



DEPARTMENT OF VETERANS AFFAIRS OFFICE OF INSPECTOR GENERAL

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BEFORE THE
SUBCOMMITTEE ON HEALTH, COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
HEARING ON
MISSION READINESS: VA'S EMERGENCY RESPONSE AND CACHE PROGRAM
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Chairwoman Brownley, Ranking Member Dunn, and members of the Subcommittee, thank you for the opportunity to discuss the Office of the Inspector General's (OIG's) oversight of the Department of Veterans Affairs' (VA's) Emergency Cache Program. The emergency cache is a critical component of VA's preparedness to ensure that medication and supplies are available in the event of a disaster—whether natural or the result of acts of violence.

The OIG is committed to serving veterans and the public by conducting oversight of VA programs and operations through independent audits, inspections, reviews, and investigations. The importance of that mission is particularly compelling during times of crisis when the provision of continuous healthcare services to veterans and others is vital. In October 2018, the OIG published a report, the *Emergency Cache Program: Ineffective Management Impairs Mission Readiness*.¹ The report examines whether the Veterans Health Administration (VHA) effectively managed its emergency drug and medical supply caches to ensure their readiness. The OIG audit team identified several deficiencies such as expired or missing drugs, excess drugs, failures to conduct mandatory annual inspections and activation exercises, missed opportunities to use soon-to-expire emergency cache drugs, and the lack of efficient program oversight. These deficiencies, if not corrected, may not only compromise VA's ability to mobilize in the event of an emergency but could also result in missed opportunities to leverage soon-to-expire (but still usable) drugs and medical supplies.

BACKGROUND

Established following the 9/11 attacks, the Emergency Cache Program is part of VA's national emergency preparedness efforts to make drugs and medical supplies available to treat veterans, VA employees, and civilians in the immediate aftermath of a terrorist attack, or biological or natural

¹ [*Emergency Cache Program: Ineffective Management Impairs Mission Readiness*](#), October 31, 2018.

disaster.² Each cache is designed to bridge the gap between a medical facility's on-hand supplies and federal relief provided by the Department of Health and Human Services' Centers for Disease Control and Prevention's Strategic National Stockpile. Federal supplies can take one to two days, if not longer, to reach the site of a catastrophic event. Because mass casualty events can occur anytime, anywhere, and with little or no warning, the Emergency Cache Program must be ready for immediate deployment. While at the time of the audit none of the caches had been activated in response to a disaster, medical facilities have used cache drugs in response to local or national shortages when other options to obtain the drug have been exhausted and patients are in life-threatening situations.

As of January 2018, there were emergency caches at 141 VA medical facilities, with a standard supply of 38 drugs (three are controlled substances) and 44 medical supplies, collectively worth about \$44 million. One of the caches in each Veterans Integrated Service Network also carries two drugs to treat medical needs arising from a nuclear disaster. Ninety-one caches are large, designed to treat 2,000 people, while 50 are small, designed to treat 1,000 people.

Three VHA program offices as well as the directors of medical facilities with caches share oversight responsibilities:

1. The Pharmacy Benefit Management's Emergency Pharmacy Service (EPS) maintains a centralized national inventory database to track drugs and supplies. EPS orders and distributes cache supplies to each cache location.
2. The Office of Emergency Management (OEM) oversees required annual cache inspections and reports on the functional and operational status of emergency caches.
3. The Office of Public Health leads the cache committees that update policies and directives.
4. Medical facility directors make sure annual cache activation exercises occur, decide when to activate the cache, and ensure the cache manager is administering the inventory.

VHA policy describes the storage requirements for the caches, which includes secure environments. The drugs and supplies are required to be stored in numbered, locked rolling carts. EPS uses the national inventory database to track each cache's supplies, drug types, quantities, lot numbers, and expiration dates. EPS is also responsible for ordering drugs and supplies to replace expiring cache inventory. According to EPS officials, most emergency cache drugs are subject to a seven-month replacement process, detailed in figure 1.

² VHA Directive 2002-026, Pharmaceutical Caches in a Weapons of Mass Destruction Event, May 13, 2002; 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; 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).

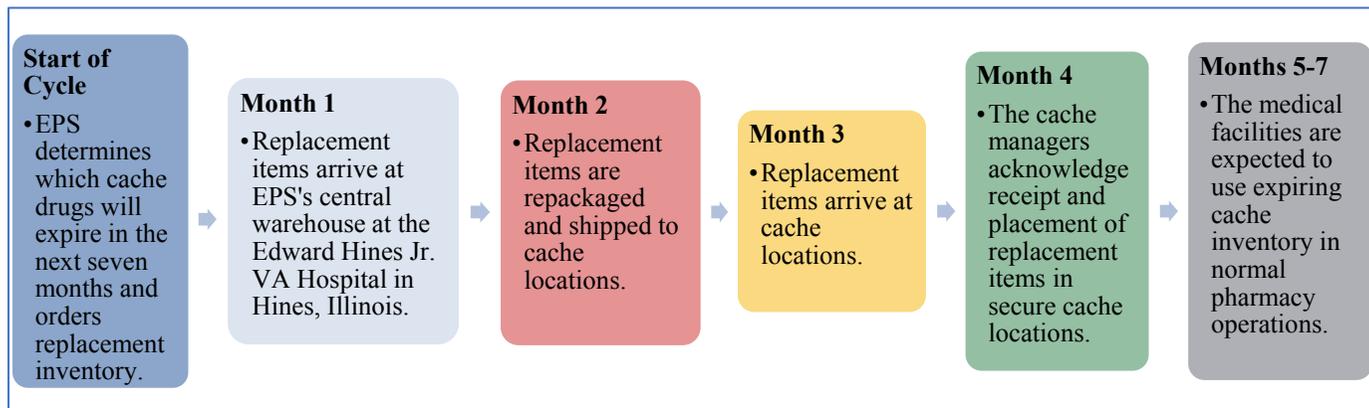


Figure 1. Emergency Cache Inventory Ordering Process
(Source: EPS staff)

VHA participates in the Food and Drug Administration’s (FDA’s) Shelf Life Extension Program (SLEP), which is used by government agencies to extend the period of use of designated drugs. FDA tests drugs for stability and extends the expiration dates for drugs that pass this testing. SLEP drugs are primarily nonbiological prescription drugs. Current SLEP testing focuses on drugs that have limited commercial use (such as nerve agent antidotes) and drugs purchased in very large quantities (such as the antibiotics ciprofloxacin and doxycycline). At the time of the OIG audit, 17 of VHA’s cache drugs were included in the SLEP, including Tamiflu, and EPS staff claimed that SLEP saved VA about \$20 million annually.

INEFFECTIVE MANAGEMENT IMPAIRED THE MISSION READINESS OF VA’S EMERGENCY CACHE PROGRAM

Because the mission of the Emergency Cache Program is critical to veterans and for the public health, the OIG decided to proactively assess VHA’s management of this program. In 2018, OIG staff conducted visits to 26 randomly selected cache locations to determine if VHA ensures caches are ready to mobilize in the event of a disaster or terrorist attack.³ The OIG’s examination of the same 25 drugs at each site, for a total of 650 drug inspections, yielded seven key findings:⁴

1. All 26 inspected caches had expired drugs.
2. Twelve inspected caches were not fully stocked.

³ Given the sensitive nature of the Emergency Cache Program contents and locations, to protect the disclosure of information that could adversely compromise the physical security of the caches, the OIG did not identify which medical facilities it visited in its report.

⁴ 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.

3. Eight inspected caches had excess quantities of cache drugs.
4. OEM did not always conduct the required annual inspections.
5. Medical facility directors did not always conduct the required activation exercises.
6. Medical facilities missed opportunities to use soon-to-expire cache drugs.
7. Lack of effective governance resulted in inefficient program oversight.

Expired Drugs Found in All 26 Inspected Caches

In almost all the cases of expired drugs, EPS failed to ship replacement drugs to caches before their current stock of drugs expired. Of the 650 drugs that the OIG inspected across the caches, 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 caches had 10 or more expired drugs. At the time of the OIG 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.

The EPS Inventory Management Specialist, responsible for ensuring cache inventory is properly stocked and unexpired, agreed with the OIG's inspection results, but he deflected his responsibility as the cause for the expired drugs. He claimed the caches contained expired drugs not because EPS did not ship the drugs in time, but rather because inexperienced cache managers did not rotate unexpired drugs into the caches to replace the expired drugs. The OIG determined this was not persuasive because inventory to replace the expired drugs was rarely available on-site during the audit team's inspections.

Ninety-five of the 178 expired drugs identified by the OIG were in the SLEP. However, the OIG found that SLEP participation poses significant risks to the Emergency Cache Program for two reasons. First, for expired drugs undergoing SLEP testing, EPS inputs in its national inventory database the date it expects the drug to pass testing as the drug's expiration date, instead of the actual date the drug expired. As a result, EPS's national inventory database does not accurately reflect the proportion of, and which cache drugs, are expired at any point in time. Second, while it used to take the FDA 90 days to complete a testing cycle, at the time of the audit, the FDA reported there could be up to a six-month wait for testing. Therefore, emergency cache drugs in SLEP testing are typically already expired by the time the FDA conducts its testing, and thus VA cannot use them while waiting for the results. While VHA could ask the FDA for permission to use these drugs in case of an emergency, this FDA approval could take time, and FDA officials noted that VHA pharmacists using expired SLEP drugs could risk their license.

The OIG estimates that about 6.1 million units of drugs were expired across all 141 caches representing about \$4.6 million in May 2018 values. The report concluded that this is a gross waste of funds and space for a program that is vital to the treatment and care of veterans, VA employees, and civilians in the immediate aftermath of a local mass casualty event.

Some Caches Were Not Fully Stocked, While Others Had Excess Drugs

Twelve of the 26 caches the OIG visited were not fully stocked. Specifically, 16 of the 650 drugs the team inspected had varying quantities missing, of which cache managers were aware of nine instances prior to the OIG's visits. OIG staff were given explanations, such as samples of drugs being in SLEP testing, drugs being destroyed because they were unsafe for human consumption, and replacement drugs never having been shipped.

The audit team also identified 16 excess drugs at eight of the 26 visited cache locations. Drugs were counted as excess if a cache site had both a current lot and replacement lot on-site in its 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, the presence of excess drugs was attributable to cache managers who failed to remove expired drugs from their cache after new replacement drugs were rotated into the cache. This practice also created the risk that old, expired drugs could be used during an emergency since both expired and nonexpired drugs were in the cache carts.

On-site cache managers faced a significant hurdle in accounting for their stocks. The EPS Inventory Management Specialist was not updating the national inventory database consistently, and the cache managers do not have access to EPS's national inventory database. Furthermore, there is no requirement for medical facilities to perform regular wall-to-wall cache inventories. Without access to EPS's national inventory database, cache managers have no assurance that their caches are fully stocked and mission ready.

VHA's Office of Emergency Management Did Not Always Conduct Mandatory Annual Inspections

OEM was not in compliance with VHA's requirement to conduct annual cache inspections at all 141 emergency cache locations. According to the OIG's survey of cache managers, only 122 managers reported that their cache was inspected in fiscal year (FY) 2017, and only 96 provided the team with an inspection report for the team to verify. OEM's Field Program Manager claimed that, in part, the failure to complete inspections at all cache locations occurred because some area emergency managers 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 exposed cache locations and their contents to unidentified or unaddressed physical security risks. Additionally, VA's current procedures do not require the inspectors to check the cart's readiness or even open it to assess whether the drugs are unexpired and in the correct quantity. Without periodic inspections to make sure emergency caches are mission ready, caches are at risk of not being prepared to activate in an emergency.

Some Medical Facility Directors Did Not Conduct Mandatory Annual Activation Exercises

Medical facility directors are responsible for ensuring that mandatory annual cache activation exercises are conducted, including making certain that there are no physical limitations such as carts not fitting through doorways, that would affect medical facilities' ability to activate their caches in an emergency. However, according to the OIG's cache manager survey, 21 of 141 cache managers did not conduct activation exercises in FY 2017. Additionally, some exercises were merely verbal discussions of activation steps, which would not involve looking at the cache area or even confirming the carts could move. OEM's Acting Director and Field Program Manager expressed concern to the OIG that medical facility directors were not fully complying with the annual cache activation requirement, but also noted OEM lacks the authority to enforce the annual cache exercise requirement and thus does not monitor compliance. In fact, there is no governance structure in place to ensure medical facility directors are complying with the activation requirement.

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

EPS did not order replacement drugs in enough 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 OIG 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 routine 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 OIG estimates VHA would waste 28 million units of drugs, a value of \$34 million, over the next five years if it continues to fail to use soon-to-expire cache drugs.⁵

The Emergency Cache Program Lacked Efficient Oversight

VHA defines the roles and responsibilities for running the Emergency Cache Program in its Directives 0320.10 and 1047(1), yet these responsibilities were not met. At the time of the audit, no single program office or person was tasked with overall responsibility to ensure that the Emergency Cache Program was mission ready. Governance is fragmented, with three separate VHA program offices having some oversight responsibilities for the program, in addition to the responsibility each medical facility director has for their own cache. Moreover, one of the national offices tasked with specific oversight

⁵ 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 drugs, that are not part of the SLEP, 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.

responsibilities—the Office of Public Health—was reorganized a year prior to the OIG audit, which affected its ability to carry out its cache oversight responsibilities such as updating policies and directives.

In addition, there was a lack of oversight accountability among the three program offices tasked with overseeing the Emergency Cache Program. For example, while OEM is responsible for the annual cache inspections, it was not consistently documenting inspection results and the associated corrective actions. Consequently, OEM did not have a way to track on a national level the status of all identified violations. 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 in the pharmacy separated by a metal fence with a locked 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. Not tracking violations like this across the nation creates a risk to the security of the cache inventory items as well as the possibility that caches are operating with violations that affect their ability to be ready to activate.

As the findings indicate, the lack of effective oversight increases the likelihood that the Emergency Cache Program will not be mission ready.

RECOMMENDATIONS

The OIG made seven recommendations to the Executive in Charge, Office of the Under Secretary for Health, based on the findings. The Executive in Charge was responsive to all OIG recommendations and agreed to make necessary changes to strengthen the program. For example, the OIG recommended that VHA develop a requirement for at least annual wall-to-wall cache inventories as well as improve cache inventory management processes and the accuracy of the national cache inventory data. The OIG also recommended that VHA assess whether the cost savings associated with participation in the SLEP outweigh the risks expired drugs pose to the program's mission. Recommendations also included updates to cache oversight responsibilities to ensure robust annual cache inspection and activation exercises, specific accountability measures, and appropriate oversight of the program.

While all seven recommendations remain open since the report's October 31, 2018 publication, VHA has made progress towards implementing the recommendations, based off information provided in March 2019. VHA provided a status update to the OIG on June 14, 2019, and that information is under review by OIG staff. Thus far, VHA has acted to

1. Provide training on conducting wall-to-wall inventories and on how to address expired, excess, incorrect, or missing cache items;

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2. Commence initial wall-to-wall cache inventories;
 3. Assess continued participation in the SLEP in conjunction with stock rotation and returns, and identify which cache drugs should remain in the SLEP;
 4. Enable each cache site to access its inventory information in the national inventory database;
 5. Begin clarifying cache policies, directives, roles, and responsibilities; and
 6. Assess which cache drugs could be used in routine medical facility operations.

CONCLUSION

The importance of an effective Emergency Cache Program cannot be overstated. The OIG found that VHA did not effectively manage the program and that VHA officials had no assurances the caches would be ready to mobilize in the event of an emergency. As a result, VHA risks not having the drugs and supplies necessary to meet the emergency needs it might face for mass casualty events. These risks are due to a poor governance structure and inadequate oversight processes (including missed inspections and activation exercises) that cannot ensure caches are secure and stocked with unexpired drugs in the appropriate quantities. Without improved oversight and accountability, the Emergency Cache Program has increased risks of being inadequately equipped and wasting drugs and medical supplies.

Madam Chairwoman, this concludes my statement, and I would be pleased to answer any questions you or other members of the Subcommittee may have.