DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

VETERANS HEALTH ADMINISTRATION

Ineffective Governance of Prescription Drug Return Program Creates Risk of Diversion and Limits Value to VA

AUDIT | REPORT # 20-00418-166 | AUGUST 12, 2021

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Executive Summary

The Veterans Health Administration (VHA) spent about $6.6 billion on prescription drugs in fiscal year (FY) 2019. Most of these drugs were dispensed to veterans visiting medical facility pharmacies. When VHA cannot use drugs it purchases because they are damaged or expired, VHA's prescription drug return program allows medical facility pharmacies to return them to the manufacturer through a reverse distributor for credit or destruction. In FY 2019, VHA expected to receive about $52 million from drug returns. The reverse distribution contractor informed the audit team that it uses a proprietary database to assign an estimated return value to each drug VHA returns for manufacturer credit, based on the manufacturer's estimated return value.[1] Throughout FY 2019, the prescription drug return program was operated by a contractor, Pharma Logistics, which all medical facilities used to return drugs for credit.[2] VA decided not to continue its contractual relationship with Pharma Logistics after October 8, 2020. However, VA will not receive the last invoices for some drugs that Pharma Logistics picked up from medical facilities until at least April 2022, as these drugs are still going through the drug return process. VA officials reported that they intend to award a new national drug return contract—although a date has not been set. Findings from this report should inform the requirements VA has for any future drug return contract.

At the time of this audit, the responsibilities for administering the drug return contract and for operating and overseeing the program were outlined in VA's contract with Pharma Logistics and in VHA Directive 1087, *Monitoring of Expired or Soon-To-Expire Medication Returns,* August 2019.[3] As outlined in these documents, at the national level, the governance of the prescription drug return program was divided among three national offices: VA's National Contract Service (NCS) oversaw contract administration, and VHA's Office of the Deputy Under Secretary for Health for Operations and Management and Office of the Deputy Under Secretary for Health for Policy and Services oversaw implementation of the drug return program by VA medical facilities. In addition, VHA's Pharmacy Benefits Management Services' deputy chief consultant for formulary management was charged with monitoring national drug return data to identify unusual reimbursement patterns and potential improvements for revenue

[1] Estimated return values are based on the manufacturers' estimated return value of the drugs. This value is not necessarily equal to or less than what VHA paid to purchase the drugs. In fact, in some cases VHA may receive more in return credits for some drugs than it paid for the drugs initially. Drug manufacturers are not required to participate in a return credit program. Each drug manufacturer that participates in the return credit program has the authority to set their own return credit terms and values.

[2] VA's National Contract Service (NCS) awarded this contract to Pharma Logistics. The contract went into effect in October 2018 for FY 2019, and was used for two years, until October 2020.

[3] This directive was rescinded on March 24, 2021, and some aspects related to the oversight of expiring medication by pharmacy chiefs were incorporated into VHA Directive 1108.07(1), *Pharmacy General Requirements,* March 10, 2017, as amended January 26, 2021.

recovery. At the local level, VHA network contracting officers oversaw administration of the drug return contract with Pharma Logistics and pharmacy chiefs oversaw the drug return program at the medical facility.

The VA Office of Inspector General (OIG) conducted this audit to determine if VHA was effectively overseeing its drug return program. Effective contract administration and oversight of the program is important because drugs waiting to be returned can be diverted and sold for profit or otherwise abused. Moreover, maximizing the value of these drug return credits promotes positive stewardship of taxpayer dollars. As part of this audit, the OIG also assessed the merits of a hotline allegation that a VA medical facility prematurely disposed of a large quantity of Tamiflu—often used to treat influenza symptoms—through the drug return program.

What the Audit Found

Medical facility pharmacy chiefs did not effectively implement the prescription drug return program and did not follow several program requirements stipulated in VA's contract with Pharma Logistics and VHA Directive 1087. These program implementation problems, which increased the risk of drug diversion and ultimately put about $18.1 million at risk, occurred because pharmacy chiefs did not fully understand what VHA Directive 1087 and the Pharma Logistics contract required of them. Specifically, local medical facility-level pharmacy chiefs did not always secure and track drugs held for return credit, or complete required analyses to maximize return credits and identify areas for improvement, as required by VHA Directive 1087. Pharmacy chiefs also failed to adhere to contract requirements to only return drugs for credit that were due to expire within 120 days. At the regional and national levels, VA's NCS and VHA network contracting officers needed to do more to ensure that the terms of the contract were met. In addition, the Office of the Deputy Under Secretary for Health for Policy and Services and the Office of the Deputy Under Secretary for Health for Operations and Management did not effectively govern the program or communicate the program's requirements to medical facilities as required by the directive.

Pharmacy Chiefs Did Not Effectively Implement the Drug Return Program, Increasing the Risk of Drug Diversion and Loss of $18.1 Million

The drug return program is intended to help VA recoup some of the funds it spends on unused drugs at its medical facilities, but pharmacy chiefs in these medical facilities did not always implement the program according to requirements. Pharmacy chiefs did not always

- secure all drugs held for return credit in locked areas separate from other pharmacy inventory,

- create and update running facility lists that detailed the names and quantities of each drug set aside for credit,
- compare their lists of drugs waiting for return against lists created by the Pharma Logistics' representative *before* these drugs left the facility,
- sort controlled drugs that should be disposed of from those that could be returned for credit, and
- conduct analyses that would determine if they received all the credits they should have received or if there were ways to maximize their drug return credits and improve their pharmacy inventory practices.

Pharmacy chiefs were often not fully aware of the requirements of VHA Directive 1087 or the terms of VA's contract with Pharma Logistics. Some believed their efforts to secure and track all drugs waiting for return were adequate and reported that on the OIG's survey. However, when the audit team assessed some pharmacy chiefs' practices to safeguard and track drugs waiting for return, they identified practices that left noncontrolled drugs vulnerable to diversion because containers used to hold returned drugs were not properly secured. In addition, the team identified several discrepancies when they compared medical facilities' lists against physical counts of drugs waiting for return, indicating that these lists were not accurate.

Pharmacy chiefs also returned drugs too soon, though the contract terms stated that drugs should only be returned to Pharma Logistics once they were within 120 days of expiration. When pharmacy chiefs returned drugs too early—before the drugs were within 120 days of expiration—they placed an estimated $18.1 million at risk in FY 2019. The OIG notified VA when it determined that Pharma Logistics was storing drugs that were returned too early and planned to destroy these drugs. Pharma Logistics planned to do so in March 2020. VA took quick action, thereafter, to modify its contract with Pharma Logistics to allow VA to recoup at least a portion of the return value from the drugs pharmacy chiefs returned too soon. Through this contract modification VA recovered about $2.2 million. Pharma Logistics also credited VA an additional about $1 million for drugs that were returned too soon that Pharma Logistics returned to manufacturers as they became eligible for credit. However, an estimated $14.6 million of the remaining about $14.9 million represents funds that could have been put to better use if pharmacy chiefs fully complied with the terms of VA's contract with Pharma Logistics. This estimated $14.6 million is made up of about

- $1.2 million in creditable drugs that were returned too soon,[4]
- $3.7 million in not creditable drugs returned too soon,[5]
- $6.8 million spent to replace the drugs returned too early, and[6]
- $2.9 million spent to replace Tamiflu that was returned too soon by a medical facility and destroyed by Pharma Logistics.[7]

VA also improperly paid about $307,365 in processing fees to Pharma Logistics.[8] The OIG questions this cost because these fees were assessed on drugs that were not returned in accordance with the contract. Overall, the OIG found that VA's poor management of the drug return program resulted in a monetary loss of about $14.9 million. Appendix B details the monetary impact of the deficiencies the OIG identified.

Improved Governance of the Drug Return Program Will Ensure More Effective Program Implementation

The program implementation problems described above occurred because, at the national level, VA did not ensure that the terms of the contract were met or adequately governed the prescription drug return program. The OIG identified three areas for improvement—contract

[4] By the end of fiscal year 2019 on September 30, 2019, the audit team determined from Pharma Logistics' data system that of the $8.8 million in drugs returned too soon—with more than 120 days left until they expired, Pharma Logistics determined that drugs with an estimated return value of about $4.42 million were creditable. It should be noted that because Pharma Logistics has up to 18 months to issue medical facilities with finalized invoices that detail the final value of returned drugs, it is possible that VA will receive more or less than Pharma Logistics' estimated return value. From Pharma Logistics' data system, the team also determined that drugs with an estimated value of about $4.36 million were found to be nonreturnable for manufacturer credit. See appendix B for additional details on the monetary benefits.

[5] Drugs may be determined to be nonreturnable for credit for reasons that include damaged drug packaging, or the drugs were returned in a partial quantity. To account for the fact that returned drug values can be affected by these factors—regardless if they were returned on time or too soon—the team reduced the total value of $4.36 million for the drugs that had no return value by 15 percent—or to $3.7 million.

[6] VA spent about $9 million to repurchase the drugs it returned too early, which could have been directed toward other necessary expenditures. The replacement cost was based on the Prime Vendor drug replacement cost data from August or September 2019, or the most recently available price paid by VHA. The team removed two high cost drugs that will not be repurchased in the same large quantities in which they were returned from this calculation. In addition, to account for the fact that some drugs will have to be repurchased before they expire because they will be damaged or spoiled, or otherwise unusable, the team reduced the total repurchase amount of $9 million for the drugs by 15 percent to $6.8 million.

[7] Based on the previously mentioned hotline complaint, the OIG reviewed an allegation that pharmacy personnel prematurely returned Tamiflu drug in November 2019, resulting in the drug's destruction. The team substantiated the allegation.

[8] NCS's director informed the OIG that about $248,733 of the $307,365 is expected to be refunded by Pharma Logistics to the applicable pharmacies.

administration and implementation, program oversight, and accurate and complete data regarding the program's performance:

- VA's NCS and VHA network contracting officers did not make sure Pharma Logistics representatives followed the requirements outlined in VA's drug return contract with Pharma Logistics, which included providing medical facilities with timely final invoices. They also did not ensure that task orders were accurate and did not assign contracting officer representatives (CORs) or maintain and complete COR oversight responsibilities.
- The deputy under secretary for health for operations and management did not take steps to implement the responsibilities outlined in VHA Directive 1087, including communicating the program's requirements to Veterans Integrated Service Network (VISN) directors, helping them comply with those requirements, and ensuring they have sufficient resources to implement the drug return program. Officials from the deputy under secretary for health for operations and management's office told the audit team that while they have direct authority over the VISNs and medical facilities, they rely on subject matter experts like those in Pharmacy Benefits Management Services to help them oversee programs. Pharmacy Benefits Management Services officials reported that they were asked to draft a communication memo for VISNs and medical facilities outlining the oversight mechanisms for the directive but explained that they do not have any authority over these entities. In October 2020, an official from the Office of the Deputy Under Secretary for Health for Policy and Services told the audit team that VHA planned to issue the memo after this report is published so the memo can address the OIG's final findings and recommendations.
- VHA leaders did not have accurate data on how well the drug return program was functioning nationally, impeding their capability to effectively monitor it. Pharma Logistics provided Pharmacy Benefits Management Services with reports that contained inaccurate and incomplete information concerning the value of drugs being returned for credit. Additionally, while analyzing this already flawed information, a Pharmacy Benefits Management Services data analyst inadvertently introduced additional errors resulting in an approximate $14.1 million overstatement. Because of the Pharma Logistics and Pharmacy Benefits Management Services errors, VHA decision makers could not use this information to reliably monitor VA's drug return program, verify that VA was receiving the drug return credits to which it was entitled, and improve the program.

In February 2020, Pharmacy Benefits Management Services notified medical facility directors that VA would not exercise the second option year of the contract with Pharma Logistics because the contract was not meeting its needs. VA would instead negotiate another contract for future

years, although a date has not been set for this effort. Until a new national drug return contract is awarded, medical facilities will have to negotiate their own local contracts, or hold their drugs set aside for return until a new national contract is awarded, according to the Pharmacy Benefits Management Services deputy chief consultant for formulary management. Pharmacy Benefits Management Services notified the OIG that VHA Directive 1087 was rescinded on March 24, 2021. Aspects of the directive that are specific to the pharmacy chief's oversight of the security and tracking of drugs set aside for return were incorporated into VHA Directive 1108.07(1). They also told the audit team that ultimately all pharmacy policies will eventually be consolidated into new, broader guidance on pharmacy inventory management. This new policy is expected to be published at its earliest by the beginning of FY 2022. However, according to the Pharmacy Benefits Management Services deputy chief consultant for formulary management other aspects of the directive were not incorporated into VHA Directive 1108.07(1) and were instead incorporated into a pharmacy guidance document.

Overall, the OIG concluded that as VHA moves forward with a new contract and new directives, or other guidance, for implementing the prescription drug return program, it should correct the deficiencies the audit team identified in FY 2019.

What the OIG Recommended

The OIG made seven recommendations to the under secretary for health. For recommendations 1 through 3 the OIG recommended the under secretary ensure medical facilities (1) properly secure drugs set aside for return in accordance with policy, (2) fully account for returned drugs when they leave the facility, and (3) maintain inventory management practices to make sure drugs are returned on time to maximize their return value and reduce their risk of overspending on drugs that were returned too soon. In recommendations 4 through 7, the under secretary should (4) make certain all offices and positions with defined national, network, or facility responsibilities for the drug return program or the administration of any future drug return contract have the support and the authority to fulfill those responsibilities, (5) require Pharmacy Benefits Management Services to review drug return data for accuracy and use this data to monitor and improve drug return revenues, (6) ensure network contracting officers or CORs oversee contractors to make certain they are performing in accordance with the terms of any future drug return contract, and (7) require network contracting officers to use a standardized template to issue task orders for any future drug return contract.

The OIG also made one recommendation to the under secretary for health to coordinate with the VA Office of Acquisition, Logistics, and Construction's principal executive director who should develop a task order template with terms that align with any future drug return contract and require the NCS to disseminate the template to VHA network contracting officers.

Management Comments

The acting under secretary for health concurred with recommendations 1 through 4 and 7 and concurred in principle with recommendations 5 and 6. The Office of Acquisition, Logistics and Construction concurred in principle with recommendation 8. Appendix C provides the full text of the acting under secretary for health's comments. The full text of the Office of Acquisition, Logistics, and Construction's comments appears in appendix D.

OIG Response

The acting under secretary's planned corrective actions are responsive to recommendations 1 through 4 and recommendation 7 and address the issues identified in the report. For recommendation 5, the OIG agrees that Pharmacy Benefits Management Services should use the data supplied by the drug return contractor to identify unusual reimbursement patterns and potential improvements for revenue recovery. However, in the absence of Pharmacy Benefits Management Services periodically testing the data for accuracy, any efforts to use the data for oversight may be in vain if the data contains errors or duplications, as identified in the current audit.

The OIG believes the acting under secretary's plan to address recommendation 6 by reminding VHA contracting officers of their oversight responsibilities is insufficient, and maintains that additional mechanisms—beyond the employee performance review process—should be put in place to make sure the contractor is performing in accordance with the terms of any future drug return contract.

The OIG agrees with the Office of Acquisition, Logistics, and Construction's plan to address recommendation 8 by developing and distributing a template to VHA network contracting officers once the required terms and conditions are determined for any future drug return contract. While the Office of Acquisition, Logistics, and Construction asked to close this recommendation, the OIG will leave this recommendation open until such time a new drug return contract is established and proposed templates are created, or a decision is made to not issue a new contract.

The OIG will monitor the implementation of the recommendations by VHA and VA's Office of Acquisition, Logistics and Construction until all proposed actions are completed.

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Contents

Abbreviations

COR	contracting officer representative
FAR	Federal Acquisition Regulation
FY	fiscal year
NCS	National Contract Service
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The Veterans Health Administration (VHA) spent about $6.6 billion on prescription drugs in fiscal year (FY) 2019. Most of this spending was on drugs that were eventually dispensed through medical facility pharmacies to veterans. Some drugs, however, cannot be dispensed to veterans because they have expired, are damaged, or will be expiring soon. When this happens, VHA's prescription drug return program allows medical facility pharmacies to return these drugs for credit or destruction to the manufacturer through a reverse distributor. In FY 2019, VHA expected to receive about $52 million from these returns. The reverse distribution contractor informed the audit team that it uses a proprietary database to assign an estimated return value to each drug VHA returns for manufacturer credit, based on the manufacturer's estimated return value for each drug.[9]

Failure to properly monitor the drug return program can increase the risk of undetected loss, theft, or misuse of drugs waiting to be returned. It can also result in missed opportunities to maximize the return value of these drugs. The VA Office of Inspector General (OIG) conducted this audit to determine if VHA provides effective oversight of its drug return program.

To review this program, the audit team examined how the drug return program is implemented at medical facilities by chiefs of pharmacy and discusses these results in the first finding. Additionally, the team assessed the merits of an OIG hotline allegation that a VA medical facility prematurely disposed of a large quantity of Tamiflu valued between $500,000 and $1 million through the drug return program.[10] The OIG substantiated this allegation. The team also evaluated VHA's administration of the drug return contract and associated task orders, and national-level monitoring of the drug return program and discusses these results in the second finding.

Prescription Drug Return Program Oversight

In October 2018, the contract awarded to Pharma Logistics went into effect for medical facilities to use to pick up drugs set aside for return by VA's National Contract Service (NCS). Under the contract, Pharma Logistics was responsible for collecting and sorting damaged, expired, or unused drugs from medical facilities and returning them to drug manufacturers for credit. Pharma Logistics provided medical facilities drug return services under this contract for two years, ending on October 8, 2020.

[9] Estimated return values are based on the manufacturers' estimated return value of the drugs. This value is not necessarily equal to or less than what VHA paid to purchase the drugs. In fact, in some cases VHA may receive more in return credits for some drugs than it paid for the drugs initially. Drug manufacturers are not required to participate in a return credit program. Each drug manufacturer that participates in the return credit program has the authority to set their own return credit terms and values.

[10] Tamiflu is often used to treat influenza symptoms.

Although medical facilities were not required to use this contract, all facilities chose to do so. According to VHA officials, before October 2018, Veterans Integrated Service Networks (VISNs) could use one of several national contracts or local contracts for drug return services for medical facilities.[11] Medical facilities could also use Pharma Logistics to facilitate the disposal of the pharmacy's nonhazardous waste, such as intravenous fluids. Pharma Logistics charged medical facilities a flat fee for pick up for this service.

At the time of the OIG audit, the responsibilities for administering VHA's drug return contract and for operating and overseeing VHA's prescription drug return program were outlined in VA's drug return contract with Pharma Logistics and VHA Directive 1087.[12] As outlined in these documents, at the nation level, the governance of the drug return program was divided among three offices:

- VA's NCS[13]
- VHA's Office of the Deputy Under Secretary for Health for Operations and Management
- VHA's Office of the Deputy Under Secretary for Health for Policy and Services

Additional information about the roles and responsibilities of these offices and the governance structure of the drug return contract and program is presented in finding 2.

Prescription Drug Return Program Operational Requirements

During the audit team's review period, VA's drug return contract with Pharma Logistics and VHA Directive 1087 detailed how drugs from medical facilities should be managed by pharmacy chiefs and how Pharma Logistics' drug return representatives would process these drugs at the medical facilities and at the Pharma Logistics' warehouse. Figure 1 provides an overview of the drug return process that typically occurred at medical facilities.

[11] VHA's 18 VISNs are regional networks for healthcare delivery. These networks work together to meet local health care needs and provide care to veterans at medical facilities in the network.

[12] VHA Directive 1087, *Monitoring of Expired or Soon-To-Expire Medication Returns*, August 2019. This directive was rescinded on March 24, 2021, and some aspects related to the oversight of expiring medication by pharmacy chiefs were incorporated into VHA Directive 1108.07(1), *Pharmacy General Requirements,* March 10, 2017, as amended January 26, 2021. Other aspects were pulled into a pharmacy guidance document, issued to the field in April 2021.

[13] VA's National Contract Services operates under the direction of the principal executive director of VA's Office of Acquisition, Logistics, and Construction.

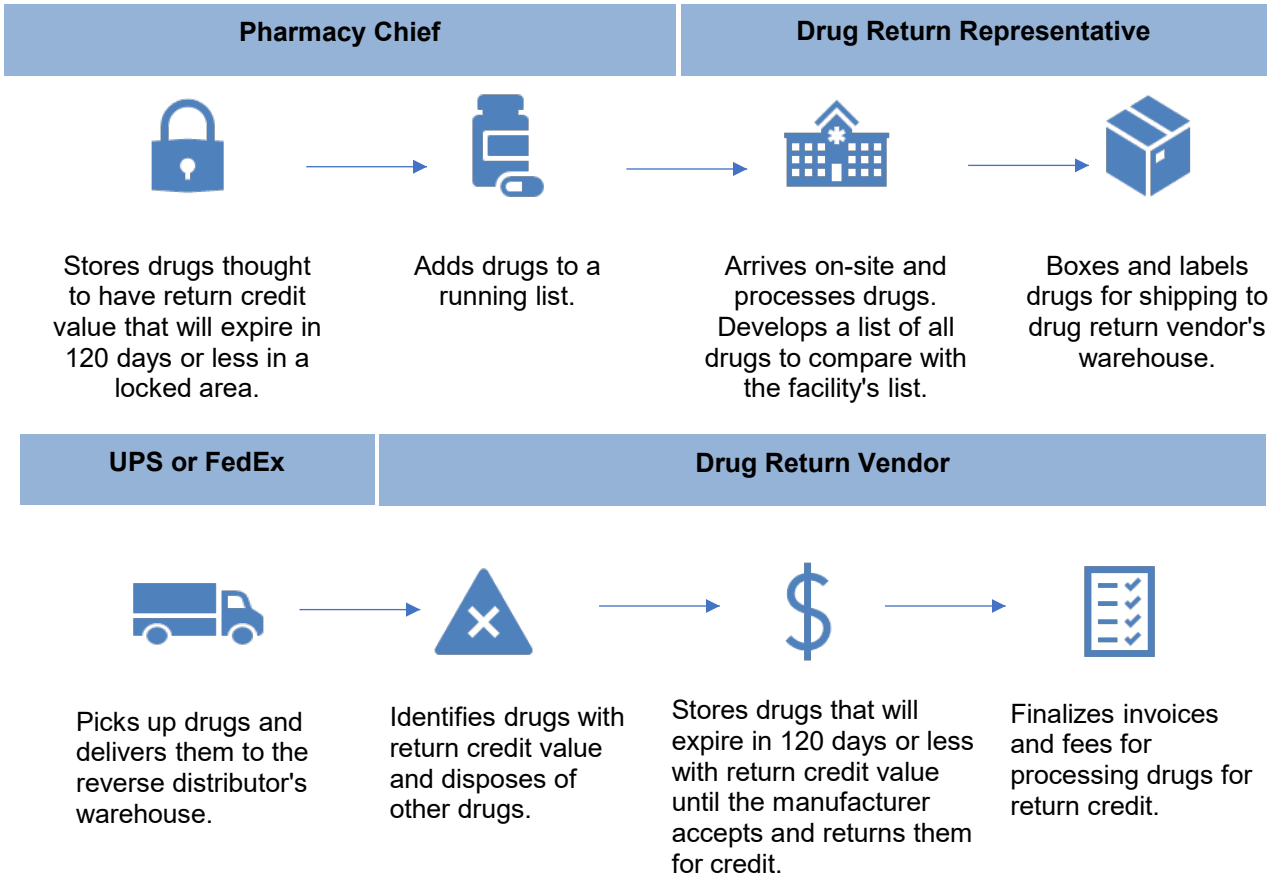

Figure 1. *Overview of reverse distribution process for drugs that pharmacy chiefs set aside for return credit. Source: VA OIG analysis of interviews with VA officials and Pharma Logistics representatives, and of VHA guidance and the drug return contract.*

According to VHA Directive 1087, pharmacy chiefs or their designees are responsible for securing and tracking drugs held for return and are also responsible for monitoring their facility's drug returns for ways to maximize drug return credit revenues. At the medical facility level, expired or soon-to-expire drugs that medical facilities hold for return credit must be secured separately from other pharmacy items. Pharmacy employees should presort and separate drugs that are expected to have a return credit value from drugs that do not. Drugs held for return credit must also be tracked through ongoing lists until they are picked up by the contracted reverse distributor to reduce the possibility of undetected loss, theft, or misuse.

According to VA's contract with Pharma Logistics, pharmacy chiefs should only return drugs for manufacturer's credit that they expect would be eligible and that would expire within 120 days. If VA returns drugs outside of this 120-day window, Pharma Logistics does not have to store or process these drugs for return credit and may destroy them. Pharma Logistics representatives processed those drugs on-site at medical facilities. While on-site, according to the contract with Pharma Logistics and VHA Directive 1087, the representative was supposed to create a list of all drugs that were processed for return credit. The pharmacy chief and the Pharma Logistics

representative were supposed to compare the facility list of drugs held for return credit with the representative's list and resolve any discrepancies before the drugs were removed from the facility.[14] The drugs were then shipped to Pharma Logistics' warehouse for final processing and storage, and returned to manufacturers as they became eligible for credit.

Under the terms of the contract, VA paid Pharma Logistics a fixed percentage based on the actual credits it received from drug manufacturers for its returned drugs. Pharma Logistics is supposed to close and finalize invoices for drugs medical facilities returned no later than 18 months after issuing the preliminary invoice. These finalized invoices should reflect a reconciliation of any over- or underpayments of return credits. Once invoices are finalized, Pharma Logistics should charge VA a fee that is based on each facility's drug return value. The last invoices associated with VA's now-expired contract with Pharma Logistics should be finalized by April 2022.

Drug Return Contract with Pharma Logistics Closed

Leaders from VHA's Pharmacy Benefits Management Services notified VISN directors in February 2020 that VHA would not exercise the second option year of the contract with Pharma Logistics because the contract was not meeting its needs. They instructed facility directors during the remainder of the first option year of the contract to

- only send already expired drugs for return credit, so that all drugs will be returnable as soon as they are processed, and
- schedule a maximum of two returns through October 8, 2020—the end of the contract's performance period.

On October 8, 2020, VA did not exercise the second option year of its contract with Pharma Logistics, and there is currently no national drug return contract in place. Until a new contract is awarded, VA's Pharmacy Benefits Management Services' deputy chief consultant for formulary management told the audit team that they advised chiefs of pharmacy to

- hold drugs set aside for return at their facilities until a new contract is awarded, or
- implement interim local drug return processes through local contracts with reverse distributors.

VA's Pharmacy Benefits Management Services' deputy chief consultant for formulary management told the OIG they had hoped to give the NCS a statement of work for a new drug

[14] VHA Directive 1087.

return contract by January 2021 but efforts to do so were impacted by higher priority work related to the COVID-19 pandemic.

Changes to Policy for the Drug Return Program

In October 2020, Pharmacy Benefits Management Services chief consultant and the deputy chief consultant for formulary management informed the audit team that VA plans to rescind VHA Directive 1087 and incorporate parts of the directive related to inventory management into a new pharmacy inventory management policy. On March 30, 2021, VA notified the OIG that VHA Directive 1087 was rescinded, effective March 24, 2021. Aspects of the directive that are specific to the pharmacy chief's oversight of the security and tracking of drugs set aside for return were incorporated into VHA Directive 1108.07(1). According to Pharmacy Benefits Management Services' deputy chief consultant for formulary management, a new policy will be developed for pharmacy operations that will consolidate information from several existing pharmacy directives into one policy. This new policy is expected to be published at its earliest by the beginning of FY 2022.

However, Pharmacy Benefits Management Services' deputy chief consultant for formulary management said that other aspects of VHA Directive 1087 were not incorporated into VHA Directive 1108.07(1) but were instead incorporated into a pharmacy guidance document. This document includes all activities that pharmacy chiefs must continue to perform at the local facility level until all open Pharma Logistics invoices are closed—such as reconciling credits received against those expected, and also includes Pharmacy Benefits Management Services' and VISN pharmacist executives requirements for the drug return program that had been part of VHA Directive 1087.

Results and Recommendations

Finding 1: Pharmacy Chiefs Did Not Effectively Implement the Drug Return Program, Increasing Drug Diversion Risk and Putting VA at Risk of Losing About $18.1 Million

VA's drug return program is intended to help the department recover some of the funds it spends on drugs at its medical facilities when those drugs go unused. However, the OIG determined that pharmacy chiefs in these medical facilities did not effectively implement the program, including not following several program requirements, as stipulated in VA's contract with Pharma Logistics and VHA Directive 1087:

- They were not securing all drugs held for return credit in locked areas separate from other pharmacy inventory.
- They did not always create and update running lists that detailed the names and quantities of each drug set aside for credit.
- They did not always compare their lists of drugs waiting for return against lists created by the Pharma Logistics' representative before these drugs left the facility.
- They did not always sort controlled drugs that should be disposed from those that could be returned for credit.
- They did not always conduct analyses that would determine if they received all the credits they should have or if there were ways to maximize their drug return credits and improve their pharmacy inventory practices.
- They did not follow contract requirements to return drugs due to expire within 120 days, putting VA at risk of losing about $18.1 million.

These problems occurred because pharmacy chiefs were not fully aware of the terms of VA's contract with Pharma Logistics and requirements of VHA Directive 1087. For instance, interviews revealed that pharmacy chiefs believed they were appropriately securing and tracking drugs, when in fact they were not, and were mistaken that their lists of drugs for return were updated correctly. In addition, pharmacy chiefs returned drugs for credit that had more than 120 days left until they expired, putting these drugs at risk of being destroyed and receiving no credit. VA's lack of oversight of the drug return program is detailed in finding 2.

Overall, because the pharmacy chiefs did not effectively implement the drug return program, as required by the contract with Pharma Logistics and VHA Directive 1087, they did not maximize the value of their drug returns, and VA risked losing an estimated $18.1 million in FY 2019. However, the OIG notes that in response to issues the audit team brought to VA's attention

during the course of its work, VA took fast action to recover about $2.2 million worth of the drugs that Pharma Logistics planned to destroy. In addition, Pharma Logistics had already returned about $1 million worth of drugs to manufacturers as they became eligible for credit. The OIG concluded that, after VA's quick action, about $14.6 million of the $18.1 million at risk were actual monetary losses, and about $307,365 was a questioned cost.

What the OIG Did

To examine how the drug return program was implemented at medical facilities by chiefs of pharmacy, the OIG team conducted five no-notice site visits in November and December 2019 to VA medical facilities to observe their drug return operations. The team inspected 12 pharmacies that were operated by five facilities.[15] Table 1 details each facility by name and location and the types of pharmacies in operation at the time of the team's site visits.

Table 1. No-Notice Site Visits Conducted in November and December 2019

VA medical facility name and location	Inpatient pharmacy (5)	Outpatient pharmacy (5)	Additional pharmacy (2)
Cincinnati VA Medical Center, OH	X	X	X - Rehab Center
Corporal Michael J. Crescenz VA Medical Center, Philadelphia, PA	X	X	X - Nursing Home
Biloxi VA Medical Center, Biloxi, MS	X	X	
Jesse Brown VA Medical Center, Chicago, IL	X	X	
Rocky Mountain Regional VA Medical Center, Aurora, CO	X	X	

Source: VA OIG site visit locations for drug return audit.

The audit team also analyzed Pharma Logistics' FY 2019 drug return data to determine the total volume and dollar value of returned drugs, the proportion of drugs returned outside the 120-day window required by the contract, and the types of drugs returned for credit. The team interviewed representatives from VHA and VA national offices with defined program or contract

[15] For site visit selection, the team used the subset of all drugs returned to Pharma Logistics for return credit between October 2018 and July 2019 with too many days left until expiring (total estimated return value of $4.7 million). Facilities should not return drugs with more than 120 days left until they expire. This was the most recent data available at the time of site selection. See appendix A for additional details on site selection.

responsibilities to discuss their drug return program oversight or contract administration roles and responsibilities.

Finally, the audit team conducted an electronic survey of facility pharmacy chiefs to collect information about medical facilities' participation in the drug return program. Ninety-four percent of the pharmacy chiefs responded to the survey. In some cases, pharmacy chiefs responding to the survey did not (or did not need to) answer every question. The team used the actual number of respondents to each question rather than the total number of surveys returned as the denominator to calculate question response percentages. Doing so removes nonresponses from the calculations. More information about the scope and methodology for this audit can be found in appendix A.

Pharmacy Chiefs Did Not Always Safeguard Noncontrolled Drugs

VHA Directive 1087 requires pharmacy chiefs to secure drugs—both controlled and noncontrolled—held for return credit in a locked area separate from other pharmacy inventory. Controlled drugs are those drugs for which distribution is regulated by the federal government based on the potential for the drug to be abused. Although controlled drugs may require more stringent security measures within the pharmacy vault or safe, noncontrolled drugs also have the potential to be diverted and abused. Similar to controlled drugs, they are subject to several security requirements set out in VHA Directive 1087.

The OIG found that there was a significant discrepancy between how the pharmacy chiefs secured controlled drugs compared to noncontrolled drugs. In response to the audit team's survey, 96 percent (145 of 151) of the pharmacy chiefs responded that they segregated controlled drugs in a secured vault apart from other pharmacy inventory. The audit team confirmed this practice, observing at all five sites visited that pharmacy chiefs secured controlled drugs that they planned to return in a pharmacy vault.

However, pharmacy chiefs did not always take required steps to fully safeguard noncontrolled drugs set aside for return. Only one of the five facilities the team visited was taking steps to properly secure noncontrolled drugs at all the pharmacies operating at the time of the team's site visit (two pharmacies). At the four other facilities the team visited, there were 10 pharmacies operating at the time of the team's site visits. The team observed lapses in how noncontrolled drugs were secured at seven of these 10 pharmacies.

Example 1

At one pharmacy, a box used to store drugs for return was locked, but an OIG auditor was able to open the hatch far enough to allow an adult's hand to fit through the box's door and remove drugs. This box was mounted on the wall in an area that was accessible to all pharmacy personnel.

Example 2

At a second pharmacy, the bin used to store noncontrolled drugs waiting for return had a round hole cut into the top of the lid to allow pharmacy personnel to drop drugs into the bin. However, the hole was so large that an OIG auditor was able to pull out drugs intended for return. The bin's lid also was not secured tightly and could be tilted up far enough to remove drugs (see figure 2).

Figure 2. *Drugs held for credit stored with loose zip ties that a hand could fit through at a VA pharmacy.*

Source: VA OIG site visit, November 13, 2019.

Example 3

At a third pharmacy, the team found that drugs were initially set aside in open bins within the pharmacy receiving area and accessible to all pharmacy personnel (see figure 3).

Figure 3. *Drugs held for credit stored in an open container accessible to anyone in a VA pharmacy area.*

Source: VA OIG site visit, December 5, 2019.

These open bins do not meet VHA Directive 1087 requirements for pharmacy chiefs to ensure noncontrolled drugs set aside for return are stored in a secure locked area separate from normal pharmacy inventory, with limited access.[16]

When the audit team spoke to pharmacy chiefs from these four facilities, the team concluded that the pharmacy chiefs at some of these facilities were unaware that their efforts to secure noncontrolled drugs waiting for return at their pharmacies were not adequate to safeguard these drugs from diversion.[17] In fact, all four pharmacy chiefs incorrectly reported on the OIG's survey that they agreed or strongly agreed with the statement, "I have enough information to know how to effectively secure drugs held for return credit." There appears to be a disconnect between the requirements of VHA Directive 1087 and the practices implemented by each of these pharmacies to secure noncontrolled drugs.

Pharmacies Did Not Effectively Use Required Running Lists to Track and Account for Returned Noncontrolled Drugs

Although VHA Directive 1087 requires pharmacy chiefs to maintain a running list with the name and quantity of any noncontrolled drugs that are removed from the pharmacy's shelves for return credit, the audit team found that pharmacy chiefs were not always tracking noncontrolled drugs set aside for credit in such a manner.

[16] VHA Directive 1087.

[17] Four pharmacy chiefs oversaw these seven pharmacies.

Seven of the 12 pharmacies did not track on running lists noncontrolled drugs removed from the shelf for return credit:[18]

- Two pharmacies did not maintain lists of noncontrolled drugs set aside for return. Pharmacy personnel reported that they did not maintain lists because often there were so few drugs being held for return that it seemed unnecessary.
- Three pharmacies created lists right before the Pharma Logistics representative came on-site to pick up noncontrolled drugs, but these lists were not updated in real time.
- The remaining two other pharmacies updated their lists weekly, rather than continuously as drugs were being removed from the shelves for return.

Overall, the audit team found that five of the 12 pharmacies had lists of at least some of the noncontrolled drugs being held for return credit on the day of the audit team's site visit. At these facilities, the team selected a sample of drugs from the lists to determine if these drugs could be physically accounted for in the locations used to store drugs set aside for return. The team also selected drugs each pharmacy stored for return to determine the extent to which these drugs were accounted for on each pharmacy's list of drugs set aside for return.

At three of these five pharmacies, the team identified at least one discrepancy when conducting this analysis:

- At one pharmacy, five drugs being held for return credit were not on the list.
- At a second pharmacy, two drugs from the list could not be located. For a third drug, there was a discrepancy between the quantity indicated on the list and the actual quantity being held.
- At the third pharmacy, two of three boxes of one drug detailed on the list were missing.

These discrepancies occurred because pharmacy chiefs were not taking steps to ensure their lists of drugs held for return were accurate and updated on a running basis. These three pharmacy chiefs were also generally unaware of and could not explain why noncontrolled drugs on the facility lists could not be found among the drugs being held for return, or why noncontrolled drugs being held for return were not accounted for on their lists. Without accurate lists, chiefs cannot detect when drugs are being diverted.

[18] These seven pharmacies were operated by three of the five medical facilities the audit team visited. Table 1 details each facility's name and location as well as the number and types of pharmacies each facility operated at the time of the team's visit.

In addition, the team found that the situation in the visited pharmacies contrasted markedly with pharmacy chiefs' responses to the OIG survey. Most of the pharmacy chiefs who reported taking actions to track noncontrolled drugs (82 percent, or 123 of 150) reported maintaining running lists as one of several ways to track noncontrolled drugs. These chiefs included those at the facilities the team visited and identified a lack of running lists.[19] This disconnect may be the result of VHA Directive 1087 not describing how such lists should be kept. Providing explicit instructions on how to keep such a list may facilitate improved compliance with this requirement.

These problems did not occur for controlled drugs, which according to VHA Directive 1087, should be accounted for using the VistA *Controlled Substance Hold for Destruction Report* when they are removed from regular pharmacy inventory.[20] Ninety-seven percent (147 of 151) of the pharmacy chiefs who reported taking some action to track controlled drugs reported they tracked them in VistA. During visits to the five facilities, the team observed that pharmacy chiefs accurately tracked controlled drugs set aside for return.[21]

Facilities Did Not Compare Their Lists of Returned Drugs to Pharma Logistics' Lists Before Pickup

When Pharma Logistics representatives visit pharmacies, they are required to create a list of the drugs they plan to take back. Both VHA Directive 1087 and the Pharma Logistics contract require pharmacy chiefs to compare their own lists with Pharma Logistics' list before drugs are removed from the medical facility.

However, for both controlled and noncontrolled drugs, pharmacy chiefs were not consistently comparing lists before the Pharma Logistics representatives left the facility. For controlled drugs, 20 percent (30 of 148) of pharmacy chiefs who reported on the actions that they take to track controlled drugs responded that they compared their facility list against the Pharma Logistics representative's list after the representative left the facility with the drugs. For noncontrolled drugs, 30 percent (45 of 150) of pharmacy chiefs who reported on the actions that they take to

[19] When asked to provide a copy of their most recent lists, 88 of the 123 chiefs provided the team with their most recent list, of which 81 were electronic and seven were hardcopy. However, it is not possible to tell if these lists were created immediately before Pharma Logistics processed drugs for return or if they were running lists.

[20] VHA Directive 1087; VHA Directive 1108.01, *Controlled Substances Management,* May 2019. The "Controlled Substance Hold for Destruction Report" is used to track drugs being held for disposal and those held for return credit. Facilities should maintain these drugs separately from each other, per the terms of the Pharma Logistics contract. The Veterans Health Information Systems and Technology Architecture (VistA) is a health information system deployed across veteran care sites in the United States to provide clinical, administrative, and financial functions for all VHA hospitals and clinics.

[21] At four of the five facilities, the OIG team conducted an analysis for controlled drugs like that conducted for noncontrolled drugs and had no significant findings.

track these drugs responded that they compared facility lists to Pharma Logistics' lists after the representative left the facility.

If pharmacy chiefs do not perform this comparison before drugs are taken from the facility, they significantly weaken this control and position themselves poorly to identify and correct any discrepancies between their lists of returned drugs and Pharma Logistics' information.

Discrepancies in Lists of Controlled Drugs

In response to the OIG's survey, 30 percent (42 of 138) of the pharmacy chiefs who reported comparing their facility's lists with Pharma Logistics lists stated that they were aware of discrepancies between their lists of returned drugs and the lists Pharma Logistics representatives created at the time of pickup. The audit team requested examples of these discrepancies from the pharmacy chiefs and confirmed that there were sometimes variations between these lists—instances where the amounts of controlled drugs that facilities recorded on their return lists did not match the amount Pharma Logistics recorded as returned.

For example, one facility reported that Pharma Logistics listed that it accepted 90 bottles (with a quantity of 100 tabs in each bottle) for a total of 9,000 tabs of a particular drug. However, the pharmacy's list indicated that it actually returned nine-tenths of only one bottle, or just 90 tabs. Neither the pharmacy nor Pharma Logistics noticed this error until the Pharma Logistics representative left the site. Pharma Logistics updated the information once the facility contacted them.

Additional discrepancies are detailed in table 2.

Table 2. Reasons Reported for Discrepancies Between Facility and Pharma Logistics Lists for Controlled Drugs

Reason	Number of examples provided*
Difference between drug name, quantity, or strength on facility list and Drug Enforcement Agency forms	16
Difference in quantity between facility and Pharma Logistics' list	3
Difference in drug strength, destruction number, or national drug code between facility and Pharma Logistics' lists	3
Discrepancy in credit amount	1

**Thirty-four of the 42 pharmacy chiefs who reported on the OIG's survey that they were aware of discrepancies between their lists of returned drugs and the lists Pharma Logistics representatives created at the time of pickup provided the audit team with at least one example of a variation. Some pharmacy chiefs provided the audit team with examples of more than one type of variation.*
Source: Follow-up with chiefs of pharmacy from VA OIG national survey of chiefs of pharmacy.

Discrepancies in Lists of Noncontrolled Drugs

In response to the OIG's survey, 23 percent (26 of 115) of the pharmacy chiefs who reported comparing their facility's lists of noncontrolled drugs to Pharma Logistics' lists stated that they were aware of at least one instance where there was a discrepancy between their facility's list of drugs to be returned for credit and Pharma Logistics' list. The audit team also was informed that none of the pharmacy chiefs at the five sites visited were consistently ensuring that pharmacy lists of noncontrolled drugs were checked against Pharma Logistics' pickup lists before the drugs left the facilities.

Based on a comparison of two pharmacies' lists and Pharma Logistics lists for the most recent pickup of noncontrolled drugs, the audit team identified the following discrepancies:

- One of the pharmacy lists did not include 23 percent (51 of 220) of the drugs on the Pharma Logistics' list. Additionally, there were 193 items on the same facility list that were not on Pharma Logistics' list.
- Another pharmacy listed 37 noncontrolled drugs that were not captured as part of the 36 items on Pharma Logistics' list. Furthermore, of the 36 items, there were 14 instances in which the quantity of drugs listed differed between the pharmacy and Pharma Logistics lists.

The pharmacy chiefs at both facilities were unaware of these discrepancies before the team's analyses. They explained that pharmacy lists and Pharma Logistics lists can have discrepancies in drug quantities, making them hard to compare to Pharma Logistics' lists. Additionally, they stated that these discrepancies may have been caused by limitations with the electronic scanners Pharma Logistics used, which cannot scan partial drug containers or vials or non-bar-coded drugs.

Without performing the required comparison of facility lists to Pharma Logistics' pickup lists, none of the pharmacy chiefs at any of the sites had internal accountability over their noncontrolled drugs set aside for return. They would not be able to confirm the accuracy of vendor's accountings. Moreover, these pharmacy chiefs have little assurance that Pharma Logistics properly processed all eligible noncontrolled drugs for credit. They are also poorly positioned to identify and address any diversion of noncontrolled drugs held for return.

When asked about this issue, Pharma Logistics representatives told the audit team that their scanners rarely fail to recognize barcodes but could not scan partial or non-barcoded drugs. They also said that field representatives were directed to scan whatever they could and bring all other items—partials, vials, or other unscanned items—back to the warehouse and enter those items manually, and that ultimately all drugs would be accounted for once they were reprocessed at the vendor's warehouse. However, the contract required Pharma Logistics to inventory all drugs processed for return credit while on-site. For that reason, Pharma Logistics should have provided the facility with a list of drugs that could not be scanned so that the facility would have a record of all drugs that left its possession.

One additional example illustrates why it is important for pharmacy officials to compare the facility and Pharma Logistics lists before the drugs leave the facilities. Pharmacy staff at one facility reported during an OIG site visit that they had an unopened bottle of the noncontrolled drug metyrosine that was set aside for return credit and should have been put on the list created by the Pharma Logistics' representative at the time of on-site processing. Because this drug is expensive ($14,000 per bottle), a pharmacy technician was paying particular attention to how this drug was processed when Pharma Logistics representatives visited the facility to pick up drugs for return. Before the drug was removed from the facility, the technician reviewed Pharma Logistics' list and determined it was not listed. The technician removed the bottle of metyrosine and kept it at the facility. This situation recurred at a second pickup visit. The Pharma Logistics representative attributed the recurring discrepancy to a faulty electronic scanner that failed to recognize and record data from the bottle's barcode. The bottle of metyrosine was properly accounted for the third time the drug was processed and appeared on the Pharma Logistics representative's pickup list. Without the pharmacy technician's attentiveness, this expensive bottle of drugs could have been diverted or otherwise not properly credited to VA.

The OIG concluded that VA needs to take steps to strengthen this control for future drug return directives and may want to clarify additional requirements in the terms of any future contracts.

When the team asked why facility lists were not always compared to Pharma Logistics' lists before the representative left the facility, one pharmacy procurement manager—responsible for overseeing drug returns at the facility—said on-site processing is time-consuming and same-day reconciliation would require staff to work overnight.

Since VA is considering the requirements for a new drug return contract and directive, it may want to consider if language specifying deadlines for when on-site processing must be completed—even if more than one drug return vendor representative is required—could help medical facilities maintain better oversight over drugs returned to the vendor without unduly burdening pharmacy staff. As another alternative, using electronic software to maintain and compare the facility's and the drug return vendor's lists may accelerate this process if VA includes this requirement in any future drug return contract.

Pharmacy Chiefs Did Not Always Sort Controlled Drugs for Credit from Those Intended for Disposal, Limiting Drugs' Return Values

According to the contract with Pharma Logistics, pharmacy chiefs should be separating controlled drugs to be picked up for disposal from those returned for credit, which helps maximize the value of returnable drugs that might otherwise be mistakenly disposed of without credit.[22] The OIG determined, however, that pharmacy chiefs were not always sorting controlled drugs that should be disposed from those that could be returned for credit. Pharmacy chiefs reported they were unaware of the requirement to sort drugs in this manner. In the OIG's survey, 31 percent (47 of 151) of pharmacy chiefs reported that they were slightly or not at all familiar with the contract—including chiefs at two of the five visited facilities, and 53 percent (80 of 151) reported being slightly or not at all familiar with the modification specific to drugs sorted for disposal. The team's site visits confirmed this lack of familiarity. At three of the five facilities the team visited, the pharmacy chiefs did not separate the controlled drugs they believed to be creditable from those set aside for nonhazardous waste disposal before Pharma Logistics arrived on-site.

In some cases, Pharma Logistics representatives were sorting drugs themselves, even though the contract stated sorting was the pharmacy chief's responsibility. While on-site, some Pharma Logistics representatives were removing drugs from the controlled drugs set aside for return credit and instead processing these drugs for disposal. Pharma Logistics representatives explained to the audit team that they were sorting drugs because they knew some drugs were not creditable. They moved those drugs from one category to the other so that they could provide

[22] Medical facilities were also able to use Pharma Logistics to process nonhazardous waste—drugs known to have no return value, such as intravenous fluids—for disposal if needed. This was a separate service from the drug return service. VA medical facilities paid Pharma Logistics a flat fee each time Pharma Logistics picked up drugs for disposal, regardless of the volume of drugs.

appropriate Drug Enforcement Administration documentation. However, the OIG noted that this work should have been performed by VA pharmacy personnel.

Additionally, the audit team noted that VA faced potential financial losses on credits due for returned controlled drugs. This was due to Pharma Logistics' processing these drugs inconsistently with the contract's terms, which stipulated that Pharma Logistics would process all drugs returned expired or due to expire within 120 days or less. For all controlled drugs that were received within the 120-day time frame, Pharma Logistics should have accepted the drugs, stored them if necessary, and returned them for credit when they were eligible. It should be noted that each drug manufacturer can determine when they will accept expired drugs for credit, for example, 30-days before they expire or only once they expire.

However, Pharma Logistics reported to the OIG that they only returned controlled drugs to manufacturers for credit if the drugs were eligible for return at the time they were processed for return at the Pharma Logistics warehouse. All other controlled drugs were destroyed, including drugs returned with 120 days or less left until they expired and were otherwise creditable. A Pharma Logistics representative told the audit team that the company did not have space to store controlled drugs and believed this approach was an industry standard. Pharmacy Benefits Management Services was not aware of this practice. The team only became aware of this during a site visit to the Pharma Logistics' warehouse when a representative reported that all controlled drugs that were not eligible for credit when they arrived on-site were destroyed, even if they were within the 120-day time frame. The OIG concluded that Pharma Logistics did not fulfill the terms of its contract, which resulted in a significant financial loss for VA.[23]

Pharmacy Chiefs Did Not Monitor Drug Return Data to Help Maximize the Value of Drug Returns and Improve Pharmacy Inventory Practices

To maximize the value of drug returns, VHA Directive 1087 requires pharmacy chiefs to

- review Pharma Logistics' electronic data system to ensure they receive credits for returned drugs,
- biannually review drug returns for drugs with high acquisition costs to determine if the credits received are reasonable,
- analyze Pharma Logistics' data to identify improvements to increase credits received and improve inventory management practices, and
- communicate the results of their reviews to VISN pharmacist executives.

[23] This amount cannot be quantified because these drugs were destroyed instead of being returned to the manufacturers for credit.

Results from the national OIG survey detailed in table 3 indicated that most pharmacy chiefs were not consistently complying with the directive's four key requirements by conducting related analyses intended to help facilities maximize their drug return values.

Table 3. Required Analyses That Pharmacy Chiefs Reported Conducting on Drug Return Data

Analyses conducted by pharmacy chiefs on drug return data	Percent of pharmacy chiefs who reported they conducted required drug return data analyses*
Review accuracy of credits received: Reconcile credits expected and received	75 percent (114 of 153)
Review drugs with high acquisition costs: Test high-value returns to determine whether the amount of credits received was reasonable	22 percent (33 of 151)
Analyze drug return data to identify improvements: • Look for trends in drugs that do not receive credit • Review web-based reports regarding drugs returned to manufacturers for credit received to identify any potential improvements that may increase the amount of credit received	52 percent (78 of 151) 50 percent (76 of 151)
Communicate results to VISN Pharmacist Executive:	23 percent (35 of 151)

Source: VA national survey of chiefs of pharmacy.
** In some cases, pharmacy chiefs responding to the survey did not (or did not need to) answer every question. The audit team used the actual number of responses to each question rather than the total number of surveys returned as the denominator to calculate response percentages for each question.*

At the five facilities visited, the audit team confirmed overall survey findings that many pharmacy chiefs were not complying with these required analyses. They were either unaware of the requirements or told the team they did not have time to complete the analyses.

Without conducting these required analyses, facilities could not determine if they received all the credits they should have, if all drugs that were processed by Pharma Logistics were either returned for credit or destroyed, or if there were ways to better maximize their drug return credits and improve their pharmacy inventory practices.

Returning Drugs Too Early Placed $18.1 Million at Risk

Because the pharmacy chiefs did not effectively implement the drug return program, they missed several opportunities to maximize the value of drugs returned for credit. Pharmacy chiefs were not adequately familiar with the VA's drug return contract with Pharma Logistics and returned drugs early—before the contractually required 120 days until expiration. Pharma Logistics did

not have to store, and could destroy, drugs returned outside of the terms of the contract. In fact, VHA was under the impression that Pharma Logistics was destroying all drugs returned with greater than 120 days left until they expired. As a result of returning drugs too early, pharmacy chiefs risked an estimated $18.1 million. While VA took quick action following the OIG's notification to recoup $2.2 million and Pharma Logistics credited VA an additional $1 million for drugs they returned to the manufacturers as they became eligible for credit, the OIG believes that an estimated $14.6 million of the remaining about $14.9 million represents funds that could have been put to better use if pharmacy chiefs fully complied with the terms of the contract. This estimated $14.6 million is composed of about

- $1.2 million in creditable drugs returned too soon,[24]
- $3.7 million in not creditable drugs returned too soon,[25]
- $6.8 million spent to replace drugs returned too soon,[26] and
- $2.9 million spent to replace Tamiflu that was also returned too soon by one facility.

The OIG also questions the estimated $307,365 VHA paid to Pharma Logistics to process drugs returned too soon.[27] Overall, the OIG found that VHA's poor management of the drug return program resulted in a monetary loss of about $14.9 million.

Table 4 details the $18.1 million pharmacy chiefs put at risk when they returned drugs too soon. Data captured in the shaded row of the table details the calculations the audit team made to

[24] As of the end of FY 2019, the OIG determined from Pharma Logistics' data system that of the $8.8 million in drugs returned too soon—with more than 120 days left until they expired, Pharma Logistics determined that drugs with an estimated return value of about $4.42 million were creditable. It should be noted that because Pharma Logistics has up to 18 months to issue medical facilities with finalized invoices that detail the final value of returned drugs, it is possible that VA will receive more or less than Pharma Logistics' estimated return value. From Pharma Logistics' data system, the team also determined that drugs with an estimated value of about $4.36 million were found to be nonreturnable for manufacturer credit. See appendix B for additional details on the monetary benefits.

[25] Based on each manufacturer's unique drug return policy, not all drugs are eligible for manufacture credit. Furthermore, drugs may be determined to be nonreturnable for credit for reasons that include damaged drug packaging, or the drugs were returned in a partial quantity. However, nondamaged drugs may also not be accepted by manufacturers for credit. By returning drugs too soon, VHA lost the ability to use these drugs for patient care. To account for the fact that returned drug values can be affected by these factors—regardless if they were returned on time or too soon—the team reduced the total value of $4.36 million for the drugs that had no return value by 15 percent—or to $3.7 million.

[26] VA spent about $9 million to repurchase the drugs it returned too early, which could have been directed toward other necessary expenditures. The replacement cost was based on the Prime Vendor drug replacement cost data from August or September 2019, or the most recently available price paid by VHA. The team removed from this calculation two high cost drugs because VA will not repurchase these drugs in the same large quantities in which they were returned. In addition, to account for the fact that some drugs will have to be repurchased before they expire because of damage or spoilage, the team reduced the total repurchase amount of $9 million for the drugs by 15 percent to $6.8 million.

[27] NCS's director informed the OIG that about $248,733 of the $307,365 is expected to be refunded by Pharma Logistics to the applicable pharmacies.

account for the amount of noncreditable drugs expected to be damaged or spoiled through normal pharmacy operations. The team summed the bolded dollar amounts in the second column to determine the estimated total amount of returned drugs VA placed at risk. See appendix B for a breakdown of the $14.9 million in total better use of funds or questioned costs.

Table 4. Risks Created When Pharmacy Chiefs Returned Drugs with Greater Than 120 Days Left Until Expiration

Risk from pharmacy chiefs prematurely returning drugs they believed to be creditable	Estimated return value VA put at risk
Drugs Pharma Logistics determined were creditable that Pharma Logistics stored instead of destroying*	**$4.4 million**
Amount of noncreditable drugs remaining that VHA lost the ability to use for patient care by returning too early.	**$3.7 million**
Value of drugs Pharma Logistics determined were not creditable. This occurs if drugs have damaged packaging, are in partial quantities, or if manufacturers do not accept nondamaged, usable drugs for credit for other reasons—$4.4 million *Amount of noncreditable drugs expected to be damaged or spoiled through normal pharmacy operations (15 percent reduction to the total of $4.4 million in noncreditable drugs)—($653,000)**,†*	
Expended by VHA to replace drugs returned too early. ††	**$6.8 million**
Replacement value of Tamiflu returned too early by a medical facility, resulting in the drug's destruction.	**$2.9 million**
Processing fee VHA paid to Pharma Logistics for the $4.4 million creditable drugs, which were returned outside the terms of the contract and no fee should have been charged.	**$307,365**†††
Total	**$18.1 million**††††

Source: VA OIG analysis of Pharma Logistics FY 2019 drug return data and drug costs as of FY 2019 or the most recent purchase price available. For the total better use of funds and questioned costs, see appendix B.
** VHA was not aware that Pharma Logistics was storing these drugs until informed by the OIG. VHA will not recoup the full credit value of the drugs through Pharma Logistics' Rapid Credit program because Pharma Logistics has already credited VA for some drugs returned too early ($1 million), and VA took action to recoup some of the funds placed at risk when drugs were returned too soon ($2.2. million).*
*** Amount noted in parentheses represent dollar values that the team deducted for reasons that included the estimated cost of noncreditable drugs expected to be damaged or spoiled through normal pharmacy operations ($653,000).*
† To account for the fact that some drugs will be spoiled or damaged and not creditable even if returned on time, the audit team applied a 15 percent drug loss rate. The team also removed two high costs drugs that would not be replaced in pharmacy inventories from the drug replacement cost calculation.

†† The replacement cost was based on the Prime Vendor drug replacement cost data from August or September 2019, or the most recently available price paid by VHA.
††† NCS's director informed the OIG that about $248,733 of the $307,365 is expected to be refunded by Pharma Logistics to the applicable pharmacies.
††† Totals may not equal the sum of the values because all amounts are rounded up to the closest full value (e.g., $8,777,634 is rounded to $8.8 million).

Although the 120-day threshold was part of previous contracts, Pharmacy Benefits Management Services leaders told the audit team they were unaware that facilities were returning excessive amounts of drugs early and missing opportunities to maximize return credits until Pharma Logistics brought this issue to their attention. In response, the leaders issued guidance to facility chiefs of pharmacy in June 2019 to remind them of the 120-day return threshold and to encourage them to reallocate excessive quantities of drugs that a facility likely cannot use to other VA medical facilities that could use the drugs before they expire.[28]

VA Returned Drugs Too Soon, Failing to Maximize Credits

Although the contract required that VA only return drugs for processing when they were within 120 days of their expiration date, all five medical facilities the audit team visited returned drugs before the 120-day window.[29] Nor was this problem confined to the five facilities the team visited. Based on Pharma Logistics FY 2019 drug return data, the OIG found that all VA medical facilities returned at least some drugs for credit early, instead of using them or storing them at the medical facility until they met the 120-day threshold. In total, medical facilities prematurely returned drugs with an estimated return value of about $8.8 million more than 120 days before expiration. According to Pharma Logistics, $4.4 million of the drugs returned too soon had no return value. Drugs may not have a return value for a variety of reasons that can include the drug's manufacturer does not accept returns, or the drugs were returned in damaged or partial packaging. Pharma Logistics determined that the remaining $4.4 million of drugs prematurely returned would have a return value once they were returned to manufacturers. According to the terms of VA's contract with Pharma Logistics, Pharma Logistics was not required to hold drugs that medical facilities returned outside of the 120-day window until they were eligible to be returned to drug manufacturers for credit. When facilities returned drugs too early to Pharma Logistics, they not only violated the terms of VA's contract with Pharma Logistics, they also failed to maximize the return value for these drugs as required by VHA Directive 1087.

Pharmacy chiefs told the audit team that they were not aware that they should not be returning drugs so early, explaining that they returned drugs early due to refrigeration temperature control issues, drugs that were shipped to patients but returned to the medical facility as undeliverable,

[28] National Pharmacy Benefits Management (PBM), "Guidance Return/Disposal of In-Dated Products," June 2019.

[29] As one site visit criteria, the audit team analyzed preliminary drug return data from October 2018 through July 2019 and selected sites that returned drugs with the highest estimated return value of drugs outside of the 120-day threshold.

and changes to the Emergency Pharmaceutical Cache footprint, resulting in reduced need for some types of drugs. However, pharmacy chiefs did not always know why they returned some drugs because they did not keep records of the reasons for the returns.

The pharmacy chiefs further explained that if they had been aware of the 120-day requirement, they would have stored the drugs on-site until that time to maximize the value of credits received for drug returns. Several of the pharmacy chiefs told the team that previous drug return contracts with vendors including Pharma Logistics allowed them to return drugs with more than 120 days before expiration.[30] However, the audit team determined previous drug return contracts with Pharma Logistics also included the requirement that drugs not be returned earlier than 120 days before expiration.

When the team asked Pharma Logistics about this issue, representatives said the volume of drugs VA medical facilities returned outside of the threshold under previous local contracts had been small enough that they were able to store the drugs until they met the 120-day threshold for return. However, as the only national contractor serving VA after October 2018, Pharma Logistics determined that they did not have the capacity to store the volume of noncontrolled drugs that facilities were returning before they were eligible for drug manufacturer credit unless VA added a storage agreement at an additional cost to the contract. VA had not wanted to add a storage agreement to the national contract in October 2018. In January 2020, Pharma Logistics officials reported to the team that they would no longer store noncontrolled drugs that were returned too early and would start processing them for disposal in March 2020. When drugs are destroyed, they provide no return value to VA.

VA Acted Quickly After OIG Notification to Recover $2.2 Million for Noncontrolled Drugs Returned Too Soon

Pharma Logistics informed the audit team that in March 2020 they planned to stop storing noncontrolled drugs that medical facilities returned too early. They also planned to destroy all drugs that had been returned too early and any additional drugs that medical facilities continued to return too early. Up until this point, Pharma Logistics was storing these drugs and returning them to the manufacturers for credit once eligible, even though the contract only required it to process drugs for credit that were returned with 120 days or less left until expiration. In part, Pharma Logistics told the audit team that they were storing noncontrolled drugs in this way because its internal processes made it difficult to identify drugs returned too soon before they entered its warehouses. Pharma Logistics was updating their internal processes so that they could

[30] Before awarding of the drug return contract that was national in scope to Pharma Logistics in 2018, medical facilities obtained drug return services through contracts that were awarded locally providing service to a single medical facility or providing services to all or some facilities in a VISN.

identify drugs that medical facilities returned too early first—before the drugs entered the Pharma Logistics warehouse for storage.

In January 2020, the OIG notified VA officials to alert them about Pharma Logistics' practice to store noncontrolled drugs that had been returned too early and the company's decision to stop this practice. Pharmacy Benefits Management Services' deputy chief consultant for formulary management and the director of NCS were unaware of Pharma Logistics' storage practices believing that the terms of the contract were being followed and that the drugs that were returned too early had been destroyed.

Following the OIG's notification, NCS took quick action to issue a contract modification to participate in Pharma Logistics' Rapid Credit program to recoup a portion of the drugs valued at $4.4 million in return value that medical facilities had returned too soon in FY 2019. Although VA received a lower credit value for these drugs than it would have if the drugs had been returned with less than 120 days left until they expired and through the normal return process, the modification allowed VA to receive a percentage of the estimated return value for the drugs that were still being stored by Pharma Logistics. This percentage was based on how much time the drugs had left until they expired. Without the Rapid Credit program VA would have received no return value for these drugs and they would have been destroyed by Pharma Logistics. Pharma Logistics retained the remaining percentage as payment for storing medical facilities' drugs until they expired.

While VA was not able to recoup the total $4.4 million in return value for the drugs that were returned too soon, its actions to modify its contract with Pharma Logistics allowed it to recoup about $2.2 million of these drugs. Because Pharma Logistics was returning VA's drugs to the manufacturers as they were eligible for credit, it was also able to credit VA with an additional $1 million.

Medical Facilities Had to Repurchase Drugs Returned Too Early

Of the 50 drugs the audit team examined, 40 were repurchased by the facilities before the original (returned) drugs would have expired, at a cost of $6.8 million.[31] This unnecessary expenditure could have been directed toward other necessary expenditures.

[31] Drugs were considered returned too early if they were returned with more than 120 days until expiration. VA spent about $9 million to repurchase the drugs it returned too early. This amount could have been directed toward other necessary expenditures. The replacement cost was based on the Prime Vendor drug replacement cost data from August or September 2019, or the most recently available price paid by VHA. The OIG calculated the cost as $6.8 million after subtracting the cost of two high-cost Emergency Cache Program drugs and then applying a 15 percent drug loss rate. Following the 9/11 attacks, VA established an emergency cache program to make drugs and medical supplies available at select VA medical facilities for the treatment of veterans, VA employees, and civilians in the immediate aftermath of a local mass casualty event or a pandemic. The cache footprint was revised in 2019 and these two drugs will not be repurchased.

A Medical Facility Returned Tamiflu Too Soon

While responding to an OIG hotline allegation, the team also determined that medical facility staff accidently returned 28,512 packages of the drug Tamiflu in November 2019. The drug, used to treat influenza, was stored in the medical facility's emergency cache. Because the drug was deemed suitable for patient care, the manufacturer's expiration date was extended by the Food and Drug Administration as part of the Shelf Life Extension Program. VHA participates in this program for drugs that are stored in its Emergency Cache Program. The Tamiflu was destroyed by Pharma Logistics because it was past its original manufacturer expiration date. The audit team substantiated the allegation, determining that the Tamiflu would not expire under the Shelf Life Extension Program until May 2021. VHA's current cost to replace this drug for the facility's emergency cache would be about $2.9 million.[32]

Incorrect Processing Fees Paid to Pharma Logistics

VA paid Pharma Logistics $307,365 for reverse distribution services for the $4.4 million in drugs that pharmacies returned too early that were otherwise creditable.[33] These drugs were not eligible for credit under the terms of the contract when they were returned because there were more than 120 days left until they expired.[34] However, Pharma Logistics still charged VA a fee to process these drugs even though they were returned outside the terms of the contract.

Finding 1 Conclusion

VHA's drug return program is intended to provide medical facility pharmacies with manufacturer credits for drugs that cannot be dispensed to patients. When medical facility chiefs of pharmacy failed to effectively implement the program by following contract and directive requirements, they increased the risk that these drugs could be misused or diverted. Additionally, VA did not maximize the value of drug returns, putting VA at risk of losing about $18.1 million.

[32] Pharmacy Benefits Management Services leaders informed the OIG team that the destroyed Tamiflu was replaced with excess stock from its warehouse at a lower cost; however, the replacement cost of the Tamiflu—under VHA's Prime Vendor contract with McKesson—related to the OIG's finding of VA's "better use of funds" is the September 2019 value of the destroyed asset and the additional cost VA will have to pay if it needs to replenish the Tamiflu.

[33] The NCS's director informed the OIG that about $248,733 of the $307,365 is expected to be refunded by Pharma Logistics to the applicable pharmacies.

[34] At the time this payment was made, it should not have been made under the contract with Pharma Logistics because Pharma Logistics should only have processed drugs returned with 120 days or less left until they expired. An improper payment is any payment that should not have been made or was made in an incorrect amount under statutory, contractual, administrative, or other legally applicable requirements. OMB, Circular A-123, app. C, "Requirements for Effective Estimation and Remediation of Improper Payments."

Recommendations 1–3

The OIG recommends that the under secretary for health ensure that responsible VA medical facility personnel do the following:

1. Secure prescription drugs set aside for return credit either by following procedures outlined in VHA Directive 1108.07(1) or by adhering to a superseding policy.
2. Account for all prescription drugs set aside for return credit when they leave the medical facility either by following procedures outlined in VHA Directive 1108.07(1) or by adhering to a superseding policy.
3. Maintain inventory management practices to make sure drugs that are returned for credit are returned in a timely manner, so that medical facilities do not miss opportunities to maximize the value of their drug returns or reduce their risk of overspending to replace drugs prematurely returned for credit.

Management Comments

The acting under secretary for health concurred with recommendations 1 through 3. To address recommendations 1 through 3, the acting under secretary for health reported Pharmacy Benefits Management Services will collaborate with the Office of the Assistant Under Secretary for Health for Operations to direct each VISN director to add new requirements for VISN pharmacist executives' routine medical facility site visit procedures. For recommendation 1, VISN pharmacist executives will inspect each medical facility's returned drug storage space. Non-compliant storage spaces will be tracked and elevated in cases of persistent noncompliance. VISN pharmacist executives' routine site visit procedures will also include an inspection of returned drug records to ensure adequate accounting for all drugs set aside for return credit to address recommendation 2. For recommendation 3, VISN pharmacist executives will review facilities' records to ensure drugs are returned for credit in a timely manner. They also will report the results of their reviews including an action plan to address any issues to a Pharmacy Benefits Management Services SharePoint site. Pharmacy Benefits Management Services will report persistent issues of facility noncompliance to the assistant under secretary for health for operations for follow-up. The full text of the acting under secretary for health's comments appears in appendix C.

OIG Response

The acting under secretary's planned corrective actions are responsive to recommendations 1 through 3 to address the issues identified in the report. The OIG will monitor implementation of the recommendations by VHA until all proposed actions are completed.

Finding 2: VHA Needs to Improve Governance of the Drug Return Contract and Program for More Effective Program Implementation

At the time of the OIG's audit, contract administration and program oversight responsibilities for VHA's drug return program were outlined in VA's drug return contract with Pharma Logistics and in VHA Directive 1087, as discussed in finding 1. Figure 4 illustrates the contract administration and program oversight responsibilities that were detailed in the contract or directive for the drug return program across national, VISN, and facility levels, at the time of the OIG's audit.

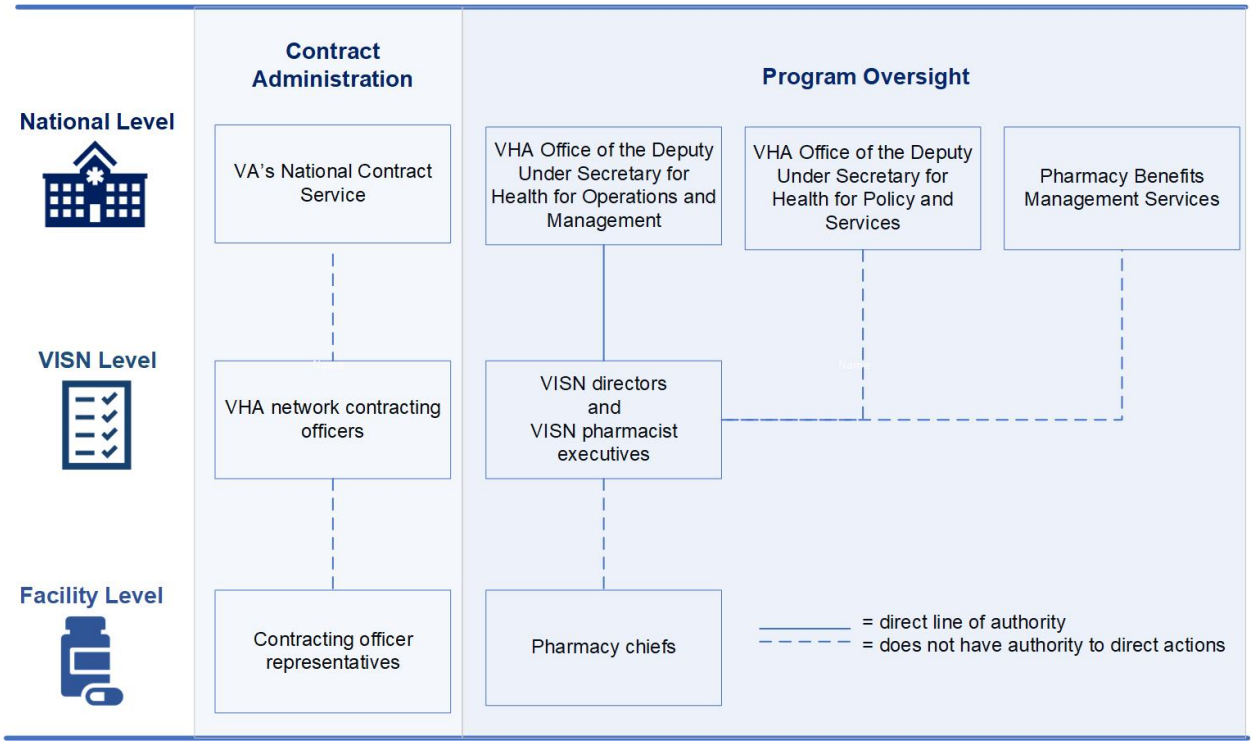

Figure 4. *Oversight structure for VHA's drug return program.*

Source: VA OIG analysis of VA organizational charts and information provided through interviews with, and documents from, VA and VHA officials.

Note: VA's NCS reports to VA's Office of Acquisition, Logistics, and Construction; and VHA network contracting officers report to VHA's Procurement and Logistics Office, through regional procurement offices.

Contract Oversight Responsibilities

VA's NCS operates under the direction of the principal executive director, Office of Acquisition, Logistics, and Construction. The NCS assigned a national contracting officer to administer VA's drug return contract with Pharma Logistics. The national contracting officer's responsibilities are

to ensure overall compliance with the terms of the contract and to evaluate the contractor's performance.[35]

VHA network contracting officers are charged with ensuring the drug return vendor is complying with the terms of the task orders they wrote to execute the contract, and that the task orders are not in conflict with the terms of the national contract.[36] To receive drug return services, medical facilities were required to have an active task order which allowed service orders to be placed against the contract. Network contracting officers issued the task orders and contracting officer representatives (CORs) monitored the day-to-day operations of the drug return contract at facilities, if they were assigned by network contracting officers.[37] If no COR was assigned, network contracting officers retained responsibility for overseeing contract administration and making sure the contractor abided by the terms of the contract.

VHA Directive 1087 Oversight Responsibilities

VHA's Office of the Deputy Under Secretary for Health for Policy and Services is charged with ensuring overall compliance with VHA Directive 1087 but does not have direct oversight authority over operations at the VISN or facility levels. According to the office's clinical nurse executive, the office facilitates the policy approval process, but does not have the authority to ensure compliance with VHA Directive 1087. In contrast, VHA's Office of the Deputy Under Secretary for Health for Operations and Management has direct authority over VISN pharmacy executives and medical facility pharmacy chiefs, according to the assistant deputy under secretary for health for administrative operations.

As outlined in VHA Directive 1087, as of August 2019, the deputy under secretary for health for operations and management is responsible for (1) communicating the contents of VHA Directive 1087 to each VISN, (2) ensuring that VISN directors have sufficient resources to implement the directive across all medical facilities, and (3) providing oversight of VISNs' compliance with the directive. At the VISN level, directors are responsible for implementing the drug return program in all VA medical facilities. VISN pharmacist executives are responsible for collecting the results of facilities' reviews of their drug return programs and providing any relevant findings about opportunities to increase drug return revenues to VHA's Pharmacy Benefits Management Services. At the medical facility level, pharmacy chiefs are responsible for managing the drug return program on a day-to-day basis.

Pharmacy Benefits Management Services' deputy chief consultant for formulary management is charged with monitoring national drug return data to identify unusual reimbursement patterns

[35] FAR 1.602-1 and 1.602-2.
[36] FAR 1.602-1 and 1.602-2.
[37] FAR 1.602-1 and 1.602-2.

and potential improvements for revenue recovery. Pharmacy Benefits Management Services operates under the deputy under secretary for health for policy and services.

VHA Lacked Adequate Oversight of Drug Return Program

As described in finding 1, pharmacy chiefs did not fully understand what VHA Directive 1087 and the Pharma Logistics contract required of them, which resulted in a number of program implementation problems. The previously identified issues in this report occurred in part because, at the national level, VHA did not have adequate controls to oversee the drug return program. NCS and network contracting officers lacked processes to ensure Pharma Logistics representatives followed the requirements outlined in VA's drug return contract with Pharma Logistics, and network contracting officers wrote inaccurate task orders for the contract. Similarly, the deputy under secretary for health for operations and management did not sufficiently communicate the program's requirements to VISN directors, helping them comply with the directive and contract requirements, and ensure they have sufficient resources to implement the drug return program.

Additionally, the ability of Pharmacy Benefits Management Services leaders to effectively monitor the drug return program nationally was hampered by their reliance on data the audit team determined was inaccurate. As discussed below, the reports Pharma Logistics provided to Pharmacy Benefits Management Services were inaccurate and incomplete. Furthermore, while analyzing this information over the first year of the contract with Pharma Logistics, from October 2018 to September 2019, a Pharmacy Benefits Management Services data analyst inadvertently introduced additional errors. VHA decision makers, as a result, could not use this information to reliably monitor the drug return program in FY 2019, verify that medical facilities were receiving the drug return credits to which they were entitled, and improve the program.

This finding addresses the following issues:

- The national contracting officer did not make sure the contractor followed the terms of the contract and issued invoices in a timely manner, and network contracting officers wrote accurate task orders.
- National and VISN officials need to improve drug return program oversight.
- Flawed data hampered Pharmacy Benefits Management Services leaders' ability to monitor program outcomes nationally.

What the OIG Did

To evaluate VHA's national-level administration of the drug return contract and oversight of the drug return program, the audit team interviewed representatives from VHA and VA national offices with responsibilities defined in the contract with Pharma Logistics or VHA Directive 1087. The team also spoke with VISN directors and pharmacist executives at the five VISNs in

which the team conducted site visits, and at a sixth VISN in which the team conducted planning work.[38] The team also analyzed Pharma Logistics' FY 2019 drug return data to determine the total volume and dollar value of returned drugs, the proportion of drugs returned outside the 120-day window required by the contract, and the types of drugs returned for credit. The team did this to determine whether VHA was using accurate data to monitor the drug return program.

The team also used data collected from the same electronic survey of facility pharmacy chiefs that informed some of the OIG's findings and conclusions discussed in the first finding of this report. Ninety-four percent of the pharmacy chiefs surveyed responded. In some cases, pharmacy chiefs responding to the survey did not (or did not need to) answer every question. The audit team used the actual number that responded to each question rather than the total number of surveys returned as the denominator to calculate question response percentages. Doing so removes nonresponses from the calculations. More information about the scope and methodology for this audit can be found in appendix A.

National and Network Contracting Officials Lacked Processes to Make Sure the Drug Return Contract Was Implemented Correctly

The national and network contracting officers did not make sure that Pharma Logistics was meeting the terms of the contract, or providing appropriate contract administration, as required by the FAR, in at least the following ways:

- The national contracting officer did not make sure that Pharma Logistics provided VA medical facilities with timely final invoices.
- Network contracting officers wrote inaccurate task orders, putting VA at risk of overpaying Pharma Logistics.
- Network contracting officers did not know if CORs or non-COR points of contact had been assigned for contract oversight.

National Contracting Officer Did Not Make Sure Pharma Logistics Provided Medical Facilities with Timely Invoices

The national contracting officer did not confirm that Pharma Logistics issued final invoices to medical facilities within 18 months of issuing the preliminary invoice, as required by the contract modification signed by the national contracting officer and Pharma Logistics representatives.[39] Pharma Logistics calculated its fee based on each facility's estimated drug return value. The

[38] The audit team did not speak with officials from the other 12 VISNs.

[39] The national contracting officer signed a contract modification specifying that Pharma Logistics would issue final invoices to correct any over or under charges from pharmacies within a period of 18 months after the initial invoices were issued.

contract allowed Pharma Logistics to directly invoice facilities for a percentage of the estimated return value of the facility's returned drugs.[40] These invoices could remain open for 18 months after the drugs were picked up from the medical facility. At this point the contract required Pharma Logistics to issue a final invoice that reflects the actual credits received from manufacturers for the drugs the facility returned and the related fees due to Pharma Logistics. Pharma Logistics should have also reconciled any over- or underpayments at the 18-month mark.

The NCS did not verify that Pharma Logistics had the technical capacity to meet the 18-month final invoicing requirement on time before awarding the drug return contract. As a result, pharmacy chiefs did not have enough information to fully reconcile the credits their facility received to determine if they received all the credits due from their drug returns. In June 2020, Pharma Logistics was finalizing the first round of invoices. This was one month after the first 18-month final invoices should have been closed and issued to VA (because preliminary invoices were issued beginning in November 2018). Pharma Logistics' delay in providing medical facilities with final invoices affected pharmacy chiefs' ability to fully comply with VHA Directive 1087. This directive requires pharmacy chiefs to review overall trends in return credits and identify opportunities to enhance their drug return revenues. To do this, pharmacy chiefs rely on timely invoices from Pharma Logistics to determine if all expected credits were received, or the reasons drugs were not creditable.

When the audit team spoke to NCS leaders, they explained that the inadequate contract oversight occurred because network contracting officers report up to VHA's Procurement and Logistics Office, through regional procurement offices, while NCS reports up to VA's Office of Acquisition Logistics and Construction.[41] In addition, NCS does not have direct access to all network contracting officers assigned to the drug return contract to provide information about the contract to them or to receive information about the contractor's performance from the network contracting officers. Since all medical facilities were not required to use the Pharma Logistics contract, NCS did not know which medical facilities were actually using the contract and did not maintain a complete list of VISN contracting officers, according to NCS officials. According to the NCS's director, a list of network contracting officers was maintained to the extent that this information was provided to the NCS by the VISNs.

However, the OIG maintains that even though all medical facilities were not required to use the contract, they all did choose to use it. Thus, the national contracting officer has a role in overseeing the contract to make sure that the terms of the contract were being met. NCS also could have maintained a list of assigned network contracting officers to strengthen its oversight

[40] According to NCS, this practice reflected a change in process based on a VA Office of General Counsel decision regarding applicable FAR language around the use of proceeds for services from prior year purchases (drug return credits) for current year purchases.

[41] Network contracting officers report to VHA's Procurement and Logistics Office, through regional procurement offices.

responsibilities. NCS leaders told the audit team they discussed delegating administrative contracting officers to the network level for any future drug return contract and whether this delegation would increase oversight and improve coordination. According to NCS leaders, under this structure—which is used for VA's pharmaceutical Prime Vendor contract—administrative contracting officers would have direct and routine contact with the national contracting officer for the purpose of helping the administrative contracting officers develop expertise in the drug return contract.[42]

During a briefing with NCS on March 25, 2021, the chief of Prime Vendors informed the OIG that, in their opinion, the NCS-assigned contracting officer does not have a responsibility to make sure that network contracting officers write, and that medical facilities implement, task orders in accordance with the terms of the national contract with Pharma Logistics. OIG disagrees with this opinion based on the contracting officer responsibilities outlined in FAR 1.602-1 and 1.602-2. Oversight responsibilities may be shared between the NCS-assigned and network contracting officers, and the network contracting officers are responsible for the task orders they issue. However, the NCS contracting officer was the only contracting officer that signed the national contract with Pharma Logistics, from which network contracting officers issued task orders. The national contract designated this NCS contracting officer as the "contracting officer" for the contract. Therefore, this NCS contracting officer was responsible for ensuring overall compliance with the terms of the contract, and for safeguarding the interests of the United States in its contractual relationships.[43]

Network Contracting Officers Wrote Inaccurate Task Orders

The OIG found errors in all nine task (delivery) orders the audit team reviewed that six network contracting officers issued against the drug return contract with Pharma Logistics.[44] According to the NCS director, task orders were supposed to be issued by network contracting officers for each option year of the contract after a medical facility confirmed it needed drug return services and had funding available. The audit team identified errors such as incorrect prices and duplications that resulted in facilities paying too much for their drug return services or paying for duplicate services. The following examples illustrate some of the errors the team identified in its review of task orders.

[42] VA uses a prime vendor contract to provide drugs and other pharmaceuticals to its medical facilities, outpatient clinics, and its Consolidated Mail Order Pharmacies. In 2019, VA awarded the McKesson Corporation a two-year prime vendor contract.

[43] FAR 1.602-2.

[44] To receive drug return services under the contract, each VA medical facility must have an active task order. A task order is a delivery order that is placed against an established contract. Task orders allow VA medical facilities to use the Pharma Logistics contract for drug return services. Once the task orders are in place, VA medical facility pharmacies and others such as Consolidated Mail Outpatient Pharmacies, may use Pharma Logistics' drug return services.

Example 4

One network contracting officer included drug destruction services in the task orders for the medical facilities in the network even though these facilities were already paying to have drugs with no return value destroyed through other mechanisms. As a result, these facilities were paying Pharma Logistics a flat fee for drug disposal services they did not need. The contracting officer reported being unaware that drug disposal was a separate, optional service when writing the task orders.[45]

Example 5

A network contracting officer wrote a task order to price disposal services at $600 per pound instead of $600 per visit, which could have obligated the government to that price if the contractor had chosen to bill by weight.

Example 6

Four task orders in one VISN were written so that the line item for processing drugs for return credit entitled Pharma Logistics to a flat fee of $6,000 instead of a percentage based on the actual return value.

These errors occurred because network contracting officers did not become familiar with the contract's invoicing requirements and did not follow NCS guidance. Task orders should be accurate because VA is obligated to purchase the specified minimum quantity. Network contracting officers are responsible under the FAR for ensuring compliance with the terms of the task orders and safeguarding the federal government's interests in its contractual relationship with Pharma Logistics.

According to VA's NCS director and the national contracting officer, the network contracting officers should have been aware of the terms of the contract and specifications of the contract before signing the task orders. While the national contracting officer provided a document to the field that included instructions on how to establish a task order under the base contract, the types of information that needed to be included in the task order, and to address frequently asked questions about the contract, there was still a lack of awareness at the network level for how to properly write task orders under this contract. During a meeting with the audit team, NCS leaders acknowledged that the drug return contract with Pharma Logistics was complex and that additional support and training on the contract for network contracting officers might have resulted in fewer task order errors. NCS's director and the national contracting officer did not

[45] Drug disposal services were available as a separate service from the drug return service under the contract with Pharma Logistics. VA medical facilities paid Pharma Logistics a flat fee each time Pharma Logistics picked up drugs for disposal, regardless of the volume of drugs.

provide network contracting officers with any training on the drug return contract with Pharma Logistics because they were not required to do so. They told the team that additional training would be a good idea for future contracts. In addition, NCS did not review or maintain copies of the task orders and did not have procedures in place to provide assurances that task orders for the contract were accurate. According to a NCS official, they do not have access to the task orders written by network contracting officers to be able to see if they were accurate. This official said that the task orders reside in an electronic system and NCS personnel cannot open the task orders; they can only see the task order numbers. Developing a task order template with terms that align with any future drug return contract for network contracting officers can reduce the risk of errors.

Network Contracting Officers Did Not Recall If Facility Contracting Officer Representatives Were Assigned for the Contract

The OIG found that three of the six network contracting officers interviewed provided the team inaccurate information about whether they assigned CORs or non-COR points of contact for the contract at each medical facility in their network. According to an NCS official, while non-COR points of contact can provide some local day-to-day oversight, they do not have the technical expertise or authority of a COR.

The drug return contract specified that "each facility will have a designated Contracting Officer's Representative (COR) who will serve as a point of contact for all matters pertaining to the technical aspects of the contract," and the national contracting officer explained that a COR was advisable as a technical expert for VA's drug return contract with Pharma Logistics because it was so complex.[46] Medical facility-level CORs are not required by the FAR for this type of contract, and according to the national contracting officer it may not have been possible to assign one if no one at a facility had the expertise to be a COR. However, according to VHA's Procurement Manual, CORs play an essential role in monitoring contract performance and ensuring VHA receives the goods and services under contract.[47] The manual also specifies that the network contracting officer must meet with the COR when the base contract is awarded and review the terms of the contract and any performance monitoring requirements with the COR. When network contracting officers did not assign a COR, COR responsibilities remained with the network contracting officer for this complex contract.[48] Therefore, network contracting officers should have known whether they assigned CORs, points of contact, or some mix to support the proper execution of the drug return contract across their network.

[46] FAR 1.602-2.

[47] VHA Procurement Manual, part 801, February 7, 2020.

[48] FAR 1.602-2.

In addition, network contracting officers who did not assign CORs and officially retained these responsibilities also did not implement procedures to make sure Pharma Logistics was executing the drug return contract in accordance with its terms. Those network contracting officers were not fulfilling their responsibilities since they were unfamiliar with the contract language and did not provide facility-level oversight when CORs were not assigned.

The OIG determined that network contracting officers were unaware of the language in the drug return contract that CORs "will be assigned" for this contract. In addition, the role of a non-COR point of contact was not defined in VA's drug return contract with Pharma Logistics. NCS and the network contracting officers were unable to provide the team with documentation to explain this role.

For the six VISNs where the audit team spoke with VISN leaders, the OIG determined that

- one VISN had CORs assigned for each facility,
- one VISN had a mix of CORs and points of contact assigned for its facilities,
- two VISNs had one COR assigned for the whole VISN, and
- two VISNs had only points of contact assigned for the drug return contract across all facilities in the VISN.[49]

The NCS director and Pharmacy Benefits Managements Services' chief consultant reported to the audit team that they were not aware network contracting officers could not accurately say if they assigned CORs or points of contact to provide local monitoring and oversight of the contract. The NCS official explained they did not need to monitor whether CORs were assigned for the contract with Pharma Logistics because it was not a mandatory contract that all medical facilities were required to use. Without CORs, or an active fulfillment of COR roles by points of contact or network contracting officers, VA could not ensure Pharma Logistics met the terms of the contract.

National and VISN Officials Need to Improve Program Oversight

While VHA Directive 1087 establishes clear oversight responsibilities for the drug return program for the Offices of the Deputy Under Secretary for Health for Operations and Management and for Policy and Services, national and VISN officials did not carry out those responsibilities. Due in part to the lack of national oversight, pharmacy chiefs did not effectively implement the drug return program, as described in finding 1.

[49] The team interviewed VISN network directors and pharmacist executives in the five VISNs in which no-notice site visits were conducted and in one VISN in which planning work was performed.

Deputy Under Secretary for Health for Operations and Management Did Not Complete Oversight Responsibilities

According to VHA Directive 1087, the deputy under secretary for health for operations and management is responsible for communicating to VISNs the contents of VHA Directive 1087, ensuring resources are available to implement the directive, and overseeing how well VISNs comply. However, as of October 2020, the deputy under secretary for health for operations and management had not completed these tasks and had not assigned these oversight responsibilities to a specific office or person.

Since VHA expects to receive about $52 million from drug returns for FY 2019, the drug return program should receive purposeful and coordinated oversight. In January 2020, the Office of the Assistant Deputy Under Secretary for Health for Clinical Operations requested that Pharmacy Benefits Management Services leaders draft a communication memo outlining oversight mechanisms in VHA Directive 1087 for VISNs and medical facilities. As of June 2020, however, this memo was not drafted. Pharmacy Benefits Management Services chief consultant explained to the audit team that the deputy's office had not followed up with them. Further, the office's chief consultant told the team that the directive clearly outlines who or what office is responsible for each aspect of the drug return program and developing a memo for VISNs and medical facilities is unnecessary. In October 2020, an official from the deputy under secretary for health for policy and services' office told the audit team that VHA planned to issue the memo after this report is published so the memo can address the OIG's final findings and recommendations.

Officials from the deputy under secretary for health for operations and management's office also questioned whether additional communication with the VISNs was necessary. They told the audit team that they have direct authority over the VISNs and medical facilities but rely on subject matter experts to help them oversee programs. In their opinion, everyone involved should have been aware that pharmacy chiefs were not meeting the directive's requirements. According to the assistant deputy under secretary for health for administrative operations, VISN directors and pharmacist executives should provide local oversight to make sure facilities are following program requirements.

In October 2020, as part of VHA's central office modernization efforts, the deputy under secretary for health for operations and management's office was realigned as the Office of the Assistant Under Secretary for Health for Operations. VHA officials explained that the responsibilities outlined in the directive would therefore move to the realigned office for operations. Because this alignment was recently implemented, the audit team could not assess its effect on oversight of the drug return program.

Deputy Under Secretary for Health for Policy and Services Lacked Authority to Oversee Compliance with Program Requirements

According to VHA Directive 1087, the deputy under secretary for health for policy and services is responsible for ensuring overall compliance with the directive; however, as previously mentioned, an official from this office told the audit team that they do not have the authority to ensure that the medical facilities, VISNs, and other VA and VHA national offices comply with the directive. Pharmacy Benefits Management Services' deputy chief consultant for formulary management explained that this was why the deputy under secretary for health for operations and management was added to the directive, because that official has the authority to implement the drug return program requirements across the VISNs and facilities. In addition, Pharmacy Benefits Management Services officials stated that, although they are the subject matter experts for pharmacy operations, they also lack the authority to compel pharmacy chiefs to comply with program or contract requirements.

The audit team's site visits confirmed that medical facilities were unsure of their oversight responsibilities. Pharmacy Benefits Management Services leaders told the team that they expect medical facility directors to ensure the drug return program is being implemented in accordance with VHA Directive 1087. However, the directive does not charge facility directors with any oversight responsibilities. Furthermore, only three of 153 pharmacy chiefs who responded to a question on the OIG survey asking about oversight responsibilities for the drug return program reported that their facility director was responsible for overseeing drug returns. Only 14 of 153 pharmacy chiefs reported that they provided their director with information and data on the drug return program. These survey results are consistent with reports from facility directors from the team's five no-notice site visits that their chiefs of pharmacy were responsible for the day-to-day oversight of the program.

Like the realignment of the deputy under secretary's office for health for operations and management, the deputy under secretary's office for health for policy and services was realigned as the Office of the Assistant Under Secretary for Health for Patient Care Services as part of VHA's central office modernization efforts. Since this alignment was recently implemented, the audit team could not assess how it would affect oversight of the drug return program.

VISN Directors and Pharmacist Executives Did Not Always Ensure Facilities Complied with Program Requirements

VISN directors are responsible for implementing the directive across medical facilities in their networks. VISN pharmacist executives are responsible for collecting the results of analytic reviews that pharmacy chiefs may conduct if Pharmacy Benefits Management Services requests the reviews. VISN pharmacist executives should also communicate pertinent findings to the deputy chief consultant regarding analytic reviews and opportunities for improvement.

In June and November 2019, Pharmacy Benefits Management Services provided PowerPoint presentations for VISN pharmacist executives on the drug return data at the semiannual VISN pharmacist executive meetings. They made similar presentations to pharmacy chiefs at the national pharmacy leadership meeting in September 2019. These presentations included instructions on navigating the online Pharma Logistics portal and identified the top drugs that were deemed nonreturnable, those that were returned in-date, and the top reasons drugs were denied credit. The training also provided tips for maximizing the value of returned drugs. However, attendance at these sessions was not mandatory. Pharmacy Benefits Management Services' chief consultant told the audit team that once Pharmacy Benefits Management provided this type of information to the field, it was the responsibility of the field to implement it correctly.

Despite these presentations, the OIG found that VISN pharmacist executives were not always familiar with the directive and as a result were not well-positioned to ensure facilities were fully complying with all drug return program requirements. For example, five of the six VISN pharmacist executives the team spoke with thought they were required to use the Pharma Logistics contract, which they are not, and three collected the results of analytic reviews from facilities in their networks, which the directive does require. One other VISN pharmacist executive told the team they were planning to start collecting the results. Only two VISN pharmacist executives told the team that they communicated key findings from their facilities' analytic reviews and ways to increase drug return revenues to Pharmacy Benefits Management Services' deputy chief consultant for formulary management.

VISN officials were also not aware of other aspects of the drug return program, including key terms of VA's drug return contract with Pharma Logistics. For example, one pharmacist executive was unaware that VA's drug return contract specified that facilities should not return drugs early. Another was unaware that one of the facilities in their VISN had a lapsed task order at the time of the audit team's site visit. Without a task order the chief of pharmacy at this facility was not able to return drugs for credit or obtain drug return data through the vendor's online portal. VISN pharmacist executives should have been aware of these details if they were collecting facilities' analytic reviews concerning opportunities to increase revenue from drug returns.

According to the OIG survey, 42 percent (62 of 146) of the pharmacy chiefs reported that they were unaware of how their VISN pharmacist executives monitored the drug return program, and only 25 percent (36) of these same pharmacy chiefs reported communicating the results of analytic reviews of their facility's drug return program to their VISN pharmacist executives. Without clearly charging an office with responsibility to ensure local monitoring of drug returns, VA risks missing opportunities to maximize the value of returned drugs.

Overall, the OIG concluded that VA needed to communicate more clearly the oversight responsibilities required by Directive 1087, as well as the key terms of any future contract(s).

These responsibilities are critical to ensuring that the drug return program is effectively implemented and operating as intended.

Flawed Data Hampered Pharmacy Benefits Management's Ability to Monitor Drug Return Program Outcomes Nationally

Pharmacy Benefits Management Services' deputy chief consultant for formulary management is required to review national drug return data biannually for unusual reimbursement patterns as well as for potential revenue recovery improvements. This requirement was not fully met and, even if conducted, the data available for this review was flawed. This section discusses how Pharma Logistics reported incomplete and inaccurate data, resulting in overstatements of the estimated drug return value by approximately $7.2 million. Adding to the problem, Pharmacy Benefits Management Services' own data analyst inadvertently introduced additional inaccuracies due to a coding error that caused duplications of at least $14.1 million. The amount of credits VHA expected to receive from drug returns was overstated because of these errors, and VA decision makers did not have the information necessary to properly oversee the program.

Pharma Logistics Drug Return Data Was Inaccurate and Incomplete

Pharma Logistics provided data that was both inaccurate and incomplete, which limited the usefulness of this information for VA decision makers. First, Pharma Logistics' data was negatively affected by a data processing error that resulted in duplicate records and overstatements of the estimated drug return value. When medical facilities returned unexpired drugs to Pharma Logistics, each drug was recorded as a line item in Pharma Logistics' national website-based dashboard under the job number associated with return shipment, and then placed in storage. When the drug became eligible to be returned for credit, it was removed from storage, assigned a new job number, and recorded in the national data again, as a new line item. In this process, Pharma Logistics logged two separate transactions for each drug that was returned as unexpired, stored, then processed for return credit, yet did not assign a variable to distinguish the duplicate from the original transaction. The OIG calculated that this duplication resulted in VA's estimated return value being overstated by approximately $4.9 million. As a result, the amount of credits due to VA was overstated, which could have resulted in misinformed decisions based on the credits VA expected to receive for certain drugs.

Second, when Pharma Logistics reported this information, it incorrectly included data from its prior contract for drug returns with the data for the national contract that went into effect in October 2018. Consequently, Pharma Logistics overstated the value of returned drugs by about $2.3 million and the data available to Pharmacy Benefits Management Services to oversee the drug return program was inaccurate. Finally, Pharma Logistics reported incomplete VISN data because it excluded VISN 8 data due to a programming error. Facilities in other VISNs were also removed from Pharma Logistics' reports when their task orders expired. Overall, the OIG

concluded that because of Pharma Logistics' errors drug return data for VHA was misstated by at least $7.2 million. This put Pharmacy Benefits Management Services at risk of using inaccurate data for decision-making and drug return program monitoring.[50]

The OIG also identified significant limitations with additional data reports that Pharma Logistics provided to Pharmacy Benefits Management Services' deputy chief consultant for formulary management at their request. The consultant requested reports on all drugs returned with greater than 120 days left until they expired to help identify how many and which drugs VA medical facilities were returning outside the terms of the contract. The intent of this was to help facilities better manage their inventory practices by sharing lists of drugs they were returning too early, risking receiving no credit for these drugs and having to repurchase the drugs for use at their facilities. Pharma Logistics reported only drugs that would have been eligible for credit and failed to include not creditable drugs.[51] As figure 5 indicates, there were more than twice as many not creditable drug items than creditable drug line items, so Pharma Logistics' exclusion of this information contributed significantly to its misstatement of the drugs medical facilities returned too early. Pharmacy chiefs do not know which drugs will or will not be creditable when they return them for credit. However, if pharmacy chiefs do not have accurate and complete data on drugs returned too early to Pharma Logistics, they are poorly positioned to correct the problem.

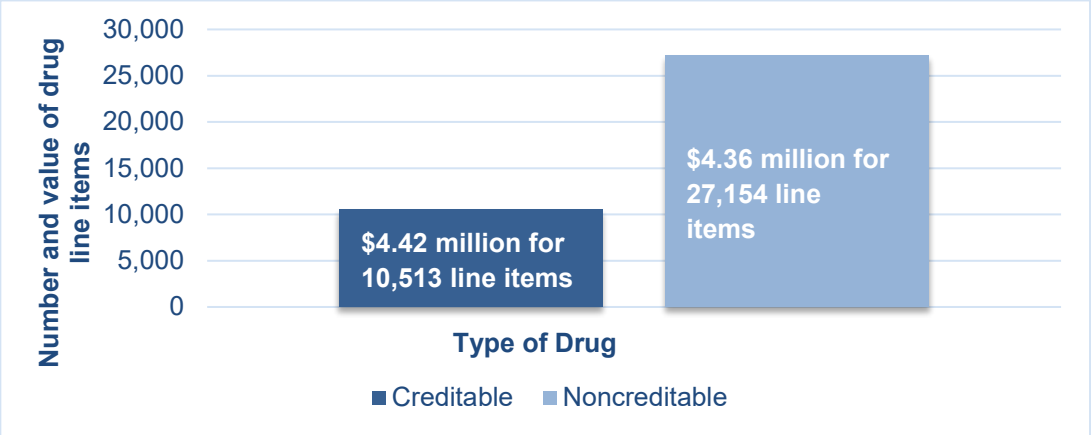

Figure 5. *Drug line items returned in FY 2019 with greater than 120 days left until expiration date. Source: OIG analysis of Pharma Logistics FY 2019 drug return data and estimated return value. Dollar amounts are rounded.*

[50] Of the $7.2 million, $4.9 was because of duplicate records and $2.3 was because of records from prior contracts.

[51] Drugs may be not creditable if they were returned outside of the 120-day window, were damaged, were in partial packages, or did not meet other manufacturer requirements for credit.

Pharmacy Benefits Management Services Introduced Data Errors

When Pharma Logistics' incomplete and inaccurate data reached Pharmacy Benefits Management Services, a data analyst inadvertently introduced additional errors. The analyst received data from Pharma Logistics in a spreadsheet and then sorted that information using computer coding. Due to a coding error that caused duplications, the data analyst introduced errors that resulted in VA's estimated drug return value being overstated by about $14.1 million, in addition to the errors already in the data because of the Pharma Logistics overstatement of about $7.2 million described above.[52] Information on the top nonreturnable drugs and top in-dated drugs was created with this data, which could have been used by pharmacy chiefs to monitor their drug returns, manage their inventory, and identify ways to maximize credits.

The audit team notified Pharmacy Benefits Management Services' deputy chief consultant for formulary management because the inaccurate and incomplete information provided by Pharma Logistics, and introduced into the data by Pharmacy Benefits Management Services, posed a serious risk to VA's ability to ensure that Pharma Logistics was accurately reimbursing medical facilities for their drug returns and that medical facilities were using accurate data to manage their drug return programs. The deputy chief consultant for formulary management was unaware of both the problems with the data Pharma Logistics reported as well as duplications introduced by their own data analyst. Pharmacy Benefits Management Services had not assessed the completeness of the contractor's data as part of its responsibility to use the contractor's data to identify unusual reimbursement patterns and to identify potential improvements for drug return revenue recovery.[53] In addition, NCS did not make sure that Pharma Logistics provided VHA with contractually required data that was accurate or complete. Once the audit team informed VHA of the problems, the deputy chief consultant took positive action, and revised the analyses Pharmacy Benefits Management Services' data analyst conducted and contacted Pharma Logistics to resolve the other data errors.

Finding 2 Conclusion

Although participation in the drug return program was expected to yield about $52 million to VHA in FY 2019, there were deficiencies in national-level oversight of the program. The national offices failed to closely monitor program implementation, which limited VHA's ability to ensure the chiefs of pharmacy and Pharma Logistics met the terms of the contract or that pharmacy chiefs met the requirements of VHA Directive 1087. These governance issues also exposed drug returns to potential fraud, waste, and abuse. VHA may have missed opportunities to identify process improvements, increase the value of medical facilities' drug returns, and

[52] For all of Pharmacy Benefits Management's data analyses from October 2018 through July 2019.

[53] VHA Directive 1087. PBM's deputy chief consultant for formulary management is also listed in the contract with Pharma Logistics as the recipient of monthly and quarterly data reports from Pharma Logistics that should outline credit recipients and reconciliation data for VA medical facilities, as part of her oversight responsibilities.

ensure its drug return program was operating as intended. In addition, the use of inaccurate data to monitor drug return credits presented the opportunity for Pharma Logistics to take advantage of VHA through fraud or abuse by, for example, inaccurately crediting returned drugs or not crediting all drugs returned within 120 days of when they expired. The OIG concludes that, as VA moves to finalize future contracts for the drug return program, it should take steps to correct these issues.

Recommendations 4–8

The OIG recommends that the under secretary for health:

4. Takes steps to provide all offices and positions with defined national, network, or facility responsibilities for the drug return program or the administration of any future drug return contract(s), to include Pharmacy Benefits Management Services, Veterans Integrated Service Network pharmacist executives, network contracting officers, contracting officer representatives, and medical facility pharmacy chiefs, with the support, such as training, and the authority needed to carry out those responsibilities.
5. Make sure that Pharmacy Benefits Management Services reviews the drug return contractor(s) data for accuracy, and uses this data to identify unusual reimbursement patterns and potential improvements for revenue recovery through the last invoices issued as part of the October 2018 Pharma Logistics contract, and for any future drug return contract(s); and coordinate with the National Contract Service on corrective action if inaccurate contractor data is identified.
6. Implement mechanisms to make sure that contracting officer representatives, if assigned, or Veterans Health Administration network contracting officers, provide oversight to ensure the contractor is performing in accordance with the terms of any future drug return contract(s).
7. To minimize the risk of errors, make sure that Veterans Health Administration network contracting officers when writing task orders off any future drug return contract(s) use a template with terms that align with any future drug return contract(s) developed by the National Contract Service.

The OIG recommends that the under secretary for health coordinate with the VA Office of Acquisition, Logistics, and Construction's principal executive director, who should:

8. Develop a task order template with terms that align with any future drug return contract(s) and require the National Contract Service to disseminate the template to Veterans Health Administration network contracting officers.

Management Comments

The acting under secretary for health concurred with recommendations 4 and 7 and concurred in principle with recommendations 5 and 6. The Office of Acquisition, Logistics and Construction concurred in principle with recommendation 8.

In response to recommendation 4, the assistant under secretary for health for operations, assistant under secretary for health for patient care services and other stakeholders as needed will make sure their respective program offices are provided with the necessary support to fulfill their responsibilities for the drug return program and the administration of any future national drug return contract.

For recommendation 5, the acting under secretary agreed that accurate and reliable data is important for oversight of the drug return program. However, Pharmacy Benefits Management Services is not responsible for ensuring the data provided by the contractor is accurate and is therefore unable to coordinate with VA's NCS on corrective actions if inaccurate data is identified. Data accuracy is the vendor's responsibility. Pharmacy Benefits Management Services will use data provided by the vendor to identify unusual reimbursement patterns and potential improvements for revenue recovery for the current drug return contract as well as potential future national drug return contract.

In response to recommendation 6, the acting under secretary noted that existing mechanisms, such as the employee performance review process, suffice to ensure contracting officers representatives, if assigned, or VHA network contracting officers provide oversight to ensure the contractor is performing in accordance with the terms of any future drug return contract. VHA's executive director of procurement will remind contracting officers of their oversight responsibilities, which include evaluating the contractor's performance, and ensuring the terms of the contract are being met, and meeting with CORs, if assigned. VHA's executive director of procurement will coordinate with the NCS to implement a task order template for use by network contracting officers on any future drug return contract to address recommendation 7. The full text of the acting under secretary for health's comments appears in appendix C.

The Office of Acquisition, Logistics, and Construction reported that a template is not necessary until the program office determines a new drug return contract is required. Once determined, the Office of Procurement, Acquisition and Logistics' National Acquisition Center will develop a template that will include required contract terms and conditions and will distribute this template to all VHA network contracting officers. The full text of comments from the Office of Acquisition, Logistics, and Construction appears in appendix D.

OIG Response

The acting under secretary's planned corrective actions are responsive to recommendations 4 and 7 to address the issues identified in the report. For recommendation 5 the OIG agrees that

Pharmacy Benefits Management Services should use the data supplied by the drug return contractor to identify unusual reimbursement patterns and potential improvements for revenue recovery. However, in the absence of Pharmacy Benefits Management Services periodically testing the data for accuracy, any efforts made to use the data for oversight may be in vain if the data contains errors like those identified during this audit. The OIG believes it is essential that Pharmacy Benefits Management Services, as the program manager, ensures the accuracy of all data it receives from the current and future drug return contractors. VHA Directive 1087 required Pharmacy Benefits Management Services to review the drug return "data two times per year … nationally for unusual reimbursement patterns and to identify potential improvement for revenue recovery." While this directive has been rescinded, Pharmacy Benefits Management Services remains required to do this in accordance with updated guidance from April 2021.[54] This could be accomplished, for example, by comparing the contractor's data to drug return data maintained by VA medical facilities.

The OIG believes the acting under secretary's plan to address recommendation 6 by reminding VHA contracting officers of their oversight responsibilities is insufficient, and maintains that additional mechanisms beyond the employee performance review process should be put in place to make sure the contractor is performing in accordance with the terms of any future drug return contract. Despite having an established employee performance review process, the OIG found that VHA network contracting officers were not always sure if they assigned a CORs to monitor the drug return contractor's performance or that they retained this responsibility in the absence of assigning such a representative to the contract.

The OIG agrees with the Office of Acquisition, Logistics, and Construction's plan to address recommendation 8 by developing and distributing a template to VHA network contracting officers once the required terms and conditions are determined for any future drug return contract. While the Office of Acquisition, Logistics, and Construction requested to close this recommendation, the OIG will leave this recommendation open until such time a new drug return contract is established and proposed templates are created, or a decision is made to not issue a new contract.

The OIG will monitor implementation of the recommendations by VHA and VA's Office of Acquisition, Logistics and Construction until all proposed actions are completed.

[54] Pharmacy Benefits Management (PBM) Guidance Document on Monitoring of Reverse Distribution Contract with Pharma Logistics, April 2021.

Appendix A: Scope and Methodology

Scope

The audit team conducted its work from November 2019 through April 2021. The scope of the audit focused on determining if VHA provides effective oversight of its drug return program to secure and account for drugs. If VHA fails to properly monitor the program, it can experience increased risk of undetected loss, theft, or misuse. VA medical facilities may also fail to maximize credits received for drug returns.

The audit work included conducting interviews with officials from national offices, VISNs, and local facilities responsible for duties related to the drug return program; completing unannounced site visits that included pharmacy tours, inventory list verifications, and interviews with pharmacy chiefs; and conducting a national survey.

The team analyzed FY 2019 drug return data from Pharma Logistics for 166 VA medical facilities and many of the associated clinics and pharmacies, to determine the total volume and dollar value of drugs returned for credit, the proportion of drugs returned outside the terms of the contract (such as those with greater than 120 days left until they expired), and the types of drugs returned for credit.

Methodology

To gain an understanding of VHA's prescription drug return program, the team reviewed relevant criteria, including applicable laws, contracts, and VHA directives. Applicable authorities include the following:

- VA's drug return contract with Pharma Logistics and related contract modifications
- VHA Directive 1087, *Monitoring of Expired or Soon-to-Expire Medication Returns*, August 2019, and VHA Directive 1087, *Monitoring of Non-Controlled Substance Medication Returns*, August 2014
- *National Pharmacy Benefits Management (PBM) Guidance Return/Disposal of In-Dated Products*, June 2019
- VHA Directive 1108.01, *Controlled Substances Management*, May 2019
- Federal and VA acquisition regulations

The team interviewed representatives from the offices of the deputy under secretary for health for operations and management and the deputy under secretary for health for policy and services, Pharmacy Benefits Management Services, NCS, and selected VISNs and VA medical facilities, to discuss topics that generally included oversight roles and responsibilities and processes to: (1) communicate to facilities about the drug return program, (2) monitor participation in the

program, (3) minimize risks that drugs might be diverted and abused, (4) maximize credits received, and (5) execute and monitor the contract with Pharma Logistics. The team also interviewed representatives from Pharma Logistics about drug return data.

The team collaborated with other OIG directorates, including the Office of Healthcare Inspections, on potential reasons why drugs with greater than 120 days of remaining shelf life were returned to Pharma Logistics. Analysis by the OIG's Office of Healthcare Inspections did not disclose any large-scale reasons why a medical facility would need to send a drug for reverse distribution with greater than 120 days of remaining shelf life (e.g., drug recalls, change to VHA's formulary). The medical facilities the team visited were able to provide site-specific reasons (e.g., mechanical issues with refrigerators used to store drugs, mailed drugs returned to the facility as undeliverable) they returned drugs with greater than 120 days left until the drugs expired. The team also collaborated with OIG's Office of Investigations to identify indicators of fraud or other potential crimes, and the Office of Audits and Evaluations' Contract Integrity Division on contract-related concerns.

Site Visits

The team conducted no-notice site visits at five medical facilities. This included four VA medical facilities with the highest estimated value for drugs returned early and another facility, the Jesse Brown VA Medical Center in Chicago, Illinois, that the team visited in conjunction with area meetings with Pharmacy Benefits Management Services and Pharma Logistics. The team conducted these site visits from November through December 2019 before access to some medical facilities was affected by the COVID-19 pandemic. To determine the four medical facilities with the highest estimated return value, the team used the subset of all drugs returned to Pharma Logistics for return credit between October 2018 and July 2019 with greater than 120 days left until they expired (total estimated return value of about $4.7 million) and selected the four VA medical facilities with the highest estimated return value. Based on this analysis, the team conducted site visits to the Cincinnati VA Medical Center in Ohio; Corporal Michael J. Crescenz VA Medical Center in Philadelphia, Pennsylvania; Biloxi VA Medical Center in Biloxi, Mississippi; and Rocky Mountain Regional VA Medical Center in Aurora, Colorado.

During the no-notice site visits, the team completed the following steps at each facility:

- Confirmed the security and tracking protocols of drugs held for return during tours of all pharmacies that participated in the drug return program
- Interviewed pharmacy staff to discuss their oversight roles and responsibilities and learn about their procedures to manage drugs held for return
- Verified the accuracy of the facility-generated lists of drugs held for return by (1) comparing a random sample of drugs from the list to the physical drugs being

held, and (2) randomly selecting a different sample of drugs from their holding receptacle to locate them on the list

Survey of Pharmacy Chiefs

The audit team developed and deployed a national electronic survey to pharmacy chiefs at VA medical facilities to collect information about whether they participate in the drug return program, and if so, details about how drugs are processed by Pharma Logistics at their facilities. The survey also collected information about how pharmacy chiefs received key program information, such as the contract and VHA Directive 1087. Finally, the survey asked questions to allow the team to measure compliance with key program requirements, such as whether pharmacy chiefs were returning drugs early and if they were separating drugs for credit from drugs for disposal before a Pharma Logistics representative arrived on-site to process the drugs. The team also followed up on select responses to gather additional information. For example, for pharmacy chiefs who reported experiencing a discrepancy between the facility and Pharma Logistics' list, the team requested an example of a discrepancy.

Pharmacy chiefs from 94 percent (154 of 163) of the facilities the team surveyed responded to the OIG survey. Twenty-two pharmacy chiefs oversaw two VA medical facilities each and three chiefs oversaw three facilities each. These 25 pharmacy chiefs received a unique survey for each VA medical facility that they oversaw, and 23 responded. In some cases, pharmacy chiefs responding to the survey did not (or did not need to) answer every question. The audit team used the actual number of respondents rather than the total number of surveys returned as the denominator to calculate question response percentages. Doing so removes nonresponses from the calculations. The numerator and denominator used to calculate question response percentages are detailed in the report.

Survey results from 154 facilities are self-reported data, which the team could not verify without conducting site visits. However, the team took steps to validate the accuracy of the data, which included reviewing the survey results to make sure respondents results were not included more than one time. Access to the survey was limited to a list of pre-programmed email addresses with station identification numbers. In addition, the survey was electronic and respondents could not forward the survey by email. The audit team followed up to verify responses with documentation, when appropriate.

Interim Briefings

Because of certain time-sensitive findings, the audit team provided four virtual briefings to VA officials during this audit to notify them of the OIG's preliminary findings, to discuss VHA's approach to addressing identified issues, and to discuss the status of VHA's upcoming new drug

return contract.[55] Following one of these briefings, at the request of NCS leaders, the team met with the NCS director, the national contracting officer assigned to the Pharma Logistics contract, and the chief of the Prime Vendor Division to share additional details about the information the team collected during interviews with VISN contracting officials and CORs. The information that was discussed focused on outreach to the field from the national contracting officer and the responses to questions and requests for information that were provided from the national contracting officer to the network contracting officers.

During this briefing call, NCS leaders provided the OIG audit team with information about an Integrated Product Team that was convened while the Pharma Logistics contract was being developed and with information about ways in which communication between NCS (a VA office) and the network contracting officers (organized under VHA's procurement office) could potentially be enhanced. The information is included in this audit report.

Internal Controls

The audit team assessed the internal controls for VHA's prescription drug return program that were considered significant to the audit objective. The team reviewed the five internal control components—control environment, risk assessment, control activities, information and communication, and monitoring—and the associated principles for each component and determined all five components of internal controls were significant to the audit objective. The following are the internal control components and associated principles considered significant to the audit objective:

- Component 1: Control Environment
    - Principle 2: Exercise Oversight Responsibility
    - Principle 3: Establish Structure, Responsibility, and Authority
    - Principle 5: Enforce Accountability
- Component 2: Risk Assessment
    - Principle 6: Define Objectives and Risk Tolerances
    - Principle 7: Identify, Analyze, and Respond to Risks
    - Principle 8: Assess Fraud Risk
- Component 3: Control Activities
    - Principle 10: Design Control Activities

[55] For example, Pharma Logistics had planned to destroy the drugs it was storing that had been returned early with no credit to VA. See finding 1.

  - Principle 12: Implement Control Activities
- Component 4: Information and Communication
  - Principle 13: Use Quality Information
  - Principle 14: Communicate Internally
  - Principle 15: Communicate Externally
- Component 5: Monitoring
  - Principle 16: Perform Monitoring Activities
  - Principle 17: Evaluate Issues and Remediate Deficiencies

The team assessed the design, implementation, or operating effectiveness of these internal controls as necessary to address the audit objective and identified several deficiencies as outlined below:

Component 1: Control Environment: While VHA Directive 1087 details specific responsibilities for the deputy under secretary for health for operations and management and the deputy under secretary for health for policy and services, Pharmacy Benefits Management, VISNs, and VA medical facilities, the team determined that VA is not fulfilling some of the associated duties and responsibilities.

Component 2: Risk Assessment: The team determined that some VA medical facilities did not follow the contract requirements or their own internal guidance as they were returning drugs that did not expire within 120 days of expiration, which creates the potential risk for waste in the drug return program. Also, VA medical facilities did not always try to identify other ways to use these drugs—such as reaching out to see if other facilities could use them. The team also learned that some facilities were not following requirements outlined in VHA Directive 1087 and VHA Directive 1108.01 to safeguard and account for drugs being held for credit, creating a risk for diversion.

Component 3: Control Activities: VHA Directives 1087 and 1108.01 clearly outline the control activities to safeguard and monitor drugs held for return. The team determined that some facilities were not following these requirements, which increases the risk for loss and diversion.

Component 4: Information and Communication: The team determined that Pharmacy Benefits Management Services lacked knowledge about deficiencies in the data obtained from Pharma Logistics' main data system that Pharmacy Benefits Management Services used to analyze drug return data nationally. These deficiencies resulted in analyses that were inaccurate and incomplete. The team also discovered a lack of communication among many of the stakeholders associated with the drug return program.

Component 5: Monitoring: The team determined that no VA office is fully carrying out contract or programmatic oversight monitoring responsibilities. This includes several key areas:

(1) safeguarding and accounting for drugs being held for return by medical facilities, (2) reconciling credits received from Pharma Logistics, and (3) enforcing the terms of the national reverse distribution contract. The team also determined that facility-level monitoring varied by facility.

Fraud Assessment

The audit team assessed the risk that fraud and noncompliance with provisions of laws, regulations, contracts, and grant agreements, significant in the context of the audit objectives, could occur during this audit by taking the following actions:

- Coordinated with the OIG's Office of Investigations concerning potential fraud risk indicators
- Examined survey results reported by pharmacy chiefs to identify potentially fraudulent activities involving drugs held for return credit
- Inquired about the risk of fraud, waste, or abuse during interviews with VA

The team coordinated with OIG's Office of Investigations throughout the audit as appropriate. The team reached out to investigators about an OIG hotline related to the possible mismanagement of drugs at another medical facility. According to the complaint, unused unexpired drugs were being picked up from multiple locations in the hospital. These drugs should either be returned to the pharmacy for patient use, or, if not feasible, be set aside and returned for drug credit.

The OIG did not identify any instances of fraud or potential fraud related to VHA's prescription drug return program during this audit; however, the potential for fraud exists because facilities were not maintaining their own internal, ongoing lists to verify the list of drugs that Pharma Logistics creates before removing drugs from the pharmacies, which provides an opportunity for undetected drug diversion.

Data Reliability

The audit team obtained data from various sources during the audit and assessed the reliability of the data that was used to support findings, conclusions, or recommendations related to the audit objectives. First, the team received contract transaction data in Excel files obtained from Pharma Logistics' data system from Pharmacy Benefits Management Services. The team assessed the data and determined it had multiple issues, such as duplication of many line items and an inaccurate representation of in-date drugs. In-date drugs included all drugs returned before the manufacturer would accept them for credit. Despite these data issues, the team determined the data was suitable for site visit selection. For all other data analysis purposes, the team received drug return data in an Excel file from Pharma Logistics' data system directly. The audit team assessed the data and noted some issues, such as data being duplicated, out of scope, or

incorrectly classified by Pharma Logistics. The team determined these issues were either immaterial and did not warrant additional audit work, or the issues could easily be remedied by additional filtering or removal of the data by the team.

Second, the team received a listing of VA medical facilities and associated chiefs of pharmacy in an Excel file from Pharmacy Benefits Management Services. Since Pharmacy Benefits Management Services stated upfront that the list was not accurate, the team compared the list to data from DRACO, the internal OIG geospatial analysis platform, provided by OIG's Data Modeling Group and identified some additional facilities not on the Pharmacy Benefits Management's list. The team then verified the list by directly emailing the chiefs of pharmacy to confirm the medical facilities under their purview. The team determined the verified list was suitable to use for the universe of survey respondents for the national electronic survey.

Finally, with the assistance of OIG's Data Services Team, the team also obtained drug cost data in an Excel file obtained from McKesson. This information was used to identify how the replacement acquisition cost compared with the drug return program estimated return value. While the Data Services Team completed their own data reliability testing, the team also performed an analysis to compare the drug return program estimated return value with the McKesson drug purchase costs. The audit team found that the FY 2019 estimated return value was very close to the corresponding purchase cost, which gave the team reasonable assurance that the McKesson data was accurate and appropriate.

Despite the identified data issues, the team obtained supplemental information or conducted additional audit work that allowed them to determine all data used were sufficiently reliable for the intended purposes and allowed the OIG to use the data for monetary findings and other calculations.

Government Standards

The OIG conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that the OIG plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for the findings and conclusions based on audit objectives. The OIG believes the evidence obtained provides a reasonable basis for the findings and conclusions based on the audit objectives.

Appendix B: Monetary Benefits in Accordance with Inspector General Act Amendments

Recommendation	Explanation of Benefits	Better Use of Funds*	Questioned Costs
3	Drugs returned with greater than 120 days until they expired	$4.9 million**	
3	Replacement cost for drugs returned with greater than 120 days until they expired	$6.8 million***	
3	Replacement cost for Tamiflu returned for credit before it expired	$2.9 million	
3	Pharma Logistics fee for processing creditable drugs returned with greater than 120 days until they expired		$307,365
	Subtotal	**$14.6 million**	**$307,365**
	Total		**$14.9 million**

**Numbers in this column are rounded to the nearest hundred thousand.*
***The $14.9 million includes $1.2 million in creditable drugs returned with greater than 120 days until they expired and $3.7 in noncreditable drugs returned with greater than 120 days until they expired. For the noncreditable drugs, a 15 percent drug loss rate was applied to account for drugs that would be expected to be unusable due to normal pharmacy use, such as refrigeration malfunctions, being returned after prescribed, or for other reasons.*
****The team removed two high-cost Emergency Pharmaceutical Cache drugs from this calculation as they would not expect to be repurchased in these quantities and then applied the 15 percent drug loss rate.*

Source: The better use of funds total is based on an analyses of Pharma Logistics FY 2019 drug return data and of the most recent drug return cost data. The questioned costs total is based on the fee paid by VA to Pharma Logistics for processing drugs that should not have been processed under the terms of the drug return contract.

Appendix C: Veterans Health Administration Management Comments

Date: June 8, 2021

From: Acting Under Secretary for Health (10)

Subj: OIG Draft Report, Ineffective Governance of Prescription Drug Return Program Creates Risk of Diversion and Limits Value to VA (VIEWS 05157174)

To: Assistant Inspector General for Audits and Evaluations (52)

1. Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report on the Department of Veterans Affairs' (VA) Prescription Drug Return Program. The Veterans Health Administration (VHA) concurs with recommendations 1-4 and 7 and concurs in principle with recommendations 5 and 6. VHA's action plan is attached.

2. We appreciate OIG's discovery of the returned-goods vendor's non-compliance with the terms and conditions of the contract that resulted in overcharges to VA for unauthorized services. OIG's alert to contracting staff regarding the vendor's performance issues allowed VA to work with the returned goods contractor to rectify those issues.

3. OIG's work is directly related to VA's decision against exercising an additional performance period under the contract due to vendor performance concerns. This will help VA determine the best way to handle expired or unusable medications in the future.

4. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at

The OIG removed point of contact information prior to publication.

(originally signed by)

Richard A. Stone, M.D.

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

Ineffective Governance of Prescription Drug Return Program Creates Risk of Diversion and Limits Value to VA

The OIG recommends that the Under Secretary for Health ensure that responsible VA medical facility personnel conduct the following activities:

Recommendation 1. Secure prescription drugs set aside for return credit either by following procedures outlined in VHA Directive 1108.07(1) or by adhering to a superseding policy.

VHA Comments: Concur

The Office of Pharmacy Benefit Services (PBM) will collaborate with the Office of the Assistant Under Secretary for Health for Operations to require each Veterans Integrated Service Network (VISN) Director to ensure adequate oversight of compliance with the procedures outlined in VHA Directive 1108.07(1) by requiring VISN Pharmacist Executives (VPE) to conduct an on-site review of each facility's returned drug storage space and processes as part of their routine site visits to VISN medical facilities. VISN Directors will report the results of the on-site review to a PBM SharePoint site noting any issues of non-compliance along with an action plan to correct observed gaps. PBM will refer any persistent issues of non-compliance to the Assistant Under Secretary for Health for Operations for follow-up. PBM will develop a checklist for use by the VPEs during site visits.

Status: In progress Target Completion Date: October 2021

Recommendation 2. Account for all prescription drugs set aside for return credit when they leave the medical facility by following procedures outlined in VHA Directive 1108.07(1) or by adhering to a superseding policy.

VHA Comments: Concur

PBM will collaborate with the Office of the Assistant Under Secretary for Health for Operations to require each VISN Director to ensure adequate accounting for all prescription drugs set aside for return credit by requiring VISN Pharmacist Executives (VPE) to conduct an on-site review of each facility's returned drug records as part of their routine site visits to VISN medical facilities. VISN Directors will report the results of the on-site review to a PBM SharePoint site noting any issues of policy non-compliance along with an action plan to correct observed gaps. PBM will refer any persistent issues of non-compliance to the Assistant Under Secretary for Health for Operations for follow-up. PBM will develop a checklist for use by the VPEs during site visits.

Status: In progress Target Completion Date: October 2021

Recommendation 3. Maintain inventory management practices to make sure drugs that are returned for credit are returned in a timely manner, so that medical facilities do not miss opportunities to maximize the value of their drug returns or reduce their risk of overspending to replace drugs prematurely for credit.

VHA Comments: Concur

PBM will collaborate with the Office of the Assistant Under Secretary for Health for Operations to require each VISN Director to ensure drugs that are returned for credit are returned in a timely manner by requiring VISN Pharmacist Executives (VPE) to conduct an on-site review of each facility's returned drug records as part of their routine site visits to VISN medical facilities. VISN Directors will report the results of

the on-site review to a PBM SharePoint site noting any issues along with an action plan to correct observed gaps. PBM will refer any persistent issues of non-compliance to the Assistant Under Secretary for Health for Operations for follow-up. PBM will develop a checklist for use by the VPEs during site visits.

Status: In progress Target Completion Date: October 2021

The OIG recommends that the Under Secretary for Health:

Recommendation 4. Takes steps to provide all offices and positions with defined national, network, or facility responsibilities for the drug return program or the administration of any future drug return contract(s), to include Pharmacy Benefits Management Services, Veterans Integrated Service Network pharmacist executives, network contracting officers, contracting officer representatives, and medical facility pharmacy chiefs, with the support, such as training and the authority needed to carry out those responsibilities.

VHA Comments: Concur

The Assistant Under Secretary for Health for Operations, Assistant Under Secretary for Health for Patient Care Services and other stakeholders as needed, will ensure their respective program offices are provided the necessary support to carry out defined responsibilities for the drug return program or the administration of any future national drug return contract(s).

Status: In progress Target Completion Date: October 2021

Recommendation 5. Make sure that Pharmacy Benefits Management Services reviews the drug return contractor(s) data for accuracy, and uses this data to identify unusual reimbursement patterns and potential improvements for revenue recovery through the last invoices issued as part of the October 2018 Pharma Logistics contract, and for any future drug return contract(s); and coordinate with the National Contract Service on corrective action if inaccurate contractor data is identified.

VHA Comments: Concur in principle

VHA agrees that ensuring accurate and reliable data is important for oversight of the Drug Return Program; however, PBM is not responsible for ensuring the data provided by the contractor is accurate, and therefore is unable to coordinate with National Contract Service on corrective actions if inaccurate contractor data is identified. As part of the terms of the contract, the vendor is responsible for ensuring data accuracy.

PBM will use data supplied by the drug return contractor to identify unusual reimbursement patterns and potential improvements for revenue recovery through the last invoices issued as part of the October 2018 Pharma Logistics contract and for any future national contracts.

Status: In progress Target Completion Date: October 2021

The OIG Recommends that the Under Secretary for Health:

Recommendation 6: Implement mechanisms to make sure that contracting officer representatives, if assigned, or Veterans Health Administration network contracting officers, provide oversight to ensure the contractor is performing in accordance with the terms of any future drug return contract(s).

VHA Comments: Concur in principle

VHA concurs in principle because existing mechanisms, such as employee performance review processes, are sufficient to ensure contracting officers are providing oversight to ensure contractors are performing in accordance with the terms of a contract.

VHA's Executive Director of Procurement will remind contracting officers of their responsibility to (1) meet with contracting officer representatives; (2) evaluate the contractor's performance; (3) document Contracting Officer Representative (COR) meetings; (4) recommend meetings be held quarterly with COR's; and (5) ensure contractor oversight is being performed by the COR if assigned or themselves if no COR, to ensure the terms of the contract are met.

Status: In Progress Target Completion Date: October 2021

Recommendation 7: To minimize the risk of errors, make sure that Veterans Health Administration network contracting officers when writing task orders off of any future drug return contract(s) use a template with terms that align with any future drug return contract(s) developed by the National Contact Service.

VHA Comments: Concur

VHA's Executive Director of Procurement will instruct contracting officers to use the VA Office of Acquisition, Logistics and Construction (OALC) National Contract Service task order template for a future drug return contract(s) based on OALC National Contract Service development of a template and determination for use by VHA network contracting officers.

Status: In Progress Target Completion Date: 90-days following OALC completion of recommendation 8

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

Appendix D: Office of Acquisition, Logistics, and Construction Management Comments

Date: June 14, 2021

From: Chief of Staff, Office of Acquisition, Logistics, and Construction and Chief Acquisition Officer (003)

Subj: Office of Inspector General Report: Veterans Health Administration - Ineffective Governance of Prescription Drug Return Program Creates Risk of Diversion and Limits Value to VA (VIEWS 05132654)

To: Assistant Inspector General for Audits and Evaluations (52)

1. The Office of Acquisition, Logistics, and Construction completed its review of the subject draft report in collaboration with the Veterans Health Administration, and concurs in principle with recommendation 8 (attached).

The OIG removed point of contact information prior to publication.

(originally signed by)

Stacey St. Holder

Attachment

Office of Acquisition, Logistics, and Construction's Action Plan

Ineffective Governance of Prescription Drug Return Program Creates Risk of Diversion and Limits Value to VA

The Office of Inspector General recommends that the Under Secretary for Health coordinate with the Office of Acquisition, Logistics, and Construction's Principal Executive Director, who should:

Recommendation 8: Develop a task order template with terms that align with any future drug return contract(s) and require the National Contract Service to disseminate the template to the Veterans Health Administration's network contracting officers.

OALC Comments: Concur in principle

A template is not necessary until the program office determines a new contract is required. The Office of Procurement, Acquisition and Logistics' National Acquisition Center will develop a template once the required contract terms and conditions have been determined. Once developed, it will be distributed to all Veterans Health Administration network contracting officers.

Status: There are no actions required until a new contract is awarded for the Prescription Drug Return Program. We request closure of this recommendation.

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

OIG Contact and Staff Acknowledgments

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