DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficiencies in Privileging a Urologist to Practice and Medication Management Processes at the VA Central Iowa Health Care System in Des Moines

HEALTHCARE INSPECTION | REPORT #20-02359-52 | JANUARY 12, 2021

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the VA Central Iowa Health Care System (facility) in Des Moines, in response to an OIG Office of Investigations referral based on facility findings that a urologist practiced, was privileged, and ordered controlled substances without a Drug Enforcement Administration (DEA) registration.[1]

The OIG confirmed the facility's findings regarding the urologist and assessed facility medical staff management processes that permitted the urologist to practice and be privileged without the required DEA registration. Additionally, the OIG reviewed medication management processes that enabled the urologist to routinely order controlled substances without the required DEA registration for nearly three years.

Previously, providers were authorized to order controlled substances using facility DEA registrations. Since January 2017, however, the Veterans Health Administration (VHA) has required most providers who prescribe controlled substances to have an individual DEA registration.[2] Facility directors were given the responsibility to ensure implementation of the policy change.

The OIG found that the urologist was able to practice and was privileged without DEA credentials for nearly three years because facility leaders did not timely implement the VHA directive requiring providers who ordered controlled substances to possess an individual DEA registration. Delays in implementing the VHA directive initially were related to a failure to identify providers who needed to obtain a DEA registration as well as poor communication to providers and credentialing staff about the new requirement. According to the former Chief of Staff, the urologist was reprivileged in October 2017, despite not having a DEA registration, due to an "error."

More than 18 months after the VHA directive went into effect, through an audit of providers' DEA registration status, facility leaders identified that the urologist was one of three providers who did not have an individual DEA registration as required. In July 2018, the three providers were instructed to obtain DEA registrations. Two of the providers resolved the issue within a few weeks. The urologist, however, did not. The urologist was permitted to continue practicing due to poor oversight. The urologist reported completing a Michigan controlled substance license application in August 2018, which is a prerequisite to obtaining a DEA registration. However,

[1] This report refers to DEA registration recognizing that the urologist was required to also hold a Controlled Substance license based on Michigan law, the state in which the urologist was licensed to practice medicine at the time of the events described in this report.

[2] VHA Handbook 1108.05(1), *Outpatient Pharmacy Services*, June 16, 2016, amended August 20, 2019. As of January 1, 2017, VA institutional DEA registration numbers were only permitted to be used by VA residents and interns, and *locum tenens* (temporary) physicians.

the license was not issued. The urologist described technical challenges with submitting the application and did not follow up with the Michigan Board of Pharmacy when the license did not arrive. Facility leaders reported assuming the urologist had complied with the instruction to obtain DEA registration. As a result, for more than a year, facility leaders failed to identify that the urologist had not obtained a DEA registration.

In October 2019, upon recognizing that the urologist verbally ordered controlled substances in the operating room without a DEA registration, facility leaders took action by notifying the OIG Office of Investigations of the urologist's unauthorized ordering, administratively suspending the urologist's privileges for one month, and implementing a process to ensure all controlled substance ordering providers, including the urologist, hold an active DEA registration.

The failure of the urologist to timely obtain a DEA registration was not related to clinical competency but rather to the urologist's delay in applying for the registration, based in part on a personal misunderstanding that the individual DEA registration requirement was not mandatory. The controlled substances ordered by the urologist in the operating room were appropriate for the types of operative procedures performed and did not pose a patient safety risk.

The OIG was concerned, however, that safeguards built into VHA and facility medication management policies were not consistently applied to operating room processes. Contrary to policy, the facility's operating room practice permitted surgeons to issue verbal orders for nonurgent medications without subsequently entering the medication orders into the pharmacy package in the Computerized Patient Record System. The operating room verbal ordering process bypassed computer controls intended to prevent providers without DEA registrations from entering orders. Since the verbal orders were not entered in the computer, pharmacist reviews, which serve as important patient safety checks, were not completed. In addition, the Controlled Substance Coordinator reported an understanding that surgeons in the operating room were not required to enter medication orders in the computer. Therefore, controlled substance inspectors did not verify medication orders for controlled substances dispensed from operating room automated dispensing cabinets as required by policy.

Through the facility's fact-finding review, facility leaders learned that surgeons who ordered controlled substances in the operating room were not identified in intraoperative documentation. Nurses were not documenting the names of providers who ordered medications in nurse intraoperative reports.[3] According to staff interviewed, nurses did not know documentation of this information was mandatory. The OIG verified that, after the operating room nurse manager educated nurses and had patient records audited for compliance, nurses entered the names of

[3] VA, Office of Information Technology, *Surgery User Manual*, July 1993, revised November 2005. Intraoperative reports detail the surgical case information related to the nursing care provided to the patient during the surgical case. Once the report is electronically signed by the nurse, the report can be viewed in the Computerized Patient Record System.

ordering providers in nurse intraoperative reports. This improvement in documentation, however, does not resolve the issue of medication orders not being entered into the pharmacy package in the Computerized Patient Record System and available for pharmacists and controlled substance inspectors to review.

The OIG found that, although the subject urologist circumvented safety measures by requesting that Urology Clinic providers with DEA registrations (including a urologist and two physician assistants) prescribe controlled substances for patients, the colleagues followed applicable laws and policies when prescribing the medications.[4] Urology Clinic providers were unaware that the urologist did not possess a DEA registration until after the urologist was temporarily removed from clinical practice. Notably, by permitting the subject urologist to serve as the supervising physician for one of the physician assistants, facility leaders exposed the physician assistant to the risk of violating Iowa state law, which limits physician assistant prescribing authority to include only controlled substances that the supervising physician has authority to prescribe.[5] The OIG confirmed that the physician assistant did have another supervising physician who had a DEA registration at all times relevant to the health care inspection.

The OIG made five recommendations to the Facility Director related to monitoring compliance with VHA and facility policies to maintain DEA registrations and management of medications in the operating room.

Comments

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

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Assistant Inspector General
for Healthcare Inspections

[4] The OIG interviewed a part-time urologist and a physician assistant. A second physician assistant retired prior to the start of the OIG inspection and was not interviewed.

[5] Iowa Administrative Code, IAC 645.327.1(1)c(5)(2020); formerly IAC 645.327.1(1)s(4)(2016).

Contents

Abbreviations

CPRS	Computerized Patient Record System
DEA	Drug Enforcement Administration
MEC	Medical Executive Committee
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the VA Central Iowa Health Care System (facility) in Des Moines, in response to a VA OIG Office of Investigations referral to review concerns related to a facility urologist who practiced, was privileged, and ordered controlled substances without a Drug Enforcement Administration (DEA) registration.[1]

Background

The facility, part of Veterans Integrated Service Network (VISN) 23, VA Midwest Health Care Network, provides medical, surgical, mental health, long-term care, and rehabilitation services. From October 1, 2018, through September 30, 2019, the facility served 32,372 unique patients throughout the coverage area and had 223 total operating beds. VA classifies the facility as Level 1c, a mid-high complexity facility.[2]

Controlled Substances and DEA Registration

Controlled substances include medications that may cause physical and mental dependence and have a potential for abuse.[3] Controlled substances are divided into five categories, known as schedules, based on accepted medical treatment in the United States, relative abuse potential, and the likelihood of causing dependence when abused.[4] VA providers must adhere to federal, state, and Veterans Health Administration (VHA) rules and regulations when prescribing controlled substances.[5]

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[1] This report refers to DEA registration recognizing that the urologist was required to also hold a Controlled Substance license based on Michigan law, the state in which the urologist was licensed to practice medicine at the time of the events described in this report.

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

[3] United States Drug Enforcement Administration, *Clarification of Registration Requirements for Individual Practitioners.* https://www.deadiversion.usdoj.gov/fed_regs/rules/2006/fr1201.htm. (The website was accessed on August 16, 2020.)

[4] United States Drug Enforcement Administration, *The Controlled Substances Act*. https://www.dea.gov/controlled-substances-act. (The website was accessed on August 16, 2020.) Schedule I drugs have a high potential for abuse and no accepted medical use. Schedule II through V drugs have acceptable medical uses and the potential for abuse ranges from high (Schedule II) to low (Schedule V). United States Drug Enforcement Administration, *The Controlled Substances Act*. https://www.deadiversion.usdoj.gov/schedules/index.html. (The website was accessed on April 15, 2020.)

[5] VHA Directive 1108.01(1), *Controlled Substances Management*, May 1, 2019, amended December 2, 2019.

The DEA is a federal agency charged with enforcing federal laws and regulations pertaining to controlled substances.[6] Among the DEA's requirements is that health care professionals who prescribe controlled substances do so with an individual or institutional DEA registration.[7] Incumbent upon DEA registrants is the obligation to maintain an active DEA registration and follow regulations, including rules related to security and recordkeeping processes.[8] A DEA registration is "based on state authority to practice medicine and prescribe controlled substances."[9]

States can authorize prescribing of controlled substances through a medical license or can require an additional registration or license.[10] According to Michigan law, in order to prescribe controlled substances, physicians must possess

- Licensure from an appropriate licensing board, such as the Board of Medicine,
- A controlled Substance license from the Board of Pharmacy, and
- A DEA registration.[11]

VA providers are required to maintain an active medical license from any state.[12] Although VA providers were previously permitted to use a VA institutional DEA registration number, as of January 2017, most VA controlled substance ordering providers were required to possess an individual DEA registration and comply with the state of licensure's criteria to prescribe controlled substances.[13]

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[6] United States Drug Enforcement Administration, *Mission.* https://www.dea.gov/mission. (The website was accessed on August 17, 2020.)

[7] DEA Diversion Control Division, *Program Description*. https://deadiversion.usdoj.gov/prog_dscrpt/index.html. (The website was accessed on August 17, 2020.)

[8] DEA Diversion Control Division, *Program Description*.

[9] DEA Diversion Control Division, *Clarification of Requirements for Individual Practitioners.* December 1, 2006. https://www.deadiversion.usdoj.gov/fed_regs/rules/2006/fr1201.htm. (The website was accessed on August 16, 2020.)

[10] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. DEA Diversion Control Division, *Practitioners State License Requirements.* https://www.deadiversion.usdoj.gov/drugreg/reg_apps/pract_state_lic_require.htm. (The website was accessed on April 15, 2020.)

[11] Michigan Prescription Drug and Opioid Task Force, *Report of Findings and Recommendations for Action.* https://www.michigan.gov/documents/snyder/Presciption_Drug_and_Opioid_Task_Force_Report_504140_7.pdf. (The website was accessed on April 29, 2020.)

[12] VHA Handbook 1100.19.

[13] VHA Handbook 1100.19; VHA Handbook 1108.05(1), *Outpatient Pharmacy Services*, June 16, 2016, amended August 20, 2019. As of January 1, 2017, VA institutional DEA registration numbers were only permitted to be used by VA residents and interns, and *locum tenens* (temporary) physicians.

Concerns

The facility's Chief of Quality, with the knowledge and approval of the Facility Director, contacted the VA OIG Office of Investigations on October 23, 2019, after a facility fact-finding review revealed that a urologist was ordering controlled substances without a DEA registration and was requesting Urology Clinic providers to prescribe controlled substances for patients. On February 24, 2020, an OIG Office of Investigations Special Agent referred the facility's findings regarding the urologist to the OIG Office of Healthcare Inspections.

Two facility issues were also communicated in the Special Agent's referral: the urologist should not have received privileges to practice without proper DEA registration, and the facility's documentation processes did not adequately reflect who ordered medications during operative procedures.

This healthcare inspection focuses on concerns regarding the facility's processes that permitted the urologist who did not have a DEA registration to practice, be privileged, and to prescribe, or request to be prescribed, controlled substances for patients.[14] The OIG also evaluated whether the documentation of controlled substances dispensed from automated dispensing cabinets in the operating room reflected ordering providers' names.[15] The OIG identified three related concerns during the inspection: pharmacists were not reviewing verbal medication orders from the operating room, controlled substance inspectors were not verifying operating room verbal medication orders, and a physician assistant's supervising physician (the subject urologist) did not have a valid DEA registration.

Scope and Methodology

The OIG initiated the inspection in April 2020. The OIG conducted the inspection virtually given the concerns with travel and the potential spread of COVID-19.[16] Telephone interviews were held from June 11 through August 5, 2020.

Initially, the OIG conducted telephone interviews with the referring OIG Office of Investigations Special Agent and the investigating DEA Diversion Investigator. Subsequently, facility leaders and staff were interviewed including the Facility Director, former and current Chiefs of Staff,

[14] The concerns did not pertain to the urologist's competency or patients experiencing adverse events related to the urologist's ordering of controlled substances.

[15] The terms "ordering" and "prescribing" are used interchangeably in this report to reference providers' practice.

[16] Centers for Disease Control and Prevention. *Travel during the COVID-19 Pandemic*. https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-during-covid19.html. (The website was accessed September 2, 2020.) COVID-19 (coronavirus disease) is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The World Health Organization, *Naming the Coronavirus Disease (COVID-19) and the Virus that Causes It*. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it. (The website was accessed on September 2, 2020.)

former and current Chiefs of Surgery, Chief of Quality, Chief of Pharmacy, nursing leaders, credentialing and privileging staff, and Urology Clinic providers. The OIG also obtained information through email correspondence with the facility Chief of Anesthesiology and Controlled Substance Coordinator, and the VISN Pharmacist Executive.

The OIG reviewed relevant federal and state controlled substance regulations, VHA and facility policies, a facility fact-finding review, the urologist's credentialing and privileging files from January 1, 2017, through May 20, 2020, and Medical Executive Committee (MEC) meeting minutes from April 1, 2016, through May 20, 2020.[17] Investigative documents provided by the referring OIG Office of Investigations Special Agent were also reviewed.

The OIG received and validated results of a facility chart audit that evaluated nurse intraoperative reports for inclusion of medication-ordering providers' names.

Additionally, the OIG received provider DEA registration data from the facility. The data were compared with data available from the VA Corporate Data Warehouse to assess whether providers reported by the facility as requiring a DEA registration possessed the required registration.

The concerns reviewed by the OIG focused on compliance with administrative procedures and not clinical competence. Therefore, a review of patient records to assess quality of care was not performed.

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, § 7, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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.

[17] The Medical Executive Committee is called the Executive Committee of the Organized Medical Staff at the facility.

Inspection Results

1. Urologist was Privileged and Practiced Without DEA Registration

The OIG confirmed the urologist practiced, including prescribing controlled substances, and was privileged without the required DEA registration. The OIG found that the urologist was able to practice without DEA credentials because facility leaders failed to comply with VHA policy and provided poor oversight. Specifically, facility leaders did not timely implement a VHA policy requiring providers who ordered controlled substances to possess an individual DEA registration, and due to poor oversight, permitted the urologist to practice and hold privileges for nearly three years without the required individual DEA registration.

Although VA providers were previously authorized to use facility DEA registrations, since January 2017, VHA has required most providers who prescribe controlled substances to have an individual DEA registration.[18] The Facility Director had the responsibility to ensure implementation of the policy change.[19]

VHA defines procedures for credentialing and privileging of healthcare providers to independently practice in a facility within the scope of the provider's license.[20] Credentialing consists of confirming a provider has the required education, training, and professional credentials, including a DEA registration, to support requested clinical privileges.[21] According to VHA policy, the status of DEA registration must be verified prior to appointment and reappointment.[22] Facility directors have the responsibility of "establishing a mechanism to ensure that multiple licenses, registrations, and/or certifications are consistently held in good standing…."[23] This obligation includes the duty to ensure that required individual DEA registrations, once obtained, are held in good standing.

Clinical privileging is the manner by which a facility permits a practitioner to independently practice within the scope of the individual's license as determined by, among other things, licensure and registration.[24] The process includes a service chief review of all credentialing information and presentation of the provider's information to the MEC. The MEC considers the information presented by the service chief and makes a recommendation to the facility director.[25]

[18] VHA Handbook 1108.05(1).
[19] VHA Handbook 1108.05(1).
[20] VHA Handbook 1100.19.
[21] VHA Handbook 1100.19.
[22] VHA Handbook 1100.19.
[23] VHA Handbook 1100.19.
[24] VHA Handbook 1100.19.
[25] VHA Handbook 1100.19.

The facility director makes final privileging decisions.[26] Reprivileging must occur at least biennially and be processed in the same manner as initial privileges.[27]

Facility medical staff bylaws mandate that medical staff continuously comply with VHA requirements; therefore, compliance with obtaining an individual DEA registration is not optional for providers who prescribe controlled substances.[28]

Facility leaders' failure to timely implement the VHA directive and to oversee the urologist's compliance with obtaining a DEA registration as well as facility leaders' response once the deficiencies were identified are described in three timeframes as highlighted in figure 1.

[26] VHA Handbook 1100.19.

[27] VHA Handbook 1100.19.

[28] Facility, *Medical Staff Bylaws*, October 30, 2014; Facility, *Medical Staff Bylaws,* February 15, 2017; Facility, *Medical Staff Bylaws,* November 28, 2017; Facility, *Medical Staff Bylaws*, May 20, 2020. All four versions have identical language regarding DEA requirements. Facility, *Medical Staff Bylaws*, May 20, 2020, contains language that explicitly states current DEA registration is required to have and maintain clinical privileges.

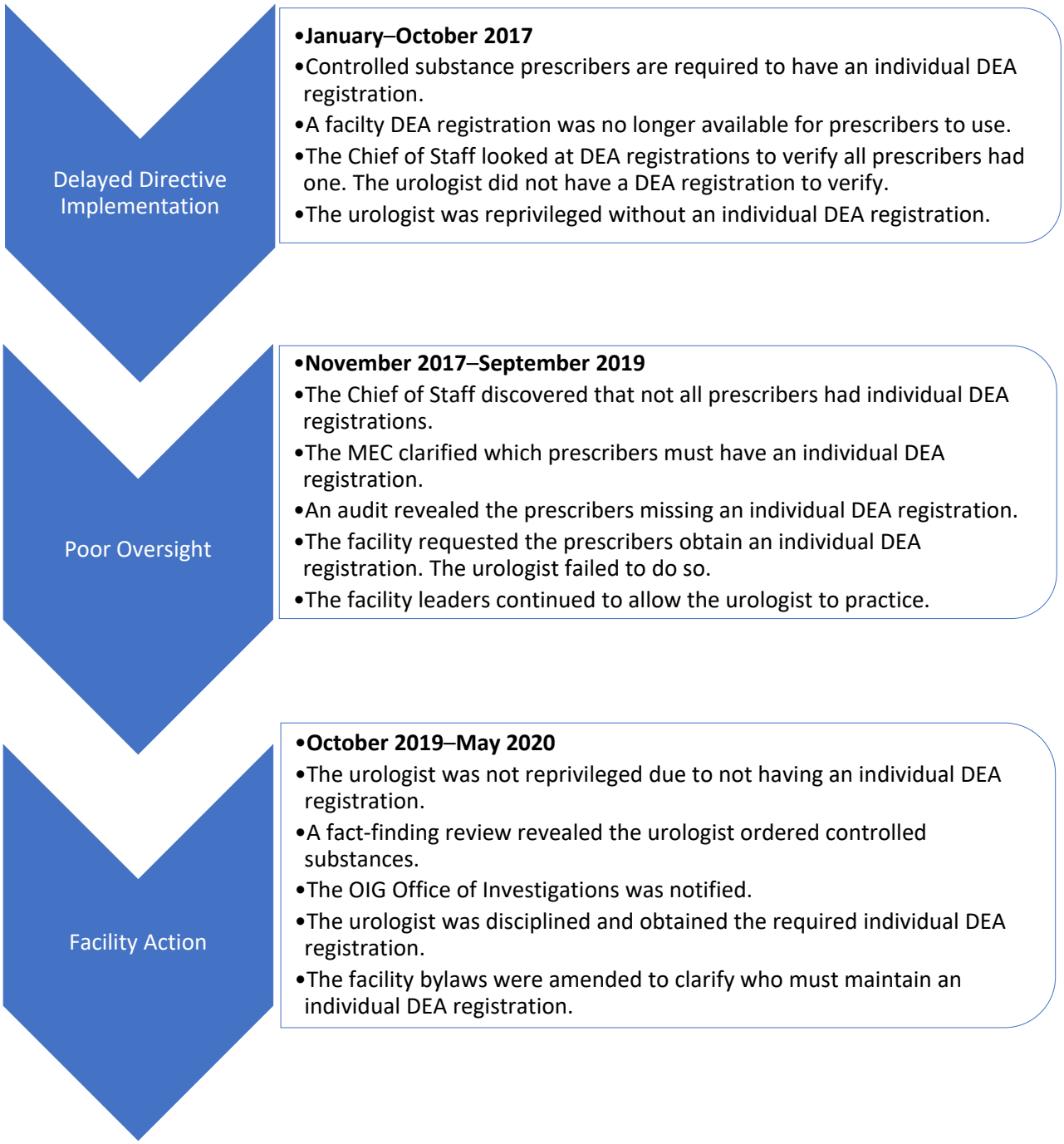

Figure 1. Facility leaders' failure to comply with the VHA directive and provide oversight as well as facility leaders' response once deficiencies were identified
Source: VA OIG

Delayed Directive Implementation—January to October 2017

The urologist began employment at the facility in February 1999. According to facility records, the urologist's DEA registration expired in August 1999. The urologist described permitting the expiration as an efficiency since the facility DEA registration was available for use. The urologist acknowledged hearing about the requirement to have an individual DEA registration as early as 2016, but reported believing the requirement was an expectation, not a mandate.

When interviewed, the Facility Director reported being aware of the requirement to ensure VA providers who prescribe controlled substances obtain an individual DEA registration. The Facility Director did not recall specific implementation steps, but assumed the notification involved a combination of methods, including medical staff meetings and bylaws. The former Chief of Staff, who was in the position at all times relevant to the credentialing and privileging events at issue, reported that facility medical staff bylaws required DEA registration and recalled reviewing DEA registrations to see if all providers possessed the necessary registration in January 2017. Notably, the urologist did not have a DEA registration to be reviewed. According to the former Chief of Staff, information about the requirement was disseminated to providers through service lines.

The former Chief of Surgery, who was the urologist's supervisor during all times relevant to the events, reported informing surgical staff of the change in policy. During the OIG interview, the former Chief of Surgery described the change in policy as being "recommended by national," and that compliance was "personally encouraged." Notably, consistent with the urologist's description of the requirement being an expectation, the former Chief of Surgery implied that the term "mandatory" was subject to personal interpretation.

Although the DEA requirement was issued through a pharmacy directive, the Chief of Pharmacy reported not being required to be involved in ensuring providers obtained individual DEA registrations or in raising awareness of the requirement.[29] The Chief of Pharmacy stated, consistent with current facility policy, that ensuring providers had required credentials was a credentialing staff function.[30] The OIG learned through interviews that facility credentialing staff verify DEA registrations and forward the information to the Chief of Pharmacy who enters applicable DEA credentials in the computer, thereby allowing only authorized providers to order controlled substances.

During an interview with the OIG, the former Credentialing Coordinator who was in the position at the time the directive went into effect, reported not being aware of the new requirement until late 2017. However, the former Credentialing Coordinator did recall the previous Chief of Pharmacy having withdrawn the ability of providers to use the institutional DEA number. The

[29] VHA Handbook 1108.05(1).

[30] Facility, *Medical Staff Bylaws*, May 20, 2020.

Chief of Pharmacy confirmed this action occurred in 2016. The action eliminated the ability of providers to order controlled substances through the Computerized Patient Record System (CPRS) without having an individual DEA registration. This action, however, did not ensure that providers who prescribed controlled substances obtained individual DEA registrations.

Reprivileging of the Urologist—October 2017

The urologist was scheduled for routine biennial clinical reprivileging in the fall of 2017 (October 24, 2017). The MEC minutes from October 2017 reflect that the credentialing staff followed the normal process for facilitating reprivileging. Figure 2 shows the facility's process for reprivileging a provider.

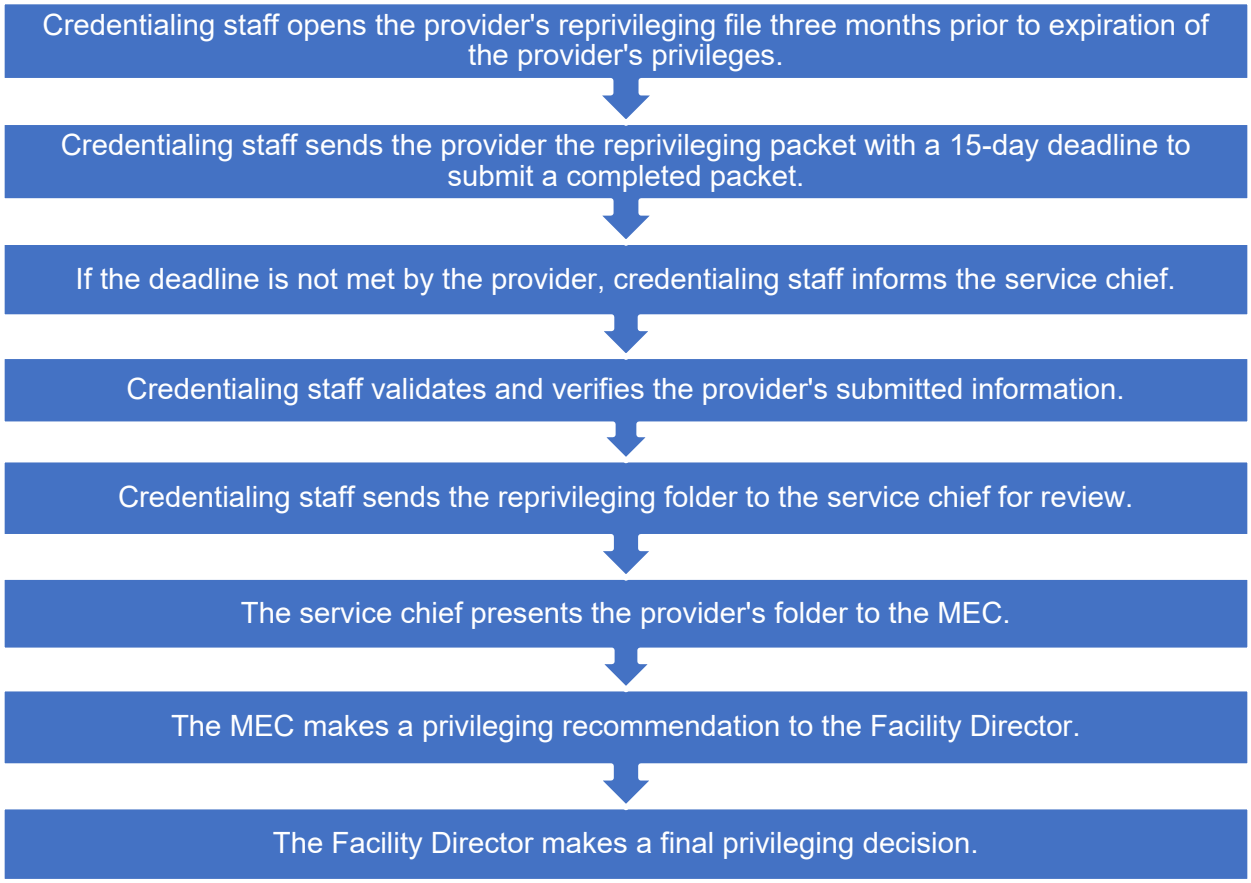

Figure 2. Facility process for reprivileging a provider
Source: OIG analysis of facility documents and interviews

The former Credentialing Coordinator informed the OIG that the urologist was late submitting paperwork, which in turn delayed the remainder of the reprivileging process. At a special MEC meeting held on October 24, 2017, the former Chief of Surgery presented the urologist's privileging documentation, which did not include an active DEA registration. Based on a

recommendation from the MEC, which was chaired by an acting Chief of Staff that day, the urologist's privileges were granted by an acting Facility Director. The OIG reviewed the minutes from the MEC and found that the urologist's lack of an individual DEA registration was notated.

The former Chief of Staff reported that the usual MEC practice included reviewing DEA registration status with every reprivileging action and was surprised to hear that privileges were recommended without an active DEA registration. During an interview with the OIG, the former Chief of Staff described the reprivileging of the urologist without a DEA registration as "an error."

The Facility Director described the usual practice for making a final privileging decision includes reviewing the reprivileging package. The Facility Director stated that individuals acting as the Facility Director have full authority to make decisions that are not subsequently reviewed. Therefore, the Facility Director would not have recognized the fact that the urologist was privileged without having a DEA registration.

Poor Oversight—November 2017 to September 2019

The OIG reviewed the facility's medical staff bylaws in effect in January 2017 and revised in February and November of that year.[31] The bylaws, consistent with VHA policy, stated that the applicant or provider asking for privileges needed to document DEA registration as either current or inactive and list any previously successful or currently pending challenges or relinquishment of DEA registrations.[32] Additionally, the bylaws instructed credentialing staff to verify "current and previously held DEA registration" of practitioners being reprivileged.[33] Although the medical staff bylaws were revised twice during 2017, the language regarding DEA registrations remained identical to the earlier version and did not explicitly identify the providers who needed DEA registrations.[34]

The former Chief of Staff recalled discovering that not all providers had required DEA registrations in late 2017. During an interview with the OIG, the former Credentialing Coordinator reported becoming aware of the new requirement in December 2017 from the Chief of Pharmacy. The former Credentialing Coordinator, whose office was responsible for ensuring providers possessed required DEA registrations, did not recall any actions taken to implement the directive prior to December 2017, nearly one year after the change had gone into effect.

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[31] Facility, *Medical Staff Bylaws*, October 30, 2014. Facility, *Medical Staff Bylaws,* February 15, 2017. Facility, *Medical Staff Bylaws,* November 28, 2017.

[32] Facility, *Medical Staff Bylaws*, October 30, 2014. Facility, *Medical Staff Bylaws,* February 15, 2017. Facility, *Medical Staff Bylaws,* November 28, 2017. VHA Handbook 1100.19.

[33] Facility, *Medical Staff Bylaws*, October 30, 2014. Facility, *Medical Staff Bylaws* February 15, 2017. Facility, *Medical Staff Bylaws,* November 28, 2017.

[34] Facility, *Medical Staff Bylaws*, October 30, 2014. Facility, *Medical Staff Bylaws* February 15, 2017. Facility, *Medical Staff Bylaws,* November 28, 2017.

In December 2017 (December 28, 2017), the MEC sought to clarify the DEA registration requirements for facility providers. The MEC determined that all licensed independent providers and physician assistants with the ability to prescribe controlled substances categorized as Schedule II through V must maintain a DEA registration.[35] The MEC exempted pathologists and radiologists who do not prescribe controlled substances. During interviews, the OIG was informed that the clarification regarding which providers required DEA registrations was disseminated through service lines. Notably, the MEC's clarification was not incorporated into the facility's medical staff bylaws until May 2020.[36]

The former Credentialing Coordinator reported completing an audit that identified providers who did not have a DEA registration in July 2018. The former Credentialing Coordinator did not recall the reason for the audit being completed seven months after recognizing the issue.

The audit revealed three providers who did not have a DEA registration. Service chiefs, through the MEC and credentialing and privileging staff, were alerted of the providers who needed to obtain a DEA registration. Two of the providers resolved the issues within a few weeks. The urologist reported attempting to complete a Michigan controlled substance license application, which is a prerequisite to obtaining a DEA registration, in August 2018; however, the license was not received. The urologist described technical challenges with submitting the application and did not follow up with the Michigan Board of Pharmacy to find out why the license was not issued. The former Chief of Staff recalled being informed that the urologist applied for the DEA registration and making the assumption that the issue would be resolved. During an OIG interview, the former Chief of Staff reported contacting the Michigan Board of Pharmacy in October 2019 and learning that the reason the controlled substance license was not issued was due to the urologist not remitting the full fee for the registration.

Throughout 2017, 2018, and most of 2019, the facility permitted the urologist to practice without the required DEA registration. The urologist reported knowing about the requirement; however, reported believing throughout this time the requirement was an expectation, not a mandate.

Facility Action—October 2019 to May 2020

In October 2019, once the MEC identified that the urologist failed to acquire the required DEA registration, facility leaders took action at the provider and facility levels.

[35] United States Drug Enforcement Administration, *Drug Scheduling*. https://www.dea.gov/drug-scheduling#:~:text=Schedule%20I%20drugs%2C%20substances%2C%20or%20chemicals%20are%20defined,%28LSD%29%2C%20marijuana%20%28cannabis%29%2C%203%2C4-methylenedioxymethamphetamine%20%28ecstasy%29%2C%20methaqualone%2C%20and%20peyote. (The website was accessed on August 24, 2020.) Schedule I controlled substances have no currently accepted medical use.

[36] Facility, *Medical Staff Bylaws*, May 20, 2020.

Administrative Suspension of Privileges—October 2019

During the summer of 2019 (August 7, 2019), credentialing staff initiated the process for having the urologist reprivileged at the October 2019 MEC meeting. Despite multiple email requests to submit the required documentation, including a request to the acting Chief of Surgery for assistance, the urologist submitted the reprivileging documentation two months later on October 7, 2019. The documents did not include a DEA registration.

During the October 10, 2019, MEC meeting, the urologist's reprivileging file was presented. The meeting minutes reflect discussion about the urologist not having a DEA registration, despite being notified multiple times to obtain the registration by the former Chief of Staff, former Chief of Surgery, and credentialing staff. As a result, the MEC recommended and the Facility Director approved, an administrative suspension of privileges for failure to obtain an individual DEA registration. The urologist was detailed to administrative duties pending the outcome of a facility fact-finding review.

Facility Fact-Finding Review and Response

In October 2019, the Chief of Staff charged the Nurse Executive with conducting a fact-finding review. The fact-finding review confirmed that the urologist did not possess an individual DEA registration, despite multiple instructions from facility leaders and credentialing staff to obtain one starting as early as August 23, 2018, and found that the urologist had been verbally ordering and requesting other providers to prescribe controlled substances.

Facility leaders responded by issuing a disciplinary action to the urologist, conducting a management review of the urologist's patients who received controlled substances, and notifying the OIG Office of Investigations of the findings. The OIG learned through interviews that facility leaders also implemented the following corrective actions to ensure all providers who prescribed controlled substances maintained DEA registrations:

- Weekly meetings with the Credentialing Coordinator and Chief of Quality to review expiring DEA registrations
- Increased attention to the vetting process prior to presentation of reprivileging to the MEC
- Credentialing reminders to providers and service chiefs 30 days prior to the expiration of a DEA registration
- Dashboard listing all the facility providers and status of licenses, registrations, and certifications

- Revision of medical staff bylaws to unambiguously state that maintaining DEA registration is a requirement for privileges[37]

The OIG assessed whether providers who the facility identified as requiring a DEA registration had one. The OIG verified facility-provided DEA registration data with data available from the VA Corporate Data Warehouse, which were current as of August 19, 2020. Although discrepancies in expiration dates were identified, the facility resolved each of the discrepancies by providing evidence of current DEA registrations. The comparison resulted in the OIG verifying that all providers identified by the facility as requiring a DEA registration had a current DEA registration.

The OIG verified the urologist was permitted to practice and was privileged due to facility leaders' failure to timely implement the VHA requirement and poor oversight. The OIG confirmed that, as of August 19, 2020, all providers, including the subject urologist, who the facility reported required a DEA registration, had one. Although the facility implemented a corrective action strategy to ensure that only providers with DEA registrations were ordering controlled substances in the facility, the OIG identified vulnerabilities in the facility's medication management processes.

2. Deficiencies in Controlled Substance Medication Management

The OIG confirmed that the urologist issued verbal orders for controlled substances to registered nurses during operative procedures without having the required DEA registration. The OIG identified several deficiencies related to the facility's management of controlled substance medications used in the operating room. Specifically, the OIG found deficiencies in

- Verbal medication ordering processes,
- Pharmacist review of medication orders,
- Controlled substance inspections, and
- Controlled substance recordkeeping.

Additionally, the OIG confirmed that, although computer safeguards were in place to prevent the urologist from ordering controlled substances for patients without having the required DEA registration, the urologist circumvented the safety measures by requesting Urology Clinic colleagues prescribe controlled substance medications for patients. The OIG also identified that a physician assistant was exposed to the risk of violating state practice laws by unknowingly being supervised by a physician without a DEA registration.

[37] Facility, *Medical Staff Bylaws*, May 20, 2020.

Unauthorized Controlled Substance Orders

The OIG confirmed that the urologist verbally ordered controlled substances in the operating room without possessing a DEA registration.

VHA policy requires providers possess an individual DEA registration when ordering controlled substances.[38] According to VHA and facility policies, providers must enter medication orders into the pharmacy package in CPRS.[39] Facility directors are mandated to ensure computer controls are in place to prevent a provider from ordering controlled substances without authority through a DEA registration.[40]

The facility fact-finding review revealed that the urologist was verbally ordering controlled substances in the operating room. The urologist acknowledged to the OIG that only providers with a DEA registration are permitted to order controlled substances and identified that the medications ordered in the operating room were controlled substances. The urologist denied knowledge that an individual DEA registration was required as of January 2017 and reported not being informed of any restriction on ordering controlled substances. However, the urologist recalled being unable to order controlled substances in CPRS in 2017 and acknowledged this limitation was due to not having a DEA registration. The Chief of Pharmacy confirmed that the urologist did not have the ability to order controlled substances in the CPRS computer package.

Through interviews and document review, the OIG determined that the urologist verbally ordered controlled substances for patients in the operating room while not having an individual DEA registration nor access to the institutional DEA registration.[41] When asked the reason for not obtaining the required DEA registration, the urologist responded that it had not been a priority. The urologist received the required DEA registration in November 2019, after having clinical privileges suspended due to not having a DEA registration.

As discussed previously, facility leaders implemented processes to ensure providers maintain required DEA registrations.[42] In spring 2020 (May 20, 2020), the facility's medical staff bylaws were revised to clarify that DEA registration was required to maintain medical staff membership. Therefore, the risk of an unauthorized provider ordering controlled substances was reduced.

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[38] VHA Directive 1108.01(1); VHA Handbook, 1108.05(1).

[39] VHA Directive 1108.06, *Inpatient Pharmacy Services*, February 8, 2017; Facility, Patient Care Programs–9, *Medication Orders*, September 2019.

[40] VHA Handbook, 1108.05(1).

[41] Notably, the urologist denied issuing verbal orders in the operating room. The urologist described observing nurses retrieve and administer a controlled substance in response to the urologist asking whether a patient had received the medication. The urologist also reported expecting that the anesthesiologist would document the medication order and administration but conceded that anesthesiologists only document medications personally administered.

[42] Facility, *Medical Staff Bylaws*, May 20, 2020.

However, the OIG identified noncompliance with the facility's medication management policies that represented ongoing patient safety and controlled substance diversion vulnerabilities.

Verbal Medication Ordering Processes

The OIG determined that verbal medication ordering practices in the operating room did not conform to VHA and facility policies and contributed to the urologist's ability to verbally order controlled substances without the required DEA registration.

VHA and facility policies direct that providers primarily order medications through the pharmacy package in CPRS.[43] However, during emergent situations, a provider may issue a verbal order to a registered nurse.[44] Facility policy directs that the provider and registered nurse take safety precautions for verbal orders, including verification of the order prior to administration and entry of the order into the CPRS pharmacy package as soon as possible.[45] Facility standard operating procedure for verbal orders emphasizes that it is "absolutely essential that the provider sign the order within 24 hours."[46] Figure 3 highlights the facility-required steps for verbal orders.[47]

[43] VHA Directive 1108.06; Facility, *Medication Orders*.

[44] Facility, *Medication Orders*.

[45] Facility, Clinical Programs–25, *Verbal, Telephone and Policy Orders*, July 19, 2013.

[46] Facility, *Verbal, Telephone and Policy Orders*.

[47] Facility, *Verbal, Telephone and Policy Orders;* Facility*, Medication Orders.* Although figure 3 only lists nurses as receivers of verbal orders, the facility authorizes registered nurses, pharmacists, and respiratory therapists to receive verbal orders.

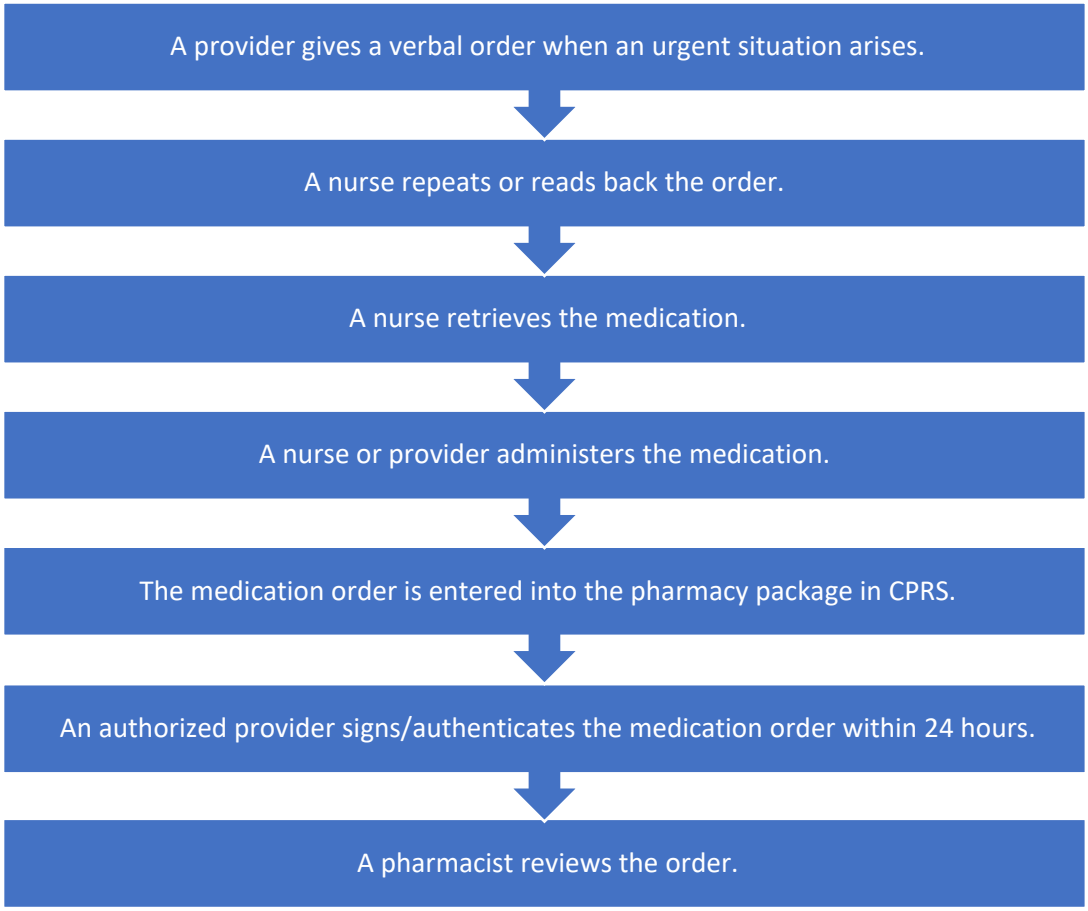

Figure 3. Facility policy required procedures for verbal ordering process[48]
Source: VA OIG

Nursing and pharmacy leaders reported that VHA and facility policies regarding verbal medication orders did not apply to the operating room setting due to the nature of operating room procedures. However, these leaders acknowledged being unaware of, and unable to provide the OIG with, a written policy or standard operating procedure that permitted operating room personnel to disregard these policies.

During interviews with the OIG, nursing leaders described the nonemergency verbal ordering process in the operating room as the same for controlled and non-controlled substances. The process did not align with the facility's standard operating procedure for verbal orders. Figure 4 depicts the verbal ordering process used in the operating room.

[48] Facility, *Verbal, Telephone and Policy Orders*; Facility, *Medication Orders.*

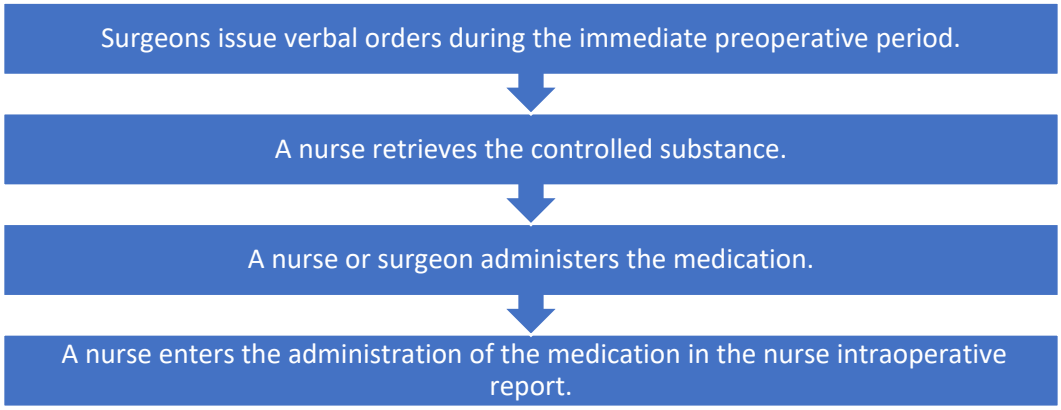

Figure 4. Operating room process for verbal orders of medications decided in preoperative period. Source: VA OIG analysis

According to nursing leaders, neither nurses nor ordering providers were expected to enter medication orders in the CPRS pharmacy package. The operating room nurse manager explained that surgeons could not be expected to stop a procedure to enter a medication order into CPRS.

The urologist described to the OIG a verbal ordering process in the operating room consistent with the process reported by nursing leaders. The urologist stated the process was the same before and after the requirement for an individual DEA registration and at no point included entering medication orders in the computer.

The Facility Director recognized that the fact-finding review identified a systems issue with the operating room verbal order process. In an interview, the Facility Director explained "interoperative [*sic*] record serves as the documentation source, but it certainly does not have the same protections, safeguards and checks and balances as entering a medication order into CPRS."

The OIG determined verbal ordering practices in the operating room failed to comply with the restriction of only using verbal orders during emergent situations and the requirement of the provider entering or authenticating the order in the computer within 24 hours. Preoperatively identifying medications to be administered during a procedure is not consistent with the requirement to use verbal orders only in emergent situations. Additionally, although a surgeon could not be expected to stop a procedure to enter a medication order, a surgeon could be expected to enter the medication order prior to or after the procedure within 24 hours as required by VHA and facility policies.

Related Concern: Pharmacist Review of Medication Orders

During the inspection, upon learning that verbal orders were not entered into the CPRS pharmacy package, the OIG identified an additional concern regarding pharmacists not reviewing verbal medication orders from the operating room.

Facility policy states "All medication orders must be entered appropriately through the electronic pharmacy package for review by a pharmacist."[49] Pharmacists ordinarily review medication orders prior to a medication being administered; however, according to facility policy, in instances when a prior review is not possible, pharmacists must review medication orders within 24 hours.[50]

The Chief of Pharmacy reported being aware that operating room verbal medication orders were not entered in the pharmacy package. The Chief of Pharmacy explained that if a pharmacist were to review records for medication orders given in the operating room, the process would entail looking at the intraoperative documentation. The Chief of Pharmacy described that, when a controlled substance discrepancy is identified by the Controlled Substance Coordinator, pharmacists conduct audits by looking at intraoperative documentation to attempt to justify removal of controlled substances from automated dispensing cabinets.

Pharmacists cannot comply with the facility requirement to review all medication orders when verbal medication orders are not entered in the CPRS pharmacy package. A pharmacist review serves an important patient safety purpose by assessing, among other things, allergies, appropriateness of the medications, contraindications, and duplication of therapy. Reviewing documentation when discrepancies are identified is not a substitution for the safeguards afforded by pharmacist review of all medication orders.

Related Concern: Controlled Substance Inspections

During the inspection, after learning that verbal orders from the operating room were not entered in the CPRS pharmacy package and that pharmacists review intraoperative documentation when controlled substance discrepancies are found, the OIG identified that controlled substance inspectors were not verifying medication orders for controlled substances dispensed from the operating room automated dispensing cabinets.

VHA's controlled substance inspection program "helps ensure compliance with federal regulations, statutes, and VA policy, minimizes the risk for loss and diversion, and enhances patient safety."[51] During inspections, controlled substance inspectors must "verify there is a hard copy order (electronic or written) in the patient's medical record." [52]

[49] Facility, *Medication Orders*.

[50] Facility, *Medication Orders.* Notably, the facility policy is more stringent than The Joint Commission policy, which states, "…a pharmacist reviews all medication orders or prescriptions unless a licensed independent practitioner controls the ordering, preparation, and administration of the medication." The Joint Commission, *Standards Manual,* MM.05.01.01, July 1, 2020.

[51] VHA Directive 1108.02(1), *Inspection of Controlled Substances*, November 28, 2016, amended March 6, 2017.

[52] VHA Directive 1108.02(1).

The OIG corresponded with the facility's Controlled Substance Coordinator who confirmed that controlled substance inspectors do not verify medication orders from the operating room, but instead look at the nurse intraoperative report. The Controlled Substance Coordinator explained that operating room medication orders were not required to be entered in the computer. When asked for a policy that provides the operating room exception, the Controlled Substance Coordinator responded that such a policy did not exist.

The practice of not verifying medication orders for controlled substances removed from the operating room automated dispensing cabinet is not consistent with VHA directive, represents a controlled substance diversion vulnerability, and does not support patient safety.

Controlled Substance Recordkeeping

The OIG found that, prior to the facility fact-finding review, recordkeeping processes for controlled substances administered in the operating room failed to comply with VHA recordkeeping requirements to tie a dispensed controlled substance to a DEA registrant.

VHA requires thorough recordkeeping of controlled substance transactions in order to demonstrate controlled substance accountability and to comply with all laws and federal regulations.[53] The Controlled Substances Act requires registrants to maintain records that indicate the controlled substance was issued to, or on behalf of, a DEA registrant.[54]

The OIG Office of Investigations referral reported a concern that medical record documentation did not adequately reflect who is ordering medications during operative procedures. The OIG learned that rather than connecting the administration of a controlled substance in the operating room to a medication order, facility leaders relied on nurses to document the name of the ordering provider in nurse intraoperative reports. During the facility fact-finding review, facility leaders found that nurse intraoperative reports documented the administration of controlled substances, but often did not list the name of the ordering provider. The operating room nurse manager took corrective actions, including nurse education and compliance monitoring, to ensure that nurses include the name of the ordering provider when documenting medication administration.

The operating room nurse manager provided the OIG with results of chart audits conducted from October 2019 through January 2020 that assessed whether nurses consistently documented the names of ordering providers in intraoperative reports. The audit demonstrated improvement in nurses documenting ordering providers' names. The OIG verified the accuracy of the evidence through chart review. In October 2019, nurses charted ordering providers' names in 32 percent of the audited records. In January 2020, nurses charted ordering providers' names in 99 percent of

[53] VHA Directive 1108.01(1).
[54] 21 CFR § 1304.22 (2014).

the audited records. Therefore, the OIG identified improvement in nurse intraoperative reports documenting the names of providers who ordered controlled substances. However, the OIG concluded that this documentation improvement does not resolve the fact that medication orders are not entered in the pharmacy package and, subsequently, are not available for pharmacists and controlled substance inspectors to review.

Colleagues Prescribing Controlled Substances

As noted above, Urology Clinic providers prescribed controlled substance medications for the urologist's patients following requests from the urologist. The OIG found the providers complied with VHA, federal, and state laws when prescribing controlled substances for the urologist's patients.

VHA and federal requirements establish that providers may only prescribe controlled substances "for a legitimate medical purpose" in the provider's usual course of practice.[55] State licensing boards may further restrict the ability of physician assistants to prescribe controlled substances.[56]

The urologist reported routinely requesting Urology Clinic providers to prescribe controlled substances for patients prior to and after being unable to personally place controlled substance orders in the computer. Urology providers confirmed that the urologist's practice of requesting prescriptions for patients preceded the requirement to possess an individual DEA registration. The urology providers reported not finding the requests unusual due to the clinic's structure, which enabled patients to be treated by multiple providers.[57]

Providers reported determining clinical necessity prior to issuing prescriptions for controlled substances by reviewing relevant medical records or assessing patients. Providers denied feeling pressured to write a controlled substance prescription based on the urologist's request.

The providers explained not questioning the urologist's credentials because verifying credentials is a function and responsibility of the credentialing department. The OIG learned during interviews that urology providers were unaware the urologist did not possess the authority to prescribe controlled substances until after learning of the urologist's suspension from clinical practice.

The OIG determined that urology providers prescribed controlled substances following the urologist's request; however, the providers issued the prescriptions after determining medical necessity, in compliance with applicable laws and VHA policy. DEA registered providers are not

[55] 21 CFR §§ 1306 *et seq*; VHA Directive 1108.01(1).

[56] VHA Directive 1063, *Utilization of Physician Assistants (PA)*, December 24, 2013.

[57] The OIG interviewed a part-time urologist and a physician assistant. A second physician assistant retired prior to the start of the OIG inspection and was not interviewed.

prohibited from writing prescriptions for controlled substances for another provider's patients for a legitimate medical purpose.

Facility leaders became aware that other urology providers were prescribing controlled substances for the urologist's patients during the facility's fact-finding review. Facility leaders acted by disciplining the urologist, strengthening credentialing and privileging processes, and updating medical staff bylaws to ensure all ordering providers have required DEA registrations. The OIG concluded that these steps reduce the risk of future instances of an unauthorized provider requesting prescriptions for controlled substances be written by an authorized provider.

Related Concern: Physician Assistant Prescribing

During the inspection, after learning that the urologist was a supervising physician for the physician assistant, the OIG identified a related concern regarding the physician assistant prescribing controlled substances that the urologist did not have authority to prescribe.

VHA requires that physician assistants prescribe controlled substances consistent with relevant scope of practice and state licensure requirements.[58] According to Iowa law, where the currently practicing physician assistant is licensed, physician assistants may only prescribe medications that the supervising physician has authority to prescribe.[59] The OIG reviewed the physician assistant's scope of practice, which showed the physician assistant worked under the auspices of two supervising physicians, one of whom was the subject urologist. Notably, unbeknownst to the physician assistant, only one of the supervising physicians possessed a DEA registration. By permitting the urologist to practice without having the required DEA registration and by not notifying the physician assistant of the urologist's loss of the ability to prescribe controlled substances, the OIG identified that facility leaders exposed the physician assistant to a risk of unknowingly violating Iowa law. The OIG recognized that this vulnerability highlights one of the multiple interconnected issues that arise from lapses in physician privileging processes in a VA facility.

Conclusion

The OIG found the facility leaders' delay in implementing a VHA directive that required providers who order controlled substances to obtain a DEA registration and poor oversight contributed to the urologist practicing and maintaining privileges for nearly three years without a DEA registration. After a fact-finding review, facility leaders implemented a process to ensure all controlled substance ordering providers hold an active DEA registration. The OIG verified the accuracy of the facility's assertion that all providers had the necessary DEA registration.

[58] VHA Directive 1063.

[59] Iowa Administrative Code. IAC 645.327.1(1)c(5)(2020); formerly IAC 645.327.1(1)s(4)(2016).

Therefore, the OIG determined the recent process enhancements reduced the risk of an unauthorized provider ordering controlled substances.

The OIG is concerned, however, that safeguards built into medication management policies were not applied to the operating room processes. That is, surgeons issuing verbal orders to have nonurgent medications administered, and not being expected to subsequently enter the order in the computer, bypassed controls that prevent unauthorized providers from entering orders. Notably, had verbal orders been entered into the CPRS pharmacy package, the urologist would not have been able to repeatedly verbally order controlled substances without a DEA registration. Furthermore, because the verbal orders were not entered in the CPRS pharmacy package, pharmacists did not review orders within 24-hours as required by policy. Consequently, this important patient safety measure was not used. Also, because verbal orders were not entered in the computer, controlled substance inspectors did not verify medication orders during inspections, resulting in vulnerabilities for patient safety and diversion of controlled substances.

Prior to taking corrective action, nurse intraoperative documentation did not consistently include the name of the provider who ordered controlled substances. The OIG verified that, since taking corrective action, nurse intraoperative reports document the names of ordering providers for controlled substances administered in the operating room. This improvement in documentation, however, did not resolve the issue of not having orders entered in the pharmacy package available for pharmacists and controlled substance inspectors to review.

The OIG confirmed that the urologist requested Urology Clinic providers to prescribe controlled substances for patients. The OIG found the urology providers verified medical necessity prior to writing prescriptions and complied with VHA policy and applicable state and federal laws. Furthermore, facility leaders took steps to reduce the risk of future instances of a provider being privileged without a DEA registration and, therefore, reduced the risk of an unauthorized provider requesting an authorized provider to prescribe controlled substances for patients. By permitting the subject urologist to serve as one of a physician assistant's supervising physicians, facility leaders exposed the physician assistant to the risk of violating Iowa state law, which limits physician assistant prescribing authority to include only controlled substances that the supervising physician has authority to prescribe.

Recommendations 1–5

1. The VA Central Iowa Health Care System Director ensures sustained compliance of providers who order controlled substances maintaining an individual Drug Enforcement Administration registration.
2. The VA Central Iowa Health Care System Director ensures verbal medication orders given in the operating room comply with Veterans Health Administration and VA Central Iowa Health Care System policies to permit verbal orders in emergent situations.

3. The VA Central Iowa Health Care System Director ensures operating room verbal medication orders are entered in the Computerized Patient Record System pharmacy package in accordance with Veterans Health Administration and VA Central Iowa Health Care System policies.
4. The VA Central Iowa Health Care System Director ensures that verbal medication orders given in the operating room are reviewed by a pharmacist in accordance with VA Central Iowa Health Care System policy.
5. The VA Central Iowa Health Care System Director ensures that controlled substance inspections include verification of medication orders for controlled substances removed from the operating room automated dispensing cabinet.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: November 16, 2020

From: Director, VA Midwest Health Care Network (10N23)

Subj: Healthcare Inspection—Deficiencies in Privileging a Urologist to Practice and Medication Management Processes at the VA Central Iowa Health Care System in Des Moines

To: Director, Office of Healthcare Inspections (54HL01)
Director, GAO/OIG Accountability Liaison office (VHA 10EG GOAL Action)

I have reviewed the DRAFT Report Healthcare Inspection—Deficiencies in Privileging a Urologist to Practice and Medication Management Processes at the VA Central Iowa Health Care System in Des Moines. I concur with the action plans and submitted documentation.

(*Original signed by*:)

Robert P. McDivitt, FACHE
Executive Director

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: November 13, 2020

From: Director, VA Central Iowa Health Care System (636A6)

Subj: Healthcare Inspection—Deficiencies in Privileging a Urologist to Practice and Medication Management Processes at the VA Central Iowa Health Care System in Des Moines

To: Director, VA Midwest Health Care Network (10N23)

Please see the attached Facility Director Response for the Healthcare Inspection—Deficiencies in Privileging a Urologist to Practice and Medication Management Processes at the VA Central Iowa Health Care System in Des Moines.

(*Original signed by*:)

GAIL L. GRAHAM
Director

Facility Director Response

Recommendation 1

The VA Central Iowa Health Care System Director ensures sustained compliance of providers who order controlled substances maintaining an individual Drug Enforcement Administration registration.

Concur.

Target date for completion: October 1, 2020.

Director Comments

To ensure the sustained compliance of providers who order controlled substances maintaining an individual Drug Enforcement Administration (DEA) registration, VA Central Iowa Health Care System has already implemented the following corrective actions, which will continue as routine processes going forward:

- Weekly meetings with the Credentialing Coordinator and Chief of Staff are held to review expiring DEA registrations. VetPro, an Internet enabled data bank for the credentialing of VHA personnel, is queried to retrieve a list of all providers with DEA registrations expiring within 45 days.
- DEA registration status is reviewed prior to presentation of re-privileging actions to the Medical Executive Committee
- Credentialing staff send reminders to providers and service chiefs 45 days prior to the expiration of a DEA registration. If no action has been taken, the Chief of Staff is sent a credentialing notification 10 days prior to the expiration of a DEA registration.
- A dashboard listing all the facility providers and status of licenses, registrations, and certifications, is maintained and updated routinely.
- Medical Staff Bylaws revised May 2020 to include: Section 3.01 (1)(e), Criteria for Clinical Privileges, now includes "*For all prescribing providers, current and active CDS [Controlled Dangerous Substance license] (if applicable based upon their state of licensure) and DEA (both) upon appointment and at all times while actively privileged, with no restrictions and with matching entire schedules (2, 2N, 3, 3N, 4, 5).*"

OIG Comment

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

Recommendation 2

The VA Central Iowa Health Care System Director ensures verbal medication orders given in the operating room comply with Veterans Health Administration and VA Central Iowa Health Care System policies to permit verbal orders in emergent situations.

Concur.

Target date for completion: November 1, 2020

Director Comments

VA Central Iowa Health Care System Policy, Patient Care Programs-9, *Medication Orders*, has been revised to require documentation of verbal orders in the Operating Room. The language now allows verbal or telephone orders to be accepted from an authorized provider in emergent situations when urgency is a factor for the provision of patient care. The policy requires the medication order to be recorded electronically into the patient's electronic health record in the pharmacy package and signed by the ordering provider as soon as possible, but no later than 24 hours after the order is given. The initial verbal order may be honored for medication administration prior to the medication order being signed by the ordering provider.

OIG Comment

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

Recommendation 3

The VA Central Iowa Health Care System Director ensures operating room verbal medication orders are entered in the Computerized Patient Record System pharmacy package in accordance with Veterans Health Administration and VA Central Iowa Health Care System policies.

Concur.

Target date for completion: November 1, 2020.

Director Comments

VA Central Iowa Health Care System Policy, Patient Care Programs-9, *Medication Orders*, has been revised to require documentation of verbal orders in the Operating Room. The language now allows verbal or telephone orders to be accepted from an authorized provider in emergent

situations when urgency is a factor for the provision of patient care. The policy requires the medication order to be recorded electronically into the patient's electronic health record in the pharmacy package and signed by the ordering provider as soon as possible, but no later than 24 hours after the order is given. The initial verbal order may be honored for medication administration prior to the medication order being signed by the ordering provider.

OIG Comment

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

Recommendation 4

The VA Central Iowa Health Care System Director ensures that verbal medication orders given in the operating room are reviewed by a pharmacist in accordance with VA Central Iowa Health Care System policy.

Concur.

Target date for completion: November 1, 2020.

Director Comments

VA Central Iowa Health Care System Policy, Patient Care Programs-9, *Medication Orders*, has been revised to require documentation of verbal orders in the Operating Room. The language now allows verbal or telephone orders to be accepted from an authorized provider in emergent situations when urgency is a factor for the provision of patient care. The policy requires the medication order to be recorded electronically into the patient's electronic health record in the pharmacy package and signed by the ordering provider as soon as possible, but no later than 24 hours after the order is given. The initial verbal order may be honored for medication administration prior to the medication order being signed by the ordering provider. Once the authorized provider enters and signs the initial verbal order in the pharmacy package, a pharmacist will review the medication order within 24 hours.

OIG Comment

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

Recommendation 5

The VA Central Iowa Health Care System Director ensures that controlled substance inspections include verification of medication orders for controlled substances removed from the operating room automated dispensing cabinet.

Concur.

Target date for completion: November 1, 2020.

Director Comments

VA Central Iowa Health Care System Policy, Patient Care Programs-9, *Medication Orders*, has been revised to require documentation of verbal orders in the Operating Room. The language now allows verbal or telephone orders to be accepted from an authorized provider in emergent situations when urgency is a factor for the provision of patient care. The policy requires the medication order to be recorded electronically into the patient's electronic health record in the pharmacy package and signed by the ordering provider as soon as possible, but no later than 24 hours after the order is given. The initial verbal order may be honored for medication administration prior to the medication order being signed by the ordering provider. Controlled substance inspectors verify the documentation of a medication order for all controlled substances removed from the operating room automated dispensing cabinet.

OIG Comment

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

Glossary

administrative suspension of privileges. An automatic suspension of privileges used when a physician is being investigated for conduct or behavior issues that do not have a direct impact on patient care, but facility leadership determine the issue could negatively impact the work environment.[60]

automated dispensing cabinets. A computerized drug storage space used to dispense medications electronically and in a controlled manner to track medication use.[61]

board of pharmacy. A regulatory body charged with facilitating and controlling the standards of pharmacy practice and drugs manufactured, distributed, prescribed, dispensed and administered as well as to set minimum requirements for equipment that dispense drugs.[62]

Computerized Patient Record System. A VA computer application system that allows clinicians to review, order and document in the electronic health records of patient.[63]

Controlled Substances Act. A federal law that created a U.S. drug policy, under which the manufacture, distribution and use of certain substances are regulated. The law created five categories of these substances based on accepted medical treatment use in the United States, relative abuse potential, and likelihood of causing dependence when abused.[64]

Controlled Substance Coordinator. A facility employee appointed by the facility director responsible for the management of the controlled substance inspection program.[65]

controlled substance inspectors. Part of a facility's inspection of controlled substance team responsible for random and unannounced inspections of controlled substance under the direction of the controlled substance coordinator.[66]

Drug Enforcement Administration. A federal agency charged with enforcing federal laws and regulations pertaining to controlled substances.[67]

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[60] Facility, *Medical Staff Bylaws*, November 28, 2017.

[61] VHA Directive 1108.02(1), Controlled Substances Management.

[62] Michigan.gov, *Michigan Board of Pharmacy.* https://www.michigan.gov/whitmer/0,9309,7-387-90501_90626-250588--,00.html. (The website was accessed on August 18, 2020.)

[63] VA, Office of Information and Technology, *Computerized Patient Record System (CPRS) User Guide: GUI Version,* July 2020.

[64] United States Drug Enforcement Administration, *The Controlled Substances Act*. https://www.dea.gov/controlled-substances-act. (The website was accessed on August 19, 2020.)

[65] VHA Directive 1108.02(1) *Inspection of Controlled Substances,* November 28. 2016. Amended March 6, 2017.

[66] VHA Directive 1108.02(1).

[67] United States Drug Enforcement Administration, *Mission.* https://www.dea.gov/mission. (The website was accessed on August 20, 2020.)

diversion investigator. A specialist position with the DEA that enforces the Controlled Substance Act and conducts investigations into the diversion of controlled substances.[68]

fact-finding review. An initial gathering of facts associated with a particular incident. The process involves collecting individual signed statements that are not made under oath and not considered sworn testimony.[69]

intraoperative. Occurring or carried out during a surgical operation.[70]

intraoperative report. A report that details the surgical case information related to the nursing care provided to the patient during the surgical case. Once the report is electronically signed by the nurse, the report can be viewed in CPRS.[71]

Medical Executive Committee. A committee that acts on the behalf of the facility medical staff with responsibilities that include maintaining a process for reviewing credentials and delineating clinical privileges. This facility refers to the name of this committee as the executive committee of the medical staff.[72]

narcotics. Drugs that dull the senses and relieve pain but also have the propensity for addiction.[73]

nurse executive. A registered nurse who leads the facility's nursing team and handles the management of clinical and patient care services.[74]

pharmacy package. An operating system in CPRS used to order medications through the electronic health record system. The pharmacy package also checks to see if a medication is a controlled substance and requires a DEA registrant to order.[75]

pathologists. Physicians that analyze and diagnose changes in body tissues and fluids that are usually caused by a disease process.[76]

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[68] United States Drug Enforcement Administration, *Diversion Investigator Careers.* https://www.dea.gov/divisions/diversion-investigator-careers. (The website was accessed on August 20, 2020.)

[69] VA, Administrative Investigations: *Do it Right the First Time Resource Guidebook*, July 2004.

[70] Merriam-Webster, *Intraoperative.* https://www.merriam-webster.com/medical/intraoperative. (The website was accessed on August 19, 2020.)

[71] Department of Veteran Affairs, Office of Information Technology, *Surgery User Manual,* July 1993, Revised November 2015.

[72] Facility, *Medical Staff Bylaws*, November 28, 2017.

[73] Merriam-Webster, *Narcotic.* https://www.merriam-webster.com/dictionary/narcotic. (The website was accessed on August 19, 2020.)

[74] Facility, *Medical Staff Bylaws,* November 28, 2017.

[75] VA, Office of Information and Technology, *Computerized Patient Record System (CPRS) User Guide: GUI Version,* July 2020.

[76] Merriam-Webster, *Pathologist*. https://www.merriam-webster.com/dictionary/pathologist. (The website was accessed on August 19, 2020.)

physician assistant. A health care professional certified to provide basic medical care usually under the supervision of a physician.[77]

privileged. Term used to describe a provider who has permission from the facility to practice independently in accordance with law and facility policies.[78]

radiologist. A physician that specializes in the use of radiant energy in the form of waves or particles for diagnostic and therapeutic purposes.[79]

VA Corporate Data Warehouse. An electronic data warehouse used to store VA clinical data in order to streamline and consolidate clinical information.[80]

urologist. A specialist who treats conditions of the urinary or urogenital organs. The urologist at issue is a surgeon.[81]

verbal orders. An order that is given face-to-face by a provider to a staff member not authorized to make such an order alone but is permitted to enter and release the order in the name of the provider.[82]

[77] Merriam-Webster, *Physician Assistant.* https://www.merriam-webster.com/dictionary/physician%20assistant. (The website was accessed on May 21, 2020.)

[78] VHA Handbook 1100.19.

[79] Merriam-Webster, *Radiologist.* https://www.merriam-webster.com/dictionary/radiologist. (The website was accessed on August 19, 2020.)

[80] Veterans Administration, *Health Services Research and Development.* https://www.hsrd.research.va.gov/for_researchers/vinci/cdw.cfm website was accessed on August 20, 2020.)

[81] Merriam-Webster, Urologist. https://www.merriam-webster.com/dictionary/urologist. (The website was accessed on May 9, 2020.)

[82] Facility, Clinical Programs–25, *Verbal, Telephone and Policy Orders*, July 19, 2013.

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