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Report to the Subcommittee on
Oversight and Investigations,
Committee on Veterans' Affairs, House
of Representatives

September 2018

VA HEALTH CARE

Pharmacy Inventory Management Could Benefit from System- Wide Oversight

GAO Highlights

Highlights of [GAO-18-658](#), a report to the Subcommittee on Oversight and Investigations, Committee on Veterans' Affairs, House of Representatives

Why GAO Did This Study

VA provides health care services, including pharmacy services, to approximately 9 million veterans each year. Since 2000, VAMCs have faced recurring challenges in managing their pharmacy inventories, including difficulties with accurately accounting for and updating inventory totals through their pharmacy systems.

GAO was asked to review VA pharmacy inventory management. This report (1) describes approaches selected VAMCs use to manage their pharmacy inventories and (2) assesses the extent to which VA oversees VAMCs' efforts to manage their pharmacy inventories.

To conduct this work, GAO visited a non-generalizable selection of five VAMCs chosen for the complexity of services offered and variation in location. GAO also reviewed VA national policies and local policies for the selected VAMCs and interviewed VA officials at the headquarters, regional, and local levels. GAO assessed VA's oversight of pharmacy management in the context of federal internal control standards.

What GAO Recommends

GAO recommends that VA designate a focal point for overseeing VAMCs' pharmacy inventory management efforts system-wide and define the focal point's responsibilities. VA concurred in principle with the recommendation.

View [GAO-18-658](#). For more information, contact Sharon Silas at (202) 512-7114 or silass@gao.gov.

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VA HEALTH CARE

Pharmacy Inventory Management Could Benefit from System-Wide Oversight

What GAO Found

Selected Department of Veterans Affairs' (VA) medical centers (VAMC) use generally similar approaches for managing their pharmacy inventories. For example, all VAMCs store certain medications in secured areas. However, GAO found that VAMCs have also taken unique approaches for procuring and tracking medications, as allowed under VA policy. For example, to better address medication shortages, one VAMC pharmacy GAO visited established a shortage committee that meets on a weekly basis. Another VAMC pharmacy uses an automated dispensing machine together with compatible software that allows the pharmacy to track the location of most inpatient medications in real-time (see figure).

Automated Dispensing Machine at a Veterans Affairs Medical Center



Source: Department of Veterans Affairs. | GAO-18-658

GAO also found that VA's oversight of VAMCs' pharmacy inventory management is limited as VA lacks a comprehensive inventory management system or a focal point for system-wide oversight. In May 2018, VA signed a contract for a new electronic health records system that should allow VA to monitor VAMCs' inventories; however, VA officials expect implementation of this system to take up to 10 years. Based on a review of VA policies and interviews with VA officials, GAO found that VA has not designated a focal point with defined responsibilities for system-wide oversight of VAMCs' pharmacy inventory management. This is inconsistent with federal internal control standards for monitoring and establishing structure and authority to achieve an entity's objectives. Without a focal point for system-wide oversight, VA has limited awareness of the unique approaches that VAMCs use to manage their inventories and is missing an opportunity to evaluate these approaches. Additionally, VA cannot effectively share and standardize inventory management best practices as appropriate. Having a focal point is especially important given that VAMCs have historically had challenges in managing their inventories and a comprehensive pharmacy inventory management system may not be available for the foreseeable future.

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Abbreviations

GS	general schedule
IT	information technology
NAC	National Acquisition Center
OIT	Office of Information and Technology
PBM	Pharmacy Benefits Management Service
VA	Department of Veterans Affairs
VACO	VA Central Office
VAMC	VA Medical Center
VA OIG	VA Office of Inspector General
VISN	Veterans Integrated Service Network
VistA	Veterans Health Information Systems and Technology Architecture
VPE	VISN Pharmacy Executive

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September 27, 2018

The Honorable Jack Bergman
Chairman
The Honorable Ann Kuster
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Veterans' Affairs
House of Representatives

The Department of Veterans Affairs (VA) provides health care services, including pharmacy services, to approximately 9 million veterans each year.¹ Veterans can receive a range of services at the approximately 170 VA medical centers (VAMC) throughout the nation, including traditional hospital-based services such as surgery, critical care, and mental health care. As a significant part of delivering health care to veterans, VAMCs also provide medications, prescription refills, and other pharmacy services.² These VAMCs are generally responsible for managing their own pharmacy inventories—that is, for procuring, storing, tracking, and dispensing medications to veterans.

Managing pharmacy inventories effectively to provide pharmacy services to veterans can be challenging. In 2000, a VA Office of Inspector General (OIG) audit found that VAMC pharmacies carried excess inventory due to a reliance on informal inventory methods and identified the need for VAMCs to use modern inventory techniques and automated pharmacy inventory management systems.³ Subsequent OIG and GAO reports have identified some of the technological challenges VA faces in overseeing its VAMC pharmacies. For example, a 2009 VA OIG report found that VA could not accurately account for the medications at VAMC

¹The VA administers its health care services through the Veterans Health Administration.

²Veterans may also receive prescribed medications through VA's mail delivery service provided by seven consolidated outpatient mail pharmacy facilities or, when needed, by mail from VAMC pharmacies.

³Department of Veterans Affairs, Office of Inspector General, *Audit of VA Medical Center Management of Pharmaceutical Inventories*, 99-00186-86 (Washington, D.C.: June 30, 2000).

pharmacies because VA lacked reliable information to do so.⁴ Similarly, in 2017 we reported that VA does not have the systems that would allow it to keep a perpetual inventory and monitor VAMC pharmacy inventory levels in real time.⁵ These reports have raised broader concerns about how VA oversees its VAMCs' pharmacies.

You asked us to review the management and oversight of VAMC pharmacy inventories. In this report, we

- describe how selected VAMCs manage their pharmacy inventories; and
- assess the extent to which VA oversees VAMCs' efforts to manage their pharmacy inventories.

To describe how selected VAMCs manage their pharmacy inventories, we identified their approaches for procuring, storing, tracking, dispensing, and disposing of medications, the main process that all pharmacies generally use to manage their pharmacy inventories. Our review focused on pharmacy inventory of all medications—including controlled and non-controlled substances—dispensed within the VAMCs' inpatient wards or at their outpatient pharmacies.⁶ Our review focused on VAMCs' management of their inpatient and outpatient pharmacy inventories; as such we did not review pharmacy inventory management at the

⁴Department of Veterans Affairs, Office of Inspector General, *Audit of Veterans Health Administration's Management of Non-Controlled Drugs*, 08-01322-114 (Washington, D.C.: June 23, 2009).

⁵GAO, *VA Information Technology: Pharmacy System Needs Additional Capabilities for Viewing, Exchanging, and Using Data to Better Serve Veterans*, [GAO-17-179](#) (Washington, D.C.: June 14, 2017).

⁶According to the Controlled Substances Act, as amended, the term "controlled substance" means "a drug or other substance, or immediate precursor, included in [one of five classification schedules]." A controlled substance is placed in a respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence. Examples of controlled substances include pain relievers, such as Percocet or OxyContin, as well as tranquilizers, stimulants, and sedatives available only by prescription. Pub. L. No. 91-513, §§ 102, 201-02, 84 Stat. 1236, 1243, 1245-52 (1970) (codified as amended at 21 U.S.C. §§ 802, 811-812); 21 C.F.R. Parts 1300 and 1308 (2018).

consolidated mail outpatient pharmacies.⁷ We conducted site visits at a non-generalizable sample of five VAMCs that we selected based on diversity in geographic regions, differences in facility complexity, and variation in pharmacy operations efficiency determined by comparing expected and observed pharmacy expenditures by VAMC for fiscal year 2016.⁸ Although VA officials identified limitations in the pharmacy expenditures data, we found that the data were sufficiently reliable to use as one criterion for selecting VAMCs to visit.⁹ The five VAMCs we visited are located in Cheyenne, Wyoming; Danville, Illinois; Philadelphia, Pennsylvania; Richmond, Virginia; and San Francisco, California. At each of these five VAMCs, we toured inpatient and outpatient pharmacy operations and conducted semi-structured interviews with VAMC officials and staff responsible for managing pharmacy inventory—including VAMC Executives, the Chief and Associate Chief of Pharmacy Services, pharmacy staff, and nursing staff. We also observed the information technology (IT) systems and automated medication dispensing machines and software that each VAMC uses to manage pharmacy inventory. In addition, we reviewed relevant national VA and local VAMC policies and guidance for managing pharmacy inventory.

To examine the extent to which VA oversees VAMCs' efforts to manage their pharmacy inventories, we assessed the extent to which VA Central Office (VACO) and the Veterans Integrated Service Networks (VISN) oversee the five selected VAMCs' management of pharmacy inventory. The VISNs report to VACO and are responsible for managing and overseeing VAMCs within their geographic area. To conduct our work, we

⁷According to the Veterans Health Administration, outpatient prescribing is performed most predominantly, with the consolidated mail outpatient pharmacies providing approximately 80 percent of all outpatient prescriptions to veterans. For fiscal year 2016, the Veterans Health Administration reported that it provided outpatient pharmacy services to approximately 5 million veterans. The agency further reported that about 31 million outpatient prescriptions were filled at VAMC and outpatient clinic pharmacies, and about 116 million prescriptions were filled by consolidated mail outpatient pharmacies.

⁸VA assigns each VAMC a complexity score based upon patient population served, clinical services offered, education and research complexity, and administrative complexity. Specifically, each VAMC is assigned a score between 1 and 3 (level 1 is broken down further into 1a, 1b, and 1c), with level 1 being the most complex, using a facility complexity model.

⁹This expenditure data is a compilation of statistical models and measures designed to help VAMCs monitor pharmacy expenditures and identify areas for improvement. However, according to VA officials, one flaw of the data is that they make assumptions that are not fully representative of the patient population.

reviewed VA policies, procedures, and guidance pertaining to the management and oversight of pharmacy inventory to determine the extent of VACO's and the VISNs' oversight responsibilities. This included a review of meeting minutes from regularly scheduled calls between VACO and VISN officials. We also interviewed VACO officials from the Pharmacy Benefits Management Service (PBM), the National Acquisition Center (NAC), and the Office of Information and Technology (OIT) to determine their roles in overseeing VAMC pharmacy inventory. In addition, we interviewed the five VISN Pharmacy Executives (VPE) responsible for assisting the selected VAMCs with pharmacy-related tasks. We examined VA's oversight in the context of federal standards for internal controls related to establishing structure and authority to achieve the entity's objectives and internal controls related to monitoring.¹⁰ To better understand other integrated health systems' best practices for managing pharmacy inventory, we also interviewed representatives from the American Society of Health-System Pharmacists, the Mayo Clinic, and the Cleveland Clinic. We also reviewed our previous work and the VA OIG's work that is related to VAMC's pharmacy inventory management.

We conducted this performance audit from September 2017 to September 2018 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

General Process for Managing Pharmacy Inventories in Hospital Settings

In general, the process for managing inventories of medications at VAMCs and non-VA pharmacies in hospital settings is similar. The steps of the process are (1) procuring medications from vendors or other suppliers, (2) receiving and storing medications, (3) tracking medications to account for all items and prevent diversion, (4) dispensing medications to patients, and (5) disposing of expired or wasted medications. Hospital settings include both inpatient and outpatient pharmacies.

¹⁰GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

Procurement. Pharmacies use a procurement process to order medications for pharmacy inventory, which includes activities such as medication selection, cost analysis, purchasing procedures, and record keeping. As part of medication selection, pharmacies may use a formulary, which is a list of medications that have been approved for prescription within a hospital or health care system.

A prime vendor or wholesaler is one of the most commonly used sources to obtain medications for the pharmacy. Prime vendors order large quantities of medications from manufacturers, allowing pharmacies to purchase various products from many drug manufacturers at once. Orders for products that are not carried by the prime vendor may need to be ordered through another source, such as directly from the manufacturer.

Receipt and storage. When medications are delivered to the pharmacy, staff are to take several steps to properly receive and store the shipment. For example, to ensure there is segregation of duties, the person responsible for ordering and purchasing the medications is supposed to be different than the person receiving and stocking pharmacy inventory. Additionally, any delivered products that require special storage conditions, such as freezing or refrigeration, are to be checked in first to maintain the stability of the medication.

Tracking. Once in storage, pharmacies use a variety of tools to account for the filling, dispensing, and removal of medications in both inpatient and outpatient settings. Some pharmacies have software that allows them to track inventory in real time, an ability known as maintaining perpetual inventory. A perpetual inventory system is a method of recording the quantity of a particular medication continuously as prescriptions are filled and dispensed. After each prescription is filled and dispensed to the patient, the amount of medication used for the prescription is removed from the inventory to ensure the quantity on hand recorded by the software is always current.

Many medications have barcodes on their packaging to allow for easy identification of the medication in a computer system. The barcode generally includes the product's National Drug Code, which indicates the name and package size of the medication. In the hospital setting, medications can be scanned out of the pharmacy and into machines for storage on hospital wards.

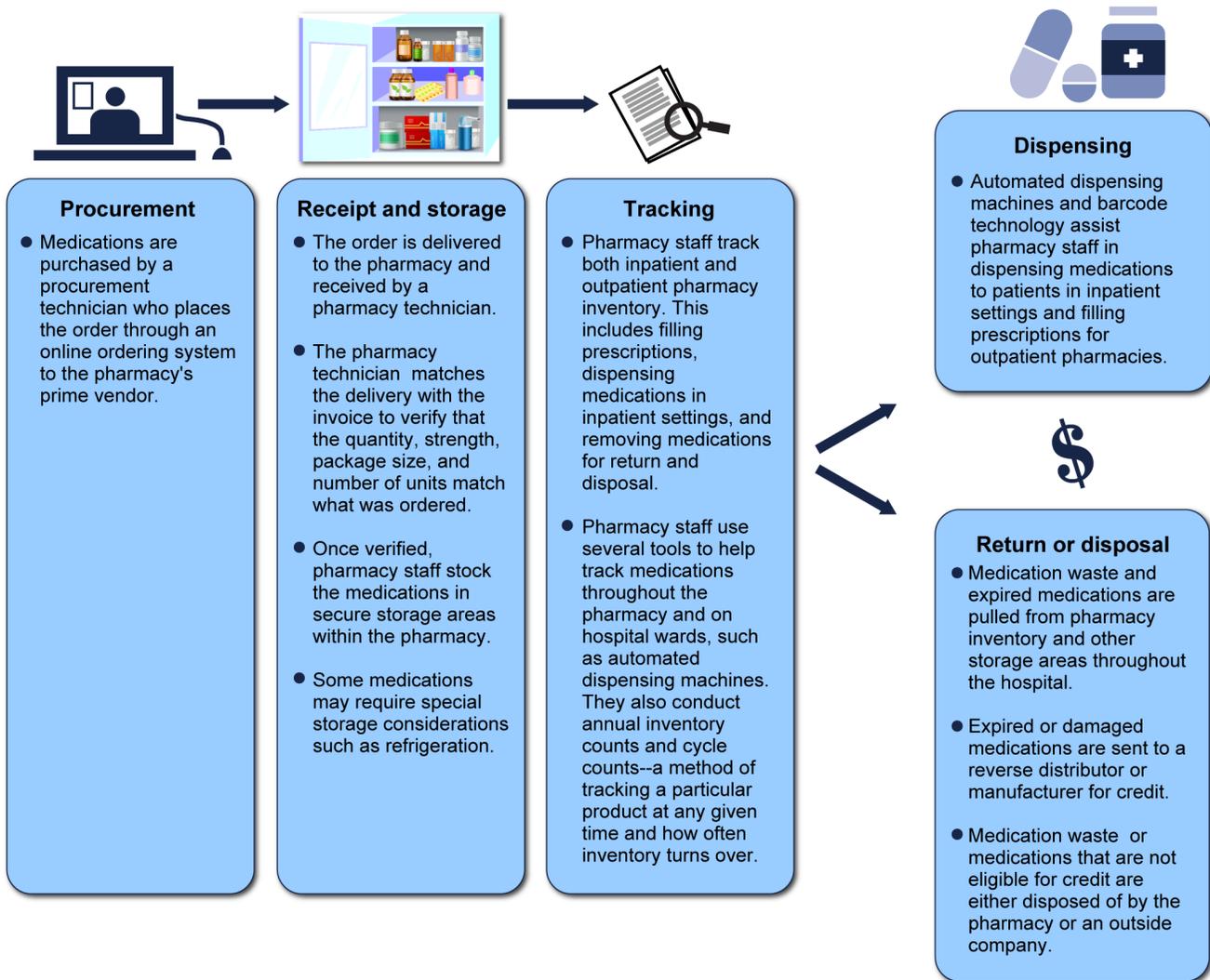
Dispensing. In both inpatient wards and outpatient pharmacies, automated dispensing machines and barcode technology can assist staff in maintaining and dispensing medications to patients. Automated dispensing machines generally include several drawers and cabinets that have pockets or trays that hold preset levels of a variety of common medications. They may also be used to hold controlled substances, generally in locked boxes or cubes within the machine. On hospital wards medication in automated dispensing machines is often packaged in unit doses—individually packaged medications for patient use. Barcodes can help verify a prescription before nurses give medication to a patient. Hospitals that do not have automatic dispensing machines use carts with drawers filled with each patient’s medication. Outpatient pharmacies use automated dispensing machines to assist with filling prescriptions. Depending on the type of automated dispensing machine, the capabilities can include label printing, pill counting, pouring pills into prescription bottles, and applying the label to the prescription bottle.

Return or disposal. Medication waste and expired medications are to be pulled from pharmacy inventory and either returned to a reverse distributor or manufacturer for credit or, if not eligible for return, disposed of by the pharmacy or sent to an outside company for destruction.¹¹ Reverse distributors charge a fee, which is generally a percentage of the refund that is automatically deducted from the final refund amount.

Figure 1 provides an overview of the steps of the pharmacy inventory management process.

¹¹Reverse distributors are companies that take back expired, recalled, or damaged medications from pharmacies and complete the necessary paperwork required by each manufacturer to receive credit for returned items.

Figure 1: Pharmacy Inventory Management Process within a Hospital Setting



Source: GAO analysis of industry guidelines for inventory management. | GAO-18-658

VA Organizational Structure and Pharmacy Policies

VA's health care system is organized into entities at the headquarters, regional, and local levels. At the headquarters level, PBM is responsible for supporting VISNs and VAMCs with a broad range of pharmacy services, such as promoting appropriate drug therapy, ensuring medication safety, providing clinical guidance to pharmacists and other clinicians, and maintaining VA's formulary of medications and supplies

VAMCs use to deliver pharmacy benefits. VA's OIT is responsible for providing technology services across the department, including the development and management of all IT assets and resources. As such, the office supports VA's health care system in planning for and acquiring IT capabilities within VA's health care system network of hospitals, outpatient facilities, and pharmacies. VA's NAC is responsible for administering various health care-related acquisition and logistics programs across VA.

At the regional level, VAMCs are located in one of 18 VISNs. Each VISN is responsible for overseeing VAMC pharmacies within a defined geographic region. At the local level, there are approximately 170 VAMCs. Each VAMC is responsible for implementing VA's pharmacy policies and programming.

VA policy establishes parameters for VAMCs to follow when managing their pharmacy inventories. These policies address various aspects of pharmacy services, including inpatient and outpatient pharmacy services, general pharmacy requirements, supply chain management, controlled substances management, and the formulary management process. For example, the Supply Chain Inventory Management directive states that all VAMC pharmacies should use the prime vendor inventory management software to calculate the amount of each inventory item they need to reorder.¹² However, the directive also states that there are additional pharmacy inventory tools available to VAMC pharmacies and that each pharmacy has the option to use its own automated inventory management systems to generate orders for its prime vendor. VA policy does not specify minimum quantities to order; instead, VAMC procurement staff is authorized to use their expertise to determine the appropriate quantity to order.¹³

¹²Veterans Health Administration Directive 1761(1), *Supply Chain Inventory Management*. (Washington, D.C.: Oct. 24, 2016).

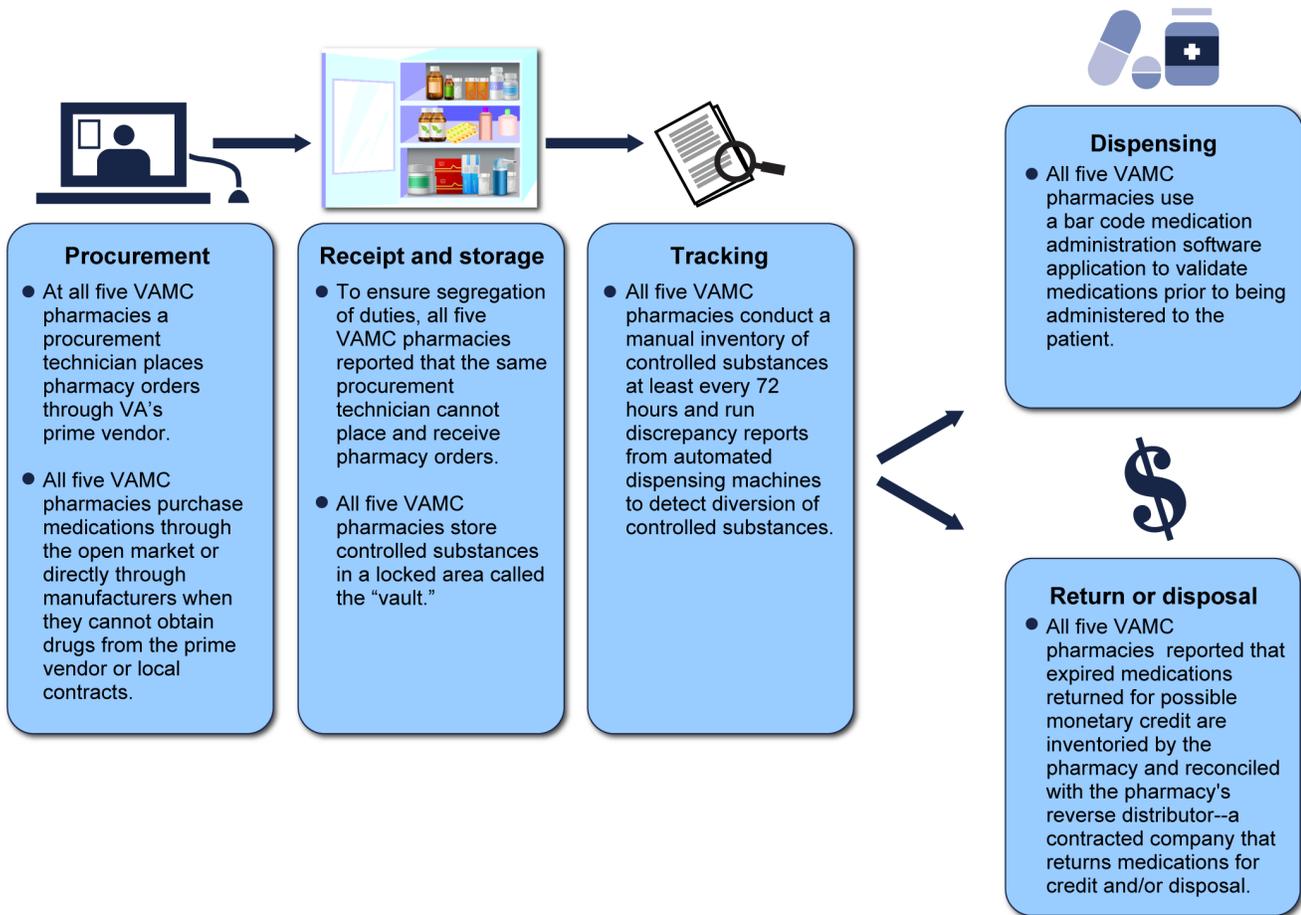
¹³VA officials also noted that there is a national rollout of inventory management orders that provides VISN officials with an opportunity to address any inventory outliers.

Selected VAMCs Have Generally Similar Approaches for Managing Their Pharmacy Inventories, with Some Unique Approaches

In general, all five of the selected VAMCs we reviewed take similar approaches for the various steps included in the pharmacy inventory management process—that is, procuring medications from vendors or other suppliers, receiving and storing these medications, tracking medications at the pharmacy to account for all items and prevent diversion, dispensing medications to patients, and disposing of expired medications.¹⁴ (See fig. 2).

¹⁴VA is currently evaluating national contracts for a reverse distributor who would both dispose of medications and also process medication returns for credits. VA officials told us that they plan to award one contract to a small, veteran-owned business to cover VA-wide reverse distribution services by August 2018.

Figure 2: Similar Approaches to the Pharmacy Inventory Management Process Used by Selected Department of Veterans Affairs Medical Centers (VAMC)



Source: GAO analysis of VA information. | GAO-18-658

We found that while the five selected VAMCs have similar approaches for receiving and storing, dispensing, and disposing of medications, some VAMCs have also taken unique approaches in implementing two steps of the pharmacy inventory management process: procurement and tracking. VA policy outlines parameters for VAMCs to manage their pharmacy inventories, and VA officials told us that VAMC pharmacy staff can use discretion to implement their own approaches for managing their pharmacy inventories.

Procurement

All five of the selected VAMC pharmacies we reviewed use several sources of information to inform future orders—including past purchase

order history reports from VA's prime vendor, manual inventory counts by pharmacy staff, and automated dispensing machine inventory information. VA officials told us that all VAMCs also track procurement spending and its impact on the VAMCs' budget and spending. However, pharmacy officials at one of the selected VAMCs we visited told us they use VA's health information system—Veterans Health Information Systems and Technology Architecture (VistA)—and additional prime vendor reports to identify specific information regarding 1) expiring medications that may need to be re-purchased, 2) medications that account for the top 80 percent of pharmacy costs, and 3) all medications that are purchased daily.¹⁵ VAMC officials told us these reports help them to better manage pharmacy inventory and track pharmacy spending.

To better anticipate and address potential medication shortages, officials at another selected VAMC pharmacy told us they established a shortage committee that meets on a weekly basis. Established in September 2017, the committee includes the Director of Pharmacy and other pharmacy staff. Our review of meeting notes shows that the committee discusses which medications could experience or are experiencing shortages and how the VAMC could adjust to these shortages by, for example, developing clinical and logistical solutions to help maintain optimal patient care. According to the officials at the selected VAMC pharmacy, the committee has been an effective resource to help manage pharmacy inventory problems should they occur.

Several VAMC officials also told us that the procurement technicians, who are responsible for ordering pharmacy inventory, are very important because they possess valuable institutional knowledge based on many years of experience and training.¹⁶ However, VAMC officials told us the salaries and potential career advancement opportunities for procurement technicians can be limited, and the officials expressed concern that these technicians could find better opportunities within the VAMC or with

¹⁵To enable the provision of health care services to veterans, VA uses its integrated health information system VistA. The system consists of approximately 200 separate computer applications and modules, 17 of which include pharmacy related applications.

¹⁶We spoke with the Chief Pharmacy Officer and pharmacy staff from Mayo Clinic who told us that procurement specialists go through intensive on-the-job training. They told us that the qualifications for inventory management procurement positions with the Mayo Clinic include a 4-year degree and previous experience, and that it takes about 2 to 3 months of intensive job training and about a full year of work experience before a procurement specialist is comfortable in the position.

external employers.¹⁷ To help retain procurement technicians, two of the selected VAMC pharmacies we visited have created higher paying procurement technician positions (General Schedule level 8 [GS-8] positions, instead of GS-6 or GS-7).¹⁸

Tracking

To better identify potential instances of diversion, two of the selected VAMC pharmacies use enhanced analytics software on the automated dispensing machines in their inpatient wards to track how frequently controlled substances and other frequently utilized medications are prescribed. For example, one of the pharmacies uses data from these reports to identify how often individual staff members are accessing automated dispensing machines. Additionally, officials at a third VAMC recently deployed automated dispensing machines that are equipped with an enhanced analytics program that can identify trends associated with diversion.¹⁹ The remaining two VAMCs we visited do not have enhanced analytic software that could help them to identify instances of potential diversion.

Across all 5 selected VAMCs, we observed several different IT systems used to help manage non-controlled inpatient inventory. One of the selected VAMC pharmacies uses a modular automated dispensing machine together with inventory management software that maintains a perpetual inventory for most non-controlled substances stored in its inpatient pharmacy.²⁰ (See fig. 3). According to officials, this software has allowed the pharmacy to reduce waste and improve staff workflow, as

¹⁷Challenges in recruiting and retaining staff are not unique to pharmacy operations and also affect other areas in the VA workforce. For example, in 2017 we reported that the Veterans Health Administration's financial incentives for recruiting and retaining physicians do not always result in competitive salary packages, and funding for incentives was often inadequate at the VAMC level. GAO, *Veterans Health Administration: Better Data and Evaluation Could Help Improve Physician Staffing, Recruitment, and Retention Strategies*, [GAO-18-124](#) (Washington, D.C.: Oct. 19, 2017).

¹⁸The General Schedule (GS) classification and pay system covers the majority of Federal employees in professional, technical, administrative, and clerical positions. The General Schedule has 15 grades--GS-1 (lowest) to GS-15 (highest). Agencies establish the grade of each position based on the level of difficulty, responsibility, and qualifications required.

¹⁹In April and May of 2018, this VAMC deployed 12 new automated dispensing machines in inpatient wards with this enhanced software.

²⁰Some items, such as bulk bottles, cannot be tracked in real time because the software detects bulk bottles as 1 unit and does not account for the individual pills within the bottles.

staff do not have to spend time tracking down inventory. None of the other VAMC pharmacies we visited have the capability to track non-controlled substances in real time.

Figure 3: Automated Medication Dispensing Machine at a Department of Veterans Affairs Medical Center



Source: Department of Veterans Affairs | GAO-18-658

Additionally, to more efficiently identify medication lot numbers during recalls, one VAMC pharmacy we visited was in the process of implementing a technology that allows pharmacy staff to scan a case of medication with the same national drug code, lot number, and expiration date and then print and attach a radio frequency identification tag to each medication bottle. The tag allows for quick electronic identification of the

medication for disposal. Other selected VAMC pharmacies manually identify recalled medications from inventory based on the name of the medication and lot number.

Oversight of Pharmacy Inventory Management Is Limited, as VA Lacks a Comprehensive Inventory Management System or a Focal Point for System-Wide Oversight

VA does not yet have a VA-wide pharmacy inventory management system in place that would allow it to monitor VAMC pharmacy inventory in real time and provide better oversight of how VAMC pharmacies manage their inventories. We found that VACO and the five VISNs we reviewed provide some oversight related to VAMC pharmacy inventory management. However, that oversight is limited, as no entity has been assigned responsibility for overseeing system-wide performance of VAMC pharmacies in managing their inventories.

VA's Oversight of VAMCs' Pharmacy Inventory Management Is Limited, in Part Because VA Has Not Yet Implemented a Comprehensive Inventory Management System

VA's oversight of VAMC pharmacy inventory management is limited in part because VA currently lacks a comprehensive system that would allow the department and its VAMCs to monitor pharmacy inventory in real time. According to PBM officials, the lack of a VA-wide system makes it difficult to oversee VAMC pharmacy inventory management, and PBM has recognized the lack of such a system as a material weakness for several years. PBM officials said that implementation of a VA-wide pharmacy inventory management system would allow them to monitor each VAMC's pharmacy inventory in real time, which would, in turn, allow them to better manage inventory and help alleviate shortages at the national level by facilitating transfers of inventory between VAMCs as needed. Additionally, officials said that such a system would lead to better planning and projections for purchasing decisions, allow PBM to track medication expiration dates and lot numbers more effectively, and improve VAMC staff response to medication recalls.

Although VA has acknowledged the need for a VA-wide pharmacy inventory management system, such a system may not be available for the foreseeable future. PBM officials told us they have requested this system since the early 2000s. However, despite the documented technological challenges VA faces in overseeing its VAMC pharmacies, changing IT priorities, funding challenges, and the narrowing of the scope

of a Pharmacy Re-engineering Project have prevented the system's development.²¹ In 2017, we reported that VA's pharmacy systems could not maintain a real-time inventory across the VAMCs, and we recommended that VA assess the priority for establishing an inventory management system capable of monitoring medication inventory levels and indicating when medications needed to be reordered.²² VA concurred with our recommendation. In June 2017, VA announced its intention to replace VistA—VA's health information system—with an off-the-shelf electronic health record system.²³ VA officials told us that the new system will have the capability to monitor pharmacy inventory in real time across VA. VA signed the contract for this new system in May 2018; however, full implementation is expected to take up to 10 years. In the interim, VA officials told us that while they will maintain current pharmacy systems, they do not plan to build any new systems—including a VA-wide pharmacy inventory management system—so they can efficiently manage resources in preparation for the transition to the new system.

²¹The Pharmacy Re-engineering Project began in 2002, and the original plans for this project included the development of inventory management capabilities. However, in June 2009 the Secretary of VA announced that VA would stop financing failed projects and improve the management of its IT development projects. Toward this end, the VA Chief Information Officer transitioned the Pharmacy Re-engineering Project to a phased development effort. According to VA pharmacy management officials, this was done because the project had faced funding delays, contracting difficulties, and differing directions from a number of VA chief information officers. The project was also re-scoped to focus on implementing clinical decision support tools, specifically to cross-check drugs in medication orders to reduce the frequency of adverse drug events and improve patient safety.

²²GAO, *VA Information Technology: Pharmacy System Needs Additional Capabilities for Viewing, Exchanging, and Using Data to Better Serve Veterans*, [GAO-17-179](#) (Washington, D.C.: June 14, 2017). In this report, we noted that industry practices stress the use of a computerized system to manage a real-time inventory so that the system displays up-to-date pharmaceutical inventory at all times. Interviews we conducted for this review with officials from the Mayo Clinic and the Cleveland Clinic—both large, integrated health systems similar to the VA—told us that they have systems in place that allow them to monitor medication levels in real time.

²³The Department of Defense currently uses the same off-the-shelf electronic health record system, which is developed by Cerner. VA cited having all patient data residing in one common system and enabling seamless care between the Department of Veterans Affairs and the Department of Defense as a factor when choosing Cerner.

**VACO and VISNs Provide
Some Limited Oversight,
but VA Lacks a Focal Point
for System-Wide
Oversight of Pharmacy
Inventory Management**

VACO and the five VISNs we spoke with provide some limited oversight related to VAMC pharmacy inventory management, but no entity has system-wide responsibility for overseeing the performance of VAMC pharmacies in managing their inventories. Instead, responsibility for overseeing pharmacy inventory management is largely delegated to each VAMC's leadership. (See fig. 4 for a description of VACO headquarters, VISN, and VAMCs' roles and responsibilities in managing pharmacy inventory.)

Figure 4: Department of Veterans Affairs' (VA) Entities That Have Pharmacy Inventory Management and Oversight Responsibilities

	Entity	Responsibility
Headquarters level	Pharmacy Benefits Management Service (PBM)	<ul style="list-style-type: none"> Develops policies for the provision of pharmacy services at the VAMCs. Collects and aggregates data from VAMCs' pharmacy inventory on a quarterly and annual basis. Facilitates regular calls with VISN and VAMC pharmacy staff to discuss pharmacy-related issues.
	National Acquisition Center (NAC)	<ul style="list-style-type: none"> Coordinates with PBM on medication shortage issues and establishes national contracts for medications. Administers the prime vendor contract.
	Office of Information and Technology (OIT)	<ul style="list-style-type: none"> Develops computer systems based upon Veterans Health Administration prioritization and funding. Assists VAMCs by troubleshooting issues that involve the Veterans Health Information Systems and Technology Architecture's pharmacy-related applications.
Regional level	Veterans Integrated Service Networks (VISN)	<ul style="list-style-type: none"> Monitors data from quarterly and annual pharmacy inventories for VAMCs in their region.
Local level	VA medical centers (VAMC)	<ul style="list-style-type: none"> Oversees VAMC pharmacy policies and the management of pharmacy inventory in accordance with VA policy.

Source: GAO analysis of VA documentation and interviews with officials. | GAO-18-658

PBM

In absence of a VA-wide inventory management system, PBM officials told us that they have employed manual workaround mechanisms to oversee pharmacy management processes. Specifically, PBM requires VAMC pharmacies to conduct an annual inventory of all medications and a quarterly inventory of 5 selected high-value non-controlled medications

at risk of diversion.²⁴ PBM officials told us they remind VAMCs of the requirement to conduct these inventories, collect and aggregate the data from these inventories, and make summary reports from these data available as a resource to the VPEs and VAMC Chiefs of Pharmacy. PBM officials acknowledged that these manual workarounds are inefficient, increase labor costs, and leave the agency with an inability to see on-hand inventory across the system in real time. Additionally, the manual workarounds may be implemented differently at each VAMC, resulting in varying degrees of data reliability and limited opportunities for high-level oversight and data consolidation. PBM officials said that they do not independently analyze these data to identify trends, and they acknowledged that both the quarterly and annual inventories have limited usefulness for overseeing inventory management system-wide.²⁵ Additionally, officials at some of the selected VAMCs told us they found the quarterly and annual inventories to have limited usefulness for managing their pharmacy inventories.

PBM officials told us they also hold regular meetings with VPEs and VAMCs, which provide the opportunity for discussion of pharmacy inventory management issues. However, our review of the minutes of the meetings between PBM and VPEs found that, over the past 3 years, pharmacy inventory management was rarely a topic of discussion. PBM officials noted that there is always an opportunity for open discussion at these meetings for VPEs to raise any issues, including issues related to pharmacy inventory management, but these discussions may or may not be captured in the meeting minutes.²⁶ PBM officials said they also regularly discuss various topics with the VAMC Chiefs of Pharmacy and other staff, but none of these calls are directly related to pharmacy inventory management.

²⁴PBM instituted the requirement to conduct a quarterly inventory of 5 selected high-value, non-controlled substances at high risk of diversion in response to a 2009 VA OIG report that found that VA could not accurately account for the non-controlled medications at VAMC pharmacies because VA lacked reliable information to do so. See Department of Veterans Affairs, Office of Inspector General, *Audit of Veterans Health Administration's Management of Non-Controlled Drugs*, 08-01322-114 (Washington, D.C.: June 23, 2009).

²⁵PBM officials told us they cannot conduct additional analyses on the self-reported data beyond calculating a high-level inventory turn rate at the VISN and VAMC level.

²⁶VA officials also noted that inventory management may also be discussed on conference calls and through email, but these discussions are not typically documented.

NAC and OIT

Officials from VACO's NAC and OIT told us that they provide some assistance related to pharmacy inventory management but do not take part in the day-to-day management at the VAMC level and also do not have any oversight responsibilities. For example, a NAC official said the office coordinates with PBM on medication shortage issues and establishes national contracts for medications. NAC also sends out a weekly shortages report to various pharmacy groups as a tool to help them with known or expected shortages. Additionally, NAC's Pharmaceutical Prime Vendor team is responsible for administering the contract with the prime vendor through daily monitoring of issues and quarterly reviews with the prime vendor and PBM. OIT develops pharmacy-related applications for VistA based on requirements from PBM, and officials said that the majority of OIT's support to VAMCs consists of assisting them with issues related to VistA.²⁷

VISNs

At the VISN level, VPEs we interviewed also said they conduct some pharmacy inventory management oversight activities for the VAMCs within their network. While in general VA policy does not outline any specific roles for VPEs related to oversight of pharmacy inventory management, all five VPEs told us that they review the results of their VAMCs' annual inventories and discuss any issues that arise from this exercise with VAMCs as needed. VPEs told us that they also review the results of the quarterly inventory of five selected high-value, non-controlled substances and may follow-up with the VAMCs if their actual inventory of the medications is inconsistent with expected levels.²⁸ Additionally, some VPEs reported that they have undertaken additional oversight activities apart from reviewing results of the mandatory inventories. For example, one VPE told us he has developed a dashboard with 53 measures that, while focused on formulary management, also have inventory management implications. Additionally, this VPE said that

²⁷Specifically, according to Veterans Health Administration officials, program offices such as PBM submit technology requests to the Office of Health Informatics for assessment. These requests are then submitted by the program offices to the Clinical Capabilities Management Board as part of their multi-year planning business plans. The Clinical Capabilities Management Board reviews these plans and provides input on the prioritization for technology requests, which are included in the Veterans Health Administration's budget request to OIT.

²⁸VPEs we spoke with reported differing levels of acceptable variance between expected versus actual inventory for VAMCs' quarterly inventories of non-controlled substances. For example, one VPE said that the acceptable level of variance for VAMCs in his VISN should not be greater than 5 percent, while another VPE told us that the acceptable level of variance for VAMCs in her VISN is 10 percent.

a VISN-wide procurement work group meets on a monthly basis and serves as a venue for procurement technicians to share inventory management best practices. Such additional activities may be helpful, but since VPEs only have responsibility for VAMC pharmacies within their network, they may not be aware of pharmacy inventory management approaches being used at other VAMCs across VA.

Although VA offices at the headquarters and regional levels provide some assistance and oversight of how VAMCs manage pharmacy inventory at the local level, VA has not designated a focal point with defined responsibilities for system-wide oversight; instead they rely on local leadership to oversee pharmacy inventory management at the VAMCs. As a result, VA cannot assess the overall performance of VAMCs' management of their pharmacy inventories. The lack of a focal point with defined oversight responsibilities is inconsistent with federal internal control standards for establishing structure and authority to achieve the entity's objectives and internal controls related to monitoring.²⁹

Specifically, internal controls state that management should establish an organizational structure, assign responsibility, and delegate authority to achieve the entity's objectives. Also, internal controls state that management should establish and operate monitoring activities to monitor the internal control system and evaluate the results. VA's actions are also inconsistent with the Office of Management and Budget's guidance for enterprise risk management and internal control in managing an agency.³⁰ Enterprise risk management is intended to yield an "enterprise-wide," strategically aligned portfolio view of organizational challenges that provides better insight about how to most effectively prioritize resource allocations to ensure successful mission delivery. Without a focal point for system-wide oversight of VAMC pharmacy inventory management, VA has limited awareness of the unique approaches that VAMCs use to manage their inventories and is missing an opportunity to evaluate these approaches. Additionally, VA cannot effectively share and standardize

²⁹GAO-14-704G.

³⁰Office of Management and Budget, *Management's Responsibility for Enterprise Risk Management and Internal Control*, Circular No. A-123 (July 15, 2016). Office of Management and Budget Circular No. A-123 prescribes requirements for conforming with the Standards of Internal Control in the Federal Government established by the Government Accountability Office, more commonly known as the Green Book. The guidance also specifies that agency management has responsibility for establishing and maintaining internal controls to achieve specific internal control objectives related to operations, reporting, and compliance. Lastly, the guidance discusses how internal control and enterprise risk management fit together to assist the agency in managing risks.

pharmacy inventory management best practices as appropriate. Having a focal point for system-wide oversight could allow VA to identify potential best practices that could be disseminated more widely across its facilities.

Conclusions

Due to the decentralized nature of VA's organization, VA policy gives VAMC pharmacies latitude in managing their pharmacy inventories. Several of the VAMCs we visited have taken unique approaches to procuring or tracking their inventory. However, because VA does not have a focal point to systematically oversee VAMCs' pharmacy management efforts, VA is missing opportunities to evaluate the effectiveness of these efforts, as well as share best practices and standardize them across VA as appropriate. PBM officials told us that the lack of a VA-wide pharmacy inventory management system limits their ability to oversee VAMC pharmacy inventory management. However, our review shows that even without this system there are existing mechanisms that a focal point could leverage to more systematically oversee how VAMC pharmacies manage their inventories. For example, a focal point could ensure that PBM officials, the VPEs, and VAMC pharmacy staff devote time to discussing pharmacy inventory management approaches and related issues during regularly scheduled telephone meetings. Leveraging these existing mechanisms is especially important given that VAMCs have historically had challenges in managing their inventories, and also because a VA-wide pharmacy inventory management system may not be available for the foreseeable future.

Recommendation for Executive Action

We are making the following recommendation to the Department of Veterans Affairs:

The Secretary of the VA should direct the Undersecretary for Health to designate a focal point for overseeing VAMCs' pharmacy inventory management system-wide and define the focal point's responsibilities. (Recommendation 1)

Agency Comments and Our Evaluation

We provided a draft of this report to VA for review and comment. In its written comments, reproduced in appendix I, VA stated that it concurred in principle with our recommendation. VA also provided technical comments, which we incorporated as appropriate.

In response to our recommendation, VA stated it plans to establish by December 31, 2018, a committee of internal stakeholders and subject matter experts to provide options for overseeing VAMCs' pharmacy inventory management. However, it was unclear from VA's response whether the planned committee will recommend or designate an entity or focal point with system-wide oversight responsibilities. VA noted in its general comments that it does have entities or individuals—referred to as focal points by VA—responsible for specific functions. However, these entities do not provide system-wide oversight that could allow the department to better understand VAMCs' approaches to pharmacy inventory management. As we noted in our report, without a focal point for system-wide oversight, VA has limited awareness of the unique approaches that VAMCs use to manage their inventories and is missing an opportunity to evaluate these approaches and standardize them across VA as appropriate.

Additionally, in its general comments, VA raised concerns regarding our characterization in the draft report of medication shortages and the use of automated dispensing units in the context of controlled substances. In response, we updated the report to include more information about one VAMC's use of a committee to address medication shortages. We also clarified that three VAMCs are using (or will soon have the capability to use) enhanced analytic software to better leverage data generated through their automated dispensing machines, which allows them to more easily identify potential diversion. Finally, VA noted that we did not discuss PBM's multiple requests for an enterprise-management system since the early 2000s; however, this information was included as part of the draft report sent to VA for review and remains in our final report on page 14 as part of our finding on the lack of a VA-wide pharmacy inventory management system.

We are sending copies of this report to the Secretary of the Department of Veterans Affairs and appropriate congressional committees. The report is also available at no charge on GAO's website at <http://www.gao.gov>.

If you or your staff has any questions regarding this report, please contact Sharon M. Silas at (202) 512-7114 or silass@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.

A handwritten signature in black ink, appearing to read "Sharon Silas". The signature is fluid and cursive, with the first name "Sharon" and the last name "Silas" clearly distinguishable.

Sharon M. Silas
Acting Director, Health Care

Appendix I: Comments from the Department of Veterans Affairs



THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON
September 11, 2018

Ms. Sharon Silas
Acting Director
Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Silas:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office (GAO) draft report: ***“VA HEALTH CARE: Pharmacy Inventory Management Could Benefit from System-Wide Oversight”*** (GAO-18-658).

The enclosure includes general and technical comments and sets forth the actions that will be taken to address the GAO draft report recommendation.

VA appreciates the opportunity to comment on your draft report.

Sincerely,

A handwritten signature in cursive script that reads "Robert L. Wilkie".

Robert L. Wilkie

Enclosure

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***“VA HEALTH CARE: Pharmacy Inventory Management Could
Benefit from System-Wide Oversight”***
(GAO-18-658)

VA General Comments:

Throughout the draft report, GAO discusses medication shortages. We find that medication shortages are not caused by VA lacking an enterprise pharmacy inventory management system. Shortages have many causes and impact the entire United States health care system. Including medication shortages in the draft report could obscure the main issue, which is VA’s long-standing lack of a pharmaceutical inventory system to track medications for accountability purposes. While we do not believe this report should include a discussion about medication shortages, if it does, there should be an explicit mention of supply chain disruptions that are unique to VA. Unlike VA, the private sector does not have restrictions through the Trade Agreements Act, the Buy American Act, or open market ordering inefficiencies. Some of the supply chain disruptions experienced by VA are legislative and regulatory in nature, and have nothing to do with inventory management deficiencies.

The Veterans Health Administration (VHA) Pharmacy Benefits Management (PBM) does not disagree that a shortage committee may be an effective resource. However, the opportunity to buy stock before it is no longer available, and when a shortage is known or expected, is generally a very tight window; and importantly, if VA hoards medications, other health care organizations will suffer. The committee would need to be extremely nimble to be effective at “preemptively mitigating shortages” should they occur, and PBM believes this is neither possible nor advisable.

VA agrees that inventory management includes procuring, receiving, storing, tracking, dispensing, and disposing of medications; however, it is only on page eleven that GAO notes that these functions are standardized and that there is a focal point for overseeing these activities: procuring (use of a national Pharmaceutical Prime Vendor based on VA National Contracts and Federal Supply Schedule contracts); receiving (separation of duties, internal control requirements); storing (policy requirements); dispensing (policy requirements); and disposing functions (VA National Contract). The major gap is that, because of a lack of an enterprise-wide system, VA has no reliable way to track medications from the time they are received until the time they are dispensed or destroyed. Some of that functionality is being performed through outpatient dispensing data; ward stock dispensing data; and inpatient drug distribution data. An exception to the lack of a tracking functionality is controlled substances, which are tracked from receipt through destruction. Tracking controlled substances through VA’s Controlled Substance Tracking Package and automated dispensing units is the one area where VA has closed the gap in this process. What was attributed to two of the five medical centers is, in fact, required (use of the Controlled Substance Tracking package) or strongly recommended (use of automated dispensing cabinets).

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***“VA HEALTH CARE: Pharmacy Inventory Management Could
Benefit from System-Wide Oversight”***
(GAO-18-658)

Additionally, the draft report fails to note that PBM has requested an enterprise-wide inventory management system since at least the early 2000s, well before numerous GAO and Office of Inspector General reviews were conducted on this topic. The lack of this type of system was not caused by PBM complacency or negligence, but rather because it has not been a development priority for VHA. The lack of this type of system also underscores and provides an important example of VA’s failure to correct known system information technology deficiencies.

In June 2017, GAO published its final report ***“VA Information Technology: Pharmacy System Needs Additional Capabilities for Viewing, Exchanging, and Using Data to Better Serve Veterans”*** (GAO-17-179) including a recommendation to establish and implement a plan for updating the pharmacy inventory system to address the inefficiencies. The recommendation remains open at this time.

Enclosure

Department of Veterans Affairs (VA) Comments to
Government Accountability Office (GAO) Draft Report
***“VA HEALTH CARE: Pharmacy Inventory Management Could
Benefit from System-Wide Oversight”***
(GAO-18-658)

Recommendation 1: The Secretary of the VA should direct the Under Secretary for Health to designate a focal point for overseeing VAMCs’ pharmacy inventory management system-wide and define the focal point’s responsibilities.

VA Comments: Concur in principle. The Veterans Health Administration (VHA) agrees that a system-wide pharmacy inventory management system is critical to ensure the VA Central Office will address GAO’s concerns. Therefore, VHA will establish a committee of internal stakeholders and subject matter experts to review GAO’s recommendation and provide options to VHA’s Executive in Charge for overseeing the VA medical centers’ pharmacy inventory management systems. The status is in process with a target completion date of December 31, 2018.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Sharon M. Silas, (202) 512-7114, silass@gao.gov

Staff Acknowledgments

In addition to the contact named above, Rashmi Agarwal, Assistant Director; Nick Bartine, Analyst-in-Charge; Muriel Brown; Kaitlin Farquharson; Krister Friday; Sandra George; Courtney Liesener; Diona Martyn; and Michelle Paluga made key contributions to this report.

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