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OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

VETERANS HEALTH ADMINISTRATION

Emergency Cache Program:
Ineffective Management
Impairs Mission Readiness

AUDIT

REPORT #18-01496-301

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Executive Summary

Why the OIG Did This Audit

The VA established an emergency cache program in 2002 following the 9/11 attacks to make drugs and medical supplies available for the treatment of veterans, VA employees, and civilians in the immediate aftermath of a local mass casualty event. Because these events can occur at any time, in any location, and with little or no warning, the Emergency Cache Program must always be ready for immediate deployment. The Emergency Cache Program stockpiles a standard supply of drugs and medical supplies, valued at \$44 million, at 141 VA medical facilities around the country. An emergency cache has never been activated in response to a disaster or attack; however, medical facility directors have authorized the release of emergency cache drugs when all options to obtain the drugs were exhausted and patients were in life-threatening situations. The VA Office of Inspector General (OIG) conducted this audit to determine whether the Veterans Health Administration (VHA) is maintaining its Emergency Cache Program in a mission-ready status.

What the OIG Did

The audit team conducted unannounced inspections at 26 randomly selected emergency cache locations in February 2018. The team inventoried the same sample of 25 drugs at each inspected cache location. A total of 650 unique drugs were inspected—25 drugs at 26 caches. At each inspected cache location, the team interviewed the medical facility director and cache managers. The team also interviewed officials from the three VHA national program offices responsible for managing the Emergency Cache Program—Emergency Pharmacy Service (EPS), Office of Emergency Management (OEM), and Office of Public Health (OPH). The team also surveyed the cache managers of the 141 emergency caches that were operational as of January 2018.

Emergency Cache Program Was Not Mission Ready

Expired, missing, and/or excess drugs hindered the mission readiness of emergency caches. The audit team determined that all 141 emergency caches had at least one expired drug, and estimated that 59 (42 percent) had at least one missing, and/or excess drug. Cache managers from at least nine of the 26 medical facilities the team visited were not aware of the extent to which their cache inventories were affected by expired, missing, or excess drugs. Because EPS does not require wall-to-wall inventories of caches, cache managers cannot know if their caches are mission ready.

All 26 Inspected Caches Contained Expired Drugs

In almost all the cases of expired drugs, EPS failed to ship replacement drugs to caches before their current drugs expired. Of the 650 drugs that the audit team inspected, 178 (27 percent) were expired. All 26 inspected caches had at least four expired drugs, while half had six or seven expired drugs, and four (15 percent) had 10 or more expired drugs. At the time of the team's inspections, over a third of the expired drugs had been expired for three months or longer, at least 22 drugs had been expired for six months or longer, and three drugs had been expired for over a year. An estimated 6.1 million units of drugs were expired across all 141 caches representing about \$4.6 million in present-day value. While the EPS Inventory Management Specialist—responsible for managing cache inventory—agreed with the team's inspection results, he deflected responsibility as to the cause for the expired drugs. According to him, caches contained expired drugs not because EPS did not ship the drugs in time, but rather because inexperienced cache managers did not timely rotate unexpired or in-date drugs into the caches to replace the expired drugs. However, the team found this to be unpersuasive because inventory to replace the expired drugs was not typically available, as established by the fact that replacement inventory was rarely on-site during the team's inspections.

Slightly more than half of the expired drugs identified by the team were in the Shelf Life Extension Program (SLEP) (95 of 178). The Food and Drug Administration's (FDA) SLEP is used to extend the shelf life of designated drugs.¹ FDA tests drugs for stability and extends expiration dates for drugs that pass its testing. As of January 2018, 17 of the cache drugs were eligible for the SLEP. EPS's Emergency Pharmacy Specialist explained to the team that participating in SLEP saves VA about \$20 million annually. However, SLEP participation poses significant risks to the Emergency Cache Program. Specifically, for expired drugs undergoing SLEP testing, EPS uses an estimated expiration date in its national inventory database for the drug expiration date. For example, 78 of the 95 expired SLEP drugs the team identified had an expiration date of March 31, 2018, in EPS's national inventory database. This date, according to EPS's Emergency Pharmacy Specialist, reflects the drug's expected end of testing date. In fact, during on-site inspections, the team found that these drugs actually had earlier expiration dates. As a result, EPS's national inventory database does not accurately reflect the proportion of cache drugs that are not expired at any point in time.

Moreover, the length of time it takes for drugs to get through SLEP testing increases the time that these drugs are unavailable for use. Specifically, EPS's Emergency Pharmacy Specialist reported that, while it used to take FDA 90 days to complete a testing cycle, as of May 2018, there could be up to a six-month wait for drugs requiring testing. Because of this, emergency cache drugs in SLEP testing are typically already expired by the time FDA conducts its testing.

¹ Additional information on the SLEP is detailed in the *Introduction* of this report, specifically page 4.

Some Caches Were Not Fully Stocked; Others Had Excess Drugs

Twelve of the 26 caches the audit team visited were not fully stocked.² Specifically, for 16 of the 650 drugs the team inspected, varying quantities were missing. The replacement cost of these drugs was about \$120,533 in present-day value as of February 2018. Cache managers were aware of nine of these instances and why they occurred prior to the team's site visits. Cache managers reported that

- In 4 cases, samples of drugs were sent to FDA for SLEP testing;
- In 2 cases, quantities of some drugs were destroyed because they were unsafe for human consumption;
- In 2 cases, EPS did not ship the drugs to the caches; and
- In 2 case, the drug sodium chloride was destroyed because of water damage.

Cache managers, however, were not aware of the seven other instances that the team identified in which drugs were not stocked in the correct quantity.

The team also identified 16 excess drugs at eight of the 26 visited cache locations. The present-day value of these drugs was about \$143,052 as of February 2018. Drugs were counted as excess if a site had both a current lot and replacement lot on-site in its cache carts, or if there were additional quantities of drugs on-site beyond what would be in a typical small or large cache. In all instances, excess drugs were attributable to cache managers who failed to remove expired drugs from their cache after new replacement drugs were rotated into the cache, creating excess inventory. This created the risk that old, expired drugs could be used during an emergency instead of new in-date drugs since both were in the cache carts. The team also observed instances in which pallets of excess drugs, still stored in the cache, kept the in-date drugs from being stored in their designated storage carts.

The team found that EPS's Inventory Management Specialist was not updating the national inventory database consistently. To make matters worse, cache managers cannot access EPS's national inventory database to monitor the accuracy of their cache inventory data. Having access to this information would allow cache managers to know what should be on-site at their cache location. Using this information in conjunction with routine wall-to-wall inventories would allow medical facilities to identify missing, or excess cache drugs. Currently there is no requirement for medical facilities to perform such wall-to-wall inventories. Without access to EPS's national inventory database, cache managers have no way of knowing their caches are fully stocked and mission ready.

² Appendix B provides additional information about how missing drugs were defined.

Office of Emergency Management Did Not Always Conduct Mandatory Annual Inspections

In accordance with VHA Directive 0320.10, OEM's Area Emergency Managers (AEMs) are required to conduct annual cache inspections at all 141 emergency cache locations.³ However, according to the team's cache manager survey, only 122 managers (87 percent) reported that their cache was inspected in Fiscal Year (FY) 2017. Of these 122 managers, a total of 96 provided the team with an inspection report for the team to verify. Failure to complete inspections at all cache locations occurred because some AEMs and Regional Area Managers were deployed at least once for at least a two-week period from August through late November 2017 for natural disaster recovery assistance or in response to a mass shooting. Because of the missed inspections, OEM was not in compliance with VHA's annual inspection requirement and OEM exposed caches to unidentified or unaddressed physical security risks. Without periodic inspections to make sure emergency caches are mission ready, caches are at risk of not being prepared to activate in an emergency.

Medical Facility Directors Did Not Always Conduct Mandatory Annual Activation Exercises

Medical facility directors are responsible for ensuring that mandatory annual cache activation exercises occur.⁴ However, the audit team determined from its survey of cache managers that medical facility directors did not always comply with the annual activation exercise. These exercises are important to ensure that there are no physical limitations, such as carts not fitting through doorways, which would affect medical facilities' ability to activate their caches in an emergency. Twenty-one of 141 cache managers (15 percent) reported they did not conduct activation exercises in FY 2017. OEM's Acting Director and Field Program Manager expressed concern to the team that medical facility directors were not fully complying with the annual cache activation requirement because these exercises are necessary to ensure mission readiness. However, OEM does not have the authority to enforce the annual cache exercise requirement among medical facility directors and does not monitor the extent to which these exercises occur. In fact, there is no governance structure in place to ensure medical facility directors are complying with the activation requirement.

³ VHA Directive 0320.10, *Inspection of VA All-Hazard Emergency Caches by the VHA Office of Emergency Management*, July 26, 2017.

⁴ VHA Directive 1047(1), *All-Hazards Emergency Caches*, December 30, 2014.

Medical Facilities Missed Opportunities to Use Soon-to-Expire Emergency Cache Drugs

Pharmacy Benefits Management's Deputy Chief Consultant did not order replacement drugs in sufficient time to allow medical facilities to use soon-to-expire drugs in the medical facilities' general medical operations, as directed in EPS's *All-Hazards Emergency Caches Replenishment Procedures* policy. The audit team found that most of the expiring drugs could have been used by the medical facilities if EPS had replaced them before the drugs expired. Cache managers at the 26 caches the team visited reported that, on average, about 80 percent of cache drugs and supplies were usable in normal medical facility operations. In addition, an OIG pharmacist determined that 95 percent of cache drugs and supplies could be used at VHA medical facilities providing inpatient and outpatient care, and up to 73 percent could be used at facilities that provide only outpatient care. The team estimates that continued failure to use soon-to-expire cache drugs that are not part of the SLEP for normal medical facility operations over the next five years will waste about 28 million units of drugs or about \$34 million.⁵

Emergency Cache Lacked Efficient Program Oversight

Finally, while VHA has articulated roles and responsibilities for the Emergency Cache Program in VHA Directives 0320.10 and 1047(1), these responsibilities were not met. At the time of this audit, no program office or person was tasked with overall responsibility to ensure that the Emergency Cache Program was mission ready. In addition, one of the national offices tasked with specific oversight responsibilities—OPH—was reorganized a year prior to the audit team's work, which affected the program office's ability to carry out its cache oversight responsibilities. The lack of effective oversight makes it likely that the Emergency Cache Program will not be mission ready.

What the OIG Recommended

The OIG recommended the Executive in Charge, Veterans Health Administration, establish policies and implement procedures to improve the oversight and management of the Emergency Cache Program. Specifically, the OIG recommended the Executive in Charge, Veterans Health Administration:

1. Develop requirements for medical facilities with emergency caches to perform at least annually a wall-to-wall inventory of all cache drugs and supplies, and develop processes to (1) label all expired or excess drugs that are purposefully maintained to respond to drug shortages or for the purposes of Shelf Life Extension Program testing, and (2) remove and rectify cases of other expired, missing, and excess drugs.

⁵ Appendix D provides more detail on how the audit team calculated the monetary benefits.

2. Conduct an assessment to determine if the cost-saving benefits of the Shelf Life Extension Program outweigh the risks expired drugs pose to the emergency cache's mission and to take corrective action as appropriate.
3. Improve cache inventory management processes to ensure cache national inventory data by location is reliable and accurately identifies the expiration dates of all cache contents, including Shelf Life Extension Program drugs, and that this information is electronically accessible to each facility.
4. Initiate steps to update and reissue Veterans Health Administration directives specifying oversight responsibilities for the Emergency Cache Program with a requirement for inventory to be timely rotated into the emergency cache after it is received.
5. Assess whether the Emergency Cache Program is properly aligned within VA and coordinate with other VA offices as necessary to determine the appropriate roles and responsibilities by program office, and then review, update, and reissue Emergency Cache Program requirements to include (1) robust annual cache inspection and activation exercise requirements; (2) processes to ensure cache inspection and activation requirements are met; (3) processes to ensure that violations identified during annual cache inspections are timely addressed; and (4) specific accountability measures for the program offices and local facility personnel responsible for program oversight.
6. Conduct a comprehensive assessment of the cache inventory to identify drugs and supplies that can be readily used in medical facilities' general operations and develop a mechanism to monitor and ensure medical facilities are maximizing the use of these items before they expire.
7. Initiate steps to update and reissue Veterans Health Administration directives specifying oversight responsibilities for the Emergency Cache Program to reflect Office of Public Health's reorganization and reassign responsibilities as needed.

Management Comments

The VHA Executive in Charge concurred with Recommendations 1, 3, 4, 5, and 7 of the report and concurred in principle with Recommendations 2 and 6. The Executive in Charge's planned corrective actions are responsive to Recommendations 1, 3, 4, 5, and 7, and should address the issues identified in the report. For Recommendation 2, determining if the information is available to conduct a cost savings benefit analysis of continued SLEP participation is an appropriate initial response. However, even if the necessary information for a full assessment is not available, Pharmacy Benefits Management should use the best available information to determine whether continued participation in the SLEP outweighs the risk associated with drugs that are expired as they await SLEP testing. For Recommendation 6, rotating soon-to-expire cache drugs into facilities' inpatient and outpatient pharmacy operations may cost more—in

some cases—than returning these drugs for credit through a reverse pharmaceutical distributor. However, VHA should immediately assess each individual cache drug and maximize the use of drugs that can be readily and efficiently used in a facility’s inpatient or outpatient pharmacy operations. VHA should also take immediate steps to ensure that inventory to replace soon-to-expire cache drugs are delivered to facilities well in advance so that the use of expiring inventory can be maximized at the facility-level. VHA should also take immediate steps to educate facility pharmacy personnel on how to maximize the use of expiring cache drugs. The OIG will monitor VHA’s progress and follow up on implementation of the recommendations until all proposed actions are completed.



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Abbreviations

AEM	Area Emergency Manager
CMOP	Consolidated Mail Outpatient Pharmacy
EPS	Emergency Pharmacy Service
FDA	Food and Drug Administration
FY	Fiscal Year
GAO	Government Accountability Office
OEM	Office of Emergency Management
OIG	Office of Inspector General
OPH	Office of Public Health
PBM	Pharmacy Benefits Management
SLEP	Shelf Life Extension Program
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Networks



Introduction

Objective

The Office of Inspector General conducted this audit to determine whether the Veterans Health Administration (VHA) effectively manages its Emergency Cache Program to ensure it is ready to mobilize in the event of a disaster or terrorist attack.

Emergency Cache Program

The Department of Veterans Affairs established an emergency cache program in 2002 following the 9/11 attacks, to make drugs and medical supplies available to treat veterans, VA employees, and civilians in the immediate aftermath of a terrorist, biological, or natural disaster. The Under Secretary for Health decides which medical facilities will hold caches.⁶ Because mass casualty events can occur at any time, in any location, and with little or no warning, the Emergency Cache Program must be ready for immediate deployment. According to Pharmacy Benefits Management's (PBM) Deputy Chief Consultant, the total value of VA's Emergency Cache inventory is about \$44 million.

The Emergency Cache Program stockpiles a standard supply of drugs and medical supplies at VA medical facilities. These emergency caches are designed to bridge the gap between a medical facility's existing supplies and limited resupply, and federal relief provided by the Department of Health and Human Services' Centers for Disease Control and Prevention's Strategic National Stockpile, which can take one to two days, if not longer, to reach the site of a catastrophic event. In the event of a mass casualty occurrence, and until the Centers for Disease Control and Prevention releases the Strategic National Stockpile, VA is required to distribute the medical supplies it has stored and maintained to treat victims of mass casualty events.⁷ The Emergency Cache Program is part of VA's national emergency preparedness efforts.

So far, none of the emergency caches have been activated in response to a disaster, but medical facilities have used cache drugs in response to local or national shortages. Medical facility directors can authorize the use of up to 50 percent of most drugs stored in their emergency cache in response to a drug shortage if other options to obtain the drug have been exhausted and patients are in life-threatening situations.⁸

⁶ VHA Directive 2002—026, *Pharmaceutical Caches in A Weapons of Mass Destruction Event*, May 13, 2002.

⁷ Public Law 107-188, *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, June 12, 2002; VHA Directive 1047(1), *All-Hazards Emergency Caches*, December 30, 2014.

⁸ VHA Directive 1047(1), *All-Hazards Emergency Caches*, Page 6. Drugs that have had their expiration dates extended through the Shelf Life Extension Program cannot be used in response to a drug shortage.

Number, Value, and Funding for Emergency Caches

As of January 2018, emergency caches were established at 141 medical facilities across the United States and its territories. Each cache contains a standard supply of 38 drugs and 44 medical supplies that are identical, except that the quantities differ between large and small caches. In addition to the 38 drugs carried by all caches, one medical facility in each Veterans Integrated Service Network (VISN) carries two drugs used to treat the specific medical needs arising from a nuclear disaster. Another drug, rimantadine HCL, is in the process of being phased out of all caches. Regardless of size, each cache carries three controlled substances—morphine, diazepam, and lorazepam.⁹ The remaining drugs are non-controlled.

A large cache is designed to treat 2,000 casualties while a small cache can handle up to 1,000 casualties in the one- to two-day period following a disaster or attack.

Table 1 provides additional facts on the emergency caches, including their value and funding.

Table 1. Emergency Cache Program Details

Facts	Description
Number of caches	141 (91 large/50 small)
Emergency Cache Program total value	Approximately \$43.7 million as of November 2017
Small cache value per cache	Approximately \$242,393 per cache
Large cache value per cache	Approximately \$343,508 per cache
Expenditures for annual purchases to replenish emergency cache inventory	FY 2016: \$11.8 million FY 2017: \$8.3 million FY 2018 (through July): \$4.9 million

Source: Deputy Chief Consultant, PBM, Emergency Pharmacy Service (EPS) and VHA's Financial Management System

Note: Dollar values presented in this table are based on purchase price of the drugs and supplies in the Emergency Cache Program.

⁹ Controlled drugs, which include painkillers such as oxycodone, are identified as such by the Drug Enforcement Administration and are tightly regulated under the Controlled Substances Act of 1970. VHA requires its medical facilities to store controlled substances in separate secure vaults and to conduct routine physical counts of each drug to reduce the risk for diversion. VA Office of Inspector General, *Audit of Veterans Health Administration's Management of Non-Controlled Drugs*, Report No. 08-01322-114, June 23, 2009.

Governance

Oversight responsibilities for the Emergency Cache Program are outlined in two directives:

1. VHA Directive 0320.10, *Inspection of VA All-Hazard Emergency Caches by the VHA Office of Emergency Management*, July 26, 2017 (VHA Directive 0320.10)
2. VHA Directive 1047(1), *All-Hazards Emergency Caches*, December 30, 2014 (VHA Directive 1047(1))

Oversight responsibilities are split among three VHA program offices and the directors of medical facilities with emergency caches:

- PBM’s Emergency Pharmacy Service (EPS) is responsible for maintaining a centralized national inventory database to track drug expiration dates, lot numbers, and locations; ordering, packaging, and shipping drugs and supplies to the emergency cache locations; and providing subject matter expertise on pharmacy issues.
- Office of Emergency Management (OEM) is responsible for managing annual cache inspections and reporting on the functional and operations status of emergency caches.
- Office of Public Health (OPH) is responsible for providing leadership of cache committee activities and reviewing and updating cache policies and directives.
- Medical facility directors are responsible for making sure an annual cache activation exercise occurs and the cache physical space is adequate. Directors are also responsible for appointing a facility liaison to EPS and for deciding when to activate the cache. In addition, directors are responsible for ensuring the cache manager is overseeing and managing the cache inventory.¹⁰

Storage and Security Requirements

Emergency caches must meet the security requirements outlined in VHA Directive 1047(1), including those involving windows, door locks, alarm and access systems, controlled substance storage, and cache inventory.¹¹ Within the cache, most of the drugs and supplies are stored in large, metal rolling carts that are numbered and locked with uniquely numbered plastic seals. The carts are sequentially numbered, and the same items are stored together in designated carts at each cache.

¹⁰ This report uses the term “cache manager” to refer to the chief of pharmacy and other local pharmacy personnel with cache-specific responsibilities. While VHA Directive 1047(1) designates the chief of pharmacy or pharmacy manager as the local pharmacy personnel responsible for the emergency cache, during on-site inspections the audit team found that cache-specific responsibilities are generally shared among pharmacy personnel and are not assigned to one person in a dedicated position.

¹¹ VHA Directive 1047(1).

The three controlled substances in the emergency cache may be stored in a safe located in the cache area or in the medical facility’s pharmacy vault in separate sealed totes that are clearly marked as emergency cache supplies. About \$1 million is available annually through EPS to medical facilities to correct any emergency cache security violations.

Inventory Management

EPS tracks the item type, quantity, lot number, expiration date, and specific cache and cart location of all drugs and supplies through a national inventory database. All drugs and supplies to replace expiring cache inventory are ordered by EPS. Most drugs and supplies are first shipped to EPS’s inventory warehouse at the Edward Hines Jr., VA Hospital in Hines, Illinois, and then repackaged and shipped to each cache location. Controlled substances, however, are shipped from EPS directly to the medical facility pharmacies. According to EPS staff, most emergency cache drugs are subject to a seven-month replacement process, detailed in figure 1.

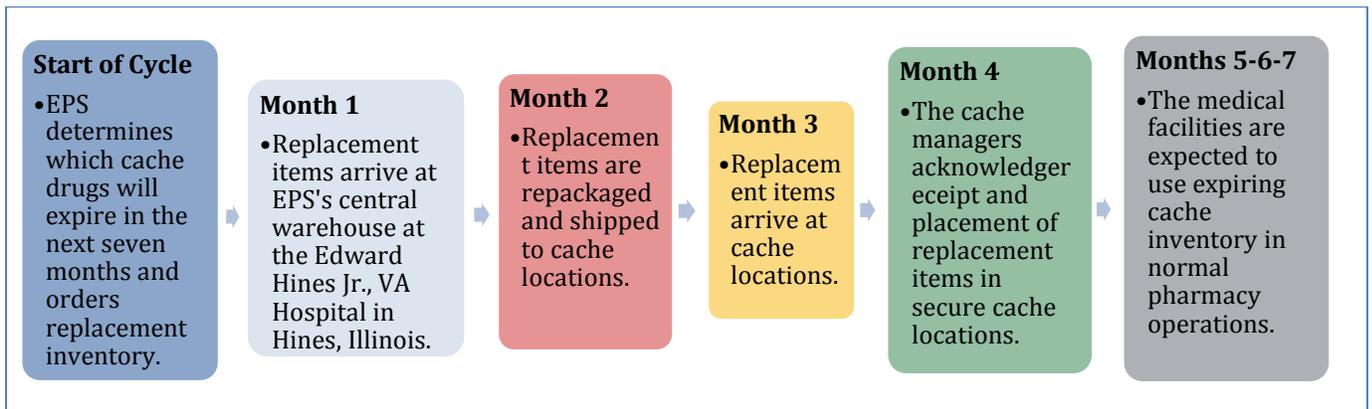


Figure 1. Emergency Cache Inventory Ordering Process (Source: EPS staff)

Shelf Life Extension Program

The Food and Drug Administration’s (FDA) Shelf Life Extension Program (SLEP) can be used to extend the shelf life of designated drugs. SLEP is a fee-for-service program that exists through an interagency agreement between FDA and the Department of Defense to defer the replacement cost of certain federally stockpiled drugs, which include 17 of the drugs VA stores in its caches. VA participates in SLEP through a memorandum of understanding with the Department of Defense.

FDA tests drugs for stability and extends the expiration dates for drugs that pass this testing. Stability testing is conducted by FDA, and the FDA’s Center for Drug Evaluation and Research analyzes the testing data to determine how long each tested drug’s shelf life will be extended. SLEP drugs are primarily non-biological prescription drugs. Current SLEP testing focuses on drugs that have limited commercial use, such as nerve agent antidotes, and drugs that are purchased in very large quantities, such as ciprofloxacin and doxycycline.

Results and Recommendations

Finding: Ineffective Management Impaired the Mission Readiness of the Emergency Cache Program and Hindered the Efficient Use of Soon-to-Expire Drugs

Expired, missing, and excess drugs affected the mission readiness of emergency caches. The audit team found that all 141 caches had at least one expired drug, and estimated that 59 of them (42 percent) had at least one missing, and/or excess drug.¹² The team found both controlled and non-controlled substances to be expired, missing, or in excess during their cache inspections. Cache managers from at least nine of the 26 sites the team visited were not aware of the extent to which their cache inventories were affected by expired, missing, or excess drugs. Because EPS does not require wall-to-wall inventories of caches, cache managers have no way of knowing if their caches are in fact mission ready. Furthermore, OEM's Director did not ensure that all required annual cache inspections occurred, exposing caches to unidentified or unaddressed physical security risks. In addition, medical facility directors did not always comply with the requirement to carry out annual cache activation exercises to ensure there were no physical limitations, such as carts not fitting through doorways, which would affect their facility's ability to activate their caches in an emergency. Finally, medical facilities missed opportunities for greater efficiency—they failed to reduce waste by using soon-to-expire cache drugs in their pharmacies because PBM's Deputy Chief Consultant did not replace the drugs before they expired.

What the OIG Did

The scope of the audit included all 141 emergency caches and focused on whether the caches were ready for immediate mobilization in the event of an emergency. The audit work included unannounced site visits at 26 medical facility emergency caches and an inventory inspection of a sample of cache drugs at these facilities. The audit team selected a sample—in consultation with an OIG statistician—of 25 of the 38 drugs stored at each emergency cache. The team inventoried the same sample of 25 drugs at each inspected cache location. This sample consisted of the five drugs with the highest time-of-purchase price, and a random sample of 20 other drugs. A total of 650 drugs were inspected—25 drugs at 26 caches.

¹² The audit team defined a missing drug as any instance in which the quantity of one of the 25 inspected drugs at one of the 26 visited caches was less than the quantity that was indicated as being on-site in EPS's national inventory database. The team defined an excess drug as any instance in which the quantity of one of the 25 inspected drugs at one of the 26 visited caches was more than was indicated as being on-site in EPS's national inventory database. The team's estimate of the number of caches with at least one missing, and/or excess drug is based on a sample count of 14 caches. Of these 14 caches, six were missing at least one drug, two had excess drugs, and six had both missing and excess drugs. Appendix C: *Statistical Sampling Methodology* provides more details.

The team also interviewed officials at each visited medical facility who were responsible for managing the emergency cache. In addition, the team interviewed officials from three VHA national program offices—Emergency Pharmacy Service (EPS), Office of Emergency Management (OEM), and Office of Public Health (OPH)—and surveyed managers of the 141 emergency caches operational as of January 2018. Appendices B and C provide additional details on the team’s methodology and inventory testing approach.

In this finding the audit team discusses:

- All 26 inspected caches had expired drugs
- Twelve inspected caches were not fully stocked
- Eight inspected caches had excess quantities of cache drugs
- OEM did not always conduct the required annual inspections
- Medical facility directors did not always conduct the required activation exercises
- Medical facilities missed opportunities to use soon-to-expire cache drugs because of ineffective management
- Lack of effective governance resulted in inefficient program oversight

Expired Drugs Found at All 26 Inspected Emergency Cache Sites

In almost all cases of expired drugs, EPS failed to ship replacement drugs to caches before their current drugs expired. While the EPS Inventory Management Specialist, who is responsible for managing the nationwide cache inventory, agreed with the audit team’s cache inspection results, he deflected responsibility regarding the cause of the expired drugs in the cache. According to this individual, caches contained expired drugs not because EPS did not ship the drugs in time, but because inexperienced cache managers did not timely rotate in-date drugs into the caches to replace expired drugs. The team found this to be largely unpersuasive because in-date inventory to replace the expired drugs was rarely on-site during the team’s inspections.

Of the 650 drugs that the team inspected, 178 (27 percent) were expired. For six of those expired drugs, a portion of the total amount of the drug on-site was expired and a portion was missing—the six drugs counted as both expired and missing. For six different expired drugs, the amount on-site was more than was reflected in the national inventory database in addition to being expired—these six drugs counted as both expired and excess. All 26 caches had at least four expired drugs, while half had six or seven expired drugs, and four (15 percent) had 10 or more expired drugs. At the time of the team’s inspections, more than a third of the expired drugs had been expired for three months or longer, at least 22 had been expired for six months or longer, and three drugs had been expired for over a year.

Based on the sample results, the team estimates that about 6.1 million units of drugs were expired across all 141 caches representing about \$4.6 million in present-day value.¹³ These expired drugs affected the readiness of VA's emergency caches. Drugs that were most frequently expired included:

- Amoxicillin and ampicillin, both used to treat bacterial infections, including conditions related to anthrax
- Propranolol, a beta blocker used to treat high blood pressure, irregular heartbeats, tremors, and other conditions
- Relenza, an antiviral medication used to treat influenza
- Morphine, an opioid pain medication generally used to treat acute and chronic pain, that could also be used to reduce pain in injuries associated with severe burns and broken bones, which may be common in a natural disaster or terror attack

As an example of the extent of expired drugs the team identified during its February 2018 site visits, consider that of the 5,120 units of Relenza the team found to be expired, 3,200 units were expired since January 2017 and 1,920 units were expired since March 2017—across four emergency cache locations. Importantly, EPS had a ready supply of about 6,800 units of in-date Relenza at its warehouse, but failed to timely ship the Relenza to these four caches to replace their expired inventory. According to EPS's Inventory Management Specialist, replacement of the Relenza did not follow EPS's seven-month inventory ordering and replacement cycle and, instead, EPS shipped the Relenza to these caches at the end of February 2018—after the team's site visits, and at least 13 months after the original Relenza expired. This occurred because EPS, again according to the Inventory Management Specialist, did not have enough personnel to repackage and ship the replacement drugs to the caches. Four employees were deployed to Dallas and Houston, Texas, for Hurricane Harvey relief efforts in August and September 2017, and two were also deployed to Puerto Rico through November 2017. However, because EPS had the replacement Relenza on hand since March 2017, the team considers this timeline to be unacceptable—EPS could have replaced the Relenza at the four caches from March through July 2017, before reportedly assisting with hurricane relief efforts. EPS's turnaround time to replace the expired Relenza exposed VA employees and veterans served by these four facilities to unnecessary risk in the event of an influenza pandemic.

The team identified only a few instances in which drugs were expired because cache managers did not timely rotate drugs into their caches. According to EPS's *All-Hazards Emergency Caches Replenishment Procedures*, when replacement inventory is received by a cache, the cache manager should place the inventory into the cache and confirm receipt through EPS's SharePoint

¹³ Drug unit refers to the smallest quantity of measurement for a specific drug, such as pill, tablet, or injection.

website. However, EPS did not have a process in place to make sure the replacement drugs were placed into the cache carts, even though EPS is ultimately responsible for managing the stock rotation of cache drugs, according to VHA Directive 1047(1).¹⁴ EPS's Inventory Management Specialist told the team that EPS considers the medical facility responsible for rotating cache inventory because without physically being at each cache, EPS staff cannot see what happens to each unique drug. VA should ensure compliance with VHA Directive 1047(1), such as the requirement for cache managers to rotate replacement inventory into the cache carts, by developing a specific time period after receiving replacement inventory in which replacement must occur.¹⁵

Example 1

During a February 2018 site visit, the audit team identified a pallet of replacement inventory from October 2017 in the cache area. It had not been rotated into the cache storage carts, which contained the expired inventory the order was sent to replace. EPS was under the impression that the facility had rotated the new inventory into the cache carts because the facility self-certified as receiving and securing the inventory in the cache area. The in-date drugs had not been rotated into the cache and would not be considered part of the cache if it had to be activated in an emergency.

It is important to ensure that in-date drugs are timely rotated into the cache to make sure these drugs are available for activation during an emergency. VA does not require caches to be periodically inventoried. Requiring medical facilities to at least annually conduct a wall-to-wall inventory of their caches would put cache managers in a position to be able to identify instances when in-date drugs have not yet been rotated into a cache. Currently, emergency cache managers are required only to conduct monthly visual inspections and a quarterly physical count of the three controlled drugs that are included in the emergency cache. These physical counts must also occur each time a cache cart or tote seal for a controlled drug is broken.

SLEP Saves Dollars but Poses Risks to Cache Readiness

Slightly more than half of the expired drugs identified by the audit team were in the SLEP (95 of 178).¹⁶ EPS's Emergency Pharmacy Specialist reported to the team that participating in the SLEP saves VA about \$20 million annually. According to the same individual, EPS's biggest cost savings from participation in SLEP is from not having to replace Tamiflu, which was

¹⁴VHA Directive 1047(1).

¹⁵VHA Directive 1047(1), and Government Accountability Office (GAO), *Standards for Internal Control in the Federal Government*, September 2014.

¹⁶As of January 2018, 17 of the 41 cache drugs were eligible for SLEP.

purchased at a discounted contracted rate of \$20 per pack in May 2009, but which would cost about \$90 per pack to replace in present-day value. EPS staff stated that they could choose which cache drugs to include in the SLEP and that they do not have to include all 17 of the current cache SLEP drugs.

For expired drugs undergoing SLEP testing, EPS used an estimated expiration date in its national inventory database to indicate the drug's expiration date. According to EPS staff, the expiration date is the date FDA is expected to be done testing the drug. FDA provides this information to EPS. This date is often 90 days or greater past the actual expiration date. This practice is risky because EPS's national inventory database does not accurately reflect the proportion of cache drugs that are in-date at any point in time. In addition, the length of time it takes for drugs to get through SLEP testing increases the time that these drugs are unavailable for use. Specifically, EPS's Emergency Pharmacy Specialist told the team that while EPS generally provides the drugs to FDA one to two months before their expiration date, it is not unusual for FDA to start SLEP testing closer to the expiration date or even after the drugs have expired.

Example 2

Seventy-eight of the 95 expired SLEP drugs identified by the audit team had an expiration date of March 31, 2018, in EPS's national inventory database. This date, according to EPS's Emergency Pharmacy Specialist, represents the date FDA is expected to complete SLEP testing. During on-site inspections, the team found that these 78 drugs were labeled with earlier expiration dates. PBM's Deputy Chief Consultant, EPS's Pharmacy Specialist, and EPS's Inventory Management Specialist confirmed that the drugs were expired, and that they were aware of how EPS used this date. EPS's Emergency Pharmacy Specialist acknowledged that using the "expiration date" variable in this manner can be misleading. The practice of using an estimated date as the actual expiration date in the national inventory database creates the illusion that far fewer drugs are expired.

EPS's Emergency Pharmacy Specialist reported that while it used to take FDA 90 days to complete a testing cycle, as of May 2018, it could take up to six-month for drugs to start the 90-day testing cycle. Because of this, emergency cache drugs in SLEP testing are often already expired and VA must wait for up to nine months for FDA to complete its testing to determine if their shelf life can be extended. As a result, expired SLEP drugs cannot be used for up to nine months while they are in, or waiting for, FDA testing. In fact, according to EPS, 78 percent of the drugs that were scheduled to complete SLEP testing in March 2018 were still in testing as of April 2018.

The length of time it can take for drugs to undergo SLEP testing is especially problematic for cache drugs that are not stocked in a medical facility's inpatient or outpatient pharmacies. For example, a drug used to treat nerve agent or insecticide poisoning is not commonly stocked in facility pharmacies. As a result, clinicians would not have access to a backup supply of the drug if it were in SLEP testing. VHA also has no assurances that FDA will grant expiration date extensions for the numerous drugs that are currently delayed in SLEP testing.

In the event of a disaster, EPS officials reported that they could petition FDA for an emergency extension for these drugs, but this process could take several months. The team confirmed with FDA that approval to use expired SLEP drugs in an emergency could take time. A potentially months-long emergency extension petition process would significantly compromise the Emergency Cache Program's readiness. One cache manager reported to the team that she would not risk her pharmacy license by dispensing outdated drugs from the cache during an emergency. FDA officials noted, however, that enforcement action against pharmacists who used expired SLEP drugs during an emergency may not necessarily occur. Continuing to participate in SLEP with its current delays is contrary to the legislative intent establishing VA's emergency pharmacy caches. Conducting a risk assessment would help VA determine whether the cost savings associated with SLEP outweigh the risks to its Emergency Cache Program.

SLEP Drugs Were Expired Without Possibility of Extension and Not Labeled Correctly

In addition to the 78 SLEP drugs that were in testing during the audit team's on-site inspections and discussed in Example 2, 10 other drugs, all atropine, were expired as of August 2017, with no option to extend their expiration dates. Atropine is used to reduce secretions during surgery or to treat poisoning. Seven other SLEP drugs were not labeled with the most recent or correct SLEP labels, most likely due to human error.

According to VHA Directive 1047(1), EPS is responsible for providing medical facilities with labels and guidance on how to label SLEP drugs.¹⁷ When SLEP drug expiration dates are extended, EPS sends replacement labels to the caches and, according to EPS's *Shelf Life Extension Product Rotation* policy, cache managers must confirm receipt of the labels through the EPS SharePoint website. However, EPS does not have procedures to ensure that cache managers affixed the updated labels correctly and in a timely manner. EPS staff told the team that EPS considers it the facilities' responsibility to keep SLEP labels up to date. EPS asked cache managers to display this policy in the cache area and the policy is also available to cache managers via the EPS SharePoint website. There is no requirement for EPS to verify if caches are accurately updating SLEP labels.

¹⁷ VHA Directive 1047(1).

PBM's Deputy Chief Consultant reported to the team that EPS tracks the proportion of cache drugs that are expired as part of its seven-month purchasing process. However, based on the amount of expired drugs the team identified, EPS's current ordering process is ineffective in ensuring the caches mission readiness.

Twelve Caches Were Not Fully Stocked

Of the 26 caches the audit team visited, 12 did not have the quantity of drugs on hand as indicated in VA's data. Specifically, for 16 of the 650 drugs the team inspected, varying quantities were missing.¹⁸ The replacement cost of these drugs was about \$120,533 in present-day value as of February 2018.¹⁹ Examples of drugs that were missing from these caches include 1,200 units of the antibiotic ciprofloxacin HCL and 40 units of the controlled substance diazepam. Prior to the team's visit, cache managers had been aware of nine of these instances of missing drugs and why they occurred. Cache managers reported and the team verified that in:

- Four cases, samples of drugs were sent to FDA for SLEP testing
- Two cases, quantities of some drugs were destroyed because they were unsafe for human use
- Two cases, EPS did not ship drugs to the caches
- One case, the drug sodium chloride was destroyed because of water damage

Cache managers, however, were not aware of the seven other instances the team identified when drugs were not completely stocked in the correct quantity. Importantly, at these sites, cache managers also could not provide the team with any documentation that would explain why their caches were missing quantities of drugs. These drugs included, for example, Relenza, sodium chloride, and atropine. EPS staff were unable to provide reasons for three of the seven instances, and told the team that one occurrence was due to SLEP testing, two were due to an overlap between old and new inventory, and one was due to a vendor delivering less inventory than ordered. In addition, for one of the instances in which a cache manager indicated a drug was never shipped to their cache, EPS reported that the drug had been stocked at the cache previously, but it was not on-site during the team's visit due to a drug shortage.

The team found that EPS's Inventory Management Specialist was not updating the national inventory database consistently. For example, the EPS database did not reflect the on-site inventory count for the instance of sodium chloride that was destroyed because of water damage, even though the cache manager had written approval from EPS to destroy the drugs. Importantly, cache managers cannot access EPS's national inventory database to monitor the accuracy of their cache inventory data. Having access to this information would allow cache managers to know

¹⁸ Appendix B provides additional information about how missing drugs were defined.

¹⁹ The audit team identified six caches with only missing drugs, and six caches that had both missing and excess drugs. The replacement cost calculated by the team includes only the cost of the drugs that were found to be missing at these 12 cache locations.

what should be on-site at their cache location. Using this information in conjunction with a routine wall-to-wall inventory requirement could position cache managers to proactively identify missing, or excess quantities of drugs. However, for a wall-to-wall inventory to be useful, cache managers need to have real-time access to accurate cache-level data. Without access to EPS's national inventory database, cache managers have no way of knowing if their caches are fully stocked and mission ready.

Eight Caches Had Excess Quantities of Drugs

Of the 26 caches the audit team visited, eight had excess drugs. Specifically, 16 of the 650 drugs the team inspected were in excess quantities on-site. The present-day value of these drugs was about \$143,052 as of February 2018.²⁰ In all instances, excess drugs were attributable to cache managers who failed to remove expired drugs from their cache after new replacement drugs were rotated into the cache, creating excess inventory. Drugs were counted as excess if a site had both a current lot and a replacement lot on-site in the cache carts, or if there were additional drugs on-site beyond what would be in a typical small or large cache. This created the risk that old, expired drugs could be used during an emergency instead of new in-date drugs since both were in the cache carts. Expired drugs can, at best, be ineffective in the treatment of a condition and, at worst, cause harm to a patient. Once cache managers certify receipt of replacement inventory via the EPS SharePoint site, EPS considers the inventory to be the responsibility of the local medical facility. VHA Directive 1047(1) ultimately places the responsibility for ensuring the cache inventory is in fact rotated in the hands of local cache managers.²¹ The team also observed instances in which pallets of excess drugs still stored in the cache kept the in-date drugs from being stored in their designated storage carts.

Example 3

During a February 2018 site visit, one emergency cache had 3,168 units of excess Relenza—expired since April 2013—in its cache. In addition to the risk that the expired drugs could be administered in an emergency, these drugs also took up significant space in the limited cache storage area. This same facility had other in-date inventory stored outside of the cache carts because of a lack of storage space.

A few cache managers characterized managing the cache as complicated and time-consuming. Specifically, updating expiration date labels for SLEP drugs—often several times over the course of the drug's shelf life—can lead to errors. Regardless, proper management of the cache at the local level is imperative to ensure the cache is ready to mobilize. Three cache managers

²⁰ The audit team identified two caches with only excess drugs, and six caches that had both excess and missing drugs. The present-day value calculated by the team includes only the value of the drugs that were in excess at these eight cache locations.

²¹ VHA Directive 1047(1).

contacted EPS after their caches had been inspected to inform EPS of the team's findings related to expired, missing, or excess drugs. One cache manager instituted a wall-to-wall cache inventory review to fully assess the status of her cache inventory items and to identify any expired, missing, or excess drugs or medical supplies. The team also shared the results of all drug inspection findings with EPS.

Office of Emergency Management Did Not Always Conduct Required Annual Inspections

The audit team surveyed all 141 emergency caches to collect information about how each cache handles expiring inventory and information on FY 2017 annual cache inspections and activation exercises. All 141 emergency caches are required to undergo annual inspections. Inspections are to be conducted by OEM's Area Emergency Managers (AEMs), using a checklist that was updated in July 2017, according to VHA Directive 0320.10.²²

According to the team's survey, cache managers at 122 caches (87 percent) reported that their cache had an inspection in FY 2017, 17 cache managers reported their caches were not inspected, and two managers did not know if their caches were inspected. Of the 122 cache managers who reported having FY 2017 inspections, 96 provided the team with requested documentation to verify that these inspections occurred, five cache managers reported that their inspection results were not available, and 21 did not provide the requested documentation.

OEM's Emergency Management Specialist told the team that OEM did not have the capacity to conduct all FY 2017 annual inspections. According to evidence provided by OEM's Field Program Manager, some AEMs and Regional Area Managers were deployed at least once, for at least a two-week period, from August through late November 2017 for natural disaster recovery assistance, or in response to a mass shooting.

OEM's Acting Director was made aware of the missed FY 2017 inspections and in response prioritized these caches for FY 2018 inspections. In addition, OEM's Field Program Manager directed all AEMs to complete all FY 2018 inspections by July 31, 2018, so that the inspections would not be delayed by this year's hurricane season. As of August 2018, OEM reported to the team that all but five of the FY 2018 cache inspections were completed and that these five inspections were expected to be completed by the end of August 2018. In addition, OEM reported that AEM's FY 2019 performance plans will include a requirement to complete all emergency cache annual inspections by July 31, 2019.

Emergency cache annual inspections are designed to (1) ensure the local emergency cache policies comply with VHA's cache requirements, such as documenting who can and how to activate the cache; (2) examine the physical environment and security of the cache; and

²² VHA Directive 0320.10.

(3) assess the cache's controlled substances security procedures and SLEP labeling processes. Without periodic inspections to make sure emergency caches are ready to activate, caches run the risk of not being prepared to activate in an emergency. For example, security issues may compromise the integrity of the cache or increase the risk for drug diversion. Moreover, pharmacy personnel could significantly delay a facility's responsiveness to an emergency if they do not know how to activate the cache.

For the 96 emergency caches that provided the team with copies of their FY 2017 annual inspections, most AEMs (69 percent) identified no violations.²³ Thirty caches had violations identified, and eight caches had more than two identified violations. The most frequent violations identified by AEM's included gaps in facilities' local emergency cache operating policies, such as not including training on the use of cache drugs and supplies (nine caches) or not incorporating information on coordination with the Strategic National Stockpile (eight caches). Other frequent violations were related to the physical security of the cache storage location, such as ventilation grills on doors and air circulation ducts (eight caches).

VA's current cache inspection procedures do not require OEM inspectors to open cache carts and examine the contents to ensure each cart has the correct quantities of in-date drugs, and that carts are in good working order to be quickly moved out of the cache storage area. In addition, the team found that at two (of 26 inspected) caches, facilities stored controlled substances intended for the cache in their pharmacy vaults but did not separate the cache controlled substances in sealed totes, as required. The team did not find this storage violation identified in the FY 2017 annual inspection report for one of these facilities—the other facility did not provide the team with its report. In addition, the team identified seven SLEP drugs that did not have a valid SLEP label that accurately indicated each drug's expiration date. However, OEM inspectors identified only five violations related to controlled-substance storage or SLEP labeling in the 96 cache inspection reports provided to the team for FY 2017. Opportunities exist for VA to strengthen its cache inspection procedures to ensure that each cache is mission ready.²⁴

²³ The audit team did not independently assess the validity of the annual inspections. The team relied on the inspection results documented by OEM's AEMs in its analysis of the identified violations.

²⁴ Appendix E provides additional information on OEM's Emergency Cache Program Annual Inspection Checklist.

Example 4

A facility stored its emergency cache supply of morphine on open shelves in its pharmacy vault, rather than in the required sealed totes.



Figure 2. Morphine incorrectly stored in the pharmacy vault at an emergency cache. (Source: VA OIG, Emergency Cache, 2/15/2018)

Meanwhile, current inspection procedures do not include reviewing whether pharmacy personnel are able to move the cache carts or navigate the cache space. The team identified several instances of inventory being stored on top of cache carts, of drugs being stored in a haphazard manner within cache carts, and of pallets of excess drugs still stored in the cache alongside in-date replacement drugs. All pose a risk to the ability of the cache manager to access necessary cache drugs and supplies in an emergency.

Example 5

Drugs had been tossed haphazardly into a cache cart.



Figure 3. Emergency cache cart with drugs tossed haphazardly into cart at an emergency cache. (Source: VA OIG, Emergency Cache, 2/8/2018)

One inspector, while finding no actual violations in the inspection checklist, stated that “the functionality of the Emergency Pharmaceutical Cache Area has been compromised due to the storage of expired fluids (11 pallets) [...] the emergency carts are not accessible at this time to be inspected, nor could they be accessed in a timely manner if any of the carts are needed to be opened or mobilized for an emergency [...] expired fluids were difficult to remove, as there is no mechanism for removal.”

Although OEM is currently responsible for overseeing cache annual inspections, OEM’s Acting Director told the team that AEMs are not best qualified to handle the physical security or clinical aspects of the inspections, such as SLEP labels and the handling of controlled substances. The same individual added that placing the overall responsibility on OEM and on the AEMs is inappropriate, and that the responsibility should be shared by the program offices with the subject matter expertise required to determine if the different aspects of the inspections are robust enough to identify violations affecting the cache’s mission-readiness. VHA does not necessarily have all the required expertise, according to the Acting Director of OEM. VA program offices, such as the Office of Security and Law Enforcement, have expertise in security and should have a role in overseeing the physical security of the caches.

The cache annual inspection checklist should be designed to identify violations that could negatively affect the ability of cache managers to activate caches in the event of an emergency and processes should be in place to ensure that the annual inspection requirement is met and violations are addressed. The expertise of the most appropriate VA and VHA program offices should be leveraged to review, update, and reissue the annual cache inspection requirements and to develop processes to ensure that inspections occur and that violations are addressed. Failing to do so will continue to expose caches to the risk of not being ready to activate in an emergency.

Medical Facility Directors Did Not Always Conduct Required Activation Exercises

Medical facility directors are responsible for ensuring that mandatory annual cache activation exercises occur.²⁵ However, the audit team determined from its survey of cache managers that medical facility directors did not always comply with the annual activation exercise requirement. According to the team’s survey, in FY 2017, 21 of 141 caches (15 percent) did not conduct mandatory activation exercises. While medical facilities are not currently required to move or open cache carts as part of their annual activation exercise, or to perform the exercise in the cache area, they are encouraged to do so. If facilities do conduct an activation exercise that involves moving cache inventory out of the storage location, they should notify EPS to minimize VA’s risk of drug diversion. Over half (28) of the 55 caches with exercises that involved moving

²⁵ VHA Directive 1047(1).

and opening cache carts, however, did not provide the team with documentation that EPS was notified as required.

OEM's Acting Director and Field Program Manager expressed concern to the team that medical facility directors were not fully complying with the annual cache activation requirement because these exercises are necessary to ensure mission readiness. In addition, they told the team that they believed that cache activation exercises could be more robust. During the team's site visits, cache managers at seven of the 26 sites told the team that their 2017 activation exercise did not even involve being in the cache area or moving cache carts. Instead, the facilities had discussions about the steps that would need to be taken if an activation was to occur. According to OEM staff, discussing what would need to happen in an emergency or moving carts and drugs to another physical location at a facility does not mimic the coordination that would need to occur between the clinical, policy, administration, and police functions of a facility in an emergency.

However, OEM does not have the authority to enforce the annual cache exercise requirement among medical facility directors and does not monitor the extent to which these exercises occur. OEM also does not have the authority to change the nature of the activation exercises to make them more comprehensive. There is no governance structure in place to ensure medical facility directors are complying with the activation requirement. The expertise of the most appropriate VA and VHA program offices should be leveraged to review, update, and reissue the annual cache activation requirements. Governance authorities to ensure medical facility directors comply with the annual cache activation exercise requirement should also be established.

Medical Facilities Used Cache Drugs to Address Shortages

The audit team's survey also identified a recent increase in medical facilities using cache drugs to respond to local or national drug shortages. Caches can use up to 50 percent of most cache items to address a shortage if they have exhausted other options for attaining the item, and patients are in a life-threatening situation. Thirty-nine of 141 caches (28 percent) used cache drugs within the past six months in response to a national or local drug shortage (e.g., recent IV fluid shortage due to a plant being destroyed in Puerto Rico following Hurricane Maria in fall 2017). By comparison, only 18 caches (13 percent) used cache drugs in response to local or national drug shortages from mid-2015 to mid-2017. The increase in the use of caches to respond to drug availability issues impacting local facility operations highlights the need for caches to be ready, as well as the risks of allowing so many cache drugs to remain expired. EPS staff told the team that they generally replace drugs that have been used to address local or national shortages through the normal quarterly replacement cycle. Until that point in time, drugs that are used during shortages will not be available should a cache need to be activated in response to another emergency.

Medical Facilities Missed Opportunities to Use Soon-to-Expire Cache Drugs Because of Ineffective Management

PBM's Deputy Chief Consultant did not order replacement drugs in sufficient time to allow medical facilities to use soon-to-expire drugs in their general medical operations, as directed in EPS's *All-Hazards Emergency Caches Replenishment Procedures* policy. This occurred because EPS allowed cache drugs to expire before they were replaced. In general, the audit team found that drugs remained in the caches until they expired and were replaced by EPS, at which point drugs were either returned via a reverse distributor for partial credit or destroyed. The team found that most of the expiring drugs could have been used by medical facilities if EPS had replaced them before the drugs expired. Cache managers at the 26 caches the team visited reported that, on average, about 80 percent of cache drugs and supplies were usable in normal medical facility operations. In addition, an OIG pharmacist determined that 95 percent of cache drugs and supplies could be used at VHA medical facilities with inpatient and outpatient care, and up to 73 percent could be used at facilities that provide only outpatient care. The team estimates that continued failure to use soon-to-expire cache drugs that are not part of the SLEP for normal medical facility operations over the next five years will waste about 28 million units of drugs or about \$34 million.²⁶

Although most cache drugs could be used in normal medical facility operations, 62 percent of the cache managers (88 of 141) reported that their own medical facilities do not use soon-to-expire cache drugs in general medical facility operations. The largest barrier reported was insufficient lead time to use the existing drugs before their expiration date and subsequent replacement by EPS. Failing to use soon-to-expire cache drugs leads to waste and missed cost-saving opportunities as these drugs could have been used instead of having been replaced by new ones. During the team's on-site inspections, most of the directors and cache managers reported being concerned about the waste created by expired cache drug inventory. VA does not have a process in place to monitor whether EPS is replacing cache drugs in a time frame that allows medical facilities to use soon-to-expire drugs in their general pharmacy operations, to reduce waste and save costs.

Example 6

One of the cache managers told the audit team that it would have cost his facility \$30,000 to destroy expired IV fluids, so, instead, the facility had their pharmacy staff destroy the product, which was time and resource

²⁶ The audit team used its estimated amount and value of expired non-SLEP drugs and multiplied these values (1.4 million units and \$1.7 million) by four because, according to EPS's Inventory Management Specialist, EPS orders replacement cache drugs four times a year. The resulting annualized 5.6 million units and \$6.8 million were multiplied by five to arrive at the five-year estimate.

consuming. He would have preferred to use the product instead of wasting it.

Lack of Effective Governance Resulted in Inefficient Program Oversight

While VHA has articulated roles and responsibilities for the Emergency Cache Program in Directives 0320.10 and 1047(1), these responsibilities were not being filled at the time of the audit team's review.

- As of November 2017, the cross-office cache committees—including the Emergency Cache Program Review Committee and the Executive Cache Subcommittee tasked with making operational decisions and providing ongoing review and evaluation of the caches—had not met for the past few years. This was due, in part, to the reorganization of OPH, which was responsible for emergency cache policy and committee leadership. According to the Chief Consultant, Population Health Services, following a series of organizational changes at VHA from 2006 through 2016, OPH was decreased in size and scope and merged into Patient Care Services in October 2016. The Deputy Chief Patient Care Services Officer for Public Health retired in December 2016 and the position has not yet been authorized to be filled. All emergency cache decisions previously overseen by OPH would need to be made by the Acting Assistant Deputy Under Secretary for Health for Patient Care Services.
- From November 2017 through May 2018, all but one of the officials from OPH, OEM, and EPS with whom the team spoke with, were unaware of which office or person was responsible for taking on OPH's cache responsibilities, as outlined in VHA Directive 1047(1).
- In April 2018, OEM's Acting Director stated that VHA needed to revisit Emergency Cache Program policies and responsibilities to make sure they aligned with the strengths and capabilities of the current national offices.

At the time of the team's review, no program office or person was tasked with overall responsibility to ensure that the Emergency Cache Program was mission ready. Without assessing the specific roles and responsibilities that reflect the current status of the offices responsible for overseeing the Emergency Cache Program and identifying and remedying gaps in oversight and subject matter expertise, ineffective inventory management by EPS and by local cache managers will likely continue, as well as missed annual inspections by OEM, and a failure by medical facility directors to ensure activation exercises occur.

In addition to OPH's reorganization, there was a lack of oversight accountability among the three national offices tasked with overseeing the Emergency Cache Program.

For example, while OEM is responsible for the annual cache inspections, OEM did not consistently document inspection results and their associated corrective actions in FY 2017, and did not have a way to track, on a national level, the status of all identified violations. This creates a risk that caches are operating with violations that affect their ability to be ready to activate, or the security of the cache inventory items.

OEM's Acting Director and Field Program Manager acknowledged in April 2018 that the office had not been tracking the status of all identified violations on a national level, but also told the team that the annual inspection should be a shared responsibility. OEM has the expertise to review whether facilities are incorporating emergency cache policies into their standard operating plans. However, OEM officials told the team that other offices should be more involved in the inspection process. For example, EPS should be assessing the cache's controlled inventory and SLEP labels.

Example 7

OEM's Emergency Management Specialist told the audit team that there were no long-term violations at any cache location. However, the team identified a location with a documented violation from 2010 in which the cache storage room failed to meet security standards—the cache was located in the pharmacy separated by a locked metal gate. The cache storage area is not in compliance with VHA Directive 0320.10 because unauthorized access could be gained by climbing over the fence, or through section gaps. According to pharmacy personnel, this facility never had another location available to store its cache. As of the team's site visit in February 2018, this security violation persisted, and the facility had not developed an action plan to correct it.



Figure 4. Emergency cache storage location at an emergency cache.
(Source: VA OIG, Emergency Cache, 2/22/2018)

After the team conducted preliminary interviews with EPS, OEM, and OPH officials in November 2017, program officials reconvened the Emergency Cache Program Review Committee.

As of June 2018, the committee had:

- Completed a review of emergency cache inventory items and quantities, and prepared a presentation recommending several changes to both the type and quantity of drugs and supplies in the cache. Examples include eliminating some of the oral antibiotics and increasing the amount of others, increasing supplies necessary to administer IV antibiotics, and not replacing some of the drugs in the SLEP as they expired. This analysis was based on current threats.
- Started a review of VHA Directive 1047(1) to determine what needs to be updated given the reorganization of OPH, the recommended changes to cache inventory, and other recent occurrences. The Chief Consultant, Population Health Services, reported to the team that he expects updates to this directive to follow the normal process for review and approval. As of August 2018, draft revisions to the directive would task VA's Office of Security and Law Enforcement with carrying out annual cache inspections and reviewing cache security issues and inspection requirements.
- Initiated an effort to move to an electronic system for conducting and documenting the results of the emergency cache annual inspections, with the goal of being able to have electronically available information about identified violations and the status of corrective actions.

In addition, as of April 2018, EPS was placed under the responsibility of the Consolidated Mail Outpatient Pharmacy (CMOP), which is also under PBM. PBM's Chief Consultant reported to the team that this move is intended to allow EPS to make use of CMOP's contracting expertise for procuring drugs and supplies. At the time of this reorganization, a local supervisor was appointed from the CMOP to EPS. In April 2018, the team discussed the finding from the on-site inventory inspections—including the number and type of expired, missing, and excess drugs—with the Associate Deputy Chief Consultant of the CMOP, now charged with overseeing the Emergency Cache Program.

As of June 2018, because of the team's findings from the on-site inspections, EPS made, in its national inventory database, changes to how the "expiration date" variable is used. Specifically, for drugs that are in SLEP testing, EPS will keep the "expiration date" variable as the most recent actual expiration date—either the original expiration date or the most recent actual extended date. However, EPS's Inventory Management Specialist noted that EPS would implement this change moving forward but would not retroactively update the dates of that variable for the drugs that appeared in the team's sample and were in SLEP testing during the team's on-site inspections.

While this change should result in a more accurate accounting of the proportion of emergency cache drugs that are expired at any point in time, this information should still be available to local emergency caches so that they can easily identify which drugs in their caches are expired, in-date, or in SLEP testing, in the event of an emergency.

Conclusion

VHA has not been effectively managing its Emergency Cache Program and VHA officials gave no assurances the cache is ready to mobilize in the event of an emergency. VHA risks not having the drugs necessary to meet the emergency needs it might be facing because its emergency cache inventories carry expired, missing, or excess drugs. In addition, skipped annual inspections and activation exercises, designed to ensure that the caches are ready for activation at all times, put VHA at risk of having caches that are not ready to mobilize because of inadequate physical (e.g., a door is not wide enough for a cache cart), or similar issues. VHA has also been missing opportunities to leverage soon-to-expire cache-stored drugs that can support normal medical facility operations. The development of a process to time the replacement, replenishment, repurposing, redistribution, and disposition of existing cache-drugs that are soon-to-expire, but still usable, would help cache managers to minimize the waste of drugs and medical supplies. Without efforts to identify and leverage VA-wide expertise to improve program oversight and accountability, the Emergency Cache Program will not be equipped, as intended, to be responsive to a terrorist, biological, or natural disaster.

Recommendations 1–7

Recommendation 1. The Executive in Charge, Veterans Health Administration, should develop requirements for medical facilities with emergency caches to perform at least annually a wall-to-wall inventory of all cache drugs and supplies, and develop processes to (1) label all expired or excess drugs that are purposefully maintained to respond to drug shortages or for the purposes of Shelf Life Extension testing, and (2) remove and rectify cases of other expired, missing, or excess drugs.

Recommendation 2. The Executive in Charge, Veterans Health Administration, should conduct an assessment to determine if the cost saving benefits of the Shelf Life Extension Program outweigh the risks expired drugs pose to the emergency cache’s mission and to take corrective action as appropriate.

Recommendation 3. The Executive in Charge, Veterans Health Administration, should improve emergency cache inventory management processes to ensure emergency cache national inventory data sorted by location is reliable and accurately identifies the expiration dates of all cache contents, including Shelf Life Extension Program drugs, and that this information is electronically accessible to each facility.

Recommendation 4. The Executive in Charge, Veterans Health Administration, should initiate steps to update and reissue the Veterans Health Administration directives specifying oversight responsibilities for the Emergency Cache Program with a requirement for inventory to be timely rotated into the emergency cache after it is received.

Recommendation 5. The Executive in Charge, Veterans Health Administration, should assess whether the Emergency Cache Program is properly aligned within VA and coordinate with other VA offices as necessary to determine the appropriate roles and responsibilities by program office, and then review, update, and reissue Emergency Cache Program requirements to include (1) robust annual cache inspection and activation exercise requirements, (2) processes to ensure cache inspection and activation requirements are met, (3) processes to ensure that violations identified during annual cache inspections are timely addressed, and (4) specific accountability measures for the program offices and local facility personnel responsible for program oversight.

Recommendation 6. The Executive in Charge, Veterans Health Administration, should conduct a comprehensive assessment of the cache inventory to identify drugs and supplies that can be readily used in medical facilities’ general operations and develop a mechanism to monitor and ensure medical facilities are maximizing the use of these items before they expire.

Recommendation 7. The Executive in Charge, Veterans Health Administration, should initiate steps to update and reissue the Veterans Health Administration directives specifying oversight responsibilities for the Emergency Cache Program to reflect the Office of Public Health’s reorganization and reassign responsibilities as needed.

Management Comments

The VHA Executive in Charge concurred with Recommendations 1, 3, 4, 5, and 7 of the report and concurred in principle with Recommendations 2 and 6. To address Recommendation 1, PBM will work with OEM to provide internal training for cache managers, AEMs, and other internal stakeholders on a new requirement to complete annual cache wall-to-wall inventory inspections, and to remove expired or excess drugs from the cache that are not being purposefully kept. PBM will also develop processes to ensure purposefully maintained expired or excess cache drugs are clearly identified and labeled. Related to Recommendation 2, the Executive in Charge explained that preliminary work will be required to determine the feasibility and generalizability of a full assessment of whether the cost saving benefits of continued participation in SLEP outweigh the risks expired drugs pose to the cache's mission. If sufficient data exist, VHA's Population Health will compare the cost and effect of full participation in SLEP to partial participation or no participation, and will collaborate with the Department of Defense and FDA on potential improvements to SLEP participation. Any change to SLEP participation will be reflected in an updated VHA policy.

To address Recommendation 3, PBM will implement changes to its national inventory database and make emergency cache contents and expiration date information available to cache managers. To address Recommendation 4, VHA's Population Health will review, update, and reissue the directives governing the Emergency Cache Program to include requirements for inventory to be timely rotated into the cache upon receipt. To respond to Recommendation 5, OEM will collaborate with Population Health, PBM, and VA's Office of Operations Security and Preparedness to review, update, and reissue Emergency Cache requirements designed to (1) increase to robustness of annual cache inspection and activation exercises, (2) ensure that these activities are occurring and that identified violations are addressed, and (3) include specific accountability measures for responsible VHA program offices and facility-personnel.

In response to Recommendation 6, the Executive in Charge reported that in some cases, specifically for very low-cost items, it can cost more to rotate supplies into general medical facility operations than to return them for reverse distribution or destruction and purchase new supplies, while in other cases, cache supplies are not used in routine medical care. PBM will conduct a feasibility analysis to determine whether any cache drugs can be used in general medical facility operations, and if such a process is deemed feasible, PBM will educate the field on how to do so. PBM will also start to ship replacement items well ahead of drug expiration dates. For Recommendation 7, Population Health will review, update, and reissue the directives governing the Emergency Cache Program to specify current oversight responsibilities, and to reflect any future reorganizations and reassignments.

In addition to commenting on the audit team's recommendations, the VHA Executive in Charge asked that the OIG consider the sensitive nature of the Emergency Cache Program contents and

locations and protect the disclosure of information that could adversely compromise the physical security of the caches.

OIG Response

The Executive in Charge's planned corrective actions are responsive to Recommendations 1, 3, 4, 5, and 7, and should address the issues identified in the report. While the Executive in Charge agreed with Recommendation 2 in principle and the planned actions are responsive, the OIG maintains that additional steps should also be taken. Determining whether the information is available to conduct a cost savings benefit analysis of continued SLEP participation is an appropriate initial response. However, even if the necessary information for a full program assessment is not available, PBM should use the best available information to determine whether continued participation in SLEP outweighs the risk associated with drugs that are expired as they await SLEP testing.

For Recommendation 6, while the Executive in Charge agreed with Recommendation 6 in principle and the planned actions are responsive, the OIG maintains that additional, immediate actions should also be taken. VHA should assess the use of, and begin to use in general pharmacy operations, soon-to-expire cache drugs that can readily and efficiently be used in a facility's inpatient or outpatient pharmacy operations. To maximize the use of soon-to-expire cache drugs at VHA facilities, VHA must take immediate steps to ensure that inventory to replace such drugs is delivered to facilities well in advance of their expiration dates. Finally, VHA should take immediate steps to educate facility pharmacy personnel on maximizing the use of expiring cache drugs.

In addition to commenting on the audit team's recommendations, the VHA Executive in Charge asked that the OIG consider the sensitive nature of the Emergency Cache Program contents and locations and to protect the disclosure of information that could adversely compromise the physical security of the caches. While there is no direct statutory or regulatory requirement for this information to be classified, the OIG shares VHA's goal of not impeding the ability of the Emergency Cache Program to meet its mission and function as intended during an emergency. The audit team took the following steps: (1) removed the names of cache drugs that are not commonly stocked by medical facility pharmacies and whose use is designated specifically for emergencies, such as nuclear disasters, (2) removed the names of the medical facilities that the audit team visited to inspect 26 caches, and (3) ensured that no metadata were linked to any pictures of cache photographs that are in the report. The examples of cache drugs that remain in this report are all examples of drugs that are commonly stocked by medical facility pharmacies, and as a result do not pose a risk to the Emergency Cache Program's operations and mission with disclosure.

The OIG will monitor VHA's progress and follow up on implementation of the recommendations until all proposed actions are completed. Appendix F provides the full text of the Executive in Charge's comments.

Appendix A: Background

Additional information on the governance structure and responsibilities of the Emergency Cache Program follows:

Governance Structure for Emergency Cache Program

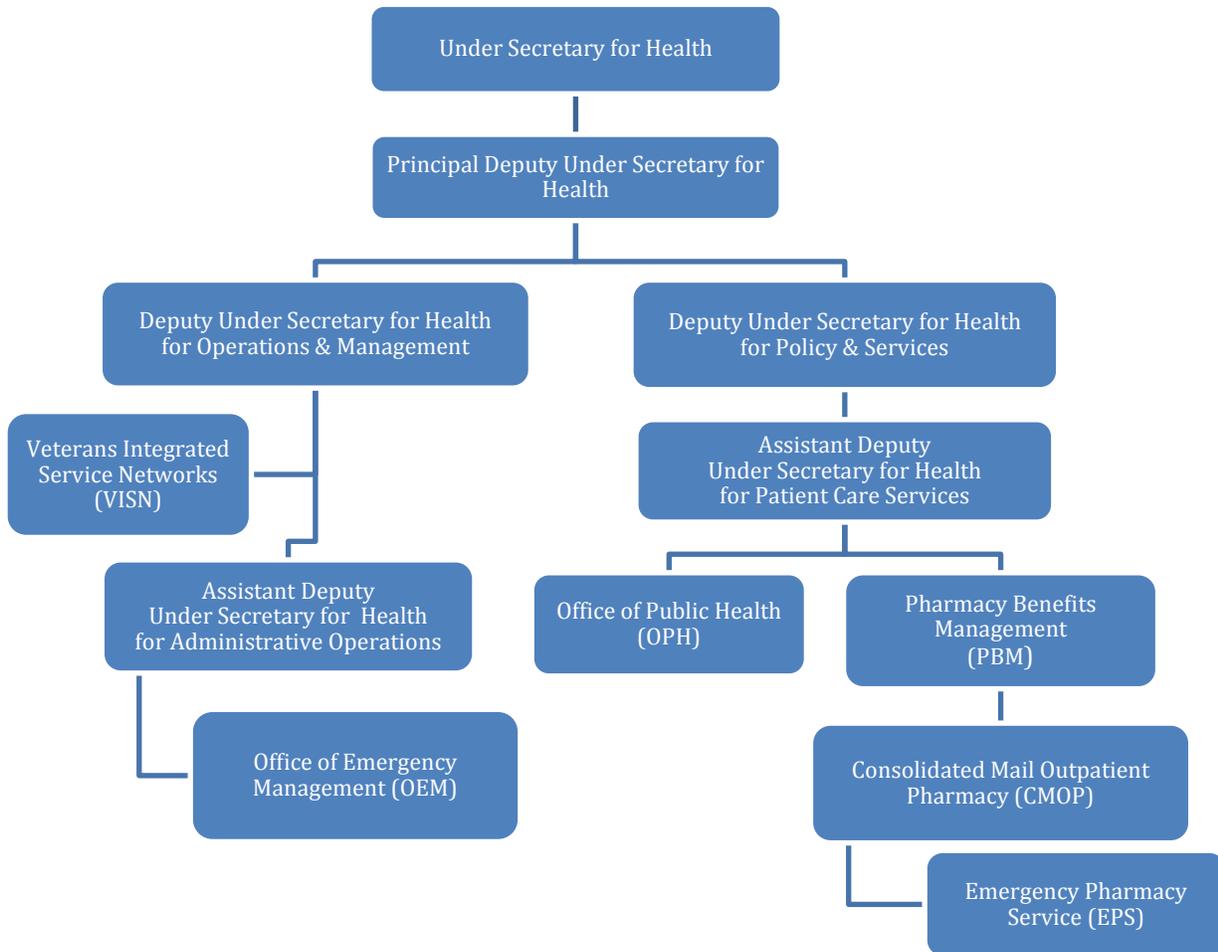


Figure 5. Emergency Cache Program governance structure.
(Source: VA OIG analysis of VHA organizational charts)

Program Oversight for the Emergency Cache Program

VHA Directive 0320.10, *Inspection of VA All-Hazard Emergency Caches by the VHA Office of Emergency Management*, July 26, 2017, and VHA Directive 1047(1), *All-Hazards Emergency Caches*, December 30, 2014, document program oversight responsibilities for the Emergency Cache Program.

VHA Directive 0320.10, Inspection of All-Hazard Emergency Caches by the VHA Office of Emergency Management

VHA Directive 0320.10 outlines the requirements for the emergency cache annual inspections, noting that it is VHA policy that inspections are conducted on an annual basis, to ensure the readiness of each cache. The Deputy Under Secretary for Health for Operations and Management or designee is responsible for ensuring “the execution and support to fulfill the operating needs of this directive” and that the requirements of this directive are met and related issues addressed through the appropriate clinical or administrative service.

- The Director, OEM is responsible for: (1) assigning Area Emergency Managers or Regional Emergency Managers to conduct inspections at VA medical facilities with caches; (2) reviewing any recommendations for improvement to OEM inspection of the emergency caches, during monthly OEM Management Review Board meetings; and (3) reviewing and forwarding the final summary report with proposed corrective actions to the Deputy Under Secretary for Health for Operations and Management.
- Area Emergency Managers and Regional Emergency Managers are responsible for: (1) coordinating and conducting a plan in conjunction with the Pharmacy Service staff to ensure that each cache in their area of responsibility is inspected on an annual basis within each fiscal year; (2) using the checklist in the directive as the foundation for the inspection; (3) drafting an inspection report/checklist for review and comment by the local VA medical facility’s chief of pharmacy, facility’s cache manager as appointed by the facility’s Pharmacy Service, and VA medical facility’s Emergency Manager within two weeks of completion of the cache inspection; (4) following the VA medical facility’s input, and within two weeks of submitting the draft report to the VA medical facility, the Area Emergency Manager forwards the final inspection report/checklist to the VA medical facility director, chief of pharmacy; VISN Director, Pharmacy Executive, and Emergency Manager, and OEM Regional Emergency Manager; and (5) making sure the Regional Emergency Manager is made responsible for forwarding the final inspection report/checklist upon receipt to EPS, OPH, OEM, and the Cache Inspection Subcommittee.
- The VA medical facility director is responsible for reviewing and approving the final Emergency Cache Inspection Report and ensures a corrective action plan is developed and approved as appropriate.
- The Cache Inspection Subcommittee, composed of subject matter experts across VHA and appointed by the Emergency Cache Program Review Committee, is responsible for providing an annual summary report of all inspections that includes findings and recommendations to the Emergency Cache Review Executive Cache

Subcommittee. The Emergency Cache Review Executive Committee is responsible for providing a copy of the annual summary report along with their recommendations to the OEM Director.

- EPS is responsible for: (1) serving as the logistical experts and collaborating with VA medical facilities to resolve any deficiencies that are identified; (2) providing follow-up site inspections to further evaluate the need for corrective action(s) at the request of VHA OEM, a VISN office, or a local VA medical facility; and (3) providing guidance to remedy identified deficiencies.
- Annual emergency cache inspections are conducted by OEM's Area and Regional Emergency Managers within assigned geographic areas using standardized criteria.

VHA Directive 1047(1) All-Hazards Emergency Caches

VHA Directive 1047(1) establishes authority and policy for the configuration, maintenance, and activation of the Emergency Cache Program.²⁷ The directive outlines the following roles:

- The Under Secretary for Health, responsible for: (1) determining which VA medical facilities receive a cache and the size of that cache; (2) ensuring that, to the extent permitted by applicable law or regulation, the contents or locations of the emergency caches are proprietary to VA and are not released to any person or agency external to VA without approval of the Under Secretary for Health; and (3) ensuring that aggregated data consisting of all cache locations, contents, or capabilities are not released, but will remain in the exclusive control of EPS personnel.
- The Emergency Cache Program Review Committee, responsible for: (1) performing/ conducting ongoing review and evaluation of the program; (2) recommending to the Under Secretary for Health when revisions in cache products, quantities, locations, and sizes are required; (3) making operational decisions concerning the cache; (4) developing directives and handbooks to meet VA's role in disaster preparedness and response; and (5) developing standardized training and educational materials, and providing medical facility staff training; and educational materials, and information regarding the cache and its contents.
- OPH, responsible for: (1) providing representation on the Emergency Cache Program Review Committee; (2) providing leadership of the committee, coordinating committee activities, and serving as a member of the Executive Cache Subcommittee; (3) providing subject matter expertise in public health and cache contents; and (4) updating caches and associated directives.

²⁷ 42 U.S.C. 5170a(1), 5170b(a), 5192; 42 U.S.C. 300hh-11(b); 38 U.S.C. 1785; 38 CFR 17.86.

- OEM, responsible for: (1) providing representation on the Emergency Cache Program Review Committee; (2) serving as a member of the Executive Cache Subcommittee; (3) conducting an annual inspection and review of each cache; (4) reporting on the functional status and operational capabilities to include expired and out-of-date cache products; and (5) providing subject matter expertise in response planning and linkage to the VHA First Receivers Decontamination Program.
- EPS, responsible for: (1) providing representation on the Emergency Cache Program Review Committee; (2) providing representation to serve as a member of the Executive Cache Subcommittee; (3) providing subject matter expertise for cache logistics and pharmacy issues; (4) maintaining a central or regional cache of limited items at the direction of the Committee; (5) centrally purchasing products, standardizing the cache configuration based on category of product (burn, biological, chemical, radiological), and shipping products to the caches; (6) maintaining a centralized inventory record; (7) centrally purchasing and shipping replacement products to each cache in advance of product expiration dates; (8) managing the shelf life extension of selected pharmaceuticals in the cache using the Shelf Life Extension Program (SLEP); (9) providing new labels and guidance on labeling of SLEP drugs; (10) managing the stock rotation program which is performed by local medical facility staff; (11) developing specific operating procedures for the storage, handling, and inspection of the cache.; (12) providing guidance as to the proper management of the caches; and (13) posting and maintaining Emergency Cache Program information on the EPS website.
- The Executive Cache Subcommittee, composed of the Emergency Cache Program Review Committee members representing OPH, OEM, and EPS, and responsible for: (1) resolving minor cache-related issues and questions that do not require full Emergency Cache Program Review Committee decisions; (2) scheduling and determining the agenda for Emergency Cache Program Review Committee conference calls and meetings; (3) preparing minutes and summaries of Emergency Cache Program Review Committee conference calls and meetings for review and approval of members; and (4) reporting on minor cache-related issues and questions raised between routine meetings and conference calls to the Emergency Cache Program Review Committee.
- Veterans Integrated Service Network Directors, responsible for: (1) Ensuring that their Emergency Operations Plans incorporate access, distribution, and use of the cache(s) located within each VISN; and (2) making sure that each medical facility in every VISN maintains compliance with cache program guidance.
- VA medical facility directors, responsible for: (1) coordinating with the OEM Regional Managers and Area Emergency Managers to work with local and state

public health and emergency officials to encourage understanding of VA medical centers' potential roles in planning and response activities and establishing agreements with applicable agencies, as appropriate, including acquisition of medical countermeasures from the Strategic National Stockpile; (2) activating the cache when a local, regional, or national emergency warrants its use; (3) ensuring the VHA Watch Office is notified immediately upon activation of a cache; (4) ensuring caches are stored and secured in compliance with criteria in this directive; (5) ensuring VA personnel comply with their responsibilities for public discussion of the VA cache, which outlines publicly releasable information; (6) providing the necessary space to ensure cache items are not intermingled with medical facility pharmacy inventory; (7) ensuring designated cache space is capable of maintaining appropriate controlled room temperature for pharmaceuticals and supplies; (8) ensuring the cache space meets the building and life safety codes requirements and has the required fire, smoke, and intrusion alarm systems; (9) ensuring all cache controlled substances are subject to the unannounced monthly controlled substance inspection process; (10) appointing a medical facility liaison to EPS; (11) providing all necessary training for emergency and medical personnel, as appropriate, on use of non-formulary pharmaceuticals, medical supplies, and equipment contained in the cache; (12) ensuring policy on access, distribution, and use of the cache is incorporated into the facility's Emergency Operations Plan that includes tracking of intended receivers and distributed pharmaceutical products as part of the plan; and (13) ensuring simulation of emergency activation and deployment of the cache is conducted at least annually. Training exercises using the actual cache carts are encouraged; removing the cache carts from the cache area and opening the cache carts for training purposes must be requested in advance via a memo to EPS.

- VA medical facility chief of pharmacy services (cache manager), responsible for: (1) ensuring all inspections and inventories are completed and documented in accordance with criteria established by EPS; (2) ensuring completion of cache product rotation and inventory system entries in a timely manner and as required by EPS; (3) making available for the medical facility use, any item rotated out of the cache in the EPS-managed rotation schedule; (4) processing expired items through the contracted reverse distributor with all credits being applied to the medical facility account using the Prime Vendor Program; (5) ensuring all cache items are stored separately from pharmacy inventory to maintain the integrity of the cache and continuous emergency preparedness. Emergency-related supplies may only be stored in the cache area if the facility has received a written waiver from EPS. The waivers need to be renewed every five years; (6) ensuring that all cache items requiring refrigeration are stored in the refrigerator provided and maintained at the appropriate temperature; and (7) ensuring complete management of all cache

controlled substances as required by VA regulations and Title 21 of the Code of Federal Regulations.

Prior VA OIG Report on the Emergency Cache Program

In 2014, the OIG issued *Combined Assessment Program Summary Report: Evaluation of the Controlled Substances Inspection Program at Veterans Health Administration Facilities* (Report No. 14-01785-184, June 10, 2014). The OIG concluded that 11 out of 63 VA medical facilities did not conduct the required quarterly physical count of controlled substances within the emergency caches, and they also did not conduct monthly verifications of the seals on the emergency cache controlled substance containers. The OIG recommended that VHA ensure that controlled substance inspectors perform quarterly physical counts of the emergency caches' controlled substance inventory, conduct monthly verifications of the seals, and monitor compliance with applicable inspection policies. VHA concurred with the recommendation and stated that it would issue a memo to reinforce these requirements. In January 2015, the OIG determined this recommendation was closed as implemented.

Appendix B: Scope and Methodology

Scope

The audit team conducted its work from January to August 2018. The scope of the audit, which included all 141 emergency caches, focused on whether the caches were ready for immediate mobilization in the event of an emergency. The audit work included interviews with program staff from the national offices responsible for overseeing the Emergency Cache Program and with medical facility staff responsible for managing the emergency cache at a sample of caches. In addition, the team performed an inventory inspection of a sample of drugs at 26 emergency caches, and reviewed annual cache inspection and activation exercise reports.

Methodology

To gain an understanding of the Emergency Cache Program, the team examined relevant criteria, including applicable laws and VHA directives. Applicable laws include:

- Public Law 107-287, Title 38 United States Code § 1785 and § 8117, *Department of Veterans Affairs Emergency Preparedness Act of 2002*
- Public Law 107-188, Title 42 United States Code § 2811 and § 121, *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*
- VHA Directive 1047(1), *All-Hazards Emergency Caches*
- VHA Directive 0320.10, *Inspection of VA All-Hazard Emergency Caches by the VHA Office of Emergency Management*

The team interviewed key staff from the three VHA offices responsible for overseeing the Emergency Cache Program—EPS, OEM, and OPH—to determine whether these offices were effectively overseeing and managing the Emergency Cache Program. During the interviews, the team discussed the oversight roles and responsibilities outlined in VHA’s cache-specific directives, whether the offices were filling these roles and whether there was coordination between offices.

Site Visits

The audit team conducted unannounced site visits at 26 medical facilities that were selected based on several factors including distance from another emergency cache and proximity to an OIG field office. During the unannounced site visits, the team interviewed staff responsible for overseeing and managing the caches, including medical facility directors, chiefs of pharmacy, and other staff with cache-specific or emergency management responsibilities. The interviews provided information on how the emergency caches were managed at the local level and the type

of oversight provided from the national offices to the local caches. The team also took pictures of cache security violations that were identified during site visits. The team worked with OIG information security specialists to ensure that the location of caches pictured in the report cannot be identified. Table 2 provides more details on the regional locations of the sites visited.

Table 2: Regional Locations of VA Medical Facilities That Received Unannounced Site Visits from VA OIG, February 2018

Region	Number of site visits
North Atlantic	2
Southeast	4
Midwest	17
Continental	2
Pacific	1
Total	26

Source: VA OIG statistical sample of emergency cache site visits

The team also interviewed VISN pharmacy executives from the eight VISNs in which the 26 caches were located, to determine whether the VISNs had any responsibility for the emergency caches.

Data Collection Instrument

The audit team developed an electronic Data Collection Instrument to use for an inventory inspection of a sample of 25 out of 38 drugs at each of the 26 emergency caches visited.²⁸ The inventory inspection was used to determine if cache drugs were expired, missing, or in excess, and if EPS’s national inventory database records were accurate. The instrument was populated with information from EPS’s national inventory database specific to each of the 26 caches in the team’s sample—drug type, quantity, lot number, expiration date—prior to the team’s site visits. During the site visits, the team documented information about the 25 drugs that were physically present at each cache (or not, if they were missing), which was compared to the information from EPS’s national inventory database. The results from this comparison were used to assess the accuracy of EPS’s national inventory database. The team took steps in the development of the Data Collection Instrument to ensure the collection of accurate information and incorporated second-level reviews of the tool by a second analyst at each site visit.

²⁸ The 38 drugs in the audit team’s universe are the drugs found at all emergency cache locations. Three additional drugs are held at selected cache locations and were not included in the sample universe.

Cache Manager Survey

The audit team conducted an online survey of the 141 VA medical facilities with operational emergency caches from February 20 through March 16, 2018. The survey focused on how cache drugs and supplies were rotated into the cache, how expiring drugs were managed, if any cache drugs or supplies had been used, and on any completed FY 2017 annual cache inspections and activation exercises. The team obtained a 100 percent response rate. The survey, which was sent to the chief of pharmacy at each medical facility with an emergency cache, requested a response from the most appropriate pharmacy personnel(s) through a SharePoint survey site. Respondents were asked to include documentation of their FY 2017 annual cache inspection and cache activation exercise if these occurred.

Fraud Assessment

The audit team assessed the risk that fraud, violations of legal and regulatory requirements, and abuse could occur within the context of the audit objective. Alerted to these risks, the team exercised due diligence in taking the following actions:

- Coordinated with the OIG's Office of Investigations concerning potential fraud indicators
- Examined the survey results reported by cache managers to identify potentially fraudulent activities involving cache inventory items
- Asked about the risk of fraud, waste, or abuse during interviews with medical center directors, chiefs of pharmacy, and with other medical facility personnel involved in the management of local emergency caches
- Considered potential fraud indicators when reviewing documentation collected during data gathering, such as looking at whether there were large variations in cache purchasing data from a month-to-month or year-to-year timeframe

The team did not identify any instances of potential fraud specific to the Emergency Cache Program during this audit.

Data Reliability

The audit team assessed the reliability of data from EPS's national inventory database—DynaMed—that include information about the type, quantity, lot number, and expiration date for all cache drugs and supplies. The team assessed the reliability of DynaMed data from January and February 2018 to determine if it was sufficiently reliable for documenting the drugs that should be on-site at each cache location. To determine the reliability of this information, an inventory inspection was performed on 25 drugs at each of the 26 site visit locations, including information on drug types, lot numbers, expiration dates, and location in the caches. In total, 650 items were inventoried and compared to the DynaMed report provided by EPS. The team

also interviewed key staff at the company that owns the hardware and software platform on which DynaMed operates and EPS staff who oversee and manage the DynaMed inventory tracking system for the emergency cache. In both interviews, the team discussed data access; any verification and internal controls in place to ensure that data entered into the system are accurate and complete; and any other data reliability, accuracy, or validity issues that may exist. Based on this reliability assessment, the team concluded these data were appropriate and sufficient for the purposes of the audit.

The team also assessed the reliability of VA's Financial Management System data to determine if they were sufficient for calculating emergency cache purchases for FY 2017 and for the first six months of FY 2018. The team discussed the reliability of cache purchasing data with responsible EPS staff. Data analysts performed data reliability tests on each data request for the Financial Management System data for FYs 2017 and 2018 on Emergency Cache Program purchases prior to providing the computer-processed data to the team. The team also reviewed the data for obvious errors and followed up on outliers. Based on these reliability assessments, the team concluded these data were appropriate and sufficient for the purposes of the audit.

Finally, the team assessed the reliability of cost data provided by EPS for the present-day value of the replacement cost of expired, missing, and excess drugs identified during the 26 site visits to determine if they were reliable enough to calculate current cost. EPS provided the team with current cost data for all 38 cache drugs, which the team verified through the VHA Prime Vendor, or through reviews of EPS specific contracts and purchase orders. Based on this reliability assessment, the team concluded these data were appropriate and sufficient for the purposes of the audit.

Government Standards

We conducted this performance audit in accordance with generally accepted government auditing standards. These standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for the report's findings and conclusions based on the audit objective. We believe that the evidence obtained provides a reasonable basis for its findings and conclusions based on the audit objective.

Appendix C: Statistical Sampling Methodology

Sampling Methodology

The audit team obtained from EPS a list of the 141 emergency cache sites that were active as of January 2018. From these data, the team selected a stratified random sample of 26 cache locations for unannounced site visits. Because the team's results were based on this sample of cache locations, the team projected findings from this sample onto the universe of 141 emergency caches.

The team obtained from EPS a list of the 85 emergency cache drugs and medical supplies (38 drugs were at all caches, three were at selected caches, and 44 were medical supplies). For the 38 drugs that were present at all cache locations, the team judgmentally selected the five drugs that had the highest cost at the time of purchase and selected a random sample of 20 additional drugs, for a total sample of 25 drugs. These 25 drugs were inspected during a physical inventory inspection at each of the 26 unannounced site visits, to document the quantity, lot number(s), location within the cache, and expiration date. Because the team's results were based on a statistical sample, the OIG statistician projected findings from the inventory inspection onto the universe of all 141 emergency cache locations. The statistician calculated the number of emergency caches with expired drugs and projected the number with missing, and/or excess drugs. The statistician also projected the total quantity and associated present-day value of the expired drugs.

The team removed Tamiflu from its national projections because this flu medication functions differently from the other 37 drugs in the emergency cache, both in terms of quantity and price. According to EPS's Emergency Pharmacy Specialist, Tamiflu is held in much greater quantities than required by the emergency cache standards because of a 2008 White House Security Council recommendation for VA to house additional pandemic supplies. As of February 2018, the emergency cache had about 35.3 million units of Tamiflu compared to the basic requirement to carry about 7.4 million units. In addition, most of the Tamiflu had been purchased at a contracted rate of about \$20 per pack but would cost about \$90 per pack to replace in present-day value—a much greater price variation between cost paid and present-day value than for other emergency cache drugs.

Population

The universe of emergency caches was all 141 emergency cache locations as of January 2018. The universe of emergency cache inventory was the 38 drugs found stored at all emergency cache locations, as of January 2018.

Sampling Design

The sampling design for the emergency cache site visits was organized into five strata. Table 3 identifies each of the five strata, the number of sites included in each stratum, and the number of sites selected in each stratum.

Table 3: VA OIG Emergency Cache Site Visit Selection Criteria

Stratum	Definition	Number of clusters	Number of emergency caches (Total = 141)	Number of emergency caches selected (Total = 26)
1	Cluster of two cache locations in which the caches are less than 70 miles apart, and one of the cache locations is served by a major or municipal airport	19 clusters of 2 sites per cluster	38	4 clusters of 2 = 8 emergency caches
2	Cluster of two cache locations in which the caches are 70 to 130 miles apart, and one of the cache locations is served by a major or municipal airport	18 clusters of 2 sites, and 2 clusters of 3 sites	42	3 clusters of 2 and 1 cluster of 3 = 9 emergency caches
3	Stand-alone cache location that is greater than 130 miles from another cache site or a closer cache is already part of strata 1 or 2	NA	43	3 emergency caches
4	Cache location that is within 50 miles of an OIG field office	NA	16	4 emergency caches
5	Training cache sites	NA	2	2 emergency caches

Source: VA OIG analysis of EPS information on emergency cache locations, map information on distance between caches, and OIG office location information, to select sample of caches for site visits

The sampling design for the emergency cache drugs inspection was organized into two strata. Prior to identifying the two strata, the audit team first analyzed the universe of 85 emergency cache inventory items and removed all medical supplies, as well as the three drugs that are not in all emergency cache locations, leaving only the 38 drugs that are stored at each emergency cache location. The resulting sample universe was comprised of the 38 remaining drugs. From the sample universe, five drugs with the highest cost based on the most recent purchase price were selected judgmentally, and 20 additional drugs were randomly sampled, for a total sample of 25 drugs.

Weights

The OIG statistician calculated estimates in this report using weighted sample data. Sampling weights are computed by taking the product of the inverse of the probabilities of selection at each stage of sampling.

Projections and Margins of Error

The OIG statistician employed WesVar software to calculate the weighted population estimates and associated sampling errors. WesVar uses a replication methodology to calculate margins of error and confidence intervals that correctly account for the complexity of the sample design.

The margins of error and confidence intervals are indicators of the precision of the estimates. If the audit team repeated this audit with multiple samples, the confidence intervals would differ for each sample, but would include the true population value 90 percent of the time.

Table 4 details the audit projection for the number of emergency cache sites that contain at least one missing, and/or excess drug.

Table 4. Number of Emergency Cache Program Locations with Missing and/or Excess Drugs

Category	Estimate	Margin of error	90% Confidence interval lower limit	90% Confidence interval upper limit	Sample count
Missing and/or excess drugs	59	22	37	82	14*
Percent	42	15	27	57	14*

Source: VA OIG analysis of random sample of 26 emergency cache inspections of 25 drugs, February 2018

**The audit team identified six caches that had missing drugs, two caches that excess drugs, and six caches that had both missing and excess drugs for a total of 14 caches.*

Table 5 details the audit projection for the quantity and present-day value of the replacement cost of drugs that are expired across all emergency cache locations, based on the drugs included in the sample universe. This projection includes the estimated potential units and monetary benefits used to calculate the five-year estimate shown in Appendix D.

Table 5. National Quantity and Present-Day Value of Expired Emergency Cache Program Drugs

Category	Estimate	Margin of error	90% Confidence interval lower limit	90% Confidence interval upper limit	Sample count
Expired quantity: SLEP eligible	4,722,748	561,906	4,160,842	5,284,654	1,561
Expired quantity: non-SLEP eligible	1,369,055	497,460	871,594	1,866,515	2,763
Total expired quantity	6,091,803	617,056	5,474,747	6,708,858	4,324
Expired cost: SLEP eligible	\$2,885,688	\$156,965	\$2,728,723	\$3,042,653	1,561
Expired cost: non-SLEP eligible	\$1,689,086	\$684,087	\$1,004,999	\$2,373,173	2,763
Total expired cost	\$4,574,774	\$709,050	\$3,865,725	\$5,283,824	4,324

Source: VA OIG analysis of 26 emergency cache inspections of 25 drugs, February 2018

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

Source: The audit team's Better Use of Funds total is based on the value of excess and missing Emergency

Recommendation	Explanation of benefits	Better use of funds	Questioned costs
1 and 6	Value of missing emergency cache drugs as of February 2018	\$120,533 ²⁹	
1 and 6	Value of excess emergency cache drugs as of February 2018	\$143,052 ³⁰	
1 and 6	Value of expired non-SLEP eligible emergency cache drugs expected to be wasted over the next five years unless better processes are developed for utilization of soon-to-expire cache drugs in normal medical facility operations	\$34,000,000 ³¹	
	Total	\$34,263,584	

Cache Program drugs that were identified during the 26 site visits in February 2018, plus the projected national value of expired non-SLEP eligible drugs, specific to the 25 drugs in the team's sample

²⁹ This value represents the cost to replace the missing drugs the audit team identified at 12 of the 26 cache locations the team inspected.

³⁰ This value represents the present-day value of excess drugs the audit team identified at eight of the 26 cache locations the team inspected.

³¹ This value represents an estimate of the value of expired drugs for all VA caches. The audit team used its estimated amount and value of expired non-SLEP drugs and multiplied these values (1.4 million units and \$1.7 million) by four because, according to EPS's Inventory Management Specialist, EPS orders replacement cache drugs four times a year. The resulting annualized 5.6 million units and \$6.8 million were multiple by five to arrive at the five-year estimate.

Appendix E: Emergency Cache Program Annual Inspection Checklist

VA Medical Facility:	VHA OEM Representative:	Month/Date/Year:	
<p>Goal: The VA Medical Facility maintains a written plan for the All-Hazard Emergency Cache in accordance with VHA Directives and Handbooks. Each medical facility is responsible for the policy and procedures for the activation and utilization of the cache items in response to an emergency or disaster.</p>			
Date of last Inspection:			
Objective 1- Facility Plans/Policy/Procedures Policy/Procedures address at a minimum the following elements:	YES	NO	COMMENTS/ RECOMMENDATIONS
<p>1.1 Is the local Pharmacy Cache policy in compliance with VHA Directive 1047(1)?</p> <p>The following should be included in the policy:</p> <ul style="list-style-type: none"> A. Does the written local policy describe procedures for the storage, handling, and inspection of a cache of pharmaceuticals, equipment and medical supplies reserved specifically for the treatment of casualties from a mass casualty event? B. Does the policy describe how to prepare to provide medication and supplies to a large influx of casualties during a mass casualty event? <ul style="list-style-type: none"> • Local Policy #: _____ Date: _____ <p>Reference: VHA Directive 1047(1); page 6, Section 4 h.</p>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>1.2 Does the policy designate a liaison to assist the Pharmacy Benefits Management Emergency Pharmacy Service (PBM/EPS) with the stock rotation program, cache inventory requirements, and accountability for the caches?</p> <p>Reference: VHA Directive 1047(1); page 7, section 4 h(10)</p>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>1.3 Does the policy describe who at the facility can activate the cache?</p> <p>Reference: VHA Directive 1047(1); page 6, section 4h</p>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>1.4 Does the policy incorporate the immediate notification of cache activation by contacting 202-461-0268 or 202-461-0269, or by emailing WatchOfficer-VHA@va.gov?</p> <p>Reference: VHA Directive 1047(1); page 7, section 4 h(3)</p>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>1.5 Does the VA medical facility cache policy describe access, distribution, and use of the cache? Is the policy incorporated into the VA medical facility's Emergency Operations Plan? Does the facility's EOP include tracking intended receivers and distributed pharmaceutical products?</p> <p>Reference: VHA Directive 1047(1); page 7, section 4 h(12)</p>	<input type="checkbox"/>	<input type="checkbox"/>	
<p>1.6 Does the policy establish stock rotation of cache supplies and drugs based on expiration dates, including procedures to rotate out expired supplies and drugs through appropriate methods?</p> <p>Reference: VHA Directive 1047(1); page 8, section 4 i(2)(4)</p>	<input type="checkbox"/>	<input type="checkbox"/>	

Objective 2- Physical Security Procedures address at a minimum the following processes:	YES	NO	COMMENTS/ RECOMMENDATIONS
2.1 Is there an electronic security system to monitor and control access to areas of the cache containing controlled substances? References: VHA Directive 1047(1); Page 6, section 4 h(4); Appendix B, page B-4, section 2i	<input type="checkbox"/>	<input type="checkbox"/>	
2.2 Is the cache space in a climate-controlled environment with room temperature between 68 to 77 degrees Fahrenheit? (Brief deviations between 59 to 86 degrees Fahrenheit are permitted) Temperature. Environmental controls must be in place to ensure that the temperature in the cache storage area is maintained. A. The cache space must contain a thermometer or equivalent electronic temperature monitoring device. B. A log of weekly ambient temperature readings including temperature excursions in case of an extended power outage is maintained and stored in the cache space. C. All cache items that need refrigeration must be stored in the refrigerator provided and set at the proper temperature. D. A log of weekly refrigerator temperature reading is maintained and stored in the cache space. References: VHA Directive 1047(1); Page 7, section 4 h(7); Page 8, Section 4 i(6); Appendix B, page B-3, section 2f	<input type="checkbox"/>	<input type="checkbox"/>	
2.3 Is the pharmacy cache area in compliance with current fire and safety codes? Note: Verification may be obtained thru Environment of Care rounds (EOC) documentation/records. Reference: VHA Directive 1047(1); page 7, section 4 h(8)	<input type="checkbox"/>	<input type="checkbox"/>	
2.4 Is the area equipped with Motion Intrusion Detectors? A. Features. Intrusion detectors must have the following features: 1. An internal, automatic charging DC standby power supply and a primary AC power operations. 2. A remote activation and deactivation switch installed outside the room and adjacent to the room entrance door frame and/or a central alarm ON-OFF control in the Police Office. 3. An automatic reset capability following intrusion detection. 4. A local alarm level of 80 decibels (dB) (minimum) to 90 dB (maximum) within configuration of the protected area. 5. An integral capability for the attachment of wiring for remote alarm and intrusion indicator equipment (visual or audio). 6. A low nuisance alarm susceptibility. Reference: VHA Directive 1047(1); Appendix B, page B-2, section 2e	<input type="checkbox"/>	<input type="checkbox"/>	

<p>2.5 Does the cache space include the following:</p> <p>A. Cache items are stored separately from pharmacy inventory and other stored items?</p> <p>The facility is required to obtain a <i>VHA All-Hazards Emergency Cache Storage Waiver</i> if other items are stored with the cache. This waiver must be renewed every 5 yrs.</p> <p>B. Doors and Door Locks.</p> <ol style="list-style-type: none"> 1. Doors are of 45 mm (1 and 3/4 in.) hardwood or hollow steel construction. 2. Dutch or half doors are unacceptable. 3. Removable hinge pins on door exteriors must be retained with set pins or spot-welded, preventing their removal. 4. All doors must be fitted with two locks. 5. Glass doors or doors with glass panes must have one lock, key operated from the interior of the protected area. 6. If a door is not set in a steel frame, one of the two locks must be a jimmy proof rim dead lock. 7. Doors set in steel frames must be fitted with a mortise lock with a deadlock pin or comparable feature. The day lock must be automatically locking on the door closure, requiring re-entry to the room with key or lock combination and allowing egress from the room by use of an inside thumb latch, push bar or other fail-safe egress latch. 8. The day lock on the main door must be automatically locking, with a minimum 19 mm (3/4 in.) dead bolt and inside thumb latch. <p>Note: <i>Combinations or keys to day locks must be restricted to service employees and combinations changed immediately on the termination or reassignment of an employee who had access to the combination.</i></p> <p>C. Other Room Access Means</p> <ol style="list-style-type: none"> 1. Barricade interstitial overhead areas that enable entry into a secure room from an unsecured room with a partition in the interstitial space that prevents "up and over" access. Install a barricade if there is none. 2. Ventilation grills on doors and air circulation ducts that exceed 0.06 m² (100 square inches) in areas must be reinforced to prevent their removal from outside the room. Other possible access points such as dumbwaiter shafts, roof or wall ventilator housings, trapdoors, etc. must be secured. <p>References: VHA Directive 1047(1); Page 7, Section 4 h(6); Page 8, Section 4 i(5); Appendix B, page B-1, section 2</p>	<input type="checkbox"/>	<input type="checkbox"/>	
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Objective 3 – Controlled Substances Accountability & Shelf Life Extension Program (SLEP) Labels Procedures that address at a minimum the following processes:	YES	NO	COMMENTS/ RECOMMENDATIONS
3.1 Is the cache Morphine – (C-II narcotic), stored in pharmacy vault or safe meeting the referenced requirements? Reference: VHA Directive 1047(1); Appendix B, page B-3, section 2g	<input type="checkbox"/>	<input type="checkbox"/>	
3.2 Is the cache morphine inspected in accordance with inspection and inventory requirements? A. Morphine- DEA schedule II, is the same as C-II. B. Inspect every 72 hours, unless the facility has received a waiver from PBM/EPS. If contained in green totes, seals do not have to be broken and can be visually verified by the person performing the inspection. C. Inspect every week; only if a Controlled Substance Waiver has been obtained. Visually verify seals. D. Inspect every month, during the unannounced controlled substance inspection, visually verify seals. Conduct a physical count (seals broken) the 1st month of every quarter. Reference: VHA Directive 1047(1); page 7, Section 4 h(9); page 8, section 4 i(7)(b); Appendix E	<input type="checkbox"/>	<input type="checkbox"/>	
3.3 Is the cache Diazepam and Lorazepam stored and inspected in accordance with inspection and inventory requirements? A. Inspect every week; perform a visual inspection of the container and cart seal. B. Inspect every month, during the unannounced controlled substance inspection, visually verify cart seals. C. Conduct a physical count of broken seals during the 1st month of every quarter during the unannounced controlled substance inspection. Reference: VHA Directive 1047(1); page 8, section 4 i(7)(f); Appendix E	<input type="checkbox"/>	<input type="checkbox"/>	
3.4 Are all controlled substances in the cache included in the Drug Enforcement Agency's (DEA's) required biennial inventory? Reference: VHA Directive 1047(1); page 8, section 4 i(7)(i)	<input type="checkbox"/>	<input type="checkbox"/>	
3.5 Are controlled substances in a sealed cache cart inventoried each time the cart seal is broken or immediately upon discovery of a broken or suspicious looking cart seal? Reference: VHA Directive 1047(1); page 8, section 4 i(7)(g)	<input type="checkbox"/>	<input type="checkbox"/>	
3.6 Are all controlled substance inventories entered into and maintained in the Veterans Health Information System and Technology Architecture (VistA) Controlled Substance software as a separate area of narcotic use? Reference: VHA Directive 1047(1); page 9, section 4 i(7)(h)	<input type="checkbox"/>	<input type="checkbox"/>	
3.7 Are there procedures in place that describe how expired pharmaceuticals are disposed, and how [that?] shelf life extended pharmaceuticals are relabeled according to EPS directions (SLEP instruction letter)? Are SLEP labels stored in the appropriate EPS cart/location? Reference: VHA Directive 1047(1); page 5, section 4 e(8)(9)	<input type="checkbox"/>	<input type="checkbox"/>	

Source: VHA Directive 0320.10, Inspection of VA All-Hazard Emergency Caches by the VHA Office of Emergency Management, July 2017

Appendix F: Management Comments

Department of Veterans Affairs Memorandum

Date: September 21, 2018

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, Veterans Health Administration Emergency Cache Program: Ineffective Management Impairs Mission Readiness (VIEWS 00102449)

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

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Veterans Health Administration (VHA) Emergency Cache Program: Ineffective Management Impairs Mission Readiness. I concur with recommendation 1, 3, 4, 5 and 7 and I concur in principle with recommendations 2, and 6. I provide the attached action plan to address all OIG's recommendations.
2. We ask that OIG remove all information revealing the contents or locations of emergency caches from the draft report, including blurring out any readable drug names from photographs, digital pop-up boxes, and metadata linked to the photographs. Under VHA policy on All-Hazards Emergency Caches (VHA Directive 1047(1)), the locations and contents of the All-Hazards Emergency Caches, as well as aggregate data consisting of all cache locations, contents, or capabilities, are VA sensitive data as defined by 38 U.S.C. § 5727 and must be protected to prevent the harm that could result from disclosure. In particular, disclosure of such information could adversely compromise the physical security for emergency caches and thus impede the ability of the Department to accomplish its mission to contribute to the Nation's well-being during national emergencies. Therefore, any information that exposes the contents or locations of emergency caches must be safeguarded in accordance with the risk of harm from unauthorized disclosure to the public.
3. We appreciate the work OIG has accomplished through their audit. We agree with their findings and will make necessary changes to strengthen our Emergency Cache Program. We take emergency preparedness seriously and will ensure that the Emergency Cache contains the necessary supplies and medication to care for Veterans during a national emergency, terrorist attack or natural disaster.
4. Through collaboration with partners both within and outside VA, such as the Food and Drug Administration, Center for Disease Control and Prevention, as well as VA's Office of Security and Preparedness, we will work to ensure adequate inventory and proper operational alignment of our Emergency Cache Program.
5. If you have any questions, please email Karen Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRSAction@va.gov.

(Original signed by)

Richard A. Stone, M.D.

Attachment

OIG Draft Report, Audit of Pharmacy Emergency Cache Program in Veterans Health Administration Facilities

Date of Draft Report: August 27, 2018

Recommendations/	Status	Completion Date
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Recommendation 1. The Executive in Charge, Veterans Health Administration, should develop requirements for medical facilities with emergency caches to perform at least annually a wall-to-wall inventory of all cache drugs and supplies, and develop processes to 1) label all expired or excess drugs that are purposefully maintained to respond to drug shortages or for the purposes of Shelf Life Extension testing, and 2) to remove and rectify cases of other expired, missing, excess, or incorrect drugs.

VHA Comments: Concur

The Veterans Health Administration's (VHA) Pharmacy Benefits Management Services office (PBM) will coordinate with Office of Emergency Management to provide training to Area Emergency Managers (AEMs), Cache Managers and other internal stakeholders to communicate a new requirement for each Department of Veterans Affairs (VA) medical facilities to complete an annual wall-to-wall inventory for cache drugs and supplies, with the first inventory due to be completed by December 31, 2018.

PBM will develop processes to ensure that expired or excess cache drugs are purposefully maintained to respond to drug shortages or to await Shelf Life Extension and that such drugs and supplies are appropriately identified to indicate their expired or excess status. PBM's process will also ensure that other expired, missing, excess or incorrect drugs are either removed from the cache or replenished.

PBM will develop processes for enhanced communication between AEMs, Cache Managers and Emergency Pharmacy Services inventory managers to resolve any discrepancies with cache inventory items, and to obtain written certification that new signage for VA medical center is in place for drugs that are expired but are being kept purposefully.

Status: In Process	Target Completion Date: May 2019
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Recommendation 2: The Executive in Charge, Veterans Health Administration, should conduct an assessment to determine if the cost saving benefits of the Shelf Life Extension Program outweigh the risks expired drugs pose to the emergency cache's mission and take corrective action as appropriate.

VHA Comments: Concur in principle

VHA concurs in principle because preliminary work to review the results from past shelf life extension submissions by VHA to the Food and Drug Administration (FDA) will be required to understand the feasibility and generalizability of a full program assessment required for this recommendation.

VHA's Population Health will review the information available regarding the Shelf Life Extension Program (SLEP) to determine the feasibility of conducting a full cost-benefit analysis. If Population Health determines that sufficient and adequate data exists, then a full analysis plan will be completed that addresses the impact of the program on VHA staffing, logistics, procurement, space, and drug supply rotation or destruction. Population Health will compare the cost and impact of full participation in SLEP to partial participation (e.g., the most expensive or high-volume items) or no participation.

Population Health will collaborate with the Department of Defense to identify potential improvements to VHA's use of SLEP and will collaborate with FDA to learn how VHA can improve the effectiveness of SLEP, improve internal and external communications regarding SLEP, and establish expectations of SLEP participation. Any change to how VHA participates in SLEP will be reflected in updated VHA policy.

At completion of this recommendation, VHA will provide OIG with full cost saving benefit analysis if feasible and recommendations for future use of SLEP.

Status:
In Process

Target Completion Date:
September 2019

Recommendation 3. The Executive in Charge, Veterans Health Administration, should improve emergency cache inventory management processes to ensure emergency cache national inventory data by location is reliable and accurately identifies the expiration dates of all cache contents, including Shelf Life Extension Program drugs, and that this information is electronically accessible to each facility.

VHA Comments: Concur

Implementing changes to the software system used to manage emergency cache inventories will require code and license changes by the software vendor. Pharmacy Benefits Management (PBM) is working with the software vendor to determine if these changes are feasible. If the vendor cannot meet the requirements, then PBM will seek a new software solution.

PBM will make emergency cache contents and expiration date information available to Cache Managers for use during annual inspections and wall-to-wall inventories and for general inventory management. Automating the availability of this information will require software changes to the existing inventory management program. It is PBM's intent to provide additional software capabilities to enable electronic access of the inventory system by cache location and to provide a mechanism for sites to electronically report any discrepancies with expected versus actual quantities or expiration dates on hand in the software system. Until this software change can be completed, printed copies of cache inventories will continue to be provided to all cache sites and sites will be required to communicate discrepancies back to Emergency Pharmacy Service staff via e-mail for remediation.

Status:
In Process

Target Completion Date:
May 2019

Recommendation 4: The Executive in Charge, Veterans Health Administration, should initiate steps to update and reissue the Veterans Health Administration directives specifying oversight responsibilities for the Emergency Cache Program with a requirement for inventory to be timely rotated into the emergency cache after it is received.

VHA Comments: Concur

VHA's Population Health will review, update, and reissue the directives governing the Emergency Cache Program to specify oversight responsibilities and requirements for inventory to be timely rotated into the emergency cache after it is received.

At completion of this recommendation, VHA will provide OIG with the updated policy.

Status:
In progress

Target Completion Date:
September 2019

Recommendation 5: The Executive in Charge, Veterans Health Administration, should assess whether the Emergency Cache Program is properly aligned within VA and coordinate with other VA offices as necessary to determine the appropriate roles and responsibilities by program office, and then review, update, and reissue Emergency Cache Program requirements to include 1) robust annual cache inspection and activation exercise requirements; 2) processes to ensure cache inspection and activation requirements are met; 3) processes to ensure that violations identified during annual cache inspections are timely addressed; and 4) specific accountability measures for the program offices and local facility personnel responsible for program oversight.

VHA Comments: Concur

Many of the Emergency Cache Program improvements are beyond the scope of VHA alone and we agree to work with our necessary department-level partners to ensure operations, policies and responsibilities are properly aligned. VHA's Office of Emergency Management will collaborate with Population Health, Pharmacy Benefits Management and VA's Office of Operations Security and

Preparedness to review, update and reissue Emergency Cache Program requirements to make the necessary long-lasting improvements needed.

Status:
In progress

Target Completion Date:
September 2019

Recommendation 6. The Executive in Charge, Veterans Health Administration, should conduct a comprehensive assessment of the cache inventory to identify drugs and supplies that can be readily used in medical facilities' general operations and develop a mechanism to monitor and ensure medical facilities are maximizing the use of these items before they expire.

VHA Comments: Concur in principle

VHA concurs in principle because ensuring the use of all cache medications before they expire has not proven to be possible. In some cases, specifically for very low-cost items, it can cost more to rotate supplies into routine medical care than it would be to return them for reverse distribution/destruction and to purchase fresh supplies. In other cases, cache medications are not used in routine medical care.

Pharmacy Benefits Management (PBM) Services will conduct a comprehensive assessment and feasibility analysis of drugs that can be readily used in medical facility operations. If such a process is deemed feasible, PBM will provide education to the field on strategies that can assist them to maximize use and will determine how best to monitor the use of these items before they expire at the enterprise level.

If reuse of some cache items is deemed feasible, VAMCs will need to implement other workflow changes such as filling prescriptions locally as opposed to sending them to the Consolidated Mail Outpatient Pharmacy, identifying appropriate storage of cache medications identified for local use, and ensuring adequate staffing is in place to process local prescriptions, etc. In addition, PBM will begin to ship replacement cache inventory stock well ahead of the expiration date instead of shipping it on a scheduled basis.

Status:
In Process

Target Completion Date:
January 2019

Recommendation 7: The Executive in Charge, Veterans Health Administration, should initiate steps to update and reissue the Veterans Health Administration directives specifying oversight responsibilities for the Emergency Cache Program to reflect the Office of Public Health's reorganization and reassign responsibilities as needed.

VHA Comments: Concur

VHA's Population Health will review, update, and reissue the directives governing the Emergency Cache Program to specify oversight responsibilities to reflect any future reorganization and reassignments.

At completion of this recommendation, VHA will provide OIG with the updated policy.

Status:
In progress

Target Completion Date:
September 2019

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

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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