a statement indicating OPPE data were reviewed by the service chief, however, no OPPEs had been completed for the COS. The meeting notes reflected that the last available professional practice evaluation for the COS was the FPPE completed for the July to December 2019 rating period, which was characterized as "acceptable." The meeting minutes made no further mention of the lack of the required OPPEs. The meeting minutes documented the COS's current licensure and medical board certification, no active reports with the National Practitioner Data Bank or Federation of State Medical Boards, and two peer references recommending continuation of privileges. The

[64] VHA Handbook 1100.19; Facility MCM 11-22-02.

[65] VHA Handbook 1100.19; Facility MCM 11-22-02. Facility, Bylaws and Rules of the Medical Staff of Veterans Health Administration (VHA) Montana VA Health Care System, Helena, Montana, updated June 2019.

[66] VHA Handbook 1100.19. VHA policy also stipulates that providers may only be granted privileges for procedures that are supported by the infrastructure and provided at the facility. Service chiefs must review service-specific clinical privilege lists annually to ensure that the privileges remain appropriate to facility resources and only privileges for services that can be provided at the facility are included. Facility MCM 11-22-02. Facility bylaws also specify annual review of clinical privilege forms and note that the annual review is documented through inclusion on the bottom of each privilege delineation form. The OIG noted an ancillary finding that the facility's form for delineation of gynecology privileges included privileges not supported by the facility's surgical complexity rating, which would allow a provider to request privileges for procedures that would not be performed at the facility. The chief of surgery described that as an "oversight" but could not recall when the delineation of privileges had last been reviewed and updated. The footer on the privilege delineation form specified "Form Approved 2/08" and "Revision Due 2/10."; VHA Office of Quality and Patient Safety Medical Staff Affairs, "VetPro," accessed on October 24, 2022, https://vaww.qps.med.va.gov/divisions/qm/msa/VetPro/msaVetPro.aspx. (This is an internal VA website and not accessible by the public.) VetPro is an electronic program used by VHA to maintain healthcare provider credentials.

[67] Facility MCM 11-22-02.

minutes also documented recommendations from the chief of surgery and credentialing committee to the Clinical Executive Board to approve the COS's re-privileging.

The OIG found that the credentialing committee meeting minutes documented that the full credentialing package was reviewed by the chief of surgery and that the provider's re-appointment application was reviewed by the credentialing committee. However, during an interview, the chief of surgery told the OIG that the list of privileges requested by the COS was not included in the re-privileging package when the chief of surgery reviewed the package with credentialing and privileging staff. The chief of surgery indicated this was not consistent with the usual process and that when reviewing a re-privileging request, the list of privileges requested by the provider would typically be compared to currently held privileges.[68] The chief of surgery reported telling the credentialing and privileging staff that "as long as [the COS] doesn't ask for any new privileges, then I will approve the [COS's] previous privileges." Subsequently, the chief of surgery indicated that the credentialing committee met on July 6, 2021, and, with the list of privileges requested still unavailable, "we said okay, we approve [the COS] to include [the COS's] previous privileges and no new ones." The OIG was unable to determine why the list of requested privileges was not included in the re-privileging package for the chief of surgery's review or at the time of the credentialing committee's review.

The chief of surgery explained that "a week later, I was called back to the credentialing and privileging office and in the file was [the COS's] paper with the list of privileges [the COS] asked for previously. [The file] also had two typed pages of privileges [the COS] was requesting. [The COS] claimed they were [for] clarification, but one of the privileges was cystoscopies, which [the COS] was not signed for previously." The chief of surgery reported advising the credentialing and privileging staff of being unable to sign off on the additional requested privileges without documentation to provide evidence of the COS's competence to perform those procedures. The chief of surgery reported being contacted by credentialing and privileging staff again with a request to sign off on the COS re-privileging request before the COS's current privileges expired. The chief of surgery also reported no additional documentation was provided to support the request for new privileges and, therefore, signed off indicating approval only for the previously granted privileges and documented that any new privileges must be presented at a credentialing committee meeting for a vote.

[68] VHA Directive 1100.21(1), *Privileging*, March 2, 2023, amended April 26, 2023. While not in effect at the time of the events under review, subsequent updates to VHA policy on credentialing and privileging added specification of the facility credentialing and privileging manager's responsibility for "[e]nsuring a comparison of privileges currently held to privileges requested is completed at the time of reprivileging," and ensuring that the requesting provider "has completed required FPPE" if an additional privilege is requested during re-privileging.

The OIG reviewed the gynecology clinical privileges delineation form, which listed privileges requested by the COS and the COS's signature, dated June 23, 2021.[69] The OIG confirmed that the privileges initialed as approved by the chief of surgery matched the COS's previously approved privilege request from June 2019. The chief of surgery did not initial the category of privileges described as "other," which contained a note referencing an attachment. The chief of surgery signed the form on July 15, 2021, and annotated "I have initialed and approve all privileges that were already in [the COS's] file. Any new privileges NEED TO BE DISCUSSED in credentialing committee as we do for every provider at MTVAHCS" (emphasis in original).

The OIG reviewed the two-page typewritten addendum to the COS's gynecology privileges request form and determined the addendum included privileges that were not found on the COS's list of previously approved privileges and could not be characterized as clarifications of the previously approved privileges.[70]

The associate chief of inpatient medicine, who was acting as the Chair of the facility's credentialing committee in place of the COS, signed the gynecology clinical privileges delineation form on July 19, 2021, and included a handwritten and signed note on the addendum stating, "this addendum is for clarification only, it does not supercede [*sic*] the prior privilege list." During an interview, the associate chief for inpatient medicine told the OIG that the committee was "told that there were no new privileges" and indicated understanding that "these [the addendum] were clarifications," but reported being unable to recall which documents had been available for review at the time of the credentialing committee meeting when the committee voted to recommend approval of the COS's re-privileging. The facility's Associate Director signed above the Clinical Executive Board's signature block on July 16, 2021, marking "Recommend Approval of Recommendation" and notated "nothing new being requested." The Facility Director approved the COS's clinical privileges on July 19, 2021. When asked about the addendum, the Facility Director reported, "I would not know that they were new privileges because I'm not a physician."

From interviews, the OIG ascertained an understanding that the COS's re-privileging in 2021 conveyed approval of the same privileges for which the COS was previously approved in 2019 and did not convey approval for new privileges introduced on the 2021 addendum to the

[69] The OIG noted that the signatures on the delineation of privileges, indicating approval by the chief of surgery and the associate chief of hospital medicine (acting as the Chair of the facility's Credentialing Committee), post-dated the Credentialing Committee meeting during which the COS's re-privileging was reviewed and recommended.

[70] The OIG uses the term "addendum" to refer to the 2-page typewritten addition to the list of privileges requested by the COS. The OIG noted that the addendum was similar to the list of procedures the COS previously submitted to credentialing and privileging staff with the initial 2019 privileging request, which had not been included in the COS's 2019 approved delineation of privileges or the facility's documentation of the COS's 2019 credentialing package.

COS re-privileging request. However, the addendum, which contained privileges that were not approved, was included with the COS's privileges.

The OIG determined that the failure to follow established facility processes during the COS's privileging, and inclusion of the addendum in the COS's privileging package, could lead to staff believing the COS was privileged to perform the procedures.[71]

Leaders' Response to COS's Care Deficiencies

The OIG did not substantiate the allegation that fear of reprisal resulted in leaders' failure to follow up on concerns regarding the provision of unprivileged pregnancy care by the COS. The OIG found that, after receiving complaints from staff, leaders initiated a management review of the COS's provision of pregnancy care for Patient 1 in early 2022.[72] However, the OIG identified additional concerns regarding leaders' failure to follow VHA policy for SLB reporting and timely completion of an exit review.

Management Review of COS's Provision of Pregnancy Care

Facility bylaws specify that "[w]henever there are concerns that a Practitioner has demonstrated substandard care, professional (clinical) misconduct, or professional (clinical) incompetence, further information will be gathered to either confirm or refute the legitimacy of the concerns."[73] The provider's immediate supervisor is typically responsible for preliminary review of the concerns "to determine whether a comprehensive focused clinical care review or other administrative review is warranted."[74] Leaders may direct a management review of a provider's clinical care when the review may provide a basis for actions that affect personnel status or clinical privileges.[75]

During interviews, the OIG learned that in late 2021, nursing staff raised concerns to a nurse manager about the pregnancy care provided to Patient 1 by the COS. The concerns were related

[71] VHA Handbook 1100.19. "Copies of current clinical privileges must be available to medical facility staff on a need to-know basis in order to ensure practitioners are functioning within the scope of their clinical privileges. Operating rooms and intensive care units are examples of areas where staff must be aware of practitioner privileges." A clinical staff member explained that the facility's clinical shared drive can be used by surgical staff to look up and confirm a provider's privileges and credentialing, such as for confirmation when scheduling procedures.

[72] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. A management review is a review non-protected review conducted for purposes other than confidential quality assurance, such as to provide basis for an action affecting clinical privileges or personnel status. Management reviews include activities such as Focused Clinical Care reviews and Administrative Investigations.

[73] Facility, Bylaws and Rules of the Medical Staff of Veterans Health Administration (VHA) Montana VA Health Care System, Helena, Montana.

[74] Facility, Bylaws and Rules of the Medical Staff of Veterans Health Administration (VHA) Montana VA Health Care System, Helena, Montana.

[75] VHA Directive 1190.

to the COS's non-adherence to VHA policy on maternity care, inadequate facility resources to support the care provided, and nursing staff's lack of training to support provision of pregnancy care. The nurse manager reported the identified concerns to a quality management staff member. A quality management staff member informed the Facility Director of the concerns. In turn, the Facility Director and chief of quality management elevated the concerns to the VISN Chief Medical Officer for review. The VISN Chief Medical Officer contacted the VHA Director of Reproductive Health on January 12, 2022, and requested a management review of pregnancy care provided by the COS to Patient 1 (see appendix A).

The management review concluded that pregnancy care provided by the COS to Patient 1 was outside the scope of the COS's approved privileges, "outside of VA policy," and "below the standard of care in the community." The management review noted that while no adverse clinical outcomes were identified as a result of this care, "the outcome could have been very different. Provision of this care by the provider at VA put the staff and facility at risk, and most importantly, put the patient and her fetus at risk of significant poor outcomes."

The VHA Director for Women's Reproductive Health provided the full report of the management review to the VISN Chief Medical Officer and Facility Director on March 22, 2022. In response to the findings of the management review, the VISN Deputy Chief Medical Officer directed an additional administrative review of pregnant patients treated by the COS within the prior year to determine whether the COS had provided pregnancy care to other patients after the first trimester of pregnancy. A facility quality management staff member reviewed EHRs of pregnant patients. The facility quality management staff member found no additional cases in which the COS provided pregnancy care outside of approved privileges and VHA policy. The facility chief of quality management notified the VISN Chief Medical Officer, Deputy Chief Medical Officer, and Facility Director of the results of the administrative review on April 20, 2022. In an OIG interview, the VISN Chief Medical Officer reported referring the matter to the Facility Director and VISN human resources staff to determine corrective action. The COS notified the Facility Director of intent to resign on July 15, 2022, with an effective date of August 27, 2022, prior to a potential corrective action determination being made.

Failure to Follow VHA Policy on State Licensing Board Reporting

The OIG determined that the Facility Director failed to follow VHA policy for SLB reporting. The Facility Director did not initiate the process to report the COS to the SLB on two separate occasions and failed to complete SLB reporting timely on a third occasion.

VHA policy requires that "SLB reporting must be initiated as soon as there is substantial evidence of the provider significantly failing to meet the generally accepted standards of clinical practice to raise reasonable concern for the safety of patients." VHA policy specifically identifies "performing procedures not included in one's clinical privileges in other than emergency situations" as a significant deficiency in clinical practice, which provides a reasonable concern

for the safety of patients that should be reported. The policy further stipulates that "SLB reporting must not wait until a personnel action has been completed or until a related hearing process has concluded."[76]

VA's authority to report to SLBs is retained regardless of whether the provider is employed or has separated from VA employment. Per VHA policy, facility directors are responsible for ensuring an exit review is completed for all licensed providers within seven business days of the final date of employment.[77] An exit review includes a summary evaluation of a provider's practice, including documentation of whether the provider met or failed to meet generally accepted standards of clinical practice.[78]

Facility directors have the ultimate decision authority to determine whether reporting to an SLB is warranted and is responsible for "prompt completion" of SLB reporting "once substantial evidence is established supporting a reasonable conclusion that a licensed health care provider significantly failed to meet generally accepted standards of clinical practice."[79] VHA policy specifies that the steps for completion of SLB reporting "should be completed in less than 100-calendar days."[80]

Facility Director Failed to Initiate SLB Reporting In Response to Management Review

The Facility Director failed to initiate the SLB reporting policy after the management review findings conclude the COS provided substandard care that was outside of the scope of privileges.

While the VHA Director of Reproductive Health's management review from March 2022 substantiated that the COS provided clinical care to Patient 1 that did not meet accepted standards of care and was outside the scope of approved privileges, the Facility Director told the OIG during an interview in August 2022 that no actions had been taken to initiate a report to the SLB. The Facility Director reported no recollection of having any discussion of SLB reporting in response to the management review findings. The Facility Director reported not being

[76] VHA Directive 1100.18.

[77] VHA Directive 1100.18.

[78] VHA Directive 1100.18.

[79] VHA Directive 1100.18.

[80] VHA Directive 1100.18. Following a review with findings of substantial evidence of failure to meet generally accepted standards of clinical practice, an evidence file must be prepared, a notice of intent to report must be sent to the provider, and the provider must be given an opportunity for response and rebuttal. Following the facility director's decision to report to the SLB, the VISN conducts a privacy review. Following the privacy review, the facility director sends a reporting letter to the SLB.

knowledgeable about the process and relying on facility credentialing and privileging staff to identify cases that required SLB reporting. [81] The Facility Director stated,

> I don't have the background or the knowledge to know that. I rely on my subject matter experts. . . they review every case that we are looking at, generally speaking. They review the licensure requirements and the reporting requirements and then they provide me with information as to what they believe to be reportable.

In an OIG interview, the credentialing and privileging manager reported normally having the responsibility to initiate the steps required to report a provider to an SLB but stated in this case the VISN Chief Medical Officer and the VISN credentialing and privileging team were responsible for initiating the process because the COS was a member of the executive leadership team. The VISN Credentialing and Privileging Officer explained to the OIG in an interview that the VISN has no role in reporting providers to SLBs, rather, that the responsibility lies with the Facility Director, consistent with VHA policy.[82]

Facility Director Failed to Ensure Timely Exit Review Completion

The OIG determined that the Facility Director failed to ensure timely completion of an exit review following the COS's resignation.

The VHA-required exit review is used to identify recently separated providers who failed to meet generally accepted standards of practice while employed at a VA facility, such as to indicate SLB reporting. The standardized VHA Provider Exit Review Form is to be completed by the first- or second-line supervisor when a provider departs the facility and requires notation of either meeting generally accepted standards of clinical practice or failing to meet general standards of practice. Examples of substandard actions listed on the form include, "Significant deficiencies in clinical practice; for example. . . performing procedures not included in one's clinical privileges in other than emergency situations." If substantial evidence of substandard care exists, this must be documented on the exit review followed by immediate initiation of SLB reporting if not already in progress.[83]

Following the COS's resignation on August 27, 2022, the acting chief of surgery was tasked with completion of the exit review. The acting chief of surgery noted on the exit review form that evidence of the COS practicing outside of privileges had been discovered, referencing the

[81] VA OIG Report No. 22-01341-43, January 26, 2023. Findings from a prior inspection also identified deficiencies in state licensing board reporting, with the Facility Director similarly citing lack of knowledge of the criteria and attributing responsibility for raising SLB reporting considerations to the facility's quality manager and risk manager in that case.

[82] VHA Directive 1100.18.

[83] VHA Directive 1100.18.

management review findings. However, the acting chief of surgery also identified the absence of OPPEs as a barrier to assessing the COS's quality of care. The acting chief of surgery signed the exit review, leaving the section requiring characterization of care provided by the COS blank, and initiated a retrospective review of the COS's care. The retrospective review was coordinated with support from VISN gynecologists, to determine whether the COS's clinical practice met standards of care.

The OIG found that although an exit review had been initiated and signed by the acting chief of surgery within seven business days of the COS's resignation, the form was incomplete. The exit review referenced evidence of the COS practicing outside of approved privileges; however, the Facility Director did not initiate SLB reporting processes.

Facility Director Failed to Complete Timely SLB Reporting In Response to Retrospective Review

The retrospective review, initiated by the acting chief of surgery, determined that the COS "failed to meet generally accepted standards of clinical practice that raised reasonable concerns for the safety of patients." However, the Facility Director failed to complete timely SLB reporting as specified by VHA policy.[84]

The retrospective review, completed in January 2023 by VISN gynecologists, evaluated the clinical care provided by the COS from October 2019 through June 2022. The review included randomly selected clinical cases for each of the six cycles during which the COS's required OPPEs were not completed. The acting chief of surgery's summarization of findings stated that "[b]ased upon review by practitioners within the specialty of Gynecology, there are findings consistent with the significant failure to meet the general accepted standard of care to raise reasonable concern for safety" of 13 patients, and "there are findings consistent with a Deficiency in Clinical practice with use of surgical care documented for treatment without testing, biopsies, or options or less invasive treatment" for eight patients. Findings from the retrospective review validated concerns described above regarding leadership failures in oversight, specifically the failure to ensure completion of OPPEs, resulting in failure to detect problems in the COS's quality of care and identify practice trends that may impact patient safety.

In follow-up, the facility credentialing and privileging manager told the OIG "since there was a significant number of findings. . . it was decided to review the remaining charts to complete a 100% review of procedures."

Based on the findings of the retrospective review, the Facility Director initiated a letter to the COS on January 19, 2023, serving as notification of the intent to report to the SLB and giving the COS seven business days to provide a response. In response to OIG requests for updates

[84] VHA Directive 1100.18.

regarding status of SLB reporting, the OIG was advised that, after a facility review identified that required documentation had not been provided to the COS with the original letter, the letter of intent to report was resent to the COS, along with the evidence file on May 24, 2023. Subsequently, the Facility Director sent an updated letter of intent to report to the SLB and redacted evidence file on July 20, 2023. The OIG made repeated requests for updates to the facility regarding SLB reporting. On November 14, 2023, approximately 20 months after the management review substantiated deficiencies, the COS was reported to SLBs in four states.

Non-adherence to the processes required by VHA policy, which may have detected quality of care concerns, presented risks to patient safety and allowed the COS to continue practice without appropriate oversight. Deficiencies in leaders' oversight resulted in a lack of timely identification of substandard quality of care by the COS and failure to take action on known and substantiated concerns. Due to the facility's repeated failures to adhere to VHA's SLB reporting policy, the COS continued to provide care to patients outside of VHA while reporting to the SLBs was significantly delayed.

Conclusion

The OIG substantiated that the COS provided pregnancy care to Patient 1 without having privileges to do so. Privileging is one process healthcare systems employ to protect patient safety by ensuring that the medical or other patient care services that a provider is permitted to perform fall within the scope of the provider's license and clinical competence and are supported by the facility's resources. By providing ongoing pregnancy care in the second and third trimesters of Patient 1's pregnancy, and by providing care that could not be safely supported by the facility's infrastructure, the COS circumvented VHA requirements put in place to protect patient safety and violated VHA policy and the facility medical staff bylaws.

In addition to being outside the provider's approved privileges at the facility, and in violation of VHA and facility policies, the OIG substantiated that the pregnancy care provided by the COS to Patient 1 failed to meet accepted evidence-based clinical standards. The COS's failures to follow requirements that have been established to ensure patient safety and quality of care ultimately resulted in actions that placed Patient 1 and her fetus at risk. Fortunately, no adverse clinical outcome resulted from the COS's deficiencies in pregnancy care.

The OIG did not substantiate that the COS provided substandard care for Patient 2 during gynecologic surgery resulting in a negative clinical outcome. The OIG identified opportunities for improvement in the COS's management of post-operative care for Patient 2, but was unable to definitively determine whether alternate management strategies would have resulted in a different clinical outcome.

The OIG identified additional quality of care concerns after finding that the COS did not follow accepted evidence-based clinical standards for another gynecologic procedure during a prior

treatment episode for Patient 2. The OIG further found that the COS also failed to follow the evidence-based clinical standards in 32 out of 35 cases (including Patient 2) when conducting the same procedure.

The OIG did not substantiate the allegation that fear of reprisal resulted in leaders' failure to follow up on concerns regarding the provision of pregnancy care by the COS. However, the OIG found deficiencies in leaders' oversight, resulting in failure to detect quality of care concerns and take action on known and substantiated concerns, which presented risks to patient safety. The OIG found deficiencies in the facility's compliance with requirements for ongoing monitoring of providers' practice and substantiated deficiencies in privileging processes for the COS. The OIG determined that the Facility Director failed to follow VHA policy for SLB reporting. The Facility Director did not initiate the process to report the COS to the SLB on two separate occasions and failed to complete SLB reporting timely on a third occasion after a retrospective review, initiated by the facility following the COS's resignation, determined that the COS "failed to meet generally accepted standards of clinical practice that raised reasonable concerns for the safety of patients."

Recommendations 1–10

1. The Montana VA Health Care System Medical Center Director ensures that all providers, including the Chief of Staff, practice within their approved privileges.
2. The Under Secretary for Health ensures review of Veterans Health Administration maternity care directives to determine if more specific guidance on the limitations of pregnancy care at VA facilities is necessary to ensure that pregnant patients receive maternity care according to evidence-based practice standards, and ensures guidance is updated as warranted.
3. The Montana VA Health Care System Medical Center Director ensures adherence to Veterans Health Administration and facility policies for pregnancy care.
4. The Montana VA Health Care System Medical Center Director ensures subject matter expert review of endometrial ablation procedures performed by the facility Chief of Staff to determine whether standards of care were followed for clinical indications, patient selection, and preoperative evaluation for patients who underwent endometrial ablation, and determine whether clinical disclosures or additional patient follow-up is indicated.
5. The Rocky Mountain Network Director ensures processes are in place to support facilities' external review process for ongoing professional practice evaluations in cases requiring external review by Veterans Health Administration policy and monitors compliance.
6. The Montana VA Health Care System Medical Center Director ensures adherence to all VHA and facility policies pertaining to privileging and re-privileging of providers including the Chief of Staff.

7. The Montana VA Health Care System Medical Center Director conducts a comprehensive review of the facility ongoing professional practice evaluation processes to ensure compliance with Veterans Health Administration and facility policy, and takes action as warranted.
8. The Rocky Mountain Network Director ensures a process is in place to monitor for timely completion of administrative actions for members of facility executive leadership team when appropriate, identifies noncompliance, and takes action as warranted.
9. The Rocky Mountain Network Director conducts a review of the state licensing board reporting processes at the facility to ensure compliance with Veterans Health Administration policy, identifies noncompliance, and takes action as warranted.
10. The Montana VA Health Care System Medical Center Director considers subject matter expert findings from the retrospective review of care provided by the Chief of Staff, determines whether clinical or institutional disclosures or additional patient follow-up is indicated, and takes action as warranted.[85]

[85] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. VHA policy requires disclosure of "the occurrence of adverse events related to the patient's clinical care" to the affected patient or the patient's personal representative. "Adverse events are untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers."

Appendix A: Case Summary—Patient 1

Patient 1 was diagnosed with pregnancy in Spring 2021. The COS ordered a community care maternity consult, and Patient 1 was scheduled for a pregnancy ultrasound and an initial prenatal appointment with the community obstetrician-gynecologist (OB/GYN) two weeks later. Patient 1 informed the facility maternity care coordinator by phone later that month that she had seen the community OB/GYN for prenatal care but that the community OB/GYN was relocating to Missoula, Montana. Patient 1 indicated she would need to find a new OB/GYN provider in the community and planned to discuss this with the community OB/GYN provider. Later that month, Patient 1 had a visit with the COS for pregnancy care; the COS performed a pregnancy ultrasound and assessed fetal movement, fetal anatomy, amniotic fluid volume, and the position of the placenta. The COS recommended Patient 1 return to clinic at 15 weeks gestation to "help co-manage" pregnancy with the community OB/GYN.

When Patient 1 returned to follow up with the COS the following month, Patient 1 was almost 16 weeks pregnant. The COS noted that Patient 1's community OB/GYN provider was relocating and that Patient 1 desired to continue prenatal care with the community OB/GYN.[86] The COS completed an ultrasound to assess the fetus, and documented a plan to "see [Patient 1] every two weeks" until Patient 1 could follow up with the community OB/GYN in Missoula, Montana.

Patient 1's next visit with the COS was a month later at 19 weeks and 6 days gestation to "follow up for [Patient 1's] obstetric care while [Patient 1's] [community OB/GYN] transitions to Missoula." The COS assessed fetal heart tones and performed an ultrasound to assess fetal movement and planned for Patient 1 to return for follow-up in two weeks.

Patient 1 returned to see the COS at 22 weeks gestation for a routine pregnancy visit. The COS assessed fundal height, fetal movement, and fetal heart rate and noted that laboratory tests would be needed at the next visit.

When Patient 1 returned two weeks later at almost 24 weeks of pregnancy, the COS documented this was the "last visit with us before getting [Patient 1's] care established" with the community OB/GYN in Missoula, Montana. The COS performed an exam and assessed fundal height and performed an ultrasound to assess the fetus.

Almost seven weeks later, the COS documented a telephone call from Patient 1 who reported blurry vision and headache. The COS advised Patient 1 to rest, to go to the hospital if symptoms worsened, and to notify the community OB/GYN. The COS also ordered laboratory tests to evaluate for HELLP syndrome and directed Patient 1 to come to the facility the following day to see the COS.

[86] Missoula, Montana, is 113 miles from Helena, Montana.

The next day, Patient 1 was evaluated by the COS. Patient 1 was 31 weeks pregnant and reported headaches and blurry vision. The COS documented the reason for the visit was to rule out HELLP syndrome. The COS examined the patient, noted fetal movement, and performed an ultrasound to assess the fetus. The COS documented that the laboratory tests that had been completed were normal, and a plan to collect a urine sample to assess for protein in the urine. The COS informed Patient 1 three days later that the urine test was normal.

Patient 1's next office visit with the COS was at 34 weeks gestation; the purpose of the visit was for pregnancy care, and the COS documented an exam and recommended Patient 1 follow up in four weeks.

Two days later, at 34 weeks and 3 days of pregnancy, Patient 1 returned to the facility to see the COS with complaints of "discomfort and some clear fluid" from the vagina. The COS evaluated the patient to rule out preterm PROM. The COS did not find any fluid in the vagina via speculum exam and then performed a digital exam of the cervix. The COS also completed a pregnancy ultrasound and noted "intact membrane." The COS noted the patient had an appointment with the community OB/GYN in a week.

Patient 1 was admitted to a community hospital under the care of the community OB/GYN for induction of labor at 37 weeks and 3 days of pregnancy due to high blood pressure, and delivered a healthy baby.

Appendix B: Case Summary—Patient 2

Patient 2 was a 37-year-old with a history of polycystic ovary syndrome and gestational diabetes. Patient 2 had heavy, painful menstrual bleeding and had tried oral contraceptive pills to manage the symptoms but had not tolerated this medication due to weight gain. A facility gynecologist performed an endometrial biopsy in early 2018, which showed benign endometrium, and a levonorgestrel IUD was placed the following month to manage the bleeding. However, Patient 2 continued to have vaginal bleeding and pelvic pain and the IUD was removed 21 months later. In early 2021, Patient 2 returned to see the facility gynecologist with complaints of heavy and painful menstrual bleeding. Patient 2 was referred for a pelvic ultrasound and advised to return to see the facility gynecologist in Spring 2021 to undergo an endometrial biopsy.

Patient 2 returned to the facility gynecology clinic in Spring 2021 and was seen by the COS. Patient 2 told the COS that the facility gynecologist advised that she have an endometrial biopsy. The COS documented reviewing results of the pelvic ultrasound, which showed a normal endometrium; noted that Patient 2 had a history of heavy menstrual bleeding; and that Patient 2 did not have a family history of endometrial cancer. The COS discussed endometrial ablation for treatment of the heavy bleeding with Patient 2. The following month, the COS performed hysteroscopy, dilation and curettage with biopsy, and endometrial ablation procedures. The pathology report of the biopsy completed on the day of the endometrial ablation procedure showed benign endometrium.

Four months later, Patient 2 saw a facility primary care physician and reported more than two weeks of lower abdominal pain. The facility primary care physician examined Patient 2, ordered laboratory tests, and documented a plan to refer Patient 2 for imaging if the pain did not improve. Several days later, the facility primary care physician ordered a pelvic ultrasound for evaluation of the pelvic pain; the ultrasound, completed in the Fall, showed an enlarged left ovary, and the radiologist documented concern for infarction or torsion of the ovary. The COS was consulted and recommended that "any torsion or possibility of torsion should immediately be sent to OR [operating room]." The COS contacted Patient 2 and advised that she report to the facility's Emergency Department. The COS alerted the chief of surgery of the planned surgical procedure, and the operating room staff prepared the operating room. That day, Patient 2 underwent a laparoscopy with findings of abdominal adhesions and left ovarian cysts; there was no sign of ovarian torsion. The COS consulted the chief of surgery during the procedure because of bleeding during dissection of adhesions. After bleeding was controlled, surgicel was placed to prevent further adhesions and the decision was made to discontinue further dissection of adhesions. Patient 2 was discharged home after the procedure.

Patient 2 went to the facility's Emergency Department five days later with complaints of left lower abdominal pain. A CT scan without contrast showed a 5-centimeter fluid collection adjacent to the left ovary. A facility emergency department physician discussed the case with the

COS, the chief of surgery, and a facility hospitalist physician, and transferred the patient to a non-VA hospital for further evaluation. A facility emergency department physician documented in an addendum that an ultrasound at the non-VA hospital showed a hemorrhagic ovarian cyst and that Patient 2 was discharged.

Patient 2 was seen by the COS two days later for follow-up. Patient 2 desired surgical intervention for the continued pelvic pain and hemorrhagic ovarian cyst. A week later, the COS performed surgery to remove the left ovary, and part of the right fallopian tube and performed lysis of adhesions. The left ovary was found to have a hemorrhagic cyst. In the operative note, the COS documented that "matted bowel seemed to have gotten worst [*sic*] now incorporating majority of the uterus" and documented performing blunt and sharp dissection of the adhesions. The COS documented good hemostasis and that copious irrigation was performed. Patient 2 was discharged after the surgery. The pathology report showed benign findings.

Two days later, Patient 2 returned to the facility Emergency Department with abdominal pain. Patient 2's white blood cell count was elevated and a CT scan with contrast showed a "mildly lobulated complex air fluid collection measuring approximately 12.6 x 5.2 cm [centimeter] within the left hemipelvis extending into the cul-de-sac with mild peripheral rim enhancement compatible with abscess formation." Intravenous fluids, pain medication, and one dose of an intravenous antibiotic, meropenem, were administered to Patient 2 in the Emergency Department. The COS was alerted, and Patient 2 was taken to the operating room where a diagnostic laparoscopy revealed "brown/yellowish" color in the area of the surgicel and a "pungent smell" of the fluid in the pelvis. A sample of the fluid was sent for culture. The COS also performed a cystoscopy and consulted a facility urologist intraoperatively to rule out injury to the ureter. The facility urologist found an intact ureter, and a ureteral stent was placed. Postoperatively, the COS admitted Patient 2 to the hospital. In the admission note, the COS documented a plan to "hold off" on consulting the hospitalist in the care of Patient 2. The COS ordered an antibiotic, cefazolin, to be administered intravenously every eight hours for a total of three doses. The COS attributed intraabdominal inflammation and discharge at the surgical site to an allergic reaction to surgicel.

The following day, preliminary results of the intraabdominal fluid culture showed the presence of gram-positive and gram-negative rods and gram-positive cocci. The COS consulted the facility hospitalist to manage the intrabdominal infection. The facility hospitalist assessed "suspected abdominal pelvic infection" and ordered piperacillin-tazobactam for broad-spectrum antibiotic coverage. The facility hospitalist also ordered a medication to prevent blood clots.

The next day, the intraabdominal fluid culture showed the presence of Bacteroides bacteria and anaerobic gram-positive rods. The COS documented a plan for a CT scan and consulted a facility general surgeon. The facility general surgeon assessed the patient the following day and noted that the pelvic fluid culture results suggested perforation of the colon and that additional surgery, to include colon resection and colostomy, may be required depending on the results of the CT

scan. The CT scan showed small bowel obstruction or ileus and a fluid collection in the left side of the pelvis consistent with an abscess measuring 5 centimeters x 5 centimeters x 8 centimeters.

An infectious disease consult was ordered by another facility hospitalist the next day, requesting recommendations on the duration of antibiotic therapy. The infectious disease consultant advised to continue the current antibiotic regimen, and that controlling the source of the infection was most important and advised aspiration or drainage of the left-sided pelvic fluid collection. The COS consulted the facility radiologist for placement of a drain in the pelvic fluid collection. CT scan images completed that day in preparation for the procedure to place the drain showed a 10 millimeter perforation of the sigmoid colon. The COS discussed the finding of colon perforation with the facility general surgeon; they determined that Patient 2 needed to be transferred to another hospital for a higher level-of-care. The facility hospitalist contacted multiple hospitals in Montana, but these hospitals were not accepting transfer admissions due to COVID-19. Patient 2 was then accepted and transferred to another facility in VISN 19.

Patient 2 underwent an exploratory laparotomy the following day at another facility in VISN 19. Intraoperative findings included turbid fluid in the pelvis, purulent fluid and stool in the space between the vagina and rectum, a one-centimeter perforation of the sigmoid colon, and two areas of serosal injury. Resection and anastomosis of the sigmoid colon, ileostomy, and repair of the serosal injuries were performed. The post-operative course was complicated by a bowel leak, which was managed with a drain and antibiotics. Patient 2 was discharged in stable condition with a plan to follow up at the facility.

Appendix C: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: January 5, 2024

From: Under Secretary for Health (10)

Subj: OIG Draft Report—Chief of Staff's Provision of Care Without Privileges, Quality of Care Deficiencies, and Leaders' Failures at the Montana VA Health Care System in Helena

To: Director, Office of Healthcare Inspections (54WH00)

1. We deeply regret the circumstances that impacted the care delivered to our Nation's Veterans. There is nothing more important to us at VA than ensuring Veterans receive quality care and that it is provided by knowledgeable, skilled staff. Thank you for the opportunity to review and comment on OIG's draft report regarding provision of care without privileges. The Veterans Health Administration concurs with recommendation 2 and provides an action plan in the attachments.

2. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at VHA10BGOALACTION@va.gov.

(Original signed by:)

Shereef Elnahal M.D., MBA

[**OIG Comment**: The OIG received the above memorandum from the Office of the Under Secretary for Health on January 19, 2024.]

Office of the Under Secretary for Health Response

VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan

VAOIG DRAFT REPORT - Chief of Staff's Provision of Care Without Privileges, Quality of Care Deficiencies, and Leaders' Failures at the Montana VA Health Care System in Helena
(2022-02975-HI-1275)

Recommendation 2. The Under Secretary for Health ensures review of Veterans Health Administration maternity care directives to determine if more specific guidance on the limitations of pregnancy care at VA facilities is necessary to ensure that pregnant patients receive maternity care according to evidence-based practice standards, and ensures guidance is updated as warranted.

VHA Comments: Concur.

The American College of Obstetrics and Gynecology collaborated with the Society for Maternal Fetal Medicine to establish levels of maternal care to ensure that pregnant people receive care at facilities that can safely manage their pregnancy care.

Facilities of the Department of Veterans Affairs (VA) generally do not meet the criteria of facilities that are able to provide Level I Basic maternity care to pregnant people beyond 20 weeks of gestation. Therefore, Veterans who choose to use VA for their maternity care receive authorized maternity care delivered in the community.

Several Veterans Health Administration (VHA) Directives address delivery of care to pregnant Veterans. These include VHA Directive 1330.03 Maternity Health Care and Coordination, VHA Directive 1330.01 Health Care Services for Women Veterans and VHA Directive 1101.05 Emergency Medicine. VHA guidance on the management of pregnant Veterans with obstetrical complaints beyond 20 weeks of gestation is to either direct them to their maternity providers in the community for care or to stabilize and transfer them to facilities capable of providing maternal care, if they present to VA facilities.

VHA reviewed all maternity care directives to determine if more specific guidance on the limitations of pregnancy care at VA facilities is necessary to ensure that pregnant patients receive maternity care according to evidence-based practice standards. VHA will add as an amendment the following language, which is already in VHA Directive 1330.01, Health Services for Women Veterans, to VHA Directive 1330.03, Maternity Health Care and Coordination.

> "VA medical facilities rarely offer limited prenatal care in the first trimester. VA medical facilities planning to provide onsite prenatal care must submit a proposal

to [the Office of Women's Health (OWH)] and the Office of Clinical Operations and Management describing capacity and proposed onsite services for review."

Status: In progress Target Completion Date: January 2024

OIG Comment:

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

Appendix D: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: November 29, 2023

From: Network Director, VA Rocky Mountain Network (10N19)

Subj: Healthcare Inspection—Chief of Staff's Provision of Care Without Privileges, Quality of Care Deficiencies, and Leaders' Failures at the Montana VA Health Care System in Helena

To: Office of the Under Secretary for Health (10)

Director, Office of Healthcare Inspections (54WH00)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. We deeply regret the circumstances that impacted the care delivered to our Veterans. There is nothing more important to us at VA than ensuring Veterans receive quality care and that it is provided by knowledgeable, skilled staff. We appreciate the opportunity to review and comment on the Office of Inspector General (OIG) report, Chief of Staff's Provision of Care Without Privileges, Quality of Care Deficiencies, and Leaders' Failures at the Montana VA Health Care System in Helena.

2. Based on a thorough review of the report by VISN 19 Leadership, I concur with the recommendations and submitted action plans of Montana VA Health Care System and VISN 19. These recommendations will be used to strengthen our processes and improve the care that is provided to our Veterans.

3. I would like to thank the Office of Inspector General for their thorough review and if there are any questions regarding responses or additional information required, please contact the VISN 19 Quality Management Officer.

(*Original signed by:*)

Sunaina Kumar-Giebel, MHA
Director, VA Rocky Mountain Network (10N19)

[**OIG Comment**: The OIG received the above memorandum from the VISN Director on January 19, 2024.]

VISN Director Response

Recommendation 5

The Rocky Mountain Network Director ensures processes are in place to support facilities' external review process for ongoing professional practice evaluations in cases requiring external review by Veterans Health Administration policy.

__X__Concur

____Nonconcur

Target date for completion: March 1, 2024

Director Comments

VISN 19 will develop a standardized reporting process to identify solo and two-deep providers at all facilities who require external professional practice reviews. This information will be utilized to link sites and providers in a more proactive manner to assist in timely external reviews. Requests for facility updates on the identification of solo and two-deep providers will occur on a semi-annual basis.

Recommendation 8

The Rocky Mountain Network Director ensures a process is in place to monitor for timely completion of administrative actions for members of facility executive leadership team when appropriate, identifies noncompliance, and takes action as warranted.

__X__Concur

____Nonconcur

Target date for completion: March 31, 2024

Director Comments

In collaboration with Human Resources, VISN 19 will develop a written process for discovery, actions, and noncompliance with timely completion of administrative actions for members of facility executive leadership team.

Recommendation 9

The Rocky Mountain Network Director conducts a review of the state licensing board reporting processes at the facility to ensure compliance with Veterans Health Administration policy, identifies noncompliance, and takes action as warranted.

__X__Concur

____Nonconcur

Target date for completion: March 1, 2024

Director Comments

VISN 19 will conduct a review of state licensing board processes, identify non-compliance areas, provide education as necessary, and will take action as appropriate.

Appendix E: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: November 28, 2023

From: Director, Montana VA Health Care System (436)

Subj: Healthcare Inspection—Chief of Staff's Provision of Care Without Privileges, Quality of Care Deficiencies, and Leaders' Failures at the Montana VA Health Care System in Helena

To: Director, VA Rocky Mountain Network (10N19)

1. Montana VA deeply regrets the circumstances that led to the investigation by the Office of Inspector General (OIG). We take such incidents with utmost seriousness, as the well-being of our patients is our top priority. We appreciate the thoroughness of the OIG's investigation and express our gratitude for the opportunity to review and comment on the Office of Inspector General's report, Chief of Staff's Provisions of Care Without Privileges, Quality of Care Deficiencies, and Leader's Failures at the Montana VA Health Care System in Helena.
2. Based on the thorough review of the report, I concur with the recommendations and have provided action plans to each recommendation.
3. If there are any questions regarding responses or additional information required, please contact Chief of Quality Management for the Montana VA Health Care System.

(*Original signed by*:)

Duane B. Gill, FACHE
Interim Executive Director, Montana VA Health Care System

[**OIG Comment**: The OIG received the above memorandum from the Facility Director on January 19, 2024.]

Facility Director Response

Recommendation 1

The Montana VA Health Care System Medical Center Director ensures that all providers, including the Chief of Staff, practice within their approved privileges.

__X__Concur

____Nonconcur

Target date for completion: June 30, 2024

Director Comments

The Montana VA Health Care System Medical Director reviewed the recommendation and identified areas of opportunity for improvement for monitoring providers practicing within their approved privileges. To ensure all providers and service chiefs are aware of their currently approved privileges, each provider and service chief will receive a copy of their approved privileges. Additionally, the Montana VA Health Care System Credentialing and Privileging Program will maintain an electronic database of all providers and their approved privileges that can be accessed by clinical staff. Education will be provided to clinical staff to include how to access provider privileges and report concerns with practicing outside of approved privileges.

Recommendation 3

The Montana VA Health Care System Medical Center Director ensures adherence to Veterans Health Administration and facility policies for pregnancy care.

__X__Concur

____Nonconcur

Target date for completion: June 30, 2024

Director Comments

The Montana VA Health Care System's Women Veterans Program Manager will educate Primary Care, Emergency Department, and Gynecology providers on VHA Directive 1330.03, Maternity Health Care and Coordination through assignment in Talent Management System. The Women's Health Maternity & Infertility Nurse Navigator will track pregnant patients to ensure they are referred to the community for care as soon as pregnancy is determined. Compliance will be monitored quarterly until performance is 90% or greater for two consecutive quarters.

Recommendation 4

The Montana VA Health Care System Medical Center Director ensures subject matter expert review of endometrial ablation procedures performed by the facility Chief of Staff to determine whether standards of care were followed for clinical indications, patient selection, and preoperative evaluation for patients who underwent endometrial ablation, and determine whether clinical disclosures or additional patient follow-up is indicated.

__X__Concur

____Nonconcur

Target date for completion: July 31, 2024

Director Comments

The Montana VA Health Care System Medical Center Director will identify subject matter experts external to Montana VA to review all endometrial ablation procedures performed by the former Chief of Staff to determine if the standard of care was met. Care will be reviewed with subject matters expert to determine if clinical or institutional disclosure is indicated. If indicated, clinical or institutional disclosures will be completed.

Recommendation 6

The Montana VA Health Care System Medical Center Director ensures adherence to all Veterans Health Administration and facility policies pertaining to privileging and re-privileging of providers including the Chief of Staff.

__X__Concur

____Nonconcur

Target date for completion: June 30, 2024

Director Comments

The Credentialing and Privileging Manager will prepare and provide a Credentialing and Privileging Report Card to Executive Leadership for internal monitoring and tracking of credentialing and privileging activities and upcoming expirations. This will include timeliness of OPPE and FPPE reports. The reports will also be shared as a recurring agenda item at the monthly Executive Committee of the Medical Staff and quarterly at the Healthcare Delivery Committee. Service chiefs who have delinquent OPPE and/or FPPE reports will be required to submit an action plan to the Healthcare Delivery Committee and will be monitored until demonstration of 90% compliance for two consecutive quarters.

Recommendation 7

The Montana VA Health Care System Medical Center Director conducts a comprehensive review of the facility ongoing professional practice evaluation processes to ensure compliance with Veterans Health Administration and facility policy, and takes action as warranted.

__X__Concur

____Nonconcur

Target date for completion: June 30, 2024

Director Comments

The Montana VA Health Care System Medical Director will ensure an external audit of the practitioner professional practice evaluation process is conducted for review of compliance with VHA Directives and Standard Operating Procedures. Results of the audit will be reported to the Healthcare Delivery Committee. Proactively, The Credentialing and Privileging Manager will prepare and provide a Credentialing and Privileging Report Card to Executive Leadership for internal monitoring and tracking of credentialing and privileging activities and upcoming expirations. This will include timeliness of OPPE and FPPE reports. The reports will also be shared as a recurring agenda item at the monthly Executive Committee of the Medical Staff and quarterly at the Healthcare Delivery Committee. Service chiefs who have delinquent OPPE and/or FPPE reports will be required to submit an action plan to the Healthcare Delivery Committee.

Recommendation 10

The Montana VA Health Care System Medical Center Director considers subject matter expert findings from the retrospective review of care provided by the Chief of Staff, determines whether clinical or institutional disclosures or additional patient follow-up is indicated, and takes action as warranted.

__X__Concur

____Nonconcur

Target date for completion: July 31, 2024

Director Comments

The Medical Center Director in conjunction with the Medical Center Chief of Staff will utilize the external retrospective review results to perform either clinical or institutional disclosures where warranted and ensure follow-up is completed if clinically indicated.

Glossary

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

abdominal adhesions. Bands of scar-like tissue that form inside the abdomen. Abdominal adhesions often develop after surgery and cause symptoms such as abdominal pain and intestinal blockage.[1]

amniotic fluid. The amnion is a thin membrane that forms a closed sac around the fetus during pregnancy. The amniotic fluid is the fluid found within the amnion.[2]

anastomosis. The joining of two tubes in the body together, such as blood vessels or parts of the intestine.[3]

Bacteroides. Bacteria that are a major component of intestinal flora. They are anaerobic bacteria.[4]

cefazolin. An antibiotic that treats infections causes by gram-positive cocci bacteria.[5]

colon. "The part of the large intestine that extends from the cecum to the rectum."[6]

colostomy. An opening made in the abdomen during surgery because of a problem causing the colon to not work properly.[7]

cystoscopy. A procedure "used to diagnose, monitor and treat conditions affecting the bladder and urethra."[8]

[1] National Institute of Diabetes and Digestive and Kidney Diseases, "Abdominal Adhesions," accessed October 18, 2022, https://www.niddk.nih.gov/health-information/digestive-diseases/abdominal-adhesions.

[2] *Merriam-Webster.com Dictionary*, "amnion," accessed November 3, 2022, https://www.merriam-webster.com/dictionary/amniotic.

[3] Cleveland Clinic, "Anastomosis," accessed August 23, 2023, https://my.clevelandclinic.org/health/treatments/24035-anastomosis.

[4] Sanford Guide Web Edition, "bacteriodes fragilis," accessed August 17, 2022, https://webedition.sanfordguide.com/en/sanford-guide-online/disease-clinical-condition/bacteroides-fragilis.

[5] Sanford Guide Web Edition, "Cefazolin," accessed August 23, 2022, https://webedition.sanfordguide.com/en/drug-information/antibacterial-agents/cephalosporins/parenteral/1st-generation/cefazolin.

[6] *Merriam-Webster.com Dictionary*, "colon," accessed October 3, 2023, https://www.merriam-webster.com/dictionary/colon.

[7] American Cancer Society, Colostomy Guide, "What Is a Colostomy?," accessed November 2, 2022, https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/surgery/ostomies/colostomy/what-is-colostomy.html.

[8] Mayo Clinic, "Cystoscopy," accessed November 25, 2019, https://www.mayoclinic.org/tests-procedures/cystoscopy/about/pac-20393694.

dilation and curettage. A procedure to open the cervix and insert an instrument into the uterus to remove tissue from the inside of the uterus. The procedure is used to diagnose and treat conditions of the uterus such as abnormal bleeding.[9]

endometrial ablation. A procedure to destroy the lining of the uterus. The procedure is used to control heavy vaginal bleeding.[10]

endometrial biopsy. "A procedure in which a small amount of the tissue lining the uterus is removed and examined under a microscope."[11]

endometrial cancer. Cancer of the lining of the uterus.[12]

endometrium. The lining of the uterus.[13]

enteric. Of or relating to the intestines.[14]

ferning. When amniotic fluid is placed on a glass slide and allowed to dry, a pattern resembling a fern leaf can be seen under a microscope.[15]

fundal height. "The distance in centimeters from the pubic bone to the top of the uterus" during pregnancy.[16]

gestation. "The period of time between conception and birth."[17]

gynecologist. A doctor who specializes in female reproductive health.[18]

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[9] The American College of Obstetricians and Gynecologists, "Dilation and Curettage (D&C)," accessed October 24, 2022, https://www.acog.org/womens-health/faqs/dilation-and-curettage.

[10] The American College of Obstetricians and Gynecologists, "Endometrial Ablation," accessed October 24, 2022, https://www.acog.org/womens-health/faqs/endometrial-ablation.

[11] The American College of Obstetricians and Gynecologists, "Endometrial Cancer," accessed October 24, 2022, https://www.acog.org/womens-health/faqs/endometrial-cancer.

[12] The American College of Obstetricians and Gynecologists, "Endometrial Cancer," accessed October 24, 2022, https://www.acog.org/womens-health/faqs/endometrial-cancer.

[13] The American College of Obstetricians and Gynecologists, "Endometrial Hyperplasia," accessed October 19, 2022, https://www.acog.org/womens-health/faqs/endometrial-hyperplasia.

[14] *Merriam-Webster.com Dictionary*, "enteric," accessed November 3, 2022, https://www.merriam-webster.com/dictionary/enteric.

[15] University of Michigan Laboratories, "Point of care-ferning, PPM," accessed November 3, 2022, https://mlabs.umich.edu/tests/point-care-ferning-ppm.

[16] Mayo Clinic, "*Pregnancy week by week*," accessed October 31, 2022, https://www.mayoclinic.org/healthy-lifestyle/pregnancy-week-by-week/expert-answers/fundal-height/faq-20057962.

[17] US National Library of Medicine MedlinePlus, "*Gestational age*," accessed October 31, 2022, https://medlineplus.gov/ency/article/002367.htm.

[18] Wooster Community Hospital Health System, "What is the difference between OB/GYN and gynecology?," accessed October 18, 2022, https://www.woosterhospital.org/what-is-the-difference-between-ob-gyn-and-gynecology/.

hemolysis, elevated liver enzymes, and low platelet count (HELLP) syndrome. "HELLP stands for hemolysis. . . elevated liver enzymes, and low platelet count" and is a severe form of preeclampsia.[19]

hemolysis. The destruction of red blood cells.[20]

hemostasis. The stoppage of bleeding.[21]

hospitalist. A physician whose medical specialty is "the delivery of comprehensive medical care to hospitalized patients."[22]

hysteroscopy. "A procedure in which a lighted telescope is inserted into the uterus through the cervix to view the inside of the uterus or perform surgery."[23]

iatrogenic. Illnesses or injuries unintentionally caused by medical or surgical treatment or diagnostic procedures.[24]

ileostomy. An opening made in the abdomen during surgery because of a problem causing the ileum to not work properly.[25]

ileum. "The lowest part of the small intestine."[26]

ileus. functional obstruction of the gastrointestinal tract and especially the small intestine that is marked by the absence of peristalsis, is usually accompanied by abdominal pain, bloating, and sometimes nausea and vomiting, and typically occurs following abdominal surgery.[27]

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[19] Mayo Clinic, "Preeclampsia," accessed October 31, 2022, https://www.mayoclinic.org/diseases-conditions/preeclampsia/symptoms-causes/syc-20355745.

[20] Cleveland Clinic, "Hemolysis," accessed November 3, 2022. https://my.clevelandclinic.org/health/diseases/24108-hemolysis.

[21] *Merriam-Webster.com Dictionary*, "hemostasis," accessed November 3, 2022. https://www.merriam-webster.com/dictionary/hemostasis.

[22] Society of Hospital Medicine, "What is hospital medicine, and what is a hospitalist?" accessed October 3, 2023, https://www.hospitalmedicine.org/about/what-is-a-hospitalist/.

[23] The American College of Obstetricians and Gynecologists, "*Dilation and Curettage (D&C)*," accessed October 24, 2022, https://www.acog.org/womens-health/faqs/dilation-and-curettage.

[24] *Merriam-Webster.com Dictionary*, "iatrogenic," accessed January 31, 2019, https://www.merriam-webster.com/dictionary/iatrogenic.

[25] American Cancer Society, "*Ileostomy Guide*" accessed November 2, 2022, https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/surgery/ostomies/ileostomy/what-is-ileostomy.html.

[26] American Cancer Society, "Ileostomy Guide," accessed November 2, 2022, https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/surgery/ostomies/ileostomy/what-is-ileostomy.html.

[27] *Merriam-Webster.com Dictionary*, "ileus," accessed October 11, 20021, https://www.merriam-webster.com/dictionary/ileus.

infarction. The death of tissue especially as a result of obstruction of blood flow.[28]

intraabdominal abscess. A collection of pus within the abdominal cavity often caused by a bacterial infection.[29]

laparoscopy. A type of surgery that uses a thin tube that is inserted into the abdomen through a small incision.[30]

obstetrician. A doctor who specializes in childbirth and a woman's reproductive system.[31]

obstetrics. A branch of medical science that deals with pregnancy, childbirth, and the postpartum period.[32]

placenta. Provides oxygen and nutrients to the fetus and removes waste products from the fetus's blood.[33]

polycystic ovary syndrome. A clinical syndrome characterized by mild obesity, irregular menses or amenorrhea, and androgen excess. Patients may also have cysts in the ovary. Patients with polycystic ovarian syndrome are at increased risk of endometrial cancer.[34]

preeclampsia. A condition that can occur during of pregnancy which may include high blood pressure or organ damage.[35]

prelabor rupture of membranes. Breaking open of the amnion with leakage of fluid prior to 37 weeks of pregnancy.[36]

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[28] *Merriam-Webster.com Dictionary*, "infarction," accessed October 24, 2022, https://www.merriam-webster.com/dictionary/infarction.

[29] Johns Hopkins, "intra-abdominal abscess," accessed November 3, 2022, https://www.hopkinsmedicine.org/health/conditions-and-diseases/intraabdominal-abscess.

[30] Johns Hopkins Medicine, "Laparoscopy," accessed October 24, 2022, https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/laparoscopy.

[31] Wooster Community Hospital Health System, "What is the difference between OB/GYN and gynecology?," accessed October 18, 2022, https://www.woosterhospital.org/what-is-the-difference-between-ob-gyn-and-gynecology/.

[32] *Merriam-Webster.com Dictionary*, "obstetrics," accessed August 15, 2023, https://www.merriam-webster.com/dictionary/obstetrics.

[33] Mayo Clinic, "Pregnancy week by week," accessed November 3, 2022, https://www.mayoclinic.org/healthy-lifestyle/pregnancy-week-by-week/in-depth/placenta/art-20044425.

[34] Merck Manual Professional Version, "Polycystic Ovary Syndrome (PCOS)," accessed October 19, 2022, https://www.merckmanuals.com/professional/gynecology-and-obstetrics/menstrual-abnormalities/polycystic-ovary-syndrome-pcos.

[35] Mayo Clinic, "Preeclampsia," accessed October 31, 2022, https://www.mayoclinic.org/diseases-conditions/preeclampsia/symptoms-causes/syc-20355745.

[36] Children's Hospital of Philadelphia, "Premature Rupture of Membranes (PROM)/Preterm Premature Rupture of Membranes (PPROM)," accessed August 23, 2023, https://www.chop.edu/conditions-diseases/premature-rupture-membranes-prompreterm-premature-rupture-membranes-pprom#.

pungent. Having an intense odor.[37]

purulent. The condition of containing pus.[38]

serosa. The outer lining of organs and body cavities of the abdomen and chest, including the stomach.[39]

speculum. A medical instrument that enlarges an opening of the body to facilitate seeing inside.[40]

stent. A thin flexible tube placed in the ureter by a doctor that holds the ureter open to allow urine to flow from the kidneys to the bladder.[41]

surgicel. A material that is used to control bleeding and aid in clot formation during surgery.[42]

torsion. Torsion is twisting of the ovary. Torsion of the ovary causes pain and may reduce or stop blood flow to the ovary.[43]

turbid. "Cloudy or muddy in appearance."[44]

ureter. A tube that carries urine from the kidney to the bladder.[45]

viability. The capability of a fetus to survive outside the uterus.[46]

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[37] *Merriam-Webster.com Dictionary*, "pungent," accessed November 4, 2022, https://www.merriam-webster.com/dictionary/pungent.

[38] *Merriam-Webster.com Dictionary*, "purulent," accessed November 17, 2022, https://www.merriam-webster.com/dictionary/purulent.

[39] National Cancer Institute, "serosa," accessed October 21, 2022, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/serosa.

[40] National Cancer Institute, "speculum," accessed on October 31, 2022, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/speculum.

[41] Cleveland Clinic, "Ureteral stents," accessed November 3, 2022, https://my.clevelandclinic.org/health/treatments/21795-ureteral-stents.

[42] Krishna Vyas and Sibu Saha, "Comparison of hemostatic agents used in vascular surgery," *Expert Opinion on Biological Therapy* 13, no. 12 (December 2013): 1663-1672 accessed November 2, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4390172/.

[43] Mayo Clinic, "Ovarian cysts," accessed November 3, 2022, https://www.mayoclinic.org/diseases-conditions/ovarian-cysts/symptoms-causes/syc-20353405.

[44] *Merriam-Webster.com Dictionary*, "turbid," accessed November 3, 2022, https://www.merriam-webster.com/dictionary/turbid.

[45] Cleveland Clinic, "Ureteral stones," accessed November 3, 2022, https://my.clevelandclinic.org/health/diseases/16514-ureteral-stones.

[46] *Merriam-Webster.com Dictionary*, "viability," accessed November 3, 2022, https://www.merriam-webster.com/dictionary/viability.

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