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OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

VETERANS HEALTH ADMINISTRATION

VA Medical Facilities Took Steps to Safeguard Refrigerated Pharmaceuticals but Could Further Reduce the Risk of Loss

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Executive Summary

In fiscal year (FY) 2021, VA spent about $1.4 billion on refrigerated medications and vaccines. Refrigerated pharmaceuticals must be stored within manufacturer-recommended temperature ranges to maintain their potency. Exposure to excessive heat, cold, or light can cause these pharmaceuticals to lose potency, risking significant waste of medical and financial resources.[1]

In January 2019, VA reported a loss of about $1.1 million because medical facilities failed to maintain appropriate storage temperatures for refrigerated pharmaceuticals.[2] These losses prompted the Veterans Health Administration's (VHA) Pharmacy Benefits Management Services (PBM) to issue three notices, published between January 2020 and August 2021, to clarify responsibilities, processes, and procedures for safeguarding refrigerated pharmaceuticals.

All three notices require the medical facility director to report through an issue brief any pharmaceutical loss that occurred due to a temperature shift. VHA established the issue brief process prior to these notices to report information to leaders in the organization regarding a serious situation or event, including drug loss. This process explicitly requires reports to be initiated when controlled or other high-value drugs are lost or for other situations that may warrant leaders' attention.[3]

The medical facility director designates the roles and responsibilities for storing refrigerated pharmaceuticals in pharmaceutical-grade purpose-built refrigerators and freezers; these roles and responsibilities involve the facility's chief of pharmacy, chief of facilities management, chief of clinical engineering, and service chiefs.[4] These chiefs are required to implement procedures to provide proper storage, handling, and dispensing of refrigerated pharmaceuticals in pharmaceutical-grade purpose-built refrigerators and freezers. Facilities are also responsible for implementing a continuous temperature-monitoring system with digital data-logging capabilities

[1] Change made based on technical comment 1 provided by VHA and detailed in appendix D.

[2] Pharmacy Benefits Management Services and the Office of Biomedical Engineering, "Monitoring and Storage of Medications Requiring Refrigerators or Freezers," January 22, 2019.

[3] VHA deputy secretary for health for operations and management (10N), *10N Guide to VHA Issue Briefs*, March 29, 2018; VHA Directive 1108.08, *VHA Formulary Management Process*, August 29, 2019. Controlled drugs are those for which distribution is regulated by the federal government based on the potential for the drug to be abused. Examples of controlled drugs include morphine and oxycodone. The guide does not define high-value drugs. VHA Directive 1108.08 makes the chief consultant for Pharmacy Benefits Management Services responsible for identifying and posting information on 10 noncontrolled drugs that are high cost or at high risk for diversion. This directive does not define thresholds for high-cost drugs. Thresholds for drugs that are high cost or at high risk for diversion are determined annually and not publicly available.

[4] A pharmaceutical-grade purpose-built refrigerator or freezer is designed specifically for storing drugs and biologics. These refrigerators and freezers often have microprocessor-based temperature control with a digital temperature sensor and fan-forced air circulation or multiple vents that promote uniform temperature. Both large and compact units are available. Change made based on technical comment 2 provided by VHA and detailed in appendix D.

and alert notifications that escalate to multiple persons when a temperature shifts outside the range recommended by the manufacturer. Such a shift is known as a temperature excursion.[5]

In early 2021, VA launched a national COVID-19 vaccination campaign for veterans and their caregivers. COVID-19 vaccines available at many medical facilities included those made by Pfizer, Moderna, and Johnson & Johnson's Janssen, which have strict temperature storage requirements. During this period, the VA Office of Inspector General (OIG) confirmed that 1,900 doses of a COVID-19 vaccine were lost due to a temperature excursion at the Jamaica Plain VA Medical Center in Boston, Massachusetts.

The OIG conducted this audit to determine if VA medical facilities implemented and met requirements to safeguard the potency and value of refrigerated pharmaceuticals. The scope of the audit included the approximately $1.4 billion of refrigerated pharmaceuticals purchased in FY 2021.[6] To conduct this audit, the OIG inspected about 150 randomly selected refrigerators or freezers used to store refrigerated pharmaceuticals at six of eight statistically sampled VA medical facilities. The audit team also visited the Jamaica Plain VA Medical Center and the Manchester VA Medical Center in Manchester, New Hampshire, during the planning phase of the audit.

What the Audit Found

The OIG found that VA medical facilities generally implemented and maintained requirements for safely storing refrigerated pharmaceuticals. For example, during the audit period, most medical facilities reported using electronic monitoring systems with software alerts for temperature excursions, and most medical facilities reported using, or being in the process of acquiring, pharmaceutical-grade purpose-built refrigerators and freezers.

Some refrigerated pharmaceutical loss is expected, and VA medical facilities reported about $1.7 million in such losses for FY 2021. PBM officials agreed that medical facility officials need to strengthen and reinforce safeguards to further reduce their risk of refrigerated pharmaceutical loss and risk to veterans who could receive compromised medications or vaccines. In the context of VA's total spending on these kinds of drugs (about $1.4 billion), this loss is relatively minimal.[7] The OIG believes that opportunities still exist to reinforce and ensure medical facilities' compliance with VHA's requirements for storing refrigerated pharmaceuticals.[8] Doing

[5] A temperature excursion is any temperature reading that is outside the manufacturer's recommended range for pharmaceutical storage.

[6] Appendix A details the audit scope and methodology.

[7] To determine the percentage of refrigerated pharmaceuticals that were lost because of temperature excursions, the audit team divided the total rounded value of drugs lost by the total rounded amount VA spent on refrigerated pharmaceuticals in FY 2021 ($1,700,000 / $1,400,000,000 = 0.12 percent).

[8] Change made based on technical comment 4 provided by VHA and detailed in appendix D.

so could further reduce the waste of medical resources and the risk of inadvertently administering compromised medications or vaccines to veterans.

More Action Is Needed

Although medical facilities have taken steps to improve their ability to detect temperature excursions for refrigerated pharmaceuticals, processes and controls should be further strengthened. From the analysis of issue briefs submitted by facilities in FY 2021, the audit team determined that 77 of 141 facilities (about 55 percent) reported experiencing at least one instance of a refrigerated pharmaceutical loss. The audit team assessed sampled medical facilities' compliance with seven key requirements—such as preventive maintenance schedules for refrigerators and freezers used to store drugs and vaccines, cascading alert notifications, and testing of the notification system at least semiannually—which are intended to reduce the risk of a refrigerated pharmaceutical loss. Based on this sample, the OIG estimates that not all facilities fully implemented required controls to protect the efficacy and value of refrigerated pharmaceuticals. Appendix B details the statistical sampling methodology.

Monitoring Systems Had Weaknesses

In addition, the audit team found that not all medical facility personnel

- properly configured monitoring system settings,
- responded to monitoring system software alerts,
- performed routine maintenance of refrigerators and freezers used to store pharmaceuticals, or
- tested the temperature-monitoring system at least semiannually.

Issue Brief Guidance Needs Clarification to Minimize Unreported Loss of Refrigerated Pharmaceuticals

VHA guidance on the issue brief process created confusion regarding when medical facility directors should submit an issue brief for the loss of refrigerated pharmaceuticals. For example, VHA's guidance directs medical facility personnel to report the loss of any refrigerated pharmaceutical through the issue brief process, whereas broader VHA guidance requires personnel to report the loss of a controlled drug—regardless of refrigeration status—or for situations or events that warrant leaders' attention.[9] In some cases, pharmacy personnel were aware of the requirement to report the loss of any refrigerated pharmaceuticals to the medical

[9] Controlled drugs are those for which distribution is regulated by the federal government based on the potential for the drug to be abused. Examples of controlled drugs include morphine and oxycodone. Change made based on technical comment 5 provided by VHA and detailed in appendix D.

facility director but did not comply with it. This is particularly concerning because VHA currently does not have a process to monitor compliance with this requirement among facility chiefs of pharmacy.

Medical facilities underreported refrigerated pharmaceutical loss because of the inconsistent guidance regarding what kind of loss to report and a lack of compliance with these requirements. Consequently, VHA lacks complete data on the value and quantity of pharmaceutical losses and, more importantly, on the number of veterans affected by these losses.

Based on the results of this review, the OIG estimates that not all medical facilities have fully implemented all required controls. Doing so would help medical facilities further reduce their risk of wasting medications and vaccines.[10] The OIG acknowledges that refrigerated pharmaceutical loss in FY 2021 (about $1.7 million) was relatively minimal when compared to total spending on these kinds of drugs (about $1.4 billion in FY 2021). Nonetheless, the OIG believes that there are opportunities to further reduce VA's risk. Given the losses medical facilities have experienced in recent years, the OIG believes VHA may lose an estimated $5.1 million over the next three years if no corrective actions are taken. This is a conservative estimate and based on data on reported loss of refrigerated pharmaceuticals that underrepresents actual loss. Appendix C provides additional information on OIG-calculated monetary benefits. VHA is also missing opportunities to refine the issue brief reporting process, which is necessary to be best positioned to comprehensively identify and address systemic issues to mitigate future loss of refrigerated pharmaceuticals.

What the OIG Recommended

The OIG made two recommendations to the under secretary for health. Requirements for storing refrigerated pharmaceuticals need to be reinforced to medical facility directors, and a procedure to ensure medical facilities follow VHA Notice 2021-16 needs to be developed and implemented. Guidance should also be updated to clarify that medical facilities must report all refrigerated pharmaceutical loss.

VA Comments and OIG Response

The deputy under secretary for health, performing the delegable duties of the under secretary for health, concurred with recommendations 1 and 2. VHA reported it will take steps to reinforce the importance of routine maintenance schedules, develop a procedure to ensure compliance with proper storage requirements, and require the reporting of findings and corrective actions that result from periodic testing of the temperature-monitoring systems to address the first recommendation. VHA reported that it already revised its *10N Guide to VHA Issue Briefs* to

[10] Appendix B provides information on the sampling methodology.

address recommendation 2. VHA also provided technical comments. Appendix D includes the full text of the management comments.

The deputy under secretary for health's planned corrective actions are responsive to recommendation 1. The OIG will monitor VHA's progress on its proposed actions until the recommendation's intent is addressed and will then close the recommendation. VHA's actions to address the second recommendation are responsive, and the OIG closed this recommendation. Regarding VHA's technical comments, the OIG revised this report when the comments were more than stylistic and enhanced the accuracy of the report. Such changes are footnoted in the report. The OIG did not change the report in response to comments that were stylistic or did not enhance the technical accuracy of the report. Appendix D provides the full text of VA's comments. The OIG's response to comments that did not result in a report change is summarized in appendix E.

LARRY M. REINKEMEYER
Assistant Inspector General
for Audits and Evaluations

Contents

Abbreviations

FY	fiscal year
OIG	Office of Inspector General
PBM	Pharmacy Benefits Management Services
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

VA spent about $1.4 billion on pharmaceuticals—medications and vaccines—that require refrigeration in fiscal year (FY) 2021. These pharmaceuticals can lose their potency if exposed to excessive heat, cold, or light, making it imperative that medical facility personnel implement safeguards for proper storage. If they do not, they risk wasting money and adversely affecting treatment outcomes.

In FY 2019, the Veterans Health Administration's (VHA) Pharmacy Benefits Management Services (PBM) and the Office of Biomedical Engineering identified weaknesses in how medical facilities stored refrigerated pharmaceuticals.[11] Specifically, officials determined that VHA was spending money to replace pharmaceuticals rendered unusable when they were stored in refrigerators and freezers that failed or when medical facility personnel did not monitor for and take prompt corrective action when temperature excursions (shifts outside recommended temperature ranges) were identified.[12] Officials also found that facility personnel unknowingly administered compromised vaccines to employees and patients, potentially resulting in adverse effects or ineffective vaccination outcomes. According to PBM, the cost of refrigerated pharmaceuticals that could not be used because of improper storage was about $1.1 million over 15 months.

In early 2021, VA launched a national COVID-19 vaccination campaign for veterans and their caregivers. COVID-19 vaccines available at many medical facilities included those made by Pfizer, Moderna, and Johnson & Johnson's Janssen, which must be stored in pharmaceutical-grade purpose-built freezers to maintain their efficacy.[13] During this same period, the VA Office of Inspector General (OIG) confirmed that 1,900 doses of a COVID-19 vaccine were lost due to a temperature excursion at the Jamaica Plain VA Medical Center in Boston, Massachusetts.

The OIG conducted this audit to determine if VA medical facilities implemented and maintained requirements to safeguard the potency and value of refrigerated pharmaceuticals.

VHA Guidance for Storing Refrigerated Pharmaceuticals

Issued in 2017, VHA Directive 1108.06 requires facilities to appropriately monitor temperatures in medication refrigerators and freezers in accordance with local medical center policy, which is

[11] PBM, "Monitoring and Storage of Medications Requiring Refrigerators or Freezers," January 22, 2019.

[12] Temperature excursion is any temperature reading that is outside the manufacturer's recommended range for pharmaceutical storage.

[13] A pharmaceutical-grade purpose-built refrigerator or freezer is designed specifically for storing drugs and biologics. These refrigerators and freezers often have microprocessor-based temperature control with a digital temperature sensor and fan-forced air circulation or multiple vents that promote uniform temperature. Both large and compact units are available.

based on the relevant standards of the Joint Commission and other professional practice standards, guidelines, and technical bulletins.[14] Subsequently, VHA issued the first of three notices on storing vaccines and medications on January 17, 2020.[15] The purpose of the notice was to mitigate the risk of pharmaceutical loss and to standardize definitions, roles, and responsibilities for the proper storage of pharmaceuticals. The two updates came out the following year:

- **January 20, 2021.** This update clarified and broadened the responsibilities for personnel who are required to implement processes and procedures for safeguarding refrigerated pharmaceuticals.
- **August 9, 2021.** This update established further guidance for community-based outpatient clinics to mitigate risks to refrigerated pharmaceuticals when power outages occur. This notice supersedes the two previous ones.

All three notices require the medical facility director to report any pharmaceutical loss that occurred due to a temperature excursion through an issue brief. Before the publication of these notices, the deputy secretary for health for operations and management issued a guide that detailed the issue brief reporting process and explicitly cited requirements to report the loss of a controlled substance or high-value drug if theft, diversion, or suspicious loss is suspected. According to the guidance, facilities should submit issue briefs for situations or events that warrant leaders' attention.[16] The OIG notes that the guide does not specifically reference reporting noncontrolled pharmaceutical loss, unless the drugs are of high value.

Governance Structures and Compliance

PBM is responsible for issuing policy and guidance related to vaccine and medication storage in pharmaceutical-grade purpose-built refrigerators and freezers. The August 2021 VHA notice established the roles and responsibilities at VA medical facilities for the proper storage of

[14] VHA Directive 1108.06, *Inpatient Pharmacy Services*, February 8, 2017, rev. June 21, 2021. Additional professional standards include those of the American Society of Health System Pharmacists; the United States Pharmacopeia General Chapter 797 (Pharmaceutical Compounding—Sterile Preparations); and federal privacy laws, including the Health Insurance Portability and Accountability Act.

[15] VHA Notice 2020-02, "Storage of Vaccines and Medications in Pharmaceutical Grade Purpose-Built Refrigerators and Freezers at VA Medical Facilities," January 17, 2020.

[16] VHA deputy secretary for health for operations and management (10N), *10N Guide to VHA Issue Briefs*, March 29, 2018; VHA Directive 1108.08, "VHA Formulary Management Process," August 29, 2019. Controlled drugs are those for which distribution is regulated by the federal government based on the potential for the drug to be abused. Examples of controlled drugs include morphine and oxycodone. The guide does not define high-value drugs. VHA Directive 1108.08 requires PBM to identify and post a list of 10 noncontrolled drugs that are high cost or at high risk for diversion. This directive does not define thresholds for high-cost drugs. PBM reviews high-cost or high-risk drugs susceptible to diversion annually, and the list is not publicly available.

vaccines and medications in pharmaceutical-grade purpose-built refrigerators and freezers.[17] Specifically, the VA medical facility director is responsible for making sure that the requirements established in the VHA notice are implemented. The VHA notice also outlines responsibilities for the chief of pharmacy and the chief of the designated responsible service (i.e., chief of facility management, chief of clinical engineering, or the service point of contact), who all have an important role in safeguarding refrigerated pharmaceuticals.[18] Table 1 illustrates the main roles and responsibilities of these key personnel.

Table 1. Roles, Responsibilities, and Best Practices for Safeguarding Refrigerated Pharmaceuticals

Role	Responsibilities and best practices
Medical facility director	• Ensures VA medical facility policy and standard operating procedures are in place to immediately detect temperature excursions • Ensures standard operating procedures require a continuous temperature-monitoring system with cascading alerts • Ensures standard operating procedures define the planned responses to excursions to prevent pharmaceutical loss • Designates oversight of maintenance and operations of medication refrigerators and freezers to the department that has the required competency and knowledge of the equipment
Chief of pharmacy	• Establishes the monitoring process for pharmacy refrigerators and freezers • Directs response to temperature excursions • Ensures food and beverages are not stored with vaccines and medications • Defines the cleaning frequency for refrigerators and freezers • Coordinates with the medical facility chief of facilities management or designee to ensure medical facility locations that store refrigerated medications do so in pharmaceutical-grade purpose-built refrigerators or freezers exclusively
Chief of facility management	• Installs and maintains temperature-monitoring systems • Develops the schedule for and performs preventive maintenance on refrigerators and freezers

[17] VHA Notice 2021-16, "Storage of Vaccines and Medications in Pharmaceutical Grade Purpose-Built Refrigerators and Freezers at VA Medical Facilities," August 9, 2021. Change made based on technical comment 9 provided by VHA and detailed in appendix D.

[18] Change made based on technical comment 10 provided by VHA and detailed in appendix D.

Role	Responsibilities and best practices
	• Ensures pharmaceutical-grade purpose-built refrigerators and freezers are included in equipment replacement plans
Chief of clinical engineering	• Performs and documents maintenance • Installs, inspects, calibrates, and tests temperature-monitoring systems semiannually • Notifies IT when software needs to be updated or installed
Chief of the responsible service	• Understands and implements the response process for temperature excursion alerts and equipment failures • Manually checks refrigerators and freezers every 60 minutes • Ensures all temperature maintenance equipment is plugged in and that refrigerator doors are closed when not in use • Ensures items exposed to temperature excursions are not used for patient care and are appropriately handled

Source: VA OIG analysis of the VHA notices and medical facilities standard operating procedures.
Note: The original wording in this table was revised to align with VHA Notice 2021-16 in response to technical comment 11 provided by VHA (appendix D).

On November 3, 2021, PBM's chief consultant informed the audit team that PBM was in the process of updating the directive but did not know when the updated directive would be issued. PBM's chief consultant also reported that PBM intends to include the requirements documented in the August 2021 VHA notice to formalize these requirements for VA medical facilities.[19]

Electronic Temperature-Monitoring Systems

Temperature-monitoring systems for refrigerated pharmaceuticals have evolved from paper logs kept near the refrigerator or freezer to electronic, automated systems. Some VA medical facilities adopted the use of electronic monitoring systems more quickly than others. The audit team identified facilities that have been using electronic monitoring systems for over 10 years and others that just upgraded to these systems in 2021.

VA does not have a national contract to purchase electronic monitoring systems. Some Veterans Integrated Service Networks (VISNs) awarded contracts to provide the same electronic monitoring system services across the entire network.[20] For example, VISN 1 and VISN 15 established contracts to purchase the same electronic temperature-monitoring system for facilities in these respective networks. In contrast, medical facilities in VISN 2 use seven different electronic monitoring systems.

[19] Change made based on technical comment 12 provided by VHA and detailed in appendix D.
[20] VHA is organized into 18 regional networks called VISNs.

Table 2 lists the electronic monitoring systems that VISN pharmacy executives reported medical facilities used during the OIG audit period.

Table 2. Electronic Monitoring Systems Used at VA Medical Facilities*

System	Number of facilities using system
TempTrak	66
CheckPoint	46
ViewPoint	11
CenTrak	13
Other	45
Total	**181***

Source: VA OIG analysis of data provided by VISN pharmacy executives as of May 2021.
**This total does not include community-based outpatient clinics. The audit team reported the kinds of electronic monitoring systems used by facility, rather than by the 170 VA medical facilities, because not every facility in the same healthcare system uses the same monitoring system. There were nine facilities that used two different types of monitoring systems and one facility that used three different monitoring systems; therefore, 11 extra monitoring systems are captured in this total, which explains why it is greater than 170 facilities.*

Most VA medical facilities use TempTrak, CheckPoint, ViewPoint, and CenTrak (134 of 170 medical facilities, or about 79 percent) to electronically monitor refrigerators and freezers. The remaining 36 facilities reported using 18 other monitoring systems, which include Aeroscout, Isensix, and SmartSense by Digi. Systems typically monitor between 25 and 75 refrigerators and freezers at each facility. The number of refrigerators or freezers at each facility reflects the range of clinical services offered—for example, inpatient care, outpatient care, or both—and the size of the veteran population that receives care at that facility. Pharmaceutical-grade purpose-built refrigerators and freezers are typically spread across the facility and its community-based outpatient clinics. For example, a medical facility that offers both inpatient and outpatient care generally uses large refrigerators and freezers in its inpatient and outpatient pharmacies to store large quantities of refrigerated pharmaceuticals. Smaller amounts of these refrigerated pharmaceuticals are then distributed as needed to small refrigerators and freezers that are operated throughout the facility. This practice ensures that these pharmaceuticals are stored near treatment areas and patients.

The contracts awarded by VISNs or medical facilities for temperature-monitoring systems generally do not include services to configure the monitoring system—for example, setting

temperature alert ranges or establishing alert notification listings. These contracts also do not include services to monitor a medical facility's alerts. Doing so is the responsibility of designated facility personnel. Table 3 compares the services performed by the contactor with the services performed by facility personnel.

Table 3. Comparison of Services Generally Performed by the Contractor to Services Performed by Medical Facility Personnel

Services performed by the contractor	Services performed by medical facility personnel
• Providing, installing, and inspecting the monitoring equipment • Monitoring the electronic monitoring systems servers • Providing telephone support, remote web support, user training, and monthly flash reports	• Configuring the applicable temperature ranges • Monitoring pharmaceutical-grade purpose-built refrigerators and freezers using in-house electronic monitoring systems and software • Responding to temperature excursion alerts

Source: VA OIG analysis of electronic monitoring system contracts, medical center standard operating procedures, and interviews with medical facility personnel.

Generally, electronic temperature-monitoring systems alert medical facility personnel to temperature excursions so that designated personnel can respond quickly to minimize the risk that refrigerated pharmaceuticals will lose their potency.[21] These systems provide web-based dashboards and can capture data-monitoring logs over time. Equipment such as temperature probes, which are installed inside refrigerators or freezers, track a unit's temperature and humidity levels 24/7. When a temperature excursion is detected, the systems are designed to send a series of escalating email notifications to designated personnel. These alarms should persist until the alarm is acknowledged by the designated administrative officer on duty. The monitoring systems can provide medical facility personnel real-time and historical data and corrective action reports associated with all alerts.

Issue Brief Process

VHA established issue briefs as a process for medical facility personnel to work through the appropriate chain of command and report information to leaders in the organization regarding a serious situation, event, or issue.

According to the guide on issue briefs, they are designed to provide clear and concise information about unusual incidents, deaths, disasters, or anything else that might generate media

[21] Change made based on technical comment 14 provided by VHA and detailed in appendix D.

interest or affect care.[22] Issue briefs are intended for internal use and are reviewed by medical facility leaders up to the Secretary. Instances and events that should trigger an issue brief include the following:

- Significant clinical incidents or outcomes that negatively affect a group or cohort of veterans (e.g., reusable medical equipment or credentialing issues)
- Breach of information security or confidential information loss
- Controlled substance losses, thefts, or diversion
- Employee-related events that may invite media interest
- Anything VISNs want VA central office leaders to know

To report a significant issue, facilities submit issue briefs via the Automated Issue Brief Tracker to their VISN leader, who then routes the briefs to the VA central office. The VISN should ensure VHA leaders can access information, anticipate critical information requirements, and determine required follow-up actions for the facility, VISN, and central office personnel and leaders.

[22] VHA deputy secretary for health for operations and management (10N), *10N Guide to VHA Issue Briefs*.

Results and Recommendations

Finding: VA Medical Facilities Took Steps to Safeguard Refrigerated Pharmaceuticals but Could Further Reduce the Risk of Loss

The OIG found that VA medical facilities generally implemented and maintained many requirements to safeguard refrigerated pharmaceuticals. All facilities reviewed reported using electronic monitoring systems with cascading notification alerts and reported being in the process of upgrading to pharmaceutical-grade purpose-built units during the OIG review. In FY 2021, medical facilities reported about $1.7 million in pharmaceutical loss due to refrigeration failures.[23] Based on a statistical sample of medical facilities, the OIG estimates that not all facilities fully implemented required controls to protect the efficacy and value of refrigerated pharmaceuticals.[24] Appendixes A details the audit's scope and methodology, and appendix B describes the statistical sampling methodology.

Although safeguards cannot mitigate all refrigerated pharmaceutical loss, PBM officials agreed that medical facility officials need to strengthen and reinforce safeguards to further reduce the risk of refrigerated pharmaceutical loss and risk to veterans who could receive compromised medications or vaccines. For example, requirements need to be reinforced for medical facility personnel to properly configure monitoring system settings and establish timeliness metrics for responding to monitoring system software alerts.[25]

The OIG also found that the process medical facilities used to report refrigerated pharmaceutical losses provided incomplete data on the value and quantity of pharmaceutical losses and the number of veterans affected by these losses. Medical facilities underreported refrigerated pharmaceutical loss because of inconsistent guidance regarding what kind of loss to report and a lack of compliance with these requirements. The August 2021 VHA notice requires medical facilities to submit issue briefs to report refrigerated pharmaceutical losses. However, not all facility directors did so. This is particularly concerning because VA has no processes to detect noncompliance with reporting requirements.

[23] The dollar amount does not include monetary loss associated with the COVID-19 vaccines because VHA does not directly pay for these vaccines.

[24] To quantify the risk that refrigerated pharmaceuticals could be lost or lose potency, the audit team analyzed processes and procedures implemented at eight sampled medical facilities to safeguard the storage of refrigerated pharmaceuticals and identified facilities not in compliance with key requirements of the VHA notice. By accounting for each sampled facility's probability of selection in the sample, OIG statisticians estimated the total number and percentage of medical facilities that were noncompliant with the tested requirements.

[25] VHA Notice 2021-16.

VA's reported refrigerated pharmaceutical loss in FY 2021 (about $1.7 million) was relatively minimal compared to FY 2021 total spending on these kinds of drugs (about $1.4 billion).[26] Nonetheless, the OIG believes that there are opportunities to further reduce VA's risk. Given the losses medical facilities have experienced in recent years, the OIG estimates VHA may lose $5.1 million over the next three years if no corrective actions are taken. Estimating VA's financial risk across three years is reasonable because refrigerated pharmaceutical loss was reported as far back as September 2017—five years ago. This estimate is conservative because the amount the team used to calculate losses for FY 2021 (about $1.7 million) does not include about $42,000 of unreported loss the team identified. It is likely that additional loss has gone unreported and cannot be included in the team's estimate.[27] Until medical facility directors are fully compliant with the issue brief process, VHA is poorly positioned to comprehensively identify and address systemic issues causing pharmaceutical loss.

What the OIG Did

The scope of the audit included about $1.4 billion of refrigerated pharmaceutical purchases in FY 2021. The team sampled eight medical facilities that purchased refrigerated pharmaceuticals in FY 2021 and conducted in-person site visits to six of these facilities and to two additional facilities that were judgmentally selected: the VA Manchester Healthcare System in Manchester, New Hampshire, and the Jamaica Plain VA Medical Center in Boston, Massachusetts.[28] The team visited the VA Manchester Healthcare System to better understand how refrigerated pharmaceuticals were stored before selecting a sample of medical facilities to review. The team visited the Jamaica Plain VA Medical Center to assess the facility's response to the refrigeration failure that resulted in the loss of about 1,900 COVID-19 vaccines. At the facilities the team visited in person, about 150 sampled refrigerators or freezers were inspected to assess compliance with the August 2021 VHA notice. The team conducted virtual site visits to two sampled facilities because of local COVID-19 outbreaks. The team tested key controls for refrigerated pharmaceuticals, reviewed standard operating procedures, analyzed monitoring system alert reports for selected refrigerators or freezers to identify unreported loss, and interviewed personnel at each site. The team analyzed an extract from the VA issue brief tracker capturing reports of refrigerated pharmaceutical loss in FY 2021. Individual medical facility reports of loss were summarized at the VA healthcare system level. VA operated 141 healthcare

[26] To determine the percentage of refrigerated pharmaceuticals that were lost because of temperature excursions, the audit team divided the total rounded value of drugs lost by the total rounded amount VA spent on refrigerated pharmaceuticals in FY 2021 ($1,700,000 / $1,400,000,000 = 0.12 percent).

[27] Appendix C provides additional information on how the OIG calculated monetary benefits.

[28] The audit team used $929 million as the basis for its sample selection of medical facilities because at the time the sample was generated, only a partial year's worth of data for FY 2021 was available. The team subsequently obtained spending data for the full fiscal year, which totaled about $1.4 billion. To identify the sample of medical facilities, the team considered the medical facility complexity levels and dollar value of pharmaceutical purchases.

systems during the audit period. In all, 142 issue briefs were analyzed.[29] The team also interviewed PBM officials and four VISN pharmacy executives. Appendix A describes the audit methodology, and appendix B details the sampling methodology.

This finding is supported by the following determinations regarding efforts to mitigate refrigerated pharmaceutical loss. Specifically, VHA

- took steps to reduce refrigerated pharmaceutical loss,
- needs to reinforce safeguards for storing refrigerated pharmaceuticals to reduce the risk of loss, and
- needs to clarify the issue brief process to minimize unreported loss of refrigerated pharmaceuticals.

VHA and Medical Facilities Took Steps to Reduce Refrigerated Pharmaceutical Loss

In January 2019, PBM and the Office of Biomedical Engineering identified weaknesses in medical facilities' storage of refrigerated pharmaceuticals, resulting in approximately $1.1 million in monetary losses over a 15-month period from September 2017 through December 2018. The review identified two primary causes for the reported refrigerated pharmaceutical loss: (1) refrigerator or freezer equipment failures and (2) gaps in processes for VA medical facility personnel to monitor and react to refrigerator or freezer temperature excursions. Facility personnel also unknowingly administered compromised vaccines to employees and patients. The issue brief did not indicate that this caused patient harm; however, it did point out that this could have resulted in adverse outcomes and ineffective vaccination.[30]

After this review, VHA issued notices to medical facilities establishing requirements for storing refrigerated drugs and vaccinations.[31] Published in January 2020, the first notice required VISN directors to report their medical facilities' compliance with all requirements to PBM by May 2020. As of December 2021, data provided by PBM showed that most medical facilities reported partial or full compliance with the notice's requirements.

[29] These issue briefs were submitted by 77 unique VA healthcare systems, meaning that some healthcare systems submitted more than one issue brief during FY 2021.

[30] PBM and the Office of Biomedical Engineering, "Monitoring and Storage of Medications Requiring Refrigerators or Freezers," January 22, 2019.

[31] VHA Notice 2020-02, January 2020; VHA Notice 2021-02, "Storage of Vaccines and Medications in Pharmaceutical Grade Purpose-Built Refrigerators and Freezers at VA Medical Facilities," January 2021; VHA Notice 2021-16. The audit team used requirements from VHA Notice 2021-16 when testing medical facilities' compliance.

Some Facilities Are Not in Compliance with the August 2021 Notice

The audit team assessed statistically sampled medical facilities' compliance with the following key requirements of the August 2021 notice:

- Implementation of an electronic monitoring system with cascading alert notifications
- Establishment of standard operating procedures including system configuration and timeliness metrics for responding to alerts
- Testing of the temperature-monitoring system at least semiannually
- Routine maintenance schedules for refrigerators and freezers

Table 4 summarizes the OIG's estimate of medical facilities that are not in compliance with these requirements.

Table 4. Estimate of Medical Facilities Noncompliant with Key Requirements of the August 2021 VHA Notice

Requirement	Estimated number of noncompliant medical facilities (lower bound in parentheses)	Estimated percent of noncompliant medical facilities (lower bound in parentheses)
Electronic monitoring system with cascading alerts	0 (0)	0.0 (0.0)
Establishment of standard operating procedures		
Standard operating procedure for refrigeration	0 (0)	0.0 (0.0)
Standard operating procedure for monitoring system configuration	33 (7)	21 (4.6)
Standard operating procedure with timeliness metrics for alert response	130 (84)	80 (52)
Temperature-monitoring system testing at least semiannually	121 (54)	75 (34)
Routine maintenance schedules for refrigerators and freezers	97 (52)	60 (32)
Noncompliance with at least one of the requirements	162* (121)	100 (75)

Source: VA OIG estimates of 162 medical facilities' compliance with the August 2021 VHA notice. Clopper-Pearson one-sided 90-percent-confidence lower bounds are provided to indicate the uncertainty associated with these estimates due to the small facility sample size. Appendix B details the OIG's statistical sampling methodology.

** The audit team collected information from 170 medical facilities on the temperature-monitoring systems used to monitor refrigerated pharmaceuticals; however, the data on purchased pharmaceuticals provided by PBM listed only 162 facilities—a difference of eight facilities. The OIG statistician excluded these eight facilities from the sample and calculated the number of refrigerators and freezers included in the sampling frame using inventory data from the Corporate Data Warehouse.*

As shown in table 4, the OIG's estimates for 162 medical facilities suggest that all facilities may have implemented key controls, such as electronic monitoring systems that have cascading notification alerts and standard operating procedures for storing refrigerated pharmaceuticals. In addition, the OIG estimates that most facilities implemented required standard operating procedures that detail temperature-monitoring system configuration, with as few as seven of

162 medical facilities (about 4.6 percent) were noncompliant.[32] However, the OIG estimates that numerous medical facilities did not fully implement three key requirements:

- Routine maintenance schedules for refrigerators and freezers used to store pharmaceuticals (estimated 32 percent noncompliance or greater)
- Metrics for alert response timeliness (estimated 52 percent noncompliance or greater)
- Processes to ensure the monitoring systems are tested at least twice a year as required (estimated 34 percent noncompliance or greater)

Some Facilities Have Developed Promising Practices

The audit team observed some practices during site visits that, although not required by the notice, could help reduce the risk of refrigerated pharmaceutical loss if universally adopted. For example, some medical facilities took extra precautions to prevent refrigerators and freezers from being unplugged, used trending data from the monitoring system to proactively identify failing refrigerators and freezers, and established procedures to include refrigerated pharmaceutical monitoring in required inspection programs such as a facility's environment-of-care review.

Facility personnel at the Jamaica Plain VA Medical Center in Boston, Massachusetts, and the White River Junction VA Medical Center in White River Junction, Vermont, installed refrigerator and freezer plug locks. These locks help prevent the equipment from being unplugged, which can occur when a refrigerator or freezer is moved for cleaning. The loss of about 1,900 COVID-19 vaccines at the Jamaica Plain VA Medical Center occurred because the freezer storing the vaccines was accidentally unplugged by housekeepers who moved the freezer to clean behind it. To mitigate the risk of freezers being unintentionally unplugged again, the VA Boston Healthcare System director reported installing plug locks on all vaccine storage freezers as of January 2021. Figure 1 shows an example of a plug lock installed at the Jamaica Plain VA Medical Center.

[32] Drug purchase data reviewed by the audit team included 170 medical facilities; however, the inventory data from the Corporate Data Warehouse listed only 162 facilities. Therefore, the OIG statistician excluded these eight facilities from the sample. In addition, the statistician calculated the number of refrigerators and freezers included in the sampling frame using inventory data from the Corporate Data Warehouse. Reported counts and percentages are rounded, but often with different rounding conventions. The results of rounding vary for different non-rounded values, based on both the rounding convention and on the magnitude of the non-rounded values themselves. As such, a reported count estimate, when divided by the known population size, will sometimes differ slightly from a reported percentage estimate. The underlying non-rounded estimates will be consistent.

Figure 1. *Refrigerator or freezer plug secured with a plug lock at the Jamaica Plain VA Medical Center.*
Source: VA Boston Healthcare System, January 2021.

The clinical engineer at the White River Junction VA Medical Center used the facility's temperature-monitoring system to proactively track historical temperature trends to identify failing refrigerators and freezers. The clinical engineer used the trend reports from the monitoring system to identify refrigerators or freezers whose average temperatures sporadically fluctuated throughout the day. When this occurred, the equipment was removed from service and scheduled for repair. If repair was not possible, the equipment was scheduled for replacement with a new functioning unit.

At the Harry S. Truman Memorial Veterans' Hospital in Columbia, Missouri, the quality management team included refrigerated pharmaceutical monitoring in the facility's required environment-of-care reviews to help ensure clinical personnel, including nurse managers and pharmacists, know how to respond to temperature excursion alerts and to refrigerator or freezer failure. Weekly environment-of-care reviews at this facility include procedures to assess clinicians' familiarity with the electronic monitoring process for refrigerators and freezers used to store pharmaceuticals and to provide training if needed. The Harry S. Truman Memorial Veterans' Hospital did not have any reported refrigerated pharmaceutical loss in FY 2021.

Standardizing these practices nationally can help further minimize VHA's financial risk, as well as the risks to patients when refrigerated pharmaceuticals are compromised because of storage issues.

VHA Needs to Strengthen Safeguards for Storing Refrigerated Pharmaceuticals to Reduce the Risk of Loss

Although it is unlikely that temperature-monitoring safeguards will completely mitigate all refrigerated pharmaceutical loss, PBM officials agreed that strengthening these safeguards can help reduce the risk of medical and financial waste and patient harm. The audit team found, through its analysis of issue briefs from FY 2021, that 77 of 141 VA healthcare systems (about 55 percent) experienced refrigerated pharmaceutical losses totaling about $1.7 million.[33] One location reported that 241 veterans received compromised pharmaceuticals and vaccines due to failures in temperature monitoring. According to the issue brief, the potential harm from the inadvertent administering may be limited to inconvenience and revaccination. In addition, during this same period, 26 healthcare systems reported wasting COVID-19 vaccines or causing the vaccines to be placed on an accelerated-use schedule due to improper storage. A total of about 11,000 vaccines were affected. The OIG estimates that over the next three years, VHA is at risk of losing an estimated $5.1 million in refrigerated pharmaceuticals if current practices persist. Appendix C details monetary benefits.

After analyzing the issue briefs, the audit team found that medical facility personnel did not properly configure monitoring system settings, consistently respond to monitoring system alerts, or consistently perform routine maintenance of refrigerators and freezers.

Medical Facilities Did Not Always Properly Configure and Test Settings on Temperature-Monitoring Systems

Medical facility personnel did not always properly set up and test temperature-monitoring systems. The audit team determined from its analysis of 142 issue briefs submitted in FY 2021 that nine reviewed issue briefs (about 6 percent) reported that facility personnel installed a temperature-monitoring system, but the alerts were not configured correctly to notify staff of a temperature excursion. During the team's visit to two medical facilities, clinical engineers at both stated that when medical facilities purchase temperature-monitoring systems, the contractor provides the system hardware and some initial training on how to use the system but does not

[33] As discussed on page 10 of this report, individual medical facilities reported pharmaceutical loss due to refrigeration through issue briefs that were summarized at the VA healthcare system level. VA operated 141 healthcare systems during the audit period. The audit team used 141 as the denominator when calculating the percentage of healthcare systems that reported a loss of refrigerated pharmaceuticals through an issue brief in FY 2021. The audit team analyzed a total of 142 issue briefs.

help configure it. System configuration includes establishing notification settings and temperature ranges that, if exceeded, will initiate an alert.

The audit team identified instances from its issue brief analysis in which facility personnel did not program the system to alert responsible personnel, such as the administrative officer of the day, when temperatures went above or below recommended ranges. The following examples show instances when improper system configuration led to refrigerated pharmaceutical loss at two separate facilities.

Example 1

At one medical facility, a refrigerator failed and, although it was connected to a CheckPoint temperature-monitoring system, the system was not correctly configured to alert medical facility personnel when the temperature excursion occurred. As a result, the facility lost about $26,000 in refrigerated pharmaceuticals.

Example 2

At a community-based outpatient clinic, a refrigerator used to store drugs and shingles vaccines failed overnight. The refrigerator was connected to a SmartSense by Digi temperature-monitoring system; however, the temperature excursion alerts were set up to be delivered to an assistant nurse manager's VA email account. The assistant nurse manager was away from the clinic and did not have remote access to this email account. As a result, the facility lost about $11,000 in drugs and vaccines and had to reschedule appointments for three patients to receive a shingles vaccine.

Configuring the monitoring system is a complex process that should be coordinated across multiple facility services—such as pharmacy, clinical engineering, and emergency preparedness. The audit team determined that this collaboration does not occur in some medical facilities. For example, two of the eight medical facilities reviewed during this audit did not include guidance for installing or configuring the monitoring system or developing the facilities' standard operating procedures. The OIG estimates that generally at least seven of 162 medical facilities (about 4.6 percent) did not include guidance for monitoring system configuration in their standard operating procedures during the audit period.[34]

[34] Reported counts and percentages are rounded, but often with different rounding conventions. The results of rounding vary for different non-rounded values, based on both the rounding convention and on the magnitude of the non-rounded values themselves. As such, a reported count estimate, when divided by the known population size, will sometimes differ slightly from a reported percentage estimate. The underlying non-rounded estimates will be consistent.

In addition, the audit team determined from its site visits and testing of medical facilities' compliance with refrigeration storage requirements that six of eight sampled medical facilities did not include the requirement to test system configuration settings at least semiannually in their policies. Overall, the OIG estimates that at least 54 of 162 medical facilities (about 34 percent) did not include the requirement to test their temperature-monitoring systems at least twice a year in their policies during the audit period.[35] The OIG estimates are based on 162 medical facilities because, although the team collected data on temperature-monitoring systems used by 170 medical facilities, the PBM pharmaceutical purchase data included information for 162 facilities—a difference of eight facilities. Therefore, the OIG statistician excluded these eight facilities from the sample.

Medical Facilities Did Not Always Respond to Monitoring System Alerts

Medical facility personnel did not consistently respond to temperature excursion alerts in a timely manner. The audit team determined from its analysis of issue briefs documented in FY 2021 that 52 of 142 of reviewed issue briefs (about 37 percent) detailed situations when facility personnel did not respond to and resolve monitoring system alerts. The team's analysis did not overlap with PBM's earlier analysis of issue briefs.[36] These temperature excursions resulted in about $1.1 million in refrigerated pharmaceutical loss. The following examples provide greater insight into what can happen when medical facility personnel do not promptly respond to monitoring system alerts.

Example 3

At one medical facility, a refrigerator malfunctioned; this refrigerator was used to store pharmaceuticals, including biologic medications to treat autoimmune conditions such as arthritis. The temperature-monitoring system appropriately alerted medical facility personnel; however, the day-shift pharmacist notified of the alert reported forgetting to respond. Later, a night-shift pharmacist was notified of the alert and sent a pharmacy technician to investigate, but no corrective action was taken—such as relocating the pharmaceuticals to another refrigerator or freezer—because the pharmacy technician failed to follow the facility process for how to handle the situation. The pharmacy chief reeducated the pharmacists regarding a twice-daily proactive review of all temperature

[35] Appendix B details the OIG's statistical sampling methodology.

[36] PBM and the Office of Biomedical Engineering, "Monitoring and Storage of Medications Requiring Refrigerators or Freezers." PBM and the Office of Biomedical Engineering's analysis of issue briefs related to the loss of refrigerated pharmaceuticals spanned a 16-month period from September 27, 2017, to December 26, 2018.

sensors, but this training did not occur before their lack of action resulted in a loss of about $302,000 in refrigerated pharmaceuticals.

Example 4

At another medical facility, the CheckPoint temperature-monitoring system detected a refrigerator malfunction during the night at a network community-based outpatient clinic. Although medical facility personnel called the facility's manager and left a voicemail, the voicemail was not received until the following morning. By then it was too late to save the refrigerated pharmaceuticals, resulting in a loss of about $17,000.

Not responding to monitoring system alerts can be especially problematic for the 112 of 170 medical facilities (about 66 percent) using TempTrak or CheckPoint because these systems will not continue to send alerts if no action is taken to reset the alert. The following example details what happened when the monitoring system remained unattended and in alert status.

Example 5

Medical facility pharmacy personnel left a refrigerator door open, triggering an alert in the CheckPoint temperature-monitoring system. However, the pharmacy personnel who were notified did not clear the alert in the CheckPoint system after closing the door, which caused the system to stay in alert status. Later that same day, the refrigerator door was left open again. The CheckPoint system did not trigger an alert because the alert from earlier in the day had not been resolved. This led to about $102,000 in refrigerated pharmaceutical loss, and three patients were administered compromised pharmaceuticals. According to the issue brief, VHA did not identify any immediate harm to these patients; however, these pharmaceuticals may have been less effective than properly stored pharmaceuticals.

Medical facilities have taken steps to improve the ability to detect when refrigerated pharmaceuticals are exposed to temperature excursions; however, processes and controls should be further strengthened. The OIG estimates that not all medical facilities fully implemented all required controls to reduce their risk of losing drugs because of refrigeration or monitoring failures. In addition to the costs associated with replacing compromised drugs and vaccines, veterans are also at risk if they are administered medications or vaccines that may be less effective because of temperature excursions.

Medical Facility Personnel Did Not Consistently Perform Routine Maintenance of Refrigerators and Freezers

Medical facility management personnel did not always perform routine maintenance of refrigerators or freezers that stored pharmaceuticals, as required by the August 2021 VHA notice. Routine maintenance includes checking door seals and cleaning unit coils. Specifically, at four of the eight selected medical facilities, maintenance personnel reported that they did not have a process to perform routine maintenance of the refrigerators and freezers and could not provide the team with maintenance logs. Nationally, the OIG estimates at least 52 of 162 medical facilities (about 32 percent) did not develop routine maintenance schedules for their refrigerators and freezers during the audit period.

In addition, one medical facility was still using a conventional refrigerator, such as those found in a home, to store pharmaceuticals. Personnel from this facility reported that the conventional refrigerators and freezers are more prone to breakdowns and malfunctions than pharmaceutical-grade purpose-built refrigerators and freezers. The facility was in the process of upgrading the refrigerator to a pharmaceutical-grade unit, as reported by facilities management personnel and observed by the audit team while on-site. The need to store COVID-19 vaccines also increased the importance of having pharmaceutical-grade purpose-built refrigerators and freezers.[37]

Issue Brief Guidance Needs Clarification to Minimize Unreported Loss of Refrigerated Pharmaceuticals

The team found that the August 2021 VHA notice and other VHA guidance on the issue brief process created confusion regarding when medical facility directors should submit an issue brief for the loss of refrigerated pharmaceuticals. The notice requires medical facilities to report any loss of refrigerated pharmaceuticals by submitting an issue brief, which is logged into VHA's issue brief tracker. However, the guide on issue briefs only explicitly cited requirements to report the loss of a controlled substance or high-value drug if theft, diversion, or suspicious loss is suspected—or for situations or events that warrant leaders' attention. According to PBM's chief consultant, the intent of the reporting requirement in the notice is for medical facilities to report all pharmaceutical loss in an issue brief without any reporting thresholds. To that end, medical facilities should submit an issue brief even if pharmaceutical loss does not represent a significant monetary loss or threaten patient safety.

[37] The audit team was not able to quantify the number of conventional refrigerators and freezers that are being used at medical facilities to store pharmaceuticals. Data that medical facilities capture on their inventories of conventional and pharmaceutical-grade purpose-built refrigerators and freezers were not complete and difficult to compare because of factors such as differences in facilities' naming conventions.

The audit team confirmed that this inconsistency resulted in some refrigerated pharmaceutical losses being unreported. The team identified seven instances of refrigerated pharmaceutical loss totaling about $42,000 that occurred in FY 2021 that were not documented in VHA's national issue brief tracker or reported to the VA central office as required by the notice. The audit team interviewed four VISN pharmacy executives and found that not all VISNs use the issue brief process as required by the notice. For example, the VISN 9 pharmacy executive reported that network personnel did not upload issue briefs into VHA's tracker because the guide did not require reporting all refrigerated pharmaceutical loss. Four of the seven unreported drug losses identified by the team happened in this VISN.

Additionally, during one of the audit team's site visits, the individual responsible for logging issue briefs into the tracker told the audit team that only pharmaceutical loss associated with controlled substances needed to be logged. This individual reported not being aware of the notice requirement to report all refrigerated pharmaceutical loss.

The audit team also identified two instances of refrigerated pharmaceutical loss that were not reported to the medical facility director, not because pharmacy personnel were unaware of the reporting requirements but because they nonetheless did not submit an issue brief. Although the available data the audit team reviewed suggest that instances of noncompliance are infrequent, compliance with the issue brief process is critical. As reported by the OIG in 2021, VHA lacks a perpetual inventory system that continuously tracks pharmacy inventory quantity and availability, which presents a risk that unreported losses can easily be hidden at the local level.[38] PBM and VISN pharmacy executives do not have any knowledge of the loss if the issue brief process is not followed. Until facilities consistently submit issue briefs when they experience refrigerated pharmaceutical loss, VHA cannot fully identify systemic issues and implement corrective actions to mitigate future loss.

Conclusion

The OIG found that VA medical facilities generally implemented and maintained requirements to safeguard the potency and value of refrigerated pharmaceuticals. However, not all medical facilities have fully implemented all required controls intended to reduce the risks facilities face when refrigerators or freezers fail. Medical facilities should fully implement safeguards to reduce their risk of losing refrigerated drugs and vaccines due to improper system configurations, a lack of routine maintenance, and personnel inaction when temperature excursion alerts occur. The OIG also found that the process medical facilities used to report refrigerated pharmaceutical loss provided incomplete data on the value and quantity of pharmaceutical losses and, more importantly, on the number of veterans affected by these losses. This process needs to be refined.

[38] VA OIG, *Systems and Tools Implemented to Track COVID-19 Vaccine Data*, Report No. 21-00913-267, December 7, 2021.

The OIG acknowledges that VA's refrigerated pharmaceutical loss in FY 2021 (about $1.7 million) was relatively minimal compared to total spending on these kinds of drugs (about $1.4 billion in FY 2021). Nonetheless, the OIG believes that there are opportunities to further reduce VA's risk. Given the losses medical facilities experienced in recent years, the OIG believes VHA may lose an estimated $5.1 million over the next three years if no corrective actions are taken. This is a conservative estimate based on refrigerated pharmaceutical loss reported in issue briefs but underrepresents actual loss. Appendix C provides additional information on how the OIG calculated these monetary benefits.

Recommendations 1–2

The OIG recommended the deputy under secretary for health take the following steps:

1. Direct the assistant under secretary for health operations to reinforce to medical facility directors the importance of establishing a process to ensure facility managers include pharmaceutical refrigerators and freezers in the facility's routine maintenance schedules and develop and implement a procedure to make sure medical facilities follow VHA Notice 2021-16.
2. Require the assistant under secretary for patient care services to coordinate with the assistant under secretary for health operations to update the *10N Guide to VHA Issue Briefs* and clarify that medical facilities must report *all* refrigerated pharmaceutical loss via the issue brief tracker.[39]

VA Management Comments

The deputy under secretary for health, performing the delegable duties of the under secretary for health, concurred with recommendations 1 and 2. To address recommendation 1, PBM, in collaboration with the Office of Healthcare Engineering and the Healthcare Operations Center, will reinforce with network directors the importance of routine maintenance schedules, develop a procedure to make sure medical facilities follow VHA Notice 2021-16, and require medical facility directors to detail findings and corrective actions resulting from periodic testing of the temperature-monitoring systems.

To address recommendation 2, PBM, in collaboration with the Office of Healthcare Engineering and the Healthcare Operations Center, updated the *10N Guide to VHA Issue Briefs* in April 2022 to clarify that VA medical facilities must report all refrigerated or frozen pharmaceutical loss as well as any system failure in a medical facility's routine maintenance and inspection program and temperature-monitoring system for refrigerators and freezers storing pharmaceuticals. The

[39] Change made based on technical comment 16 provided by VHA and detailed in appendix D.

updated guide was disseminated to VHA action groups with a request to forward the email to all medical facility directors on April 6, 2022.

The deputy under secretary for health also provided technical comments. Appendix D provides the full text of the management comments.

OIG Response

The planned corrective actions reported by the deputy under secretary for health, performing the delegable duties of the under secretary for health, are responsive to recommendation 1. The OIG will monitor VHA's progress on its proposed actions for this recommendation until the intent is addressed and will then close this recommendation. VHA's actions on the second recommendation were responsive, and the OIG closed this recommendation.

The OIG evaluated the technical comments provided by the deputy under secretary for health and made changes when the comments enhanced the accuracy of the report. Changes that were more than stylistic are footnoted in the report. The OIG did not change the report in response to comments that were stylistic or did not enhance the technical accuracy of the report. The OIG's response to comments that did not result in a report change is summarized in appendix E.

Appendix A: Scope and Methodology

Scope

The audit team conducted its work from August 2021 through March 2022. The scope of the audit focused on determining if VA medical facilities implemented and maintained requirements to safeguard the potency and value of refrigerated pharmaceuticals during FY 2021.

Methodology

To gain an understanding of VHA's processes for safeguarding the potency and value of refrigerated pharmaceuticals, the audit team reviewed relevant criteria, including the following:

- VHA Notice 2020-02, "Storage of Vaccines and Medications in Pharmaceutical Grade Purpose-Built Refrigerators and Freezers at VA Medical Facilities," January 17, 2020
- VHA Notice 2021-02, "Storage of Vaccines and Medications in Pharmaceutical Grade Purpose-Built Refrigerators and Freezers at VA Medical Facilities," January 20, 2021
- VHA Notice 2021-16, "Storage of Vaccines and Medications in Pharmaceutical Grade Purpose-Built Refrigerators and Freezers at VA Medical Facilities," August 9, 2021
- VHA Directive 1108.06(1), *Inpatient Pharmacy Services*, June 21, 2021
- VHA Handbook 7002, *Logistics Management Procedures*, January 8, 2020

Additionally, the team conducted site visits at eight sampled medical facilities that purchased refrigerated pharmaceuticals in FY 2021. The team conducted in-person site visits to six of the eight selected medical facilities and conducted virtual site visits at the remaining two. The team could not visit these two medical facilities in person because of the COVID-19 pandemic and outbreaks in and around these medical facilities. In addition, the team sampled about 25 refrigerators or freezers at six of the eight medical facilities (about 150 refrigerators and freezers) to test controls related to the proper storage of pharmaceuticals.[40] For example, at each of these six sites the team observed for each selected refrigerator or freezer the placement of the temperature probe, the appliance's power source, the contents stored in each refrigerator or freezer, and type of monitoring (manual or electronic monitoring) system in use. The team was

[40] Early audit results suggested that, for the most part, VA medical facilities implemented effective storage procedures for refrigerators and freezers; therefore, the audit team determined that there was minimal risk that the audit findings would be affected by not sampling refrigerators and freezers at the remaining two sites.

not able to physically inspect 50 refrigerators and freezers operated at the two medical facilities for which the team conducted virtual site visits.

In addition to these six site visits, the audit team conducted an in-person site visit to the Jamaica Plain VA Medical Center in Boston, Massachusetts, to test the facility's response to losing 1,900 COVID-19 vaccines due to refrigeration failure. The team also conducted an in-person site visit at the Manchester VA Medical Center in Manchester, New Hampshire, during the planning phase of the audit. Both of these medical facilities were judgmentally selected. Table A.1 provides additional details about the facilities the team reviewed during the audit period.

Table A.1. Detail of Medical Facilities Visited

Medical facility name and location	Sample type	Visit type
Buffalo VA Medical Center, Buffalo, NY	Probabilistic	In-person
Harry S. Truman Memorial Veterans' Hospital, Columbia, MO	Probabilistic	In-person
Jamaica Plain VA Medical Center, Boston, MA	Judgmental	In-person
Manchester VA Medical Center, Manchester, NH	Judgmental	In-person
Nashville VA Medical Center, Nashville, TN	Probabilistic	In-person
Olin E. Teague Veterans' Center, Temple, TX	Probabilistic	Virtual
Pittsburgh VA Medical Center-University Drive, Pittsburgh, PA	Probabilistic	In-person
Royal C. Johnson Veterans' Memorial Hospital, Sioux Falls, SD	Probabilistic	In-person
White River Junction VA Medical Center, White River Junction, VT	Probabilistic	In-person
Wm. Jennings Bryan Dorn Department of Veterans Affairs Medical Center, Columbia, SC	Probabilistic	Virtual

Source: VA OIG sampling plan.

To ensure inclusion of key requirements established in the above-documented criteria, the team reviewed standard operating procedures from the medical facilities selected for site visits.

The team also analyzed excursion reports for a sample of refrigerators and freezers and reviewed text integration utility notes—i.e., medical notes—entered in veterans' electronic healthcare records by medical providers at the time of patient service to identify instances of pharmaceuticals being unavailable due to refrigerator or freezer malfunction. Both steps were performed with the goal of testing for potentially unreported pharmaceutical loss due to temperature excursions.

To identify the causes of pharmaceutical loss and the monetary impact, the team reviewed 142 issue briefs submitted by medical facilities during FY 2021 in response to a loss of refrigerated pharmaceuticals. These issue briefs were extracted from the VA issue brief tracker

system. Individual medical facility reports of loss were summarized at the VA healthcare system level. VA operated 141 healthcare systems in the United States during the review period.

The team also interviewed VHA's PBM, Office of Healthcare Engineering, Healthcare Operations Center, and VISN pharmacy executives. In addition, at each of the site visits, the team interviewed key personnel (or their delegates), such as the chief of pharmacy, the chief of clinical engineering, facilities management representatives, and quality management personnel.

Internal Controls

The audit team assessed the internal controls related to VA medical facilities policies and procedures designed to safeguard the potency and value of refrigerated pharmaceuticals. This included an assessment of the five internal control components: control environment, risk assessment, control activities, information and communication, and monitoring.[41] In addition, the team reviewed the principles of internal controls associated with the objective. The team identified the following two components and six principles as significant to the objective. The team identified internal control weaknesses during this audit and proposed recommendations to address the following control deficiencies:

- Component 1: Control Environment
    - Principle 2: Exercise Oversight Responsibility
    - Principle 3: Establish Structure, Responsibility, and Authority
    - Principle 4: Demonstrate Commitment to Competence
    - Principle 5: Enforce Accountability
- 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

Although the August 2021 VHA notice requires VA medical facilities to submit an issue brief when refrigerated pharmaceuticals are lost due to a temperature excursion, the audit team found instances in which this requirement was not followed. Additionally, the team's site visits identified medical facilities that did not have a routine maintenance program for pharmaceutical

[41] Government Accountability Office (GAO), *Standards for Internal Control in the Federal Government*, GAO-14-704G, September 2014.

refrigerators and freezers, as required by the notice. Furthermore, although medical facilities had temperature-monitoring systems to identify temperature excursions, the audit team found multiple instances in FY 2021 in which a temperature excursion was not identified by pharmacy staff and compromised pharmaceuticals were administered to patients.

Component 5: Monitoring

From the FY 2021 issue brief data, the audit team identified many VA medical facilities that had a temperature-monitoring system installed but either failed to act when a temperature excursion alert occurred or did not properly configure the monitoring system to alert the appropriate personnel when an excursion alert occurred. These situations resulted in unnecessary monetary loss as well as patients receiving pharmaceuticals that were exposed to improper storage temperatures.

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. The team exercised due diligence in staying alert to any fraud indicators by

- soliciting the OIG's Office of Investigations for indicators and
- asking about concerns related to fraud, waste, and abuse in relation to the proper storage of pharmaceuticals at the site entrance conference and project entrance conference.

The OIG did not identify any instances of fraud or potential fraud during this audit.

Data Reliability

The audit team obtained issue brief data from the national issue brief tracker to assess the reported monetary loss and the reasons for loss associated with failure to properly store refrigerated pharmaceuticals. To test the accuracy, reliability, and completeness of the issue brief data that were used to support findings, conclusions, and recommendations related to the audit objectives, the team performed multiple steps such as analyzing site-specific historical temperature-monitoring reports, interviewing pharmacy and VISN pharmacy executive staff, and querying medical notes in the Veterans Health Information Systems and Technology Architecture to identify refrigerator and freezer failures.

These steps did not disclose any inaccuracies with the issue brief data obtained from the national tracker; however, the team did identify multiple issue briefs and refrigerated pharmaceutical losses that were missing from the tracker due to the failure of some VA medical facilities to follow required reporting policy.

The audit team also used text integration utility notes reports to identify facilities that did not follow the required reporting policy to submit an issue brief when pharmaceuticals are lost due to temperature excursions. Text integration utility notes reports were obtained by the OIG's Data Services Team from the Corporate Data Warehouse. Data Services Team members completed their own data reliability testing, and the audit team also followed up with the medical facilities for additional details and documentation to verify the information captured in the notes report.

Performing these steps gave the team reasonable assurance that the issue brief data were accurate and appropriate. Despite the identified data issues, the team used issue briefs received from site visits to check the completeness of the data received from VHA, which allowed the team to determine that all data used were sufficiently reliable for the intended purposes.

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: Statistical Sampling Methodology

Approach

To accomplish the objective, the audit team probabilistically selected a sample of eight medical facilities using VA inventory system data, FY 2021 refrigerated pharmaceutical purchase data, and electronic monitoring-system data. The team also judgmentally selected two additional facilities. The team used the results of the analysis of the selected facilities to estimate the extent to which VA implemented and maintained requirements to safeguard the potency and value of refrigerated pharmaceuticals. The team randomly selected about 25 refrigerators or freezers at six of the eight selected medical facilities to observe and test compliance with storage procedures.

The team originally intended to estimate the number of refrigerators and freezers that lacked appropriate controls for storing refrigerated pharmaceuticals. However, early audit results suggested that, for the most part, VA medical facilities implemented effective storage procedures for refrigerators and freezers. For example, medical facilities generally placed the electronic monitoring-system temperature probes in the refrigerators and freezers properly, plugged the refrigerators and freezers into emergency power sources, and only used the refrigerators and freezers to store medical items. Therefore, the results provided in this appendix are limited to large-scale controls at the medical facility level. These controls include

- electronic monitoring system with cascading alert notifications;
- standard operating procedures for refrigerated pharmaceutical storage, including guidance for monitoring system configuration and timeliness metrics for responsiveness to alerts;
- routine maintenance schedules for refrigerators and freezers; and
- system testing at least semiannually.

To quantify the risk that refrigerated pharmaceuticals could lose potency or be lost due to temperature excursions, the audit team analyzed processes and procedures implemented by the sampled medical facilities to safeguard the storage of refrigerated pharmaceuticals and identify medical facilities that lacked any of the above-mentioned controls. Next, accounting for each sampled facility's probability of selection in the sample, the OIG statisticians estimated the total number and percentage of the population of medical facilities that were noncompliant with each of the requirements.

Population

The target population included all refrigerators and freezers that were used to store refrigerated pharmaceuticals at all VA medical facilities during FY 2021. The sampling frame used for this audit included 5,114 refrigerators and freezers identified from inventory data at 162 medical facilities.[42]

Sampling Design

The audit team evaluated refrigerated pharmaceutical purchases identified from PBM data during FY 2021, Corporate Data Warehouse inventory data on refrigerators and freezers appropriate for the storage of refrigerated pharmaceuticals, and electronic monitoring-system data.

The team obtained inventory data from the Corporate Data Warehouse and refrigerated pharmaceutical purchase data from PBM. The team also obtained equipment listings from the electronic monitoring systems, provided by the VISN pharmacy executives at the eight sampled medical facilities, to identify the specific location of the refrigerators and freezers.

The team used a two-stage sample design to select medical facilities and refrigerators for examination. The OIG statistician identified inventory data for 5,114 refrigerators and freezers that store refrigerated pharmaceuticals at 162 medical facilities.

Stage 1

The sampling frame consisted of eight sampled medical facilities (three high-complexity [1a], three medium-complexity [1b and 1c], and two low-complexity facilities [2, 3, or blank complexity rating]).[43] The OIG statisticians sampled these medical facilities with probability proportionate to each facility's share of aggregate spending on refrigerated drugs.[44] These eight selected facilities had 276 of 5,114 refrigerators or freezers listed in the sampling frame (table B.1). The audit team also judgmentally selected one additional medical facility and completed a planning site visit to another facility.

[42] Data the team collected on temperature-monitoring systems included 170 medical facilities; however, the inventory data from the Corporate Data Warehouse and pharmaceutical purchase data only included 162 facilities. The OIG statistician excluded these eight facilities from the sample. In addition, the statistician calculated the number of refrigerators and freezers included in the sampling frame using inventory data from the Corporate Data Warehouse.

[43] The Facility Complexity Model classifies VHA facilities at levels 1a, 1b, 1c, 2, or 3 with level 1a being the most complex and level 3 being the least complex. Classifications are based on factors such as patient population, clinical services offered, and educational and research missions.

[44] The selection was based on all available FY 2021 PBM data as obtained by the audit team on August 3, 2021.

Stage 2

The audit team, in coordination with the OIG statisticians, sampled about 25 refrigerators and freezers from the inventory list obtained from the Corporate Data Warehouse and the inventory list provided by the six sampled medical facilities in stage 1 that the team visited in person.

Table B.1. Counts by Medical Center Group/Facility Complexity

VA medical facility complexity level	VA medical facilities	Number of refrigerators and freezers	Spending on refrigerated pharmaceuticals in FY 2021 ($)
Complexity 1a	56	2,254	728,857,728.12
Complexity 1b and 1c	49	1,478	466,140,023.63
Complexity 2, 3, and blank	57	1,382	180,718,034.00
Total	**162**	**5,114**	**1,375,715,785.75**

Source: VA OIG statistician's stratified population. Data were obtained from VA, Corporate Data Warehouse, and PBM.
Note: The audit team used $929 million as the basis for its sample selection because at the time the sample was generated, only a partial year of data for FY 2021 was available. The team subsequently obtained spending data for the full fiscal year, which is represented in this table.

Weights

Samples were weighted to represent the population from which they were drawn, and the weights were used in the estimate calculations. For example, the team calculated the error rate estimates by first summing the sampling weights for all sample records that contained the given error, then dividing that value by the sum of the weights for all sample records.

Because statistical estimation for this audit was only performed at the first stage of sample selection (medical facility selection) and not at the second stage (refrigerator or freezer selection), sample weights account for selection probabilities at the first stage only. Each facility's sampling weight is the inverse of the probability with which the facility was included in the first-stage sample.

Projections and Margins of Error

The projection is an estimate of the population value based on the sample. The associated margin of error and confidence interval show the precision of the estimate. If the OIG repeated this audit with multiple sets of samples, the confidence intervals would differ for each sample but would include the true population value approximately 90 percent of the time.

The OIG statistician calculated the weighted population estimates and associated sampling errors by accounting for the complexity of the sample design. Because the first-stage sample size was small, Clopper-Pearson intervals were used to conservatively bound the estimated number of, and proportion of, population facilities with each identified type of error.

The sample size was determined after reviewing the expected precision of the projections based on the sample size, potential error rate, and logistical concerns of the sample review. Although precision improves with larger samples, the rate of improvement decreases significantly as more records are added to the sample review.

Figure B.1 shows the effect of progressively larger sample sizes on the margin of error.

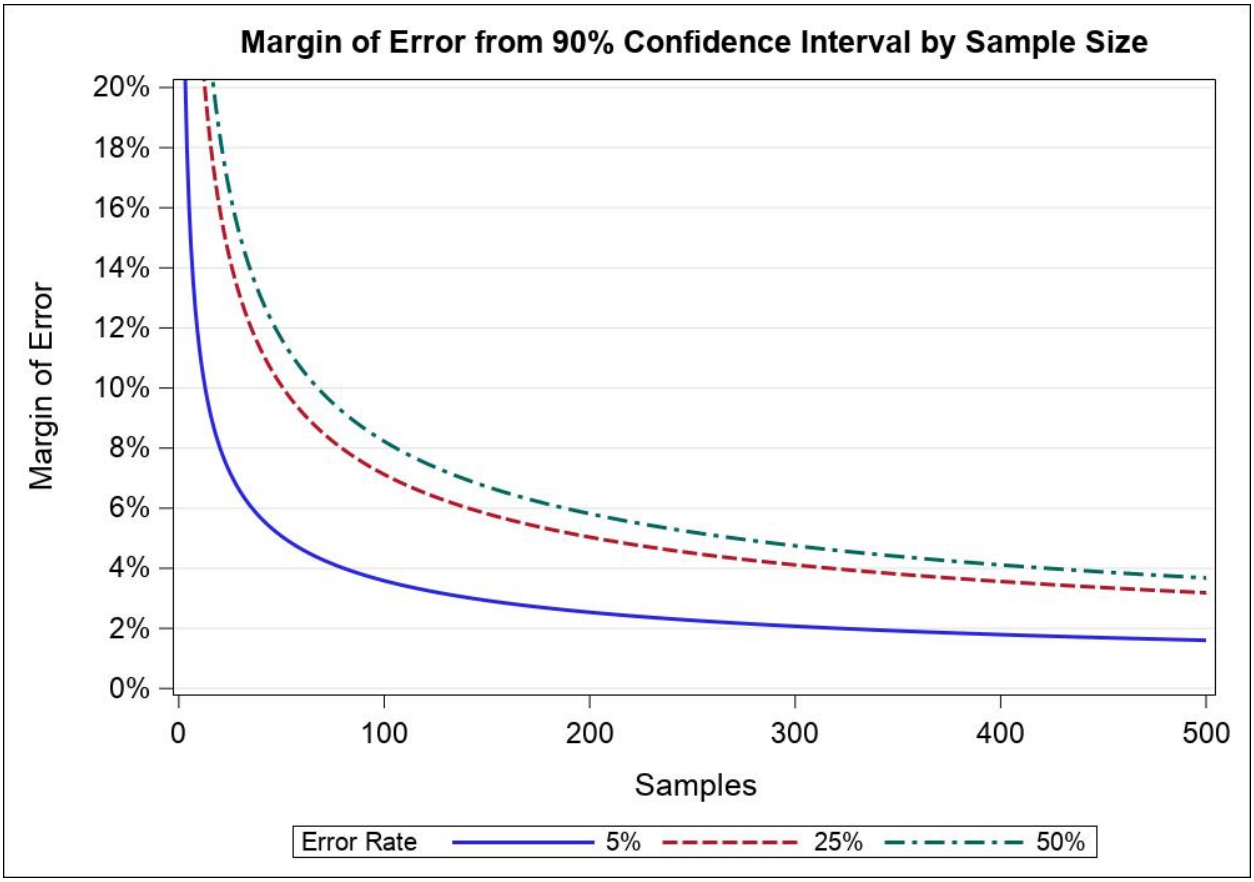

Figure B.1. *Effect of sample size on margin of error.*
Source: VA OIG statistician's analysis.

Projections

The team identified necessary controls medical facilities are required to implement to help safeguard the potency and value of refrigerated pharmaceuticals. The team evaluated these controls at medical facilities. The estimates in table B.2 were calculated based on the

documentation and data obtained during in-person and virtual site visits to the eight sampled sites out of 162 medical facilities. Table A.1 provides details of the site visits.

Table B.2. Summary of Estimates for Medical Facilities Not in Compliance with Key Requirements of VHA Notice 2021-16 (August 2021)

Requirement	Number of sampled medical facilities with error	Estimated number and percent of noncompliant medical facilities (%)	Two-sided 90% confidence interval			One-sided 90% confidence interval lower limit (%)
			Margin of error (%)*	Lower limit (%)	Upper limit (%)	
Cascading alert notifications	0	0 (0)	26 (16)	0 (0)	51 (31)	0 (0.0)
Standard operating procedure	0	0 (0)	26 (16)	0 (0)	51 (31)	0 (0.0)
Guidance for monitoring system configuration	2	33 (21)	43 (27)	5 (2.9)	90 (56)	7 (4.6)
Timeliness metrics for responsiveness to alerts	6	130 (80)	43 (26)	73 (45)	158 (97)	84 (52)
Routine maintenance schedules	4	97 (60)	49 (30)	43 (27)	141 (87)	52 (32)
System testing at least semiannually	6	121 (75)	59 (36)	42 (26)	160 (98)	54 (34)
Any error	8	162 (100)	26 (16)	111 (69)	162 (100)	121 (75)

Source: VA OIG analysis of data and information obtained from the eight sampled medical facilities. These estimates relate to the percentage and count of medical facilities in error. Percentages are rounded.
Note: The team conducted in-person and virtual site visits to eight of 162 medical facilities. These eight medical facilities were selected randomly.
** The margin of error represents half the distance between the lower bound and the upper bound of a Clopper-Pearson two-sided 80% confidence interval on the number of (percentage) medical facilities in error.*

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

Recommendation	Explanation of Benefits	Better Use of Funds	Questioned Costs
1	The estimated value of refrigerated pharmaceutical loss by medical facilities over the next three years. Medical facilities lost an estimated $1.7 million in FY 2021.	$5,100,000	
	Total	**$5,100,000**	

Source: VA OIG analysis of issue briefs resulting in refrigerated pharmaceutical loss in FY 2021.

To calculate these potential monetary benefits, the team

- considered PBM's analysis of issue briefs that covered about 15 months from September 29, 2017, to December 26, 2018;
- conducted its own analysis of issue briefs submitted in FY 2021; and
- analyzed patient medical records to identify unreported loss.

PBM Issue Brief Analysis

As reported by PBM and the Office of Biomedical Engineering, from September 29, 2017, to December 26, 2018, VHA received approximately nine issue briefs from eight medical facilities that reported loss of refrigerated medication or vaccines due to improper storage, improper equipment configuration, and/or nonresponse to temperature-monitoring alert systems. These incidents resulted in a monetary loss of over $1.1 million.

OIG Analysis

The audit team analyzed 142 issue briefs submitted by 77 VHA medical facilities that resulted in about $1.7 million in refrigerated pharmaceutical loss in FY 2021. In addition, the team also conducted limited testing of medical facilities' compliance with submitting issue briefs when a loss occurred by reviewing veterans' medical records for indications that medications were unavailable because of a refrigeration failure. Based on this analysis, the OIG identified instances of medication loss that occurred in FY 2021 and were not reported by medical facility personnel in the issue brief tracker as required. The OIG identified seven unreported losses totaling about $42,033.

The audit team annualized the about $1.7 million over three years to estimate that VA is at risk for continuing to lose at least an estimated $5.1 million from FY 2022 through FY 2024 if medical facilities do not improve safeguards for storing refrigerated pharmaceuticals. The OIG believes that estimating VA's financial risk across three years is reasonable because refrigerated pharmaceutical loss was reported as far back as September 2017—five years ago. The OIG's estimate is conservative because the amount the team used to calculate losses for FY 2021 (about $1.7 million) does not include the unreported loss of about $42,000 the team identified. It is likely that additional loss has gone unreported and cannot be included in the team's estimate.

Appendix D: Management Comments

Department of Veterans Affairs Memorandum

Date: April 29, 2022

From: Deputy Under Secretary for Health,
Performing the Delegable Duties of Under Secretary for Health (10)

Subj: OIG Draft Report, Medical Facilities Safeguarded Refrigerated Pharmaceuticals, but Additional Actions Could Reduce Loss (2021-01898-AE-0087)

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

1. Thank you for the opportunity to review the Office of the Inspector General's (OIG) draft report, *Medical Facilities Safeguarded Refrigerated Pharmaceuticals, But Additional Actions Could Reduce Loss*. OIG's review has supported the Veterans Health Administration's (VHA) efforts in emphasizing the importance of proper medication and vaccine storage, including equipment maintenance and process testing, to ensure system wide improvements and to continue to mitigate potential loss.
2. VHA concurs with OIG's recommendations and is providing an action plan as well as technical comments.

(original signed by)

Steven Lieberman, M.D.

Attachments

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

Medical Facilities Safeguarded Refrigerated Pharmaceuticals, But Additional Actions Could Reduce Loss

OIG Project # 2021-01898-AE-0087

Recommendation 1. Direct the assistant under secretary for health operations to (1) reinforce to medical facility directors the importance of establishing a process to ensure facility managers include pharmaceutical refrigerators and freezers in the facility's routine maintenance schedules, and (2) develop and implement a procedure to make sure medical facilities are in compliance with VHA Notice 2021-16.

VHA Comments: Concur. VHA Pharmacy Benefit Services (PBM), in collaboration with Healthcare Engineering and the Healthcare Operations Center (HOC), will first reinforce with the Network Directors the importance for each VA medical facility Director to ensure there is an established process for the facility's managers to include pharmaceutical refrigerators in the facility's routine maintenance schedules. PBM, in collaboration with Healthcare Engineering and the HOC, will also develop a procedure to make sure medical facilities are in compliance with VHA Notice 2021-16, *Storage of Vaccines and Medications in Pharmaceutical Grade Purpose-Built Refrigerators and Freezers at VA Medical Facilities*. Additionally, the *10N Guide to VHA Issue Briefs* and VHA Notice 2021-16, or superseding policy will be updated. To ensure compliance with VHA Notice 2021-16, within a submitted Issue Brief, VA medical facility directors will be expected to detail findings and corrective actions resulting from testing of the temperature monitoring, power and cascade alarm systems. These actions will take place at a frequency defined in policy, thereby ensuring enterprise awareness of the corrective action plan.

Status: In progress **Target Completion Date**: June 2022

Recommendation 2. Require the Assistant Under Secretary for Health Operations to coordinate with the Assistant Under Secretary for Health Patient Care Services to update the *10N Guide to VHA Issue Briefs* and clarify that medical facilities must report *all* refrigerated pharmaceutical loss via the issue brief tracker.

VHA Comments: Concur. PBM, in collaboration with Healthcare Engineering and the HOC, have updated the 10N Guide to VHA Issue Briefs to clarify that VA medical facilities must report all refrigerated pharmaceutical loss via the Issue Brief Tracker.

The April 6, 2022, update, Guide to VHA Issue Briefs, highlights changes made regarding pharmaceuticals. Programmatic changes made to the guide regarding pharmaceuticals include:

- Pharmaceuticals: Added additional requirements for submitting Issue Briefs for:
    - Pharmaceutical refrigerator or freezer failures that result in the loss of medications or vaccines; and
    - any system failure in a facility's routine maintenance and inspection program and temperature monitoring system for pharmaceutical refrigerators and freezers.

The HOC provided the updated guide to VHA facilities. VHA has completed actions to resolve this recommendation and asks OIG to consider closing it.

Status: Completed **Completion Date**: April 2022

VHA Technical Comments

OIG Draft Report: Medical Facilities Safeguarded Refrigerated Pharmaceuticals, But Additional Actions Could Reduce Loss

(Project Number 2021-01898-AE-0087)

Comment 1

Draft location: Page i, paragraph 1, line 3

Current language: "…, or light can spoil these pharmaceuticals, …"

Comment and justification: Please consider changing this statement to "…, or light can cause these pharmaceuticals to lose potency, …" This edit is consistent with pharmaceutical terminology and the change would result in the report having the same verbiage used in this report on PDF page 9, line 2.

Comment 2

Draft location: Page i, paragraph 4, lines 2-3

Current language: "…involves each facility's chief of pharmacy, chief of facilities management, chief of clinical engineering, and service chiefs.[3] These chiefs are…"

Comment and justification: Recommend changing to "…are designated by the medical center director. The designated department for oversight must have the required competency and knowledge of the equipment and are …" This edit is in alignment with VHA Notice 2021-16 that states the medical center director is responsible for designating the oversight, maintenance and operation to the department that has the required competency and knowledge of the equipment.

Comment 3

Draft location: Page ii, paragraph 4, line 4

Current language: "… and most medical facilities reported using, or being in the process of acquiring …"

Comment and justification: Recommend changing to "all medical facilities, with the exception of one which was in the process of, acquired …" or "almost all medical facilities reported using, or being in the process of acquiring …" This edit would more capture the current status of pharmaceutical grade refrigerators and freezers in use at medical facilities more accurately. This edit is also in alignment with verbiage on PDF page 16, paragraph 1, lines 2-4, "… All reviewed facilities … reported being in the process of upgrading to pharmaceutical grade purpose-built units…"

Comment 4

Draft location: Page ii, paragraph 5, line 7

Current language: "…Pharmacy Benefits Management Services' requirements…"

Comment and justification: Recommend changing to "…VHA's requirements…" This edit reflects the current guidance issued in VHA Notice 2021-16.

Comment 5

Draft location: Page iii, paragraph 3, line 3

Current language: "…Pharmacy Benefits Management Services guidance …"

Comment and justification: Recommend changing to *"…VHA's guidance…"* As with Comment 4, this edit reflects the current guidance issued in VHA Notice 2021-16.

Comment 6

Draft location: Page iii, paragraph 3, lines 6-10

Current language: *"…In some cases, pharmacy personnel were aware of the requirement to report the loss of any refrigerated pharmaceuticals but did not comply with it. This is particularly concerning because VHA currently does not have a process to monitor compliance with Pharmacy Benefits Management Services requirements among facility chiefs of pharmacy."*

Comment and justification: Recommend changing to *"…In some cases, medical facility personnel were not clear how to follow the requirement to report refrigerated pharmaceutical losses. This is concerning because VHA does not have a process to monitor compliance with VHA Notice 2021-16."* This edit accurately reflects the process that it is the medical center director's responsibility to report pharmaceutical losses via the issue brief process; medical facility personnel would not report through the issue brief process. The edit also reflects that the current requirements are not Pharmacy Benefits Management Services', but VHA Notice 2021-16.

Comment 7

Draft location: Page iv, paragraph 1, line 2

Current language: "…a lack of noncompliance…"

Comment and justification: Recommend changing to "…a lack of compliance…" or "…noncompliance…" This edit will ensure clarity that noncompliance was found.

Comment 8

Draft location: Page 2, paragraph 2, line 7

Current language: "…According to the guidance, facility personnel should…"

Comment and justification: Recommend changing to "…Medical facility leadership should…" This edit will accurately capture the issue brief process where medical facility leadership have the responsibility to submit issue briefs to VISNs.

Comment 9

Draft location: Page 2, paragraph 3, line 3

Current language: "…for inpatient pharmacy services…"

Comment and justification: Recommend changing to "at VA medical facilities…" This edit captures the scope of the guidance from VHA Notice 2021-16 for all pharmaceutical refrigerators and freezers used at a facility versus the narrower scope of the guidance in VHA Directive 1108.06, Inpatient Pharmacy Services.

Comment 10

Draft location: Page 3, paragraph 1, lines 3-5

Current language: *"…The VHA notice also outlines responsibilities for the chief of pharmacy, chief of facility management, chief of clinical engineering, and chief of the responsible service (or the service point of contact), who all…"*

Comment and justification: Recommend changing to *"…The VHA notice also outlines responsibilities for the chief of pharmacy and the chief of the designated responsible service, who all…"* This edit clarifies only the medical facility service chief responsibilities defined in the notice.

Comment 11

Draft location: Page 4, table 1, rows 1-6

Current language: Roles Column, Responsibilities and Best Practices Column

Comment and justification: Recommend updating the table roles and responsibilities to align with VHA Notice 2021-16 published on August 9, 2021. The table omits several responsibilities defined in the notice. For example, VHA Notice 2021-06, under the VA Medical Facility Director, "Designating the oversight of the maintenance and the operation of medication refrigerators and freezers to the department that has the required competency and knowledge of the equipment" needs to be included. Another omission example is the VA Medical Facility Chief of Pharmacy is responsible for "Coordinating with the VA medical facility Chief of Facilities Management or designee to ensure Pharmacy Services and other VA medical facility locations that store medications which must be refrigerated or frozen, use pharmaceutical grade purpose-built refrigerators or freezers exclusively". In addition, the table lists the Chief of Facility Management and Chief of Clinical Engineering; however, the titles are not listed in VHA Notice 2021-16. Also, including best practices under responsibilities creates confusion from defined responsibilities and potential best practices.

Comment 12

Draft location: Page 4, paragraph 1, line 4

Current language: "…for inpatient pharmacy services."

Comment and justification: Recommend changing to "for VA medical facilities." This edit captures the scope of the guidance from VHA Notice 2021-16 for all pharmaceutical refrigerators and freezers used at a facility versus the narrower scope of the guidance in VHA Directive 1108.06, Inpatient Pharmacy Services.

Comment 13

Draft location: Page 6, paragraph 3, line 3

Current language: "…pharmaceuticals will be spoiled. …"

Comment and justification: Recommend changing to "pharmaceuticals will lose potency." This edit is consistent with pharmaceutical terminology and the change would result in the report having the same verbiage here as used in this report on PDF page 9, line 2.

Comment 14

Draft location: Page 8, footnote 16, line 1; Page 26, paragraph 3, line 1

Current language: "…pharmaceuticals could be lost or spoiled, …"

Comment and justification: Recommend changing to "pharmaceuticals could lose potency or be lost, …" This edit is consistent with pharmaceutical terminology and the change would result in the report having the same verbiage here as used in this report on PDF page 9, line 2.

Comment 15

Draft location: Page 21, paragraph 1, line 1

Current language: "…through TBD. …"

Comment and justification: Change to "…end date of audit needs entered. …" This edit will reflect the review timeframe.

Comment 16

Draft location: Page 20, paragraph 1, line 1

Current language: “Direct the assistant Under Secretary for Health Operations...”

Comment and justification: Pharmacy Benefit Services (PBM) requests that the language be changed to “Direct the Assistant Under Secretary for Patient Care Services to coordinate with the Assistant Under Secretary for Health Operations…”

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 E: OIG Response to Technical Comments

The OIG appreciates the acting under secretary's 16 technical comments, detailed in appendix D. The audit team evaluated each comment and made changes to the report after verifying the accuracy of the information provided. Changes were not made to the report that were stylistic or did not enhance accuracy. Revisions to the report in response to VHA's technical comments are indicated in footnotes.

The OIG disagreed with four technical comments:

- **Comment 3.** Draft location: page ii, paragraph 4, line 4
  - **Current language.** "and most medical facilities reported using, or being in the process of acquiring"
  - **Comment and justification.** "Recommend changing to 'all medical facilities, with the exception of one which was in the process of, acquired … ' or 'almost all medical facilities reported using, or being in the process of acquiring …' This edit would more capture the current status of pharmaceutical grade refrigerators and freezers in use at medical facilities more accurately. This edit is also in alignment with verbiage on PDF page 16, paragraph 1, lines 2-4, '… All reviewed facilities … reported being in the process of upgrading to pharmaceutical grade purpose-built units …'"
  - **OIG response.** Incorporating this technical comment would affect the accuracy of the report. The audit team did not review every medical facility to confirm the use of temperature-monitoring systems. Rather, the team verified that all medical facilities reviewed in the sample used temperature-monitoring systems.
- **Comment 6.** Draft location: page iii, paragraph 3, lines 6–10
  - **Current language.** "… In some cases, pharmacy personnel were aware of the requirement to report the loss of any refrigerated pharmaceuticals but did not comply with it. This is particularly concerning because VHA currently does not have a process to monitor compliance with Pharmacy Benefits Management Services requirements among facility chiefs of pharmacy"
  - **Comment and justification.** "Recommend changing to '… In some cases, medical facility personnel were not clear how to follow the requirement to report refrigerated pharmaceutical losses. This is concerning because VHA does not have a process to monitor compliance with VHA Notice 2021-16.' This edit accurately reflects the process that it is the medical center director's responsibility to report pharmaceutical losses via the issue brief process; medical facility personnel would not report through the issue brief process. The edit also reflects that the current requirements are not Pharmacy Benefits Management Services', but VHA Notice 2021-16"

- **OIG response.** Incorporating this technical comment would affect the accuracy of the report. The team did identify some instances where facility personnel did understand the requirement to report pharmaceutical loss in an issue brief but did not report the loss to the medical facility director as required.

- **Comment 8.** Draft location: page 2, paragraph 2, line 7
  - **Current language.** "… According to the guidance, facility personnel should …"
  - **Comment and justification.** "Recommend changing to '…Medical facility leadership should…' This edit will accurately capture the issue brief process where medical facility leadership have the responsibility to submit issue briefs to VISNs"
  - **OIG response.** Incorporating this technical comment would affect the accuracy of the report. The audit team reviewed the referenced guidance, which does not specifically put the requirement to submit issue briefs on medical facility leaders. The referenced guidance states that issue briefs are drafted to provide specific information to leaders within an organization, working through the appropriate chain of command. The OIG believes that all facility personnel—regardless of their position and authority—who first identify the issue have a responsibility to report that information.
- **Comment 11.** Draft location: page 4, table 1, rows 1-6
  - **Current language.** Roles Column, Responsibilities and Best Practices Column
  - **Comment and justification.** "Recommend updating the table roles and responsibilities to align with VHA Notice 2021-16 published on August 9, 2021. The table omits several responsibilities defined in the notice. For example, VHA Notice 2021-06, under the VA Medical Facility Director, 'Designating the oversight of the maintenance and the operation of medication refrigerators and freezers to the department that has the required competency and knowledge of the equipment' needs to be included. Another omission example is the VA Medical Facility Chief of Pharmacy is responsible for 'Coordinating with the VA medical facility Chief of Facilities Management or designee to ensure Pharmacy Services and other VA medical facility locations that store medications which must be refrigerated or frozen, use pharmaceutical grade purpose-built refrigerators or freezers exclusively.' In addition, the table lists the Chief of Facility Management and Chief of Clinical Engineering; however, the titles are not listed in VHA Notice 2021-16. Also, including best practices under responsibilities creates confusion from defined responsibilities and potential best practices"
  - **OIG response.** The audit team made some changes to table 1 based on this technical comment. However, information on the roles and responsibilities of the chief of facility management and chief of clinical engineering was not removed from the table

because these positions are important in the overall safeguarding of temperature-controlled pharmaceuticals at medical facilities.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Audit Team	Irene J. Barnett, Director Brittany Baker Marco Chan Abigail Genitempo Richard Pesce
Other Contributors	Kendal Ferguson Victor Rhee Jill Russell Clifford Stoddard

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