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Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Review of Veterans Health Administration's Response to a Medication Recall

HEALTHCARE INSPECTION | REPORT #21-02194-198 | JULY 19, 2022

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Executive Summary

The VA Office of Inspector General (OIG) conducted an inspection to assess the Veterans Health Administration's (VHA) process in responding to a December 2020 medication recall. The recall included two medications, an antidepressant and erectile dysfunction treatment, which were incorrectly packaged together in the same bottle by the distributor, AvKARE.[1] The OIG received and reviewed three allegations of an incorrect medication mistakenly received by veterans at three different VHA medical facilities.[2]

The OIG determined that in the December 2020 AvKARE medication recall, the reviewed VHA medication recall process generally met VHA requirements. However, the OIG identified potential vulnerabilities related to the monitoring and reporting of medication recall adverse drug events and variations in the software and processes used to record medication lot numbers in two VHA medical facilities named in the allegations—the VA Oklahoma City Healthcare System and the VA North Texas Health Care System.

The OIG found that during the AvKARE medication recall, the VHA National Center for Patient Safety (NCPS) monitored communications and responded according to VHA policy requirements relating to the identification and review of the recall. NCPS emailed designated VHA leaders and staff of the AvKARE medication recall providing known details, required actions, and instructions for the NCPS web application completion, and monitored web application completion compliance.

During the AvKARE medication recall, VHA Pharmacy Benefits Management (PBM) followed VHA requirements to distribute medication recall safety information throughout VHA medical center facilities and ensured notification of patients affected by the recalled medications.[3] In the event of a patient level medication recall, VHA requires PBM to develop and disseminate detailed information to key staff throughout the VHA healthcare system within a time frame determined by PBM's Deputy Chief Consultant.[4]

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[1] The two medications packaged together in the same bottle were trazodone (an antidepressant medication) and sildenafil (an erectile dysfunction treatment medication).

[2] The VHA medical facilities included the VA Oklahoma City Healthcare System on December 20, 2020; VA North Texas Health Care System in Dallas, Texas, on February 23, 2021; and the James A. Haley Veterans' Hospital in Tampa, Florida, on March 31, 2021. The OIG identified that the James A. Haley Veterans' Hospital allegation was not part of the AvKARE medication recall.

[3] PBM is a VHA national program office managed by senior pharmacy leaders with expertise in pharmacy practice that "works to enhance the clinical outcomes and improve the health of Veteran patients through the appropriate use of pharmaceuticals."

[4] PBM emails key staff, including VHA national leaders, NCPS, Veterans Integrated Service Network and Consolidated Mail Order Pharmacy leaders, Primary Care Chiefs or Directors, and Chiefs of Staff and Chiefs of Pharmacy via an email group named the Drug Safety Alert Mail Group.

The OIG found that VHA medical facility staff were responsible for notifying all affected patients, whether medication was supplied by the Consolidated Mail Order Pharmacy or by the VHA medical facility. The OIG discovered that pharmacy staff from the two reviewed VHA medical facilities used different software and processes to record medication lot numbers and identify patients receiving recalled medication, which is important for sequestering the recalled medication.

Adverse drug events resulting from recalled medications are not identified specifically as a category nor required to be reported in the VA Adverse Drug Event Reporting System.[5] Therefore, the OIG could not determine if VHA monitored all adverse drug events from recalled medications. The OIG found that VHA medical facility leaders and providers were responsible to report patient safety issues or adverse drug events resulting from a recalled medication into the VA Adverse Drug Event Reporting System, a voluntary reporting system.[6]

The OIG made two recommendations to the Under Secretary for Health related to the monitoring and reporting of medication recall adverse drug events and vulnerabilities in the medication recall process due to variances in VHA medical facility processes.

Comments

The Deputy Under Secretary for Health Performing the Delegable Duties of the Under Secretary for Health concurred with the recommendations and provided acceptable action plans (see appendix B). The OIG will follow up on the planned actions until they are completed.

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[5] VHA Directive 1070, *Adverse Drug Event Reporting and Monitoring*, May 15, 2020.
[6] VHA Directive 1070.

Contents

Abbreviations

CMOP	Consolidated Mail Order Pharmacy
FDA	Food and Drug Administration
NCPS	National Center for Patient Safety
OIG	Office of Inspector General
PBM	Pharmacy Benefits Management Services
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted an inspection to assess Veterans Health Administration's (VHA) process to respond to a medication recall.

On December 3, 2020, VHA initiated a recall on a medication, which staff at the Murfreesboro, Tennessee, Consolidated Mail Order Pharmacy (CMOP) identified as incorrectly packaged with another medication in the same bottle by the distributor, AvKARE.[1] Additionally, the OIG received and reviewed three allegations of an incorrect medication mistakenly received by veterans at three different VHA medical facilities.[2] Although a preliminary review did not warrant inspection of the allegations, the OIG evaluated medication recall processes at the national and regional office levels. To examine and understand the medication recall process from a VHA medical facility level perspective, the OIG included select reviews at two facilities named in the allegations, VA Oklahoma City Healthcare System in Oklahoma, and VA North Texas Health Care System in Dallas, Texas.[3]

Background

The Food and Drug Administration

The Food and Drug Administration (FDA) is the federal agency responsible for regulating products that affect the general public's health.[4] When a medication (product) is identified as defective or potentially harmful, the FDA works with the manufacturer to initiate a medication

[1] The two medications packaged together in the same bottle were trazodone and sildenafil. Trazodone is an antidepressant medication commonly prescribed for the treatment of depression. Sildenafil works by relaxing blood vessels to increase blood flow for the treatment of erectile dysfunction in men. AvKARE is a distributor of pharmaceuticals.

[2] The VHA medical facilities included the VA Oklahoma City Healthcare System, Oklahoma, on December 20, 2020; VA North Texas Health Care System in Dallas, Texas, on February 23, 2021; and the James A. Haley Veterans' Hospital in Tampa, Florida, on March 31, 2021. The OIG identified that the James A. Haley Veterans' Hospital allegation was not part of the AvKARE medication recall.

[3] The OIG reviewed the VA Oklahoma City Healthcare System allegation in which a patient received a letter that "the generic Viagra I have been getting may be the wrong medicine from the manufacture." In the VA North Texas Health Care System allegation, the OIG reviewed a patient's electronic health record and noted the patient was hospitalized approximately four weeks after receiving the pharmacy letter. Facility staff placed a cardiology consult, and cardiology staff addressed the patient's concerns. No correlation was found between the hospitalization and the recalled medication.

[4] VHA Directive 1068, *Removal of Recalled Medical Products, Drugs, and Food from VA Medical Facilities*, June 19, 2020.

recall and sequester widely distributed medications.[5] Product recalls are classified by the FDA into three levels:

- Class I Product Recall "will remove a dangerous or defective product that could cause serious health problems or death."[6]
- Class II Product Recall "will remove a product that might cause a temporary health problem or pose a slight threat of a serious nature."[7]
- Class III Product Recall "will remove a product that is unlikely to cause any adverse health reaction, but that violates FDA labeling or manufacturing laws."[8]

The FDA classifications determine the deadlines set for product removal during a medication recall. According to VHA leaders, specifically within VHA, a Class I Product Recall has a deadline of one business day. A Class II or Class III Product Recall has a deadline of 10 business days.

AvKARE Recall Action Summary

On December 1, 2020, Murfreesboro, Tennessee, CMOP staff discovered two different medications, sildenafil and trazodone, comingled in one AvKARE bottle labeled as sildenafil.[9] The CMOP staff sequestered the AvKARE sildenafil-labeled product, entered the information into VA Adverse Drug Event Reporting System, filed a report with the FDA, and notified AvKARE.[10] On December 2, 2020, CMOP leaders reported the comingled medication to Pharmacy Benefits Management Services (PBM), and the Deputy Chief Consultant of PBM also contacted AvKARE. On December 3, 2020, the National Center for Patient Safety (NCPS) initiated an internal VHA recall for AvKARE's affected sildenafil, and PBM distributed a National PBM Patient Level Recall Communication to VHA staff that noted the affected sildenafil's distribution date, and lot and batch numbers. After the recall communication was

[5] VHA Directive 1068. *Merriam-Webster.com Dictionary*, "sequester," accessed August 11, 2021, https://www.merriam-webster.com/dictionary/sequester. Sequestered medication is set apart from the rest of stock to prevent distribution to pharmacies or patients.

[6] VHA Directive 1068.

[7] VHA Directive 1068.

[8] VHA Directive 1068.

[9] AvKARE purchases medication from a manufacturer or wholesaler, repackages the medication from the original container into another container, and supplies the medication to its customers such as VHA. AvKARE distributed but did not manufacture either of the two affected medications; however, for purposes of the report distributor and manufacturer will be used interchangeably.

[10] VHA Directive 1070, *Adverse Drug Event Reporting and Monitoring*, May 15, 2020. VA's Adverse Drug Event Reporting System is an integrated web-based application that standardizes how adverse drug event data is submitted and coded.

sent, NCPS and PBM gave VHA staff 10 business days to complete the recall actions for sildenafil.[11]

On December 9, 2020, AvKARE issued a manufacturer recall of the affected sildenafil lot number and one lot number of trazodone, "due to a product mix-up of the listed two separate products inadvertently packaged together during bottling." NCPS followed AvKARE's recall directions and posted a trazodone recall with a due date of December 23, 2020, in addition to the previously recalled sildenafil. On December 10, 2020, NCPS expanded the scope of the initial VHA internal sildenafil recall including medication sequestering information provided by the AvKARE manufacturer. NCPS subsequently reset the due date for VHA staff to complete the recall actions from December 17, 2020, to December 24, 2020, allowing VHA staff additional time to return the sequestered product. On December 14, 2020, PBM distributed a second National PBM Patient Level Recall Communication to VHA staff that identified the trazodone recall and assigned a due date for completion of December 28, 2020, for trazodone patient notification.

NCPS reported that on December 30, 2020, the FDA classified the AvKARE recall as a Class II, and NCPS amended the internal VHA recall to include the FDA information.

Scope and Methodology

The OIG initiated this inspection in April 2021 and conducted virtual interviews with national, CMOP, and VHA medical facility staff from June 4 through July 20, 2021.

The OIG team interviewed the PBM Chief Consultant and two Deputy Chief Consultants; NCPS's Chief Patient Safety Systems Specialist and Chief Nurse Executive; National CMOP's Logistics Manager and Supply Systems Analyst; and the permanent and acting Chiefs of Staff, Chiefs of Pharmacy, and relevant staff at the VA Oklahoma City Healthcare System and VA North Texas Health Care System.

OIG staff reviewed national processes and compared those to the two facilities in two Veterans Integrated Service Networks (VISNs) where the OIG received complaints about the medication recall. The review included applicable VHA directives, patient recall letters, recall reports, The Joint Commission and FDA regulatory standards, VA Oklahoma City Healthcare System and VA North Texas Health Care System facility policies, and Pharmacy and Therapeutic Committee meeting minutes, and NCPS web application data.[12]

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[11] VHA Directive 1069, *National Pharmacy Benefits Management Drug Safety Alert Distribution*, October 24, 2019.

[12] Christy Ciccarello et al., "ASHP [American Society of Health System Pharmacists] Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System." *American Journal Health-System Pharmacist* 78, no. 10 (May 15, 2021):907-918. https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/gdl-pharmacy-therapeutics-committee-formulary-system.ashx. The Pharmacy and Therapeutics Committee is "an advisory committee that is responsible for developing, managing, updating and administering a formulary system."

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1101, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Inspection Results

The OIG determined that in the December 2020 AvKARE medication recall, the reviewed VHA medication recall process generally met VHA requirements. Although the two reviewed facilities had similarities in medication recall processes, the OIG discovered differences including the software and processes used by pharmacy staff to record medication lot numbers, important for sequestering recalled medication.

Providers were encouraged to report any adverse drug events resulting from recalled medications in VA Adverse Drug Event Reporting System; however, VHA policy did not require reporting. Therefore, the OIG could not determine if the December 2020 AvKARE medication recall adverse drug events were captured and monitored by VHA.

To protect patients from defective or potentially harmful medications, VHA staff must consistently and effectively communicate recalls to relevant healthcare personnel, who sequester the product and notify affected patients if required.[13] VHA assigns responsibility for communicating product recalls to NCPS when recalled products have not reached patients, and to PBM when recalled medications have reached patients and require patient notification but NCPS still maintains a role in data collection.[14] VHA also requires VISN and VHA medical facility staff to contact NCPS with any recall information that could affect patient safety.[15] During an interview, the OIG learned that these requirements were designed to provide overlap and redundancies to ensure VHA leaders received notification of medication recalls. Table 1 shows the summary timeline for VHA's actions to the December 2020 AvKARE medication recall.

[13] VHA Directive 1068.

[14] VHA Directive 1069.

[15] VHA Directive 1068.

Table 1. December 2020 AvKARE Recall Action Summary Timeline

Date	Action
December 1, 2020	Staff at the Murfreesboro, Tennessee, CMOP discovered trazodone tablets comingled into one AvKARE bottle labeled as sildenafil. Staff quarantined the sildenafil-labeled product and reported the issue in the VA Adverse Drug Event Reporting System, to the FDA, and to AvKARE.
December 2, 2020	CMOP leaders reported the comingled medication to PBM. A PBM leader also contacted AvKARE.
December 3, 2020	NCPS issued a VHA internal recall for AvKARE's affected sildenafil. PBM distributed a National PBM Patient Level Recall Communication regarding the sildenafil recall to VHA staff. NCPS and PBM gave VHA staff until December 17 to complete the recall actions for sildenafil.
December 9, 2020	AvKARE issued a manufacturer recall of the affected sildenafil lot number and included one lot number of trazodone.[16] NCPS posted the additional trazodone recall to VHA staff with a due date of December 23.
December 10, 2020	NCPS amended the initial sildenafil response due date from December 17 to December 24, due to the scope change and inclusion of AvKARE sildenafil recall sequestering information.
December 14, 2020	PBM distributed a National PBM Patient Level Recall Communication regarding the trazodone recall to VHA staff with a due date of December 28.
December 30, 2020	NCPS classified the AvKARE sildenafil recall as a Class II, in accordance with the FDA classification.

Source: OIG analysis of interviews from June 4 through July 20, 2021, VHA national PBM recall letters, notification from CMOP leaders, NCPS email communication, and the NCPS web application.

1. NCPS Medication Recall Communications

The OIG found that in the December 2020 AvKARE medication recall, NCPS monitored communications and responded according to VHA policy requirements relating to the identification and review of the recall. NCPS emailed designated VHA leaders and staff of the AvKARE medication recall providing known details, required actions, instructions for the NCPS web application completion, and monitored web application completion compliance.

VHA's NCPS was created in 1999 "to develop and implement VHA's patient safety programs" in order to reduce and prevent patient harm resulting from medical care.[17] NCPS is solely responsible for administration and communication of product recalls that have not reached the patient level, to ensure removal of "defective or potentially harmful" products from

[16] According to AvKARE, both sildenafil and trazodone were recalled "due to a product mix-up of the listed two separate products inadvertently packaged together during bottling."

[17] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011.

distribution.[18] NCPS monitors and receives information related to product recalls from manufacturers, the FDA, and VHA's patient safety event reporting system.[19] The OIG learned that notifications could originate from a manufacturer, distributer, re-packager, or from front-line staff who noticed an error during the regular course of their work.[20]

When a recall is issued, VHA requires NCPS to email VISN and VHA medical facility recall coordinators.[21] Additionally, NCPS and PBM leaders explained they work closely together to ensure communication between both agencies. National recall coordinators at the VISN and CMOP level work with VHA medical facility recall coordinators to oversee the recall response.[22] VHA medical facility recall coordinators work with designated staff throughout the facility to complete the recall response.[23] These designated VHA medical facility staff ensure recalled products are "found, removed, sequestered, and returned for credit, refund, or replacement if applicable," and document completion in the NCPS VHA Alerts and Recalls Web application (NCPS web application).[24]

NCPS also monitors its internal NCPS web application for mail order pharmacy and VHA medical facility staff responses to medication recalls.[25] The NCPS web application tracks 154 primary VA sites for communicating recalls affecting VHA medical facilities and CMOP locations.[26]

The OIG reviewed NCPS documentation of VHA medical facility response to the AvKARE medication recall and found that all 154 VHA medical facilities completed the required recall actions. For the sildenafil recall, 152 of 154 VHA medical facilities completed required actions by the assigned due date, and 153 of 154 VHA medical facilities completed required actions by the assigned due date for the trazodone recall.

[18] VHA Directive 1068.

[19] VHA Directive 1068. VHA Handbook 1050.01. VHA's patient safety event reporting system is an internal mechanism for facility staff to report adverse events, including adverse medication reactions, experienced by patients.

[20] FDA, *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities: Guidance for Industry*, accessed March 17, 2022, https://www.fda.gov/media/90978/download. Repackaging is the "act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug."

[21] VHA Directive 1068.

[22] VHA Directive 1068.

[23] VHA Directive 1068.

[24] Staff must document completion in the NCPS web application by the assigned due date. NCPS determines due dates based on the recall circumstances and severity (for example, Class I, Class II, or Class III Product Recall).

[25] VHA Directive 1068.

[26] Although VHA provides health care for veterans at 171 VA Medical Centers, some VHA medical facilities are combined in the reporting process.

The OIG learned in an interview with the NCPS Chief Patient Safety Systems Specialist that NCPS tracked and trended VHA medical facility compliance to medication recalls, which was reported monthly to VHA medical facilities and compared across VISNs. In the interview, the NCPS Chief Patient Safety Systems Specialist reported the VHA medical facility staff completion rate (completing and reporting assigned recall actions) was 100 percent across VHA, historically, while compliance (completing and reporting actions within the set deadline) was 98-99 percent. The OIG noted that responsibility for monitoring VHA medical facility NCPS web application compliance was shared by leaders, providing an additional system safeguard to ensure compliance.[27]

2. PBM Medication Recall Safety Information

The OIG determined that during the AvKARE medication recall, PBM followed VHA requirements to distribute medication recall safety information throughout VHA medical center facilities and ensured notification of patients affected by the recalled medications.

PBM is a VHA national program office managed by senior pharmacy leaders with expertise in pharmacy practice that "works to enhance the clinical outcomes and improve the health of Veteran patients through the appropriate use of pharmaceuticals."[28] PBM provides guidance on pharmacy issues to leaders and clinical staff across VHA.[29]

In the event of a patient level medication recall, VHA requires PBM to develop and disseminate detailed information to key staff throughout the VHA healthcare system within a time frame determined by PBM's Deputy Chief Consultant.[30] PBM's communication, called a National PBM Patient Level Recall Communication, includes standard sections describing what occurred, as well as "specific recommendations for product sequestering, patient notification, and feedback actions [NCPS web application] from the field to confirm completion of recommended actions."[31] At the VHA medical facility level, the Director must relay recall information to the Chief of Staff who, in turn, notifies VHA medical facility providers and oversees the VHA

[27] VHA Directive 1068. VHA Directive 1069. VHA tasks the Deputy Under Secretary for Health for Operations and Management; Deputy Chief Consultant, PBM; CMOP and VISN national recall coordinators; and VISN and facility directors to monitor for compliance.

[28] VHA Directive 1108.08(1), *VHA Formulary Management Process*, November 2, 2016, amended August 29, 2019. Patient Care Services, "Pharmacy Benefits Management Services," March 4, 2020, accessed July 20, 2021, https://www.patientcare.va.gov/pbm.asp.

[29] Patient Care Services, "Pharmacy Benefits Management Services," March 4, 2020, accessed July 20, 2021, https://www.patientcare.va.gov/pbm.asp.

[30] PBM emails key staff, including VHA national leaders; NCPS, VISN and CMOP leaders; Primary Care Chiefs or Directors; Chiefs of Staff; and Chiefs of Pharmacy via an email group named the Drug Safety Alert Mail Group.

[31] VHA Directive 1069.

medical facility recall response, including ensuring the Chief of Pharmacy completes and documents recall actions, as required.[32]

The OIG reviewed National PBM Patient Level Recall Communication distributed to VHA staff during the AvKARE medication recall and found that it was thorough. Specifically, PBM included

- affected item (medication name and strength),
- specific incidents (what happened and why),[33]
- general information (medication National Drug Codes and lot numbers, expiration date, and initial ship date),[34]
- provider and patient notification requirement guidelines, and
- contact information.

PBM's recall communication instructed VHA medical facility Chiefs of Pharmacy to identify if affected medication was dispensed to any patients. VHA medical facilities contacted affected patients by letter or other means, instructing patients to discontinue use of the affected product. PBM communication also included a link to a sample templated letter for patient notification (see appendix A). Facility leaders informed the OIG that medical facility pharmacy staff provided replacement medication to patients with an affected product. VHA medical facility Chiefs of Pharmacy documented completion of the patient level recall process in the NCPS web application, as previously described.[35]

3. CMOP and Medication Sequestering Processes

The OIG found CMOPs followed the manufacturer's instructions to destroy or return the undispensed product for reimbursement in the December 2020 AvKARE recall.

[32] VHA Directive 1069. Although VHA tasks the facility Director with relaying recall information to the Chief of Staff, both parties receive PBM notification simultaneously.

[33] The specific incident in the AvKARE recall occurred "due to issues during packaging that resulted in mixed product found in bottle."

[34] FDA, "National Drug Code Database Background," accessed August 12, 2021, https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information. U.S. Food & Drug, "CFR – Code of Federal Regulations Title 21," accessed August 11, 2021, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.3. The FDA assigns a unique number to each drug product, called a National Drug Code, which identifies the manufacturer, product, and package size. A lot number is a unique sequence of numbers, letters, and symbols assigned to a medication batch to identify the manufacturing history.

[35] VHA Directive 1069.

A VA CMOP is a centralized mail order pharmacy that uses automated systems to process a high volume of prescriptions from multiple VHA medical centers.[36] There are seven CMOP facilities throughout the United States located in Leavenworth, Kansas; Tucson, Arizona; Chelmsford, Massachusetts; Dallas, Texas; Murfreesboro (Nashville), Tennessee; Hines (Chicago), Illinois; and Charleston, South Carolina.[37] VA CMOPs process and dispense over 90 million prescriptions per year, which accounts for approximately 80 percent of outpatient prescriptions mailed to veterans.[38]

VHA requires each CMOP to identify a national recall coordinator who works at the CMOP level to communicate with VHA medical facility recall coordinators and implement the product recall process.[39] Additionally, the CMOP national recall coordinator reports any product issues or unpublished recall notices to NCPS, monitors the NCPS web application for CMOP compliance, and performs regular CMOP audits.[40]

In the December 2020 AvKARE recall, NCPS and PBM oversaw the medication sequestration process to track credits or refunds for CMOP and VHA medical facility-returned medication through the NCPS web application.[41] The NCPS web application status showed credits and refunds as "pending" until the manufacturers issued reimbursement.

4. VHA Medical Facility Role in a Medication Recall

The OIG found through interviews that VHA medical facility staff were responsible for notifying all affected patients, whether medication was supplied by the CMOP or by the VHA medical facility. The OIG discovered that the two reviewed VHA medical centers' pharmacy staff used different software and processes to record medication lot numbers and identify patients receiving recalled medication. During interviews, the OIG learned that PBM gave VHA medical facilities guidelines for informing patients what to do with dispensed recalled medications, which allowed VHA medical facilities some discretion. Therefore, methods varied amongst VHA medical facilities.

[36] Consolidated Mail Outpatient Pharmacy, "History," June 3, 2021, accessed June 3, 2021, https://vaww.cmop.med.va.gov/History.aspx.

[37] Consolidated Mail Outpatient Pharmacy, "History," June 3, 2021, accessed June 3, 2021, https://vaww.cmop.med.va.gov/History.aspx.

[38] Pharmacy Benefits Management Services, "VA Mail Order Pharmacy," August 21, 2020, accessed July 16, 2021, https://www.pbm.va.gov/PBM/CMOP/VA_Mail_Order_Pharmacy.asp. Consolidated Mail Outpatient Pharmacy, "History," June 3, 2021, accessed June 3, 2021, https://vaww.cmop.med.va.gov/History.aspx. VA medical center pharmacies typically fill new or emergent prescriptions for veterans onsite, whereas VA CMOPs mail maintenance medications to veterans.

[39] VHA Directive 1068.

[40] VHA Directive 1068.

[41] VHA Directive 1069.

The VHA health system is divided into 18 geographical areas or regions called VISNs.[42] Each VISN is responsible for overseeing the VA healthcare facilities within the region "to better meet local health care needs."[43]

VHA requires each VISN to identify a national recall coordinator who works to ensure VHA medical facilities within the VISN implement the product recall process and document completion of actions in the NCPS web application.[44] Additionally, the VISN national recall coordinator reports any product issues or unpublished recall notices to NCPS, monitors the NCPS web application for VHA medical facility compliance, and performs regular VHA medical facility audits.[45]

The VHA health system provides health care at 171 medical facilities "to over 9 million Veterans enrolled in the VA health care program."[46] A VHA medical facility director leads operations and oversees services, including VHA medical facility medication recall responses.[47]

In the event of a recall, VHA requires each VHA medical facility director to ensure a recall coordinator and back-up coordinator are identified, and that recalled products are removed, sequestered, and documented in the NCPS web application.[48] Recalled medications must be sequestered to prevent future medication distribution to patients.[49] Recalled products may be located in the pharmacy or in automated dispensing cabinets, all of which need to be collected and returned to the manufacturer for credit, refund, or replacement.[50] At the patient level, the OIG was told in interviews that the VHA medical facility staff notify affected patients and replace their product, if warranted.

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[42] VHA, "Veterans Integrated Services Networks (VISNs)," accessed July 28, 2021, https://www.va.gov/HEALTH/visns.asp. VISNs are located within the United States and its territories, and the Philippines.

[43] VHA, "Veterans Integrated Services Networks (VISNs)," accessed July 28, 2021, https://www.va.gov/HEALTH/visns.asp.

[44] VHA Directive 1068. Each VISN must designate its VISN Chief Supply Chain Officer as the national recall coordinator.

[45] VHA Directive 1068.

[46] VHA, "About VHA," February 17, 2022, accessed March 15, 2022, https://www.va.gov/health/aboutvha.asp.

[47] VHA Directive 1068. VAntage Point, "Be a front-line leader in caring for Veterans as an Executive Director of a VA medical center," accessed August 12, 2021, https://blogs.va.gov/VAntage/61638/front-line-leader-caring-veterans-executive-director-va-medical-center/.

[48] VHA Directive 1068.

[49] According to PBM leaders, at the wholesale level stock is sequestered before it reaches VHA pharmacies. At the pharmacy level, staff from the CMOPs and VHA pharmacies sequester their stock before it reaches patients.

[50] VHA Directive 1068. VHA Directive 1108.01(1), *Controlled Substances Management*, May 1, 2019, amended December 2, 2019. VHA Directive 1108.06(2), *Inpatient Pharmacy Services*, February 8, 2017, amended August 26, 2021. An automated dispensing cabinet is a computerized drug storage space used to dispense medications electronically and in a controlled manner to track medication use.

VHA medical facility recall coordinators oversee the facility response, including the coordination of designated area specialists, who respond to product recall information within a specific area of service. Additionally, designated area specialists complete product recall actions such as searching for recalled products in their assigned area, to ensure recalled products were located.[51]

The OIG heard during interviews that in circumstances where few patients are affected by a recall, facility staff might choose to notify patients by phone. In cases where a recall affects thousands of patients, VHA medical facility staff report mailing letters to notify patients. VHA medical facility staff reported typically not documenting patient notifications in the electronic health record. Instead, VHA medical facility pharmacy staff typically keep internal records of affected patients contacted.

To understand the AvKARE medication recall responsibilities at the VHA medical facility level, the OIG team interviewed key staff at the VA Oklahoma City Healthcare System and the VA North Texas Health Care System.

VA Oklahoma City Healthcare System

The VA Oklahoma City Healthcare System, part of VISN 19, consists of a medical center in central Oklahoma, 12 community-based outpatient clinics, and two military clinics in partnership with the Department of Defense. The facility is classified by VHA as level 1b.[52]

According to the Chief of Pharmacy, the following groups notify pharmacy staff or the Chief of Pharmacy for each medication recall:

- The pharmaceutical supplier
- The purchasing team
- PBM
- Director's office staff
- VISN staff

During the December 2020 AvKARE recall of sildenafil and trazodone, facility staff confirmed that PBM sent the first email notification on December 3, 2020, regarding sildenafil, and the second recall notification of trazodone on December 14, 2020.

[51] VHA Directive 1068.

[52] VHA Office of Productivity, Efficiency and Staffing, "Facility Complexity Level Model Fact Sheet," December 15, 2017. The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, and educational and research missions. Complexity levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered the most complex and level 3 facilities are the least complex.

Pharmacy staff reported using CMOP data to identify patients who received the recalled medications from the CMOP and the software programs, OptiFill and Innovation to identify prescriptions filled for patients from the facility with recalled medication.[53]

Pharmacy staff also reported that in alignment with typical facility medication filling procedures, pharmacy staff scanned medication barcodes and manually entered medication lot numbers and expiration dates, which were not included in the barcode, into the OptiFill program. The medication barcodes, lot numbers, and expiration dates in OptiFill allowed pharmacy staff to identify prescriptions filled with the recall medication and the patients who received the recall medications from the facility.[54] Two community-based outpatient clinics utilized different software systems for medication barcode scanning. South Oklahoma City and Lawton outpatient clinics utilized the Innovation software system; however, the process of barcode scanning the medication and manually entering the lot number and expiration date was the same.

Following the PBM guidelines, Pharmacy Service sent letters to affected patients to notify them of the sildenafil and trazodone recalls on December 14, 2020. The letters included a picture of sildenafil tablets with directions for patients to look at their medication and if applicable dispose of the incorrect medications. The letters also described the side effects of the two medications and informed the patients to call the pharmacy or their providers with questions. These letters were not included as part of the patients' electronic health records; however, pharmacy leaders informed the OIG they maintained a spreadsheet of patient information for the letters sent.

The OIG learned during interviews that facility staff notified by letter 1,474 CMOP patients who were provided sildenafil from CMOPs that the lot number they received had been affected by a recall. Facility staff notified 49 patients who were provided trazadone by the facility pharmacy and 149 patients provided trazadone by the CMOP that the medication they received had been recalled. In total, 198 patient letters were sent. Replacement medications were available to meet patients' needs. No adverse events related to the recalled medications were reported by facility staff in the VA Adverse Drug Event Reporting System but reporting was not required.

Pharmacy formulary managers notified all facility providers of the recall with instructions on how to proceed and respond to patients by email.[55] The pharmacy formulary manager also

[53] Innovation "About Us," accessed June 28, 2022, https://iarx.com/about-us/. Innovation Associates produces pharmacy automation and software solutions specifically for pharmacy.

[54] OptiFill "Fact sheet," accessed August 31, 2021, https://www.arxium.com/wp-content/uploads/2018/07/OptiFill-Fact-Sheet-PCN2017-101-A-1.pdf. OptiFill prescription fulfillment solution is a high-volume pharmacy automation system that enhances the pharmacy production process and increases operational efficiency.

[55] Christy Ciccarello et al., "ASHP [American Society of Health System Pharmacists] Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System." *American Journal Health-System Pharmacist* 78, no. 10 (May 15, 2021):11. https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/gdl-pharmacy-therapeutics-committee-formulary-system.ashx. A pharmacy formulary is "A continually updated list of medications and related information, representing the clinical judgement of physicians, pharmacists, and other experts in the diagnosis, prophylaxis or treatment of disease and promotion of health."

notified the Pharmacy and Therapeutic Committee and Chair to devise an action plan for replacement of the affected medication. The January 7, 2021, Pharmacy and Therapeutics Committee meeting minutes documented the PBM Recall Communications for the sildenafil and trazodone recalls as well as patient and provider communications.

NCPS web application reflected this facility was compliant with the December 24, 2020, due date for the completion of sildenafil recall and the December 23, 2020, due date for the completion of the trazodone recall.

VA North Texas Health Care System

The VA North Texas Health Care System, part of VISN 17, consists of medical centers in Dallas, Garland, and Bonham, Texas, and five community-based outpatient clinics. The facility is classified by VHA as level 1a.[56]

Facility leaders explained that the facility's role in the December 2020 AvKARE recall included removing medication still in circulation and notifying the patients who may have received the recalled medication. The pharmacy procurement program manager explained the NCPS product recall office maintains the recall web application database. The facility logistics department monitors this recall database and notifies the pharmacy procurement team of any medication or related supply item recalls. The procurement team received notification of the sildenafil and trazodone recall medications and the lot number(s). The procurement team then assigned the recall to the affected pharmacies at Dallas, Fort Worth, and Bonham. Pharmacy staff reviewed the purchase history, physically checked the stock, and sequestered the affected medication lot number, if present. These staff then worked with the pharmacoeconomics pharmacist who completed a data pull to see if the purchased medication and lot numbers were dispensed to patients.[57]

The OIG learned that the Bonham and Fort Worth pharmacies used the ScriptPro database for outpatients, while Dallas used the OptiFill database until mid-December 2020 and updated their database to ScriptPro after the recall.[58] Pharmacy leaders explained that pharmacy technicians did not consistently enter or verify lot numbers. As a workaround to the lot number omission and

[56] VHA Office of Productivity, Efficiency and Staffing, "Facility Complexity Level Model Fact Sheet," December 15, 2017. The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, and educational and research missions. Complexity levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered the most complex and level 3 facilities are the least complex.

[57] University of South Carolina, College of Pharmacy, accessed August 31, 2021, https://sc.edu/study/colleges_schools/pharmacy/research_and_practice/research_areas/pharmacoeconomics/index.php. "Pharmacoeconomics is the description and analysis of the costs of drug therapy to health care systems and society. It identifies, measures, and compares the costs and consequences of pharmaceutical products and services."

[58] ScriptPro "VA Pharmacy Industry News," accessed September 8, 2020, https://www.scriptpro.com/blog/va-award-inventory-management-software. ScriptPro Inventory Management software is an operating system for VA outpatient pharmacies to manage pharmacy inventories.

to ensure all possibly affected patients were contacted, pharmacy staff sent notification letters to patients who received sildenafil and trazodone after the distribution dates. Pharmacy leaders reported that pharmacy technicians have since been educated to enter medication lot numbers into ScriptPro.

PBM notified the Chief of Staff by email to provide medication recall information as well as the link to the NCPS recall web application with instructions and a recommended distribution list for provider notification. The Chief of Staff reported sending the sildenafil recall information to provider leaders including the chiefs of medicine, general internal medicine, research, urology, and surgery, and to primary care providers and urologists. However, the Chief of Staff did not send the recall information to mental health providers as they were not on the recommended sildenafil distribution list. The patients' letter of notification of the sildenafil recall was dated December 16, 2020. The trazodone recall communication was sent to primary care providers and mental health providers. The patients' notification letter of the trazodone recall was dated December 17, 2020. The letters did not describe side effects of the two medications but informed the patients of the medications' use and instructed the patients to discard the medication. Further, the letters stated that for the sildenafil recall, if the original prescription was filled before December 5, 2020, the patient should request a refill; however, the pharmacy would send a new prescription for trazodone. Additionally, the letters stated the contact numbers for the pharmacy service or providers. Although the letters were not included as part of the patients' electronic health records, pharmacy leaders informed the OIG that the facility logistics department maintained a recall information database with pharmacy procurement staff managing the medication information.

According to a facility leader, the pharmacoeconomic pharmacist reports to the Pharmacy and Therapeutics Committee to inform providers of a medication recall. The Pharmacy and Therapeutics Committee met on December 17, 2020, and reported that 6,857 patients would receive letters informing them of the sildenafil recall and 737 patients would receive letters informing them of the trazadone recall.

The NCPS web application reflected the VA North Texas Health Care System was compliant with the December 24, 2020, due date for the completion of sildenafil recall and the December 23, 2020, due date for the completion of the trazodone recall.

In conclusion, to ensure patient safety and minimize adverse medication outcomes, facilities must have an established process to quickly notify patients of possible medication issues due to manufacturer recalls.

5. Monitoring and Reporting of Adverse Drug Events in a Medication Recall

The OIG could not determine if VHA monitored all adverse drug events from recalled medications because reporting in the VA Adverse Drug Event Reporting System was not required.

VHA defines an adverse drug event as "an injury resulting from the use of a drug" and encourages providers to voluntarily record any adverse drug event in the VA Adverse Drug Event Reporting System.[59] VHA leaders stated that adverse events related to a medication recall are reported in the VA Adverse Drug Event Reporting System. The VA Adverse Drug Event Reporting System application allows healthcare providers to identify adverse drug events of clinical significance and review reports on potential problems with medications. The reports aggregate adverse drug events by year, drug, or event, which assists with patient safety and sustains process improvement.[60] Adverse drug events resulting from recalled medications are not identified specifically as a category of adverse drug events nor are such events required to be reported in the VA Adverse Drug Event Reporting System.[61]

VHA leaders reported to the OIG that VHA medical facility leaders and providers were responsible to report patient safety issues or adverse drug events resulting from a recalled medication into the VA Adverse Drug Event Reporting System, a voluntary reporting system.[62] Facility leaders reported not being aware of adverse drug events occurring due to the incorrect packaging of medications leading to the recall.

When interviewed, NCPS leaders explained that if a recalled medication caused an adverse drug event with serious patient harm, patient disclosure was not part of the NCPS process. NCPS leaders depend on the program offices to review the event, which in the case of medication events is PBM.[63] According to PBM leaders, the VA Adverse Drug Event Reporting System gives the VHA medical facility the opportunity to review the adverse drug event. VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, establishes the policy for VHA medical facility leaders to provide disclosures related to clinical care to patients or personal representatives when needed.[64]

Although adverse drug event reporting systems are voluntary for recalled medications, the OIG acknowledges the professional accountability and healthcare responsibilities of facility leaders to

[59] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018; VHA Directive 1070.

[60] VHA Directive 1070.

[61] VHA Directive 1070.

[62] VHA Directive 1070.

[63] VHA Directive 1004.08. Disclosure is a notification process for health care providers to inform patients of adverse events that have caused or may cause harm.

[64] VHA Directive 1004.08.

report adverse drug events. Reporting adverse drug events related to a recall provides data to recognize trends and further ensure patient safety.

Conclusion

During the AvKARE medication recall, NCPS monitored communications and responded according to VHA policy requirements relating to the identification and review of the recall. NCPS emailed designated VHA leaders and staff of the AvKARE medication recall providing known details, required actions, and instructions for the NCPS web application completion, and monitored web application completion compliance. PBM also followed VHA requirements to distribute medication recall safety information throughout VHA medical center facilities and ensured notification of patients affected by the recalled medications during the AvKARE medication recall.

During interviews, the OIG learned CMOP staff provided a list of patients receiving the recall medication to VHA medical facility staff. The VHA medical facility staff were responsible for notifying all affected patients in their facility, whether medication was supplied by the CMOP or by the VHA medical facility. CMOPs and VHA medical facilities followed the manufacturer's instructions to destroy or return the undispensed product for reimbursement in the December 2020 AvKARE recall.

The OIG found certain facility processes varied. For example, the OIG discovered that the two reviewed VHA medical center's pharmacy staff used different software and processes to record medication lot numbers and identify patients receiving recalled medication. During interviews, the OIG learned that PBM gave VHA medical facilities guidelines for informing patients what to do with dispensed, recalled medications, which allowed VHA medical facilities some discretion. However, to ensure patient safety and minimize adverse medication outcomes, facilities must have an established process to quickly notify patients of possible medication issues due to manufacturer recalls.

The OIG could not determine if VHA monitored all adverse drug events from recalled medications because reporting in the VA Adverse Drug Event Reporting System was not required. Although adverse drug event reporting systems are voluntary, the OIG acknowledges the professional accountability and healthcare responsibilities of facility leaders to report adverse drug events. Reporting adverse drug events provides data to recognize trends and further ensure patient safety.

Recommendations 1–2

1. The Under Secretary for Health evaluates current guidance regarding the monitoring and reporting of medication recall adverse drug events and makes changes as necessary.

2. The Under Secretary for Health reviews vulnerabilities in the medication recall process due to variances in Veterans Health Administration medical facility processes and makes changes as necessary.

Appendix A: Sample Patient Recall Letter Template

Department of Veterans Affairs
Veterans Health Administration

<INSERT DATE HERE>

Dear Veteran:

You are receiving this letter because your prescription for **<INSERT DRUG NAME HERE>** is being recalled for **<INSERT REASON FOR RECALL HERE>**. **<INSERT DRUG NAME HERE>** is a medication used for **<INSERT INDICATION HERE>**.

☐ We were unable to contact you by phone on_____.

☐ Please return ALL of your OLD supply of **<INSERT DRUG NAME HERE>** to

_____.

☐ Enclosed is a NEW supply of **<INSERT DRUG NAME HERE>**. Please begin taking medication from your NEW supply with your next dose and stop taking any old supply of this medication.

☐ **Aspirin should be a small yellow tablet**. In the case that you find tablets that do not fit this description please contact your provider or pharmacy at **< INSERT PHONE NUMBER HERE>** for further instructions.

Call your Healthcare Provider and/or seek care immediately if you feel that you are experiencing <INSERT SYMPTOMS HERE>.

Contact your VA Pharmacy **<INSERT CONTACT INFORMATION HERE>** if you have any questions about this letter or your medications.

Sincerely,

Source: National PBM Patient Level Recall Communication, August 12, 2021.

Appendix B: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: June 8, 2022

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

Subj: OIG Draft Report, Review of Veterans Health Administration's Response to a Medication Recall (2021-02194-HI-1172) (VIEWS 07702020)

To: Assistant Inspector General for of Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the Office of Inspector General's (OIG) draft report, Review of Veterans Health Administration's Response to a Medication Recall. The Veterans Health Administration (VHA) concurs with the draft report and provides the attached action plan to address both recommendations.
2. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at VHA10BGOALACTION@va.gov.

(Original signed by:)
Steven L. Lieberman, M.D.

Under Secretary for Health Response

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

Review of Veterans Health Administration's Response to a Medication Recall

(2021-02194-HI-1172) (VIEWS 07702020)

Recommendation 1.

The Under Secretary for Health evaluates current guidance regarding the monitoring and reporting of medication recall adverse drug events and makes changes as necessary.

VHA Comments: Concur.

The Veterans Health Administration (VHA) notes that the current process for reporting adverse events related to medication recalls aligns with voluntary reporting for adverse drug events as outlined in VHA Directive 1070, "Adverse Drug Event Reporting and Monitoring," dated May 15, 2020. VHA agrees that it is difficult to discern whether an adverse drug event is related to a medication recall in the current database. The VHA Office of Pharmacy Benefits Management (PBM) will add specific language to the draft patient letter that is included with each patient level medication recall. The letter will advise patients to contact their provider(s) to report any suspected adverse drug(s) event related to recalled medications to encourage proactive patient reporting. The VHA Center for Medication Safety's (VA MedSAFE) VA Adverse Drug Event Reporting System (VA ADERS) technical team will add a check box to the adverse drug event reporting form where a site can determine if an adverse drug event is related to a drug recall. The addition of this field will make it feasible to query VA ADERS and determine whether there are adverse drug event reports specifically related to a medication recall.

Status: In progress Target Completion Date: August 2022

Recommendation 2.

The Under Secretary for Health reviews vulnerabilities in the medication recall process due to variances in Veterans Health Administration medical facility processes and makes changes as necessary.

VHA Comments: Concur.

VHA PBM reviewed processes related to patient level medication recalls. The PBM patient level recall process is intentionally designed to allow for flexibility at the facility level to determine how to identify affected patients and initiate patient contact. Within the VHA system, facilities have different levels of complexity, different staffing constraints related to pharmacy and

different types of dispensing equipment allowing automation being used at individual sites to adapt a workflow that best fits the facility. Based on these nuances, it would be challenging and costly to standardize automation across the enterprise for tracking dispensing and lot numbers. VHA believes that this type of standardization would be disruptive to existing and validated pharmacy workflows at the facility level. As a contractual requirement, all VHA pharmacy facilities have access to lot number information for all contracted product purchases through the VHA Pharmaceutical Prime Vendor database. All facilities can determine if they purchased products regardless of which type of dispensing equipment is used. VHA PBM tracks compliance with patient level recall actions and when applicable, compliance in confirming patient contact has been 100% across recalls. VHA PBM has not been advised of any patient safety events related to medication recalls. This further demonstrates that the current system is sufficient and effective. VHA does not believe that further standardization would lead to improved outcomes at this time and VHA will continue to follow this compliance tracking. VHA requests closure of this recommendation.

Status: Completed Completion Date: May 2022

OIG Comments

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

Appendix C: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: May 23, 2022

From: Director, Rocky Mountain Network (10N19)

Subj: Healthcare Inspection—Review of Veterans Health Administration's Response to a Medication Recall

To: Office of the Under Secretary for Health (10)
Director, Office of Healthcare Inspections (54HL02)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. Thank you for the opportunity to review and respond to the OIG Report.

2. VISN 19 has reviewed the draft for accuracy and found no inaccuracies.

(*Original signed by:*)

Ralph T. Gigliotti, FACHE
Director, VA Rocky Mountain Network (10N19)

Appendix D: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: May 20, 2022

From: Director, VA Oklahoma City Healthcare System (635/00)

Subj: Healthcare Inspection—Review of Veterans Health Administration's Response to a Medication Recall

To: Director, Rocky Mountain Network (10N19)

1. We appreciate the opportunity to work with the Office of Inspector General as we continuously strive to improve the quality of healthcare for America's Veterans.
2. Thank you for the opportunity to review the Office of Inspector General draft report Review of Veterans Health Administrations' Response to a Medication Recall. I have reviewed the report and have identified no inaccuracies in regards to the review of the VA Oklahoma City Healthcare System.

(*Original signed by*:)

Wade Vlosich
Director, VA Oklahoma City Healthcare System

Appendix E: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: May 24, 2022

From: Director, VA Heart of Texas Health Care Network (10N17)

Subj: Healthcare Inspection—Review of Veterans Health Administration's Response to a Medication Recall

To: Office of the Under Secretary for Health (10)
Director, Office of Healthcare Inspections (54HL02)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. Attached is the VA North Texas VA Health Care System's response to the OIG Healthcare Inspection Review of Veterans Health Administration's Response to a Medication Recall.

2. I have reviewed and concur with the facility's response and action plan to the recommendations in the report.

(Original signed by:)

Jamie Park, Ed.D
VISN 17 Deputy Network Director

Appendix F: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: May 23, 2022

From: Acting Executive Director, VA North Texas Health Care System (549/00)

Subj: Healthcare Inspection—Review of Veterans Health Administration's Response to a Medication Recall

To: Network Director, VISN 17 (10N17)

1. The purpose of this memorandum is to respond to the recent OIG Healthcare Inspection review for the VA North Texas Health Care System.

2. The facility has implemented an action plan for the first recommendation (monitoring and reporting of adverse drug events related to recalled drugs) by including specific verbiage on patient recall letters and educating providers to report adverse drug events if they receive communications from the affected patient.

3. The facility has implemented an action plan for the second recommendation (improving the medication recall process) by including lot numbers in pharmacy automated dispensing machines.

(*Original signed by*:)

Kendrick D. Brown, CHFM
Acting Executive Director

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