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VETERANS HEALTH ADMINISTRATION

Alleged Deficiencies in Pharmacy Service Procedures at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia

HEALTHCARE INSPECTION | REPORT #19-09776-223 | AUGUST 4, 2020

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Executive Summary

The VA Office of Inspector General (OIG) received allegations of inadequate orientation and training of newly hired pharmacy staff specific to inpatient pharmacy, aseptic technique and intravenous (IV) admixture preparation, and accessing the cache at the Louis A. Johnson VA Medical Center (facility) in Clarksburg, West Virginia.[1] The allegations also claimed a lack of pharmacist oversight of pharmacy technicians preparing IV admixtures.[2] This matter is not related to the recent criminal case involving a former nursing assistant at the facility.

The OIG initially referred these allegations for review and a response to the Veterans Integrated Service Network (VISN) Director, who did not substantiate the allegations. However, the VISN Director noted that the required annual IV compounding competencies of some pharmacy staff members had lapsed. Pharmacy managers were in the process of having staff complete these competencies. The OIG received a second complaint alleging that pharmacy management was noncompliant with Veterans Health Administration (VHA) controlled substance policies, including storage and maintenance of inventory records. The OIG initiated a healthcare inspection to evaluate the allegations and follow up on the completion of the required annual IV compounding competencies noted in the VISN Director's response.

The OIG did not substantiate that newly hired pharmacist orientation and training was inadequate. Staff pharmacists reported that the orientation and training provided by facility leadership, coupled with their formal pharmacy education and prior experience, was adequate to prepare them to perform the job in all areas of pharmacy, including inpatient pharmacy, aseptic technique and IV admixture preparation, and cache access. As required by the VHA directive, pharmacy managers developed an orientation checklist to identify elements for training and assessing the competence of newly hired pharmacists specific to their roles. However, the orientation checklist lacked a tracking mechanism to ensure all relevant elements were addressed in the orientation and training process.[3]

In addition to the orientation process, the VHA directive and facility policy require documentation of annual staff competencies working in or overseeing the IV room. The OIG team confirmed that the required annual pharmacy staff IV compounding competencies were

[1] Aseptic technique is a method of preventing infection. A cache is a separate area outside of the pharmacy, where medications and supplies are stocked for use in the event of a mass casualty situation.

[2] IV admixtures are one type of compounded sterile preparation, often medications, administered to patients intravenously. The terms IV admixtures, IV preparations, and IV compounds are synonymous terms and used interchangeably throughout the report.

[3] VHA Directive 1108.06, *Inpatient Pharmacy Services,* February 8, 2017.

current. However, the OIG found that pharmacy managers lacked a tracking mechanism to maintain required annual pharmacist competencies.

The OIG team's review of pharmacy staff competency records also revealed that compounding pharmacy technicians, but not compounding pharmacists, had been tested in the written pharmaceutical calculations exam as required by facility policy. The Chief of Pharmacy confirmed that the intent of the policy was to ensure the compounding competency of pharmacy technicians but acknowledged that this was not specifically stated within the policy. As of January 6, 2020, all compounding pharmacists had passed the calculations exam.

Pharmacists access the cache during an emergency, such as a mass casualty. In preparation for this eventuality, pharmacists are trained and provided with written instructions on cache access during orientation and as part of annual competencies. The OIG team reviewed the staff pharmacist's annual competencies and found all pharmacists requiring cache access had received annual training.

The OIG did not substantiate a lack of pharmacist oversight of pharmacy technicians preparing IV admixtures. According to VHA policy, VA facilities are required to follow United States Pharmacopeia (USP) standards for compounding IV preparations.[4] The OIG team reviewed the method used by pharmacy technicians to prepare IV admixtures and by pharmacists to provide verification of the final IV admixture and found consistency with USP chapter <797>, VHA directives, and facility policy.

Pharmacy managers were generally compliant with the VHA controlled substance directive including the storage and maintenance of inventory records. As required by the VHA directive, the facility's controlled substances were stored in a vaulted area, which was closed and locked.[5] The OIG did not find evidence that staff were advised by pharmacy managers not to lock the cage or vault doors.

Pharmacy managers required staff to conduct an inventory of the controlled substances in the vault three times per week (more frequently than required by the VHA directive) and report any inventory discrepancies. The OIG team reviewed the reported inventory discrepancies from October 1, 2018, through September 30, 2019, and found that discrepancies were tracked to resolution and pharmacy managers cited the cause for each discrepancy.

Through interviews with pharmacy staff, the OIG learned of an August 29, 2018, incident, when pharmacy staff found three different controlled substance bottles containing half and quarter tablets while conducting an inventory count and noted the discrepancies. Staff explained to the

[4] VHA Directive 1108.12; VHA Directive 1108.06; The USP is a scientific organization that creates standards aimed at ensuring "the quality, safety, and benefit of medicines and foods."

[5] VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock),* November 16, 2010. This handbook was rescinded and replaced by Directive 1108.01 on May 1, 2019. VHA Directive 1108.01, *Controlled Substances Management,* May 1, 2019.

OIG team that the broken tablets registered as whole tablets in the automated pill counter, making the count appear to match the expected inventory. The number of broken tablets in several different bottles triggered the staff to report the incident to the Chief of Pharmacy. The OIG determined the Chief of Pharmacy took appropriate actions upon discovering the missing medications and reported the suspected diversion to facility leaders and VA police. The VA police notified the OIG. However, due to an oversight, facility leaders did not send a report of the incident to the Pharmacy Reporting Controlled Substance Diversion/Loss email group as required by the VHA directive that was in effect at the time of the incident. Failure of facilities to report possible prescription drug diversion does not allow VHA to ensure comprehensive oversight and controlled substance accountability.[6]

The OIG team learned of a single instance where a controlled substance, testosterone, was not added to inventory records or secured in the vault due to staff oversight over a long weekend. Although this appeared to be an isolated occurrence, the OIG found that further investigation was needed by facility leaders to determine the circumstances that resulted in the unsecured misplacement of testosterone for nine months.

The OIG made three recommendations to the Facility Director related to developing a process to document and track orientation, training, and annual competencies of pharmacy staff; ensuring facility leaders are trained on current VHA drug diversion and loss reporting requirements; and conducting a review of the circumstances that resulted in the misplacement of testosterone and developing an action plan to prevent a similar recurrence, if warranted.

Comments

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

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[6] VHA Directive 1108.01 dated November16, 2010, was in effect during the events of this inspection and stated diversion and loss incident reports must be emailed to the group, "VHAPBH Pharmacy Reporting CS Diversion/Loss." This directive was rescinded and replaced with the May 2019 VHA Directive 1108.01, which includes a different reporting requirement, stating diversion or loss reports must be entered into the VHA issue brief tracker system.

Contents

Abbreviations

EHR	electronic health record
IV	intravenous
OIG	Office of Inspector General
USP	United States Pharmacopeia
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to review allegations of inadequate orientation and training of pharmacy staff, a lack of pharmacist oversight of preparing intravenous (IV) admixtures, and noncompliance with controlled substance policies at the Louis A. Johnson VA Medical Center (facility) in Clarksburg, West Virginia.[1] This matter is not related to the recent criminal case involving a former nursing assistant at the facility.

Background

The facility is part of Veteran Integrated Service Network (VISN) 5 and served 22,113 patients between October 1, 2017, and September 30, 2018. The facility has 58 inpatient beds and 30 community living center beds. Designated as Mid-High Complexity Model Level 1c, the facility provides primary care, medical, surgical, mental health, and rehabilitation services, and has an on-site pharmacy.[2]

Pharmacy Service

The Pharmacy Service consists of two operational areas, inpatient and outpatient, with staff pharmacists and pharmacy technicians working in both areas.[3] Pharmacy Service staff are also responsible for the maintenance of the emergency cache, a separate area outside of the pharmacy, where medications and supplies are stocked for use in the event of a mass casualty situation.[4] The Pharmacy Service managers are the Chief of Pharmacy, Assistant Chief of Pharmacy, and Pharmacy Supervisor.

[1] The terms IV admixtures, IV preparations, and IV compounds are synonymous terms and used interchangeably throughout the report.

[2] The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered the most complex. Level 3 facilities are the least complex. VHA Office of Productivity, Efficiency and Staffing. (The website was accessed on September 24, 2019, and is an internal VA website not publicly accessible.)

[3] Pharmacy Procedural Manual 26, *Pharmacy Services Vision, Mission, Scope of Services and Values*, November 2017.

[4] VHA Directive 1047(1), *All-Hazards Emergency Caches,* December 30, 2014. This directive expired on December 31, 2019, and has not been replaced; Medical Center Memorandum No 119-28, *All-Hazards Emergency Cache,* August 2018.

Outpatient Pharmacy

The outpatient pharmacy includes a vault with two doors that lock for storing and distributing controlled substances. A vault pharmacist works with a pharmacy technician in the secured area to fill and verify controlled substance outpatient prescriptions and dispense controlled substances to inpatient units and clinics. The facility's outpatient pharmacy operates Monday–Friday between 8:00 a.m. and 5:30 p.m., excluding holidays.

Inpatient Pharmacy

The inpatient pharmacy includes a specialized area, the IV room, dedicated to the preparation of IV admixtures using aseptic technique.[5] Staff pharmacists and inpatient pharmacy technicians must complete training and annual competencies specific to compounding IV admixtures before working in the IV room. Pharmacists working in the inpatient pharmacy are responsible for verifying the accuracy of IV admixtures prepared by technicians. Prior to September 2019, the facility's inpatient pharmacy operated from 7:00 a.m. to 10:30 p.m.; since September 2019, the inpatient pharmacy operates 24-hours a day.

Prior OIG Report

One OIG report was published within the last three years with similar issues, the Comprehensive Healthcare Inspection Program Review of the Louis A. Johnson VA Medical Center, October 24, 2018.[6] The OIG recommended the Facility Director ensure that controlled substance inspectors perform reconciliation of controlled substance dispensing from the pharmacy to automated dispensing cabinets and those medications returned to pharmacy stock during monthly area inspections and monitor compliance. The VISN and Facility Directors agreed with the finding and recommendation and provided an acceptable plan for improvement. The recommendation was closed on June 27, 2019.

Allegations

On April 18, 2019, the OIG received the following allegations:

- Inadequate pharmacist training as evidenced by

[5] The IV room was not being used when the OIG team was on-site due to a construction project that included additional airflow environmental controls. The Chief of Pharmacy was awaiting certification of project completion and estimated the room would be operational early in February 2020. In the absence of an IV room, nurses were using premixed medications.

[6] VA Office of Inspector General, *Comprehensive Healthcare Inspection Program Review of the Louis A. Johnson VA Medical Center*, Clarksburg, WV, Report No. 18-01136-313, October 24, 2018.

  - Only two to three days of inpatient training and a 15-minute review of aseptic technique and IV admixture training is provided during the six-week orientation period, and
  - Emergency cache orientation is inadequate.[7]

- Lack of pharmacist oversight in IV admixture preparation:
  - Pharmacists are responsible for IV admixtures prepared by pharmacy technicians and asked to 'sign off' without being present in the IV room or visually supervising medication preparation.

On May 2, 2019, the OIG sent these allegations to the VISN for review and a response. The VISN Director's response, received by the OIG on July 23, 2019, did not substantiate the allegations. However, the response noted that the required annual compounding competencies of some pharmacy staff members had lapsed, and pharmacy managers were in the process of having staff complete these competencies.

On August 7, 2019, the OIG received a second complaint with the following allegations:

- Pharmacy management is noncompliant with Veterans Health Administration (VHA) controlled substance policies, including storage and maintenance of inventory records:
  - Pharmacy managers advise staff to shut the vault door so that it appears locked and not to use the combination lock, as policy requires.
  - Pharmacy managers advise pharmacy technicians to account for missing controlled substances as 'stock bottle shortages.'[8]
  - Inventory management and security of a controlled substance over a long weekend was inappropriate.

On September 24, 2019, the OIG opened a healthcare inspection to evaluate the allegations and follow up on the completion of the required annual IV compounding competencies as noted in the VISN Director's response.

[7] The words "training and orientation" were used interchangeably in the allegations and refer to the orientation received by newly hired pharmacists, which includes training for competency in pharmacy work areas. Annual assessments to demonstrate competency are required for pharmacists in specific work areas including IV training and aseptic technique. The words "cache" and "emergency cache" refer to the same location and are used interchangeably throughout the report.

[8] A stock bottle shortage occurs when there is an error by the manufacturer resulting in a shortage of pills per bottle.

Scope and Methodology

The OIG team initiated the inspection on September 24, 2019, and conducted a site visit November 18–22, 2019.

The OIG team interviewed facility leaders, the Chief of Pharmacy, the Assistant Chief of Pharmacy, the Pharmacy Supervisor, the Controlled Substances Coordinator, the Chief of Police, and inpatient and outpatient staff pharmacists and pharmacy technicians.

The OIG team reviewed applicable VHA directives and handbooks; facility policies and procedures; pharmacist and pharmacy technician competency records; controlled substances inspection reports, inventory sheets, discrepancy reports from October 1, 2018, through September 30, 2019; and the vault lock and access log. The OIG team reviewed records of controlled substances ordered and received October 1–5, 2018.

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

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, 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 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

1. Pharmacy Staff Orientation and Training, and Annual Competencies

The OIG did not substantiate that pharmacist training was inadequate; that pharmacists received only two to three days of inpatient training, a 15-minute review of aseptic technique, and IV admixture training during the six-week training period; and that cache orientation was inadequate. The OIG determined that pharmacy managers tailored the time spent on orientation and training to the newly hired pharmacist, depending on background and experience, to ensure each pharmacist was adequately trained, including inpatient pharmacy, IV admixture and aseptic technique, and cache training. Pharmacy managers developed an orientation checklist to identify elements for training and assessing the competence of newly hired pharmacists on skills specific to their roles. However, the orientation checklist lacked a tracking mechanism to ensure all relevant elements were addressed in the orientation and training process. The OIG found that in response to the VISN's identification of lapsed pharmacist competencies, facility leaders acted and brought all pharmacists' annual competencies up to date. However, the OIG team found that pharmacy managers lacked a mechanism to track completion of required staff annual competencies.

Orientation and Training

According to the VHA directive, the Chief of Pharmacy is responsible for ensuring that a process is in place to document orientation and training for competency of newly hired pharmacists; however, the directive lacks specific guidance for how the Chief of Pharmacy should conduct this orientation.[9] The facility's Chief of Pharmacy implemented an orientation checklist to identify required elements of pharmacists' orientation and training, which included the inpatient pharmacy area, IV admixture and aseptic technique, and access to the cache.

Since 2015, newly hired pharmacists have received six to eight weeks of service-specific orientation and training in the Pharmacy Service areas. During the orientation and training process, new pharmacists shadowed experienced pharmacists and rotated through the inpatient and outpatient pharmacy work areas. The focus and time frame of orientation and training was tailored to the needs of each pharmacist, taking previous work experience into account. One pharmacist may have oriented and trained for a few days in one area while another pharmacist may have needed to spend much longer in the same area. For example, a pharmacist whose recent work included IV admixtures may have only needed two to three days to review compounding and aseptic technique, while another who had not recently prepared IV admixtures, may have needed additional time.

[9] VHA Directive 1108.06, *Inpatient Pharmacy Services,* February 8, 2017.

In interviews with the OIG team, staff pharmacists reported that the orientation and training provided throughout their orientation period, coupled with their formal pharmacy education and prior relevant job experience, was adequate to prepare them to perform their job in all areas of the pharmacy. Additionally, staff pharmacists reported that if they encountered an unfamiliar situation or task that they did not feel adequately prepared to perform, other pharmacists willingly assisted, and pharmacy managers also provided an extension in their orientation and training in that area. The Chief of Pharmacy also reported that pharmacy managers did not require pharmacists to independently oversee or work in areas of the pharmacy until pharmacists were fully oriented, trained, and comfortable to work in that area.

Pharmacy staff oriented more than a year prior to this inspection reported that the process did not include use of a checklist. The Chief of Pharmacy told the OIG that an orientation checklist is now in place for use with all new hires. The OIG team reviewed the orientation checklist and found that while thorough it lacks a mechanism for tracking completion of each element covered in the orientation process.

Annual Competencies

In addition to the orientation and training process described above, the VHA directive and facility policy require pharmacy staff working in or overseeing the IV room to maintain annual competencies in IV admixture compounding and aseptic technique, which includes a written calculations exam. Accessing the cache is also reviewed as part of pharmacists' annual competencies.

VISN Response

The VISN Director's response to the OIG noted that some pharmacists' annual compounding competencies had lapsed, and reported that pharmacy managers planned to track the completion of annual competencies through resolution. The OIG team confirmed that the required annual pharmacy staff compounding competencies were current. However, the OIG found that pharmacy managers lacked a tracking mechanism to ensure the required pharmacist annual competencies were completed.

Additional Finding: Annual Compounding Competency

The OIG team's review of pharmacy staff's annual competency records revealed that compounding pharmacy technicians had passed the required calculations exam; however, compounding pharmacists had not been tested. The Chief of Pharmacy confirmed that the intent of the facility policy was to ensure the compounding competency of pharmacy technicians, but acknowledged that this was not specifically stated within the policy. On December 26, 2019, the Chief of Pharmacy required all compounding pharmacists to pass the calculations exam. As of January 6, 2020, all compounding pharmacists had passed the calculations exam.

Cache

Pharmacists access the cache during an emergency, such as a mass casualty. In preparation for this eventuality, pharmacists are trained and provided with written instructions on cache access during orientation and training, and annually. While on-site, the OIG team visited the cache and observed the process to access this area. On November 6, 2019, the OIG team reviewed the staff pharmacist's annual competencies and all pharmacists requiring cache access had received annual training.

Summary

The OIG determined that pharmacy staff received adequate orientation and training in inpatient pharmacy, aseptic technique and IV admixture, and in accessing the cache. However, the orientation checklist lacked a tracking mechanism to ensure all relevant elements were addressed in the orientation and training process. As a follow up to the VISN Director's response, the OIG confirmed that the annual compounding competencies were current. The OIG found that compounding pharmacists had not been required to pass the calculations exams portion of the annual compounding competency. As of January 6, 2020, all compounding pharmacists had passed the calculations exam. All pharmacists requiring cache access received annual training. Although the annual competencies were up to date, pharmacy managers did not have a tracking mechanism for required annual competencies. Pharmacy managers stated to the OIG team that they were developing new orientation and training, and annual competency processes, which would address the lack of tracking mechanisms.

2. Pharmacist Oversight of IV Admixture Preparation

The OIG did not substantiate a lack of pharmacist oversight in IV admixture preparation. Although pharmacists are not present in the IV room or visually supervising pharmacy technicians preparing the IV admixtures, pharmacists were not asked to "sign off" without proper oversight. The OIG determined that staff pharmacists followed VHA and facility policies when verifying the accuracy of IV admixtures prepared by pharmacy technicians. Additionally, in interviews with the OIG team, staff pharmacists reported confidence that the process they used was an effective method of verification.[10]

According to VHA directives, VA facilities are required to follow United States Pharmacopeia (USP) standards for compounding sterile preparations.[11] USP chapter <797> describes the

[10] Pharmacy Procedure Manual-62, *Compounding Sterile Preparations*, December 2018; VHA Directive 1108.12, *Management and Monitoring of Pharmaceutical Compounded Sterile Preparations*, November 5, 2018; Pharmacopeia Revision Bulletin 797, *(797) Pharmaceutical Compounding – Sterile Preparations*, 2008.

[11] VHA Directive 1108.12; VHA Directive 1108.06.

procedures, environmental requirements, personnel training, and evaluation for compounding sterile preparations, including IV admixtures.[12] The process for the oversight of IV admixture preparations outlined in the facility policy is in accordance with USP chapter <797>.[13]

In interviews with pharmacy staff, the OIG team learned of the process used by pharmacy technicians and pharmacists to prepare and verify IV admixtures. This process was in alignment with the facility policy.[14] While working in the IV room, pharmacy technicians prepared and labeled each IV admixture and placed it on a tray with the medications and syringes used for the preparation. The syringes, pulled back to the syringe barrel line, designated the amount of medication added.[15] The tray was then handed via a "pass through" window to the pharmacist responsible for providing the oversight and verification of the IV admixture accuracy. The pharmacist checked the IV admixture for particulate matter in the solution, reviewed the label, and compared it to the medications on the tray to confirm the accuracy of the medications and dosages used.[16] If the pharmacist detected a possible error, the IV admixture was discarded and a new preparation was made. In interviews with the OIG team, staff pharmacists reported confidence that the process they used was an effective method of verification.

Summary

The OIG team reviewed the method used by pharmacy technicians to prepare IV admixtures and by pharmacists to provide verification of the final IV admixture and found consistency with USP chapter <797>, VHA directives, and facility policy.

3. Controlled Substances Storage and Inventory Records

The OIG substantiated that pharmacy managers were generally compliant with the VHA controlled substance directive including the storage and maintenance of inventory records. The OIG team learned of a single instance where a controlled substance was improperly stored and of an inappropriate inventory record maintenance. The OIG team did not find evidence that staff were advised by pharmacy managers to not lock the cage or vault doors, or to attribute missing controlled substances as stock bottle shortages. While on-site, the OIG team learned of a controlled substance diversion that facility leaders properly investigated but did not fully report to VHA as required by policy.

[12] Pharmacopeia Revision Bulletin 797.
[13] Pharmacy Procedure Manual-62.
[14] Pharmacy Procedure Manual-62.
[15] Pharmacy Procedure Manual-62.
[16] Pharmacy Procedure Manual-62.

Storage

The VHA directive stipulates that bulk inventory of controlled substances must be stored in the pharmacy vault.[17] Cameras capturing vault access provide additional security and are highly recommended by the VHA directive.[18]

The OIG team observed that the pharmacy vault had two access doors; an outer door like a bank vault, and a secondary inner door referred to as the "the cage" (see figure 1). The heavy metal outer vault door had a dial combination lock and access could not be tracked. The secondary cage door prevented unauthorized staff entry while allowing for ventilation, and observation and communication with other staff outside the vault. Entry through the cage door required a two-step process. To enter, an individual scanned their personal identification verification badge and entered a personal identification number code into an electronic keypad.

The OIG team noted one camera located inside the vault, one outside the vault pointing toward the entrance, and another one outside of the vault pointing toward the dispensing window of the outpatient pharmacy. The VA police had access to the electronic record providing the names and times individuals entered the vault through the cage as well as video recordings captured by the cameras.

Pharmacy managers reported that cage access was limited to the two staff assigned to work in the vault each weekday—the vault technician and the staff pharmacist; and to the pharmacists working the weekend and night shifts. Staff reported that the cage was usually secure with the cage door closed. When the cage door was open, the vault was visually observed by assigned vault staff working adjacent to the door. Prior to becoming a 24-hour operational pharmacy, pharmacy staff reported that the vault and cage doors were closed and locked when the last pharmacist left for the day.[19] None of the pharmacy staff interviewed by the OIG team reported that pharmacy managers advised them to leave the vault door(s) unlocked.

[17] VHA Directive 1108.01, *Controlled Substances Management,* May 1, 2019. VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock),* November 16, 2010. This handbook was rescinded and replaced by Directive 1108.01 on May 1, 2019.

[18] VHA Directive 1108.01.

[19] Memorandum No. 119-16, S*ecurity of Pharmacy,* January 2018. The vault door had not been routinely closed and locked since the pharmacy converted to 24-hour operation in September 2019. With a pharmacist on duty 24/7, the vault door remains open and unlocked and the cage door is closed with limited access.

Figure 1: Pharmacy vault doors, an outer heavy metal and inner cage doors.
Source: VA OIG team photograph

Inventory

Inventory refers to the process of conducting and documenting a physical count of the pharmacy supply of controlled substances.[20] Until May 1, 2019, the VHA directive required staff to complete an inventory of the vault contents a minimum of three times a week.[21] The updated directive published on May 1, 2019, decreased the frequency of the inventory requirement to twice-weekly.[22] The Chief of Pharmacy stated that pharmacy staff have continued to complete inventory three times a week, more frequently than required, because they do not have sufficient weekend staff to complete the inventory should a required twice-weekly inventory day fall on the weekend. Pharmacy leaders maintained inventory records to track the controlled substances received from the manufacturer, and identify and resolve inventory discrepancies in order to account for each dosage unit of controlled substance stored in the pharmacy.

Discrepancies and Resolutions

Facility staff reported that inventory discrepancies could occur for several reasons including manufacturer-supplied stock bottles containing over or under the designated amount; a pill inadvertently dropping to the floor when opening bottles and filling prescriptions; or a human error in recording and electronically accounting for dispensed medications.

The OIG team reviewed inventory discrepancies and resolutions from October 1, 2018, through September 30, 2019, and found that discrepancies were not solely or inappropriately reported as stock bottle shortages and were investigated to resolution. The OIG determined that during the

[20] VHA Directive 1108.01.
[21] VHA Handbook 1108.01.
[22] VHA Directive 1108.01; Memorandum No. 119-30, *Controlled Substances Procedures,* March 2015.

one-year inventory review period, 36 of the 63 reported discrepancies were due to controlled substance shortages and the remaining 27 were due to controlled substance overages. In reviewing the 36 cases, four were attributed to stock bottle shortages. In interviews with the OIG team, pharmacy staff denied being advised to account for missing controlled substances as "stock bottle shortages." Rather, the OIG found that discrepancies were attributed to a variety of causes including internal transfers of medications to automated dispensing machines, delays in recording of dispensed medications, and human errors in inventory counts.

Through interviews with pharmacy staff, the OIG learned of an August 29, 2018, incident, when pharmacy staff found three different controlled substance bottles containing half and quarter tablets while conducting their inventory count, and noted the discrepancies. Staff explained to the OIG team that the broken tablets registered as whole tablets in the automated pill counter, making the count appear to match the expected inventory. The number of broken tablets in several different bottles triggered staff to report the incident to the Chief of Pharmacy, who then ordered the vault be closed, and the vault technician and pharmacist to complete a hand count of the inventory. Facility leaders and police were notified, and access records and security camera videos reviewed. The OIG determined the Chief of Pharmacy took appropriate actions upon discovering the missing medications and reported the suspected diversion to facility leaders and VA police. The VA police notified the OIG. However, facility leaders did not send a report of the incident to the Pharmacy Reporting Controlled Substance Diversion/Loss email group as required by the VHA directive that was in effect at the time of the incident. Failure by facilities to report possible controlled substance diversion does not allow VHA to ensure comprehensive oversight and accountability.[23]

Tracking of a Controlled Substance

In order to minimize diversion, VHA requires controlled substances delivered to the pharmacy to be entered into an electronic inventory tracking system and stored in the controlled substance vault.[24] When medication is unused or expired, pharmacy staff arrange for the medication to be returned to the manufacturer for destruction.[25]

During interviews, the OIG team was informed of one instance of a controlled substance, testosterone, that was ordered in error, and received at the pharmacy over a long weekend. Due to staff oversight, the testosterone was not added to the facility controlled substance inventory or

[23] VHA Directive 1108.01. VHA Directive 1108.01 dated November16, 2010, was in effect during the events of this inspection and stated diversion/loss incidents reports must be emailed to the group, "VHAPBH Pharmacy Reporting CS Diversion/Loss." This rescinded directive was replaced with the May 2019, VHA Directive 1108.01 which includes a different diversion/loss reporting requirement, stating diversions/loss incidents must be reported into the VHA Issue Brief tracker.

[24] VHA Directive 1108.01; MCM 119-30.

[25] MCM 119-30.

stored in the vault as required. Documentation showed that the incorrect dosage of testosterone was received in October 2018, and went undiscovered until April 2019, when it was found in the inpatient pharmacy, outside of the vault. The item was returned to the manufacturer for destruction in July 2019. Staff reported that the occurrence of incorrectly ordered controlled substances was rare.

Summary

The OIG determined that pharmacy managers stored controlled substances in accordance with the VHA directive, and controlled substance inventories were performed more frequently than required. Additionally, pharmacy managers appropriately resolved inventory discrepancies and cited the cause of specific discrepancies. The OIG learned of an incident of missing medications involving three pill bottles in the pharmacy. The Chief of Pharmacy reported the unaccounted-for medications to VA police and facility leaders. VA police notified the OIG. However, facility leaders did not forward a report of the incident to the Pharmacy Reporting Controlled Substance Diversion/Loss email group as required by the VHA directive that was in effect at the time of the incident. Although the issue regarding the testosterone appeared to be an isolated occurrence, the OIG found that further investigation is needed by facility leaders to determine the circumstances that resulted in the unsecured misplacement of testosterone for nine months to prevent a similar recurrence in the future.

Conclusion

The OIG did not substantiate that newly hired pharmacist orientation and training for inpatient pharmacy, aseptic technique and IV admixture, and the cache was inadequate. The OIG determined that pharmacy managers tailored the time spent on orientation and training to the individual pharmacist, depending on background and experience, to ensure each pharmacist was adequately trained to perform the job, including inpatient pharmacy, aseptic technique and IV admixture, and cache training. The Chief of Pharmacy told the OIG that an orientation checklist template was in place for future hires. The OIG team reviewed that orientation checklist and found that while the checklist was thorough and included specific elements for review, it lacked a mechanism for tracking the completion of relevant elements. The OIG team followed up with the VISN Director's response and confirmed that the annual required pharmacy staff competencies were current. However, the OIG team found that pharmacy managers lacked a tracking mechanism to maintain required annual competencies. The OIG team review of pharmacy staff competency records revealed that compounding pharmacy technicians but not compounding pharmacists had been tested in the written calculations exam as required by facility policy. As of January 6, 2020, all compounding pharmacists had passed the calculations exam. As of November 6, 2019, the staff pharmacist's annual competencies indicated all pharmacists requiring cache access received annual training.

The OIG did not substantiate a lack of pharmacist oversight in IV admixtures prepared by pharmacy technicians. The OIG team reviewed the method used by pharmacy technicians to prepare IV admixtures and by pharmacists to provide verification of the final IV admixture and found consistency with USP chapter <797>, VHA directives, and facility policy. Additionally, in interviews with the OIG team, staff pharmacists reported confidence that the process they used was an effective method of verification.

The OIG substantiated that pharmacy managers were generally compliant with the VHA controlled substance directive including the storage and maintenance of inventory records. The OIG did not find evidence that staff were advised by pharmacy managers to not lock the cage or vault doors, or attribute missing controlled substances as stock bottle shortages. The OIG determined that pharmacy managers generally stored controlled substances in accordance with the VHA directive; and controlled substance inventories were performed more frequently than required. Pharmacy managers also appropriately resolved inventory discrepancies and cited the cause of specific discrepancies. The OIG determined the Chief of Pharmacy took appropriate actions upon discovering the unaccounted-for medications and reported the suspected diversion to facility leaders and VA police. The VA police notified the OIG. However, facility leaders did not send a report of the incident to the Pharmacy Reporting Controlled Substance Diversion/Loss email group as required by the VHA directive that was in effect at the time of the incident. Failure to report does not allow comprehensive oversight and controlled substance accountability. Although the issue regarding the testosterone appeared to be an isolated occurrence, the OIG found that further investigation is needed by facility leaders to determine the circumstances that resulted in the misplacement of testosterone.

Recommendations 1–3

1. The Louis A. Johnson VA Medical Center Director ensures implementation of a process to document and track orientation, competency assessment, and annual competencies of pharmacy staff, and monitors compliance.

2. The Louis A. Johnson VA Medical Center Director ensures facility leaders are trained in the process of reporting any and all future diversions and loss incidents according to requirements outlined in VHA Directive 1108.01, Controlled Substance Management, May 1, 2019.

3. The Louis A. Johnson VA Medical Center Director conducts a review of the circumstances that resulted in the misplacement of testosterone and develops an action plan to prevent a similar recurrence, if warranted.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: June 26, 2020

From: Director, VA Capitol Health Care Network (10N05)

Subj: Healthcare Inspection—Alleged Deficiencies in Pharmacy Service Procedures at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia

To: Director, Office of Healthcare Inspections (54HL05)
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. I have reviewed and concur with the findings and recommendations in the Office of Inspector General's (OIG's) draft report entitled—Alleged Deficiencies in Pharmacy Service Procedures at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia.
2. I have reviewed the attached comments provided by the Medical Center Director, Louis A. Johnson VA Medical Center, and concur with the responses and actions to the three (3) facility recommendations.
3. Should you require any additional information please contact VISN 5 network office at 410-691-1321.

(*Original signed by*:)

Robert M. Walton, FACHE

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: June 16, 2020

From: Director, Louis A. Johnson VA Medical Center (540/00)

Subj: Healthcare Inspection—Alleged Deficiencies in Pharmacy Service Procedures at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia

To: Director, VA Capitol Health Care Network (10N05)

1. I have reviewed the report titled Alleged Deficiencies in Pharmacy Service Procedures at the Louis A. Johnson VA Medical Center in Clarksburg, West Virginia.
2. Actions are underway to implement each of the three recommendations outlined within the report.
3. The courteous and professional manner that was displayed by the OIG during this visit was appreciated.

(*Original signed by*:)

Glenn R. Snider, Jr., MD, FACP
Medical Center Director

Facility Director Response

Recommendation 1

The Louis A. Johnson VA Medical Center Director ensures implementation of a process to document and track orientation, competency assessment, and annual competencies of pharmacy staff, and monitors compliance.

Concur. The Medical Center Director concurs with this recommendation.

Target date for completion: June 15, 2020

Director Comments

In response to this recommendation the pharmacy service has implemented tracking documents to record the review date for all pharmacy employee orientation documents and competency assessments. The tracking documents are reviewed by pharmacy administration every 6 months to ensure compliance.

OIG Comments

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

Recommendation 2

The Louis A. Johnson VA Medical Center Director ensures facility leaders are trained in the process of reporting any and all future diversions and loss incidents according to requirements outlined in VHA Directive 1108.01, Controlled Substance Management, May 1, 2019.

Concur. The Medical Center Director concurs with this recommendation.

Target date for completion: June 23, 2020

Director Comments

In response to this recommendation the Louis A. Johnson VA Medical Center Executive Leadership Team, Chief of Pharmacy Service, and Chief of Police Service will review VHA Directive 1108.01 and confirm understanding, with specific attention to Appendix B of VHA Directive 1108.01.

OIG Comments

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

Recommendation 3

The Louis A. Johnson VA Medical Center Director conducts a review of the circumstances that resulted in the misplacement of testosterone and develops an action plan to prevent a similar recurrence, if warranted.

Concur. The Medical Center Director concurs with this recommendation.

Target date for completion: June 23, 2020

Director Comments

In response to this recommendation pharmacy service has implemented the following process for handling controlled substance (CS) items procured in error and documented in Pharmacy Policy and Procedure Manual (PPM) 19:

a. Controlled Substance items procured in error must be kept in the Outpatient Vault until item is picked up by vendor for return.
b. All return documents will be kept with the container storing the controlled substance item pending return, and the item will be inventoried as part of the pharmacy stock inventory counts completed by controlled substance technician or Clinical Staff Pharmacist.
c. The item waiting for return will not be listed on the Veterans Health Information System Technology Architecture (VistA) generated inventory sheet, so the item description and quantity will need to be handwritten on the inventory sheet.

OIG Comments

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

Glossary

aseptic technique. A method of preventing infection.[26]

automated dispensing cabinet. An electronic drug storage cabinet that tracks the addition and removal of individual medications via computer. There are several products from different manufacturers, but the facility uses the Pyxis™ cabinet.[27]

compounding. To form by combining, such as compounding a medicine.[28]

compounding sterile preparations. The process of creating a sterile preparation "by combining, diluting, pooling, or otherwise altering a drug product or bulk drug substance."[29]

controlled substances. A substance (as a drug) whose use and possession is regulated by law (as title 21, chapter 13 of the U.S. Code).[30]

hand count. Hand count is accomplished by placing the pills on a tray and using a pharmacy spatula to physically move the pills as they are counted, so the pharmacy staff do not touch the pills.

intravenous. Situated, performed, or occurring within or entering by way of a vein.[31]

IV admixtures. One type of compounded **s**terile preparation, often medications, administered to patients intravenously.[32]

IV room. The IV room contains environmental controls that minimize the concentration of airborne microorganisms by maintaining air pressure that flows from clean to dirty areas.[33]

pass through. This "window" is an environmental control which is located between the buffer room and the ante room. It has doors with windows on both sides and space between where the trays with the IV admixtures and their components are placed for pharmacist verification. Each door is latched close when not in use. To use, the technician opens the door on the side used for

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[26] Merriam-Webster Dictionary*, Definition of aseptic technique*, https://www.merriam-webster.com/dictionary/aseptic. (The website was accessed on January 24, 2020.)

[27] Directive 1108.01, Controlled Substances Management, May 1, 2019.

[28] Merriam-Webster Dictionary, *Definition of compounding*, https://www.merriam-webster.com/dictionary/compounding. (The website was accessed on January 30, 2020.)

[29] VHA Directive 1108.12, *Management and Monitoring of Pharmaceutical Compounded Sterile Preparations*, November 5, 2018.

[30] Merriam-Webster Dictionary, *Definition of controlled substance,* https://www.merriam-webster.com/dictionary/controlled substance. (The website was accessed on February 19, 2020.)

[31] Merriam-Webster Dictionary, *Definition of Intravenous, https://www.merriam-webster.com/dictionary/intravenous*. (The website was accessed on December 18, 2019.)

[32] United States Pharmacopeial Convention, (797) Pharmaceutical Compounding – Sterile Preparations, 2008.

[33] Directive 1108.12.

compounding, places the tray with the admixture and components inside, then closes the door. The pharmacist then opens the door on the ante room side, remove the tray and closes the door. This procedure reduces the risk of particulates passing into the sterile IV room from the ante room.

syringe. A syringe is an instrument consisting of a hollow barrel with a plunger and hollow needle, used to withdraw fluids from, or inject them into something; Syringe barrels are calibrated with lines to measure the amount of liquid withdrawn and/or injected.[34]

United States Pharmacopeia. The United States Pharmacopeia is a scientific organization that creates standards aimed at ensuring "the quality, safety, and benefit of medicines and foods."

[34] Merriam-Webster Dictionary, *Definition of syringe*, https://www.merriam-webster.com/dictionary/syringe. (The website was accessed on January 24, 2020.)

OIG Contact and Staff Acknowledgments

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