

# MISSION READINESS: VA'S EMERGENCY RESPONSE AND CACHE PROGRAM

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## HEARING

BEFORE THE  
SUBCOMMITTEE ON HEALTH  
OF THE  
COMMITTEE ON VETERANS' AFFAIRS  
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## **MISSION READINESS: VA'S EMERGENCY RESPONSE AND CACHE PROGRAM**

**Wednesday, June 19, 2019**

COMMITTEE ON VETERANS' AFFAIRS,  
U. S. HOUSE OF REPRESENTATIVES,  
*Washington, D.C.*

The Subcommittee met, pursuant to notice, at 3:23 a.m., in Room 210, House Visitors Center, Hon. Julia Brownley presiding.

Present: Representatives Brownley, Brindisi, Rose, Cisneros, Dunn, Meuser, and Steube.

### **OPENING STATEMENT OF JULIA BROWNLEY, CHAIRWOMAN**

Ms. BROWNLEY. Good afternoon. Thank you all for joining us here today for a hearing to discuss the VA's readiness to perform one of its most crucial functions, its fourth mission that seeks to improve the Nation's preparedness to respond to public health emergencies both, natural and manmade. Today we examine one piece of that mission, the All-Hazards Emergency Cache program.

Following the attacks on 9/11, VA established an Emergency Cache program to make drugs and medical supplies available for the treatment of veterans, VA employees, and civilians in the aftermath of a mass-casualty event.

As it is hurricane season, this hearing will also assess the readiness of the Office of Emergency Management and Emergency Pharmacy Services as the frequency of extreme weather events increase.

The Cache Program is charged with being the Nation's safety net for up to 3 days between a catastrophic event and the arrival of the Department of Health and Human Services Disease Control and Prevention's Strategic National Stockpile, SNS for short. The Emergency Cache program stockpiles drugs and medical supplies at 141 sites across the country with standard supply of 38 drugs and 44 medical supplies worth around \$44 million.

An Inspector General's report from October of 2018 found that the Veterans Health Administration is not maintaining its Emergency Cache program in a mission-ready status; in fact, all 141 sites had expired, missing, and/or excessive—too many drugs. The IG found VA failed to adequately store supplies, conduct mandatory inspections, and run physical activation drills.

The program suffers from inconsistent oversight and a confusing governance structure that leaves no one accountable for its inability to activate. Of particular concern is the timely rotation and re-supplying of drugs that, until recently, relied on the competency of one person, an inventory-management specialist who was charged with supplying VHA's caches with in-date drugs.

The IG found that in almost all cases of expired drugs, this specialist had failed to ship replacements before the drugs' expiration. The impact of this ineptitude was severe. Of the 650 drugs the IG inspected, 27 percent were expired. Of those drugs that were expired, over a third had been expired for more than 3 months or longer and several had been expired for more than a year.

One facility has 3,168 units of a drug that expired in April of 2013. The drugs that were most frequently expired were anthracic prophylaxis, beta blockers, antivirals used to treat influenza, and morphine. In 2018, an estimated 6.1 million units of drugs were expired across the 141 caches, worth around \$4.6 million. VA has informed my staff that this person is no longer with the VA and the responsibility for the supply process is now with a consolidated-mail, outpatient pharmacy.

I wish I could say VA is ready to fulfill this duty to our veterans and the public, but it just simply isn't. Even with a full and properly stocked cache, there is no governance structure in place that ensures the medical center directors are conducting the required annual drill exercises.

In fiscal year 2017, 15 of cache sites did not conduct drills. Similarly, only 87 percent of caches reported that they were inspected by the Office of Emergency Management, but just 68 percent could provide documentation of the inspection.

There currently is no one person tasked with the responsibility of overall cache readiness for VHA. While no cache has ever been officially activated, medical center directors have accessed them during natural disasters and epidemics; in fact, such use has increased in recent years, particularly in response to drug shortages at medical centers. Twenty-eight percent of VA's cache sites accessed drugs in a 6-month period in 2018.

We need to better understand why VA facilities are falling back on their emergency supplies this frequently and how dynamic the Cache Program is to accommodate such frequent drug shortages.

Further, it is unclear how well VA facilitates each established plans of action and trains staff to deploy cache contents to an effective area. Frontline staff have informed this Subcommittee they feel underrepresented, and drills, if they happen at all, are more often done by phone, freight elevators and doorways aren't big enough to allow cache carts through, controlled substances are marked off with baby gates, staff shortages make activation drills and inventorying a particularly taxing effort. While we all desperately hope that this training never has to be put to use, we know the cost of not being prepared.

Lastly, we hope to hear how VA is or is not modifying the role of the cache to meet the new emerging threats of climate change. How does VA plan to meet the changing nature of disaster, as weather events intensify, and diseases spread to new climates? The findings of the Inspector General show the Cache Program has alarmingly weak protections in place to maintain critical resources and ensure VHA is able to treat a devastated population.

VA's fourth mission is one of the most sacred duties and the scathing findings of this report, compounded by the Subcommittee's oversight visits offer us no reason to believe VA is ready to fulfill its role, should a disaster strike.

Dr. Dunn and I both come from districts that have recently been affected by extreme weather and we are eager to hear of VA's efforts to improve. And with that, I now recognize Ranking Member Dunn for his opening remarks.

**OPENING STATEMENT OF NEAL P. DUNN, RANKING MEMBER**

Mr. DUNN. Thank you very much, Madam Chair.

Emergency management, the topic of today's hearing is a particularly poignant and timely one for me. As the chairwoman noted, last year, my district was—the Second District of Florida by the way—was devastated by Hurricane Michael. Many of my friends, neighbors, and constituents suffered truly terrible losses and are still living with the daily reality from recovering from the hurricane. As we are now at the start of another hurricane condition, there is no better time for us to be discussing the role of the Department of Veterans Affairs in responding to disasters, whether they be manmade or natural.

The VA's so-called fourth mission is to be the primary backup health care system to the Department of Defense, but also to assist in the Federal response efforts and ensure safety and continuity of care not only for veterans, but even for civilians, as needed, during times of emergency or conflict. So, this is an area where we would expect the veterans to excel. As a national health care system, the VA is often able to leverage its scale and its footprint to ensure that veterans are cared for when disaster strikes.

However, today, we are discussing a rather alarming report by the VA Inspector General that found serious deficiencies in the management of the VA's emergency medication Cache Program. This emergency medication program was created after 9/11 to ensure that needed medications and supplies were readily accessible to treat veterans, VA employees, civilians, et cetera, following mass casualties.

As the IG's testimony rightly notes, the serious nature of that mission demands some professionalism and careful oversight; however, the IG found that the Emergency Cache program were seriously deficient in execution, appropriate oversight, and accountability.

When reviewing the emergency sites, the IG found drugs were expired, missing—and by the way, I would like to visit that a bit; I wonder what is missing—was the morphine among the missing drugs—or purchased in excess. The IG also found mandatory inspections that were never performed, missed opportunities to use soon-to-be-expired drugs that cost the modern taxpayers an average of \$6.8 million a year.

All of this means that the VA's ability to ensure the availability of needed medications and supplies in the event of terrorist attacks or catastrophic natural disasters is in question. It also means that the modern veterans and the modern taxpayers cannot be assured that the VA is spending that money wisely, nor is it adequately prepared to prepare its fourth mission. That is failure twice over. I understand the VA has been working in the months since this IG report to rectify the serious issues and I look forward to hearing about that today.

With that, Madam Chair, I thank you and yield back.

Ms. BROWNLEY. Thank you, Dr. Dunn.

So, we shall begin. And on today's panel we have Mr. Lewis Ratchford, Deputy Assistant Secretary for the Office of Emergency Management and Resilience at the Office of Operations, Security, and Preparedness for the VA. Mr. Ratchford is accompanied by Dr. Paul Kim. Dr. Kim is the Director of the Office of Emergency Management at the Veterans Health Administration. Dr. Larry Mole is the Chief Consultant, Population Health Services, in the Office of Public Health at the Veterans Health Administration. And Dr. Steve Steinwandt is the Director of the Consolidated Mail Outpatient Pharmacy at the Veterans Health Administration.

Also here is Mr. Larry Reinkemeyer, Assistant Inspector General for Audits and Evaluations, Office of Inspector General, Department of Veterans Affairs.

So, thank you all, gentlemen, for being here.

Mr. Ratchford, you are now recognized for 5 minutes.

#### **STATEMENT OF LEWIS RATCHFORD**

Mr. RATCHFORD. Good morning, Chairwoman Brownley, Ranking Member Dunn, and Members of the Subcommittee. Thank you for the opportunity to discuss the VA Emergency Response and All-Hazards Emergency Cache Program.

I am accompanied today by my colleagues from the Veterans Health Administration, Dr. Larry Mole, chief consultant of Population Health Services; Dr. Steve Steinwandt, Consolidated Mail Outpatient Pharmacy, director and emergency pharmacy director; and Dr. Paul Kim, director of VHA Office of Emergency Management.

In response to the terror attacks on 9/11, the United States Government took on a herculean task to overhaul Homeland Security efforts across all sectors of government. On November 7th, 2002, the VA Emergency Preparedness Act of 2002 became law and began the transformation of VA preparedness mission. This Act not only enhanced VA's role as part of the Federal response aimed at preventing the events like 9/11 and the anthrax attacks of 2001. It also served as the catalyst for VA to develop resilient capabilities that would support continuous delivery of services to veterans in an all-hazards environment.

Simultaneously, the Department of Health and Human Services was in the process of implementing the Public Health and Bioterrorism Preparedness and Response Act of 2002, which enhanced the viability and capability of the Nation's Strategic National Stockpile, designed to mitigate consequences of a chemical, biological, nuclear, radiological, or other public health emergency within the U.S.

To complement these efforts, VA established the All-Hazards Emergency Cache program to bridge the gap until the NSNS was operational—their local VA Medical Center. The cache includes medical countermeasures that are either not stocked in the local VA pharmacy's inventory or quantities that would augment what is on hand to enable a rapid response to a public health emergency or CBRN event.

Today, the mission and the cache remain unchanged. As a direct result of the VA Office of Inspector General audit, dated October

31st, 2018, VA continues to implement improvements to increase and ensure the readiness of the cache to support consequence management operations and ensure continued delivery of services to our Nation's veterans.

One of VA's proudest moments occurred during the 2017 hurricane response season when the Department was identified as a major contributor to the overall Federal response while sustaining local VA operations in the Caribbean. As a testimony to VA's preparedness and emergency response capabilities, the San Juan VAMC was the only hospital that remained operational throughout the response phase of Hurricane Maria. This was achieved by VA transporting over 128 short tons of critical resources and response equipment to Puerto Rico and deploying over 1,039 personnel to support both, VA and Federal mission requirements. This included deploying mobile medical units, satellite communication systems, a mobile pharmacy, a mobile nutritional unit, generators, and oxygen cylinders to name a few of these resources that enabled VA's successful response.

VA appreciates the OIG review as it has led to strengthening the Cache Program. Since the publication of the report, VA has implemented improvements to inventory management and internal controls for the Cache Program. VA has conducted training and has assisted medical centers with wall-to-wall inventories of all cached drugs and supplies.

Training is the foundation for a reliable, efficient, and accurate cache management program. Additionally, VA has developed processes to identify all expired excess drugs that are purposely maintained to respond to drug shortages or for potential shelf-life extension program testing.

Training has also been provided on a process to ensure expired, excess, incorrect, or missing items discovered during inventory activities are handled appropriately. A comprehensive review of VHA directives that govern the Cache Program is underway which includes assessment of roles and responsibility for all entities responsible for cache management and oversight.

We appreciate the opportunity to share our efforts to strengthen the VA's readiness to respond to public health or CBRN emergencies and our continued commitment to develop resilient capabilities to respond to crisis. Our objective is to give our Nation's veterans the top-quality care they have earned and deserve, even in an all-hazards environment.

Chairwoman Brownley, we appreciate this Subcommittee's continued support and encouragement in identifying and resolving challenges as we find new ways to ensure care for veterans, regardless of the circumstances. This concludes my testimony. My colleagues and I are prepared to respond to any questions you may have.

[THE PREPARED STATEMENT OF LEWIS RATCHFORD APPEARS IN THE APPENDIX]

Ms. BROWNLEY. Thank you, Mr. Ratchford.

Mr. Reinkemeyer, you are now recognized for 5 minutes. I hope I am pronouncing your name—

Mr. REINKEMEYER. Very close, Reinkemeyer.

Ms. BROWNLEY. Thank you for being here.

#### **STATEMENT OF LARRY REINKEMEYER**

Mr. REINKEMEYER. Thank you, Chairwoman Brownley, Ranking Member Dunn, and Members of the Subcommittee. Thank you for the opportunity to discuss our recent oversight of the Emergency Cache Program.

I would like to highlight the findings from our October 2018 report, the “Emergency Cache Program: Ineffective Management Impairs Mission Readiness.” It examined whether VHA effectively managed its emergency drug and medical supply caches to ensure their readiness.

The emergency cache is a critical component of VA’s preparedness to ensure that drugs and supplies are available in the event of a disaster, whether natural or the results of acts of violence. The OIG audit team identified several deficiencies, such as expired, missing, or 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.

This report’s findings mirror findings from other recent OIG reports such as poor governance structures, poor planning, inadequate or outdated policies, and a failure to communicate effectively between VHA offices.

Responsibility for the policy and supply of the Cache Program is shared between 3 different VHA programs. Additionally, the facility director makes sure annual cache activation exercises occur, decides when to activate the cache, and ensures the cache manager is administering the inventory.

As of January 2018, there were emergency caches at 141 VA medical facilities. We conducted this audit by visiting 26 caches around the country to inspect the caches and their contents as well as conducting a survey of all 141 cache managers. In reviewing the 26 caches across the country, we determined there were common problems at VHA’s national level, as well as at the facility level.

Our audit found that VHA’s ineffective management and lack of effective governance impaired the cache’s mission readiness. Our audit made 7 findings: all 26 caches had expired drugs; 12 of the inspected caches were not fully stocked; 8 of the inspected caches has excess quantities of drugs; VHA’s Office of Emergency Management 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; and a lack of effective governance resulted in inefficient program oversight and increased the likelihood that the Emergency Cache Program will not be mission ready.

We made 7 recommendations to the Executive in Charge, Office of the Under Secretary for Health. All our recommendations were agreed with and the Executive in Charge’s action plan was responsive to all of our recommendations.

While all 7 recommendations remain open, VHA has made progress toward implementing the recommendations. They provided our staff with an additional update last Friday, and we are

currently reviewing those materials to see if several of the recommendations could be closed.

The importance of an effective Emergency Cache Program cannot be overstated for veterans, employees, and the public. VHA officials has no assurances the caches would be ready to mobilize in the event of an emergency. Without improved oversight and accountability, the Emergency Cache Program continues to risk being improperly supplied and appropriated funds put at risk for waste.

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

[THE PREPARED STATEMENT OF LARRY REINKEMEYER APPEARS IN THE APPENDIX]

Ms. BROWNLEY. Thank you very much for your testimony, and I now recognize myself for 5 minutes.

I think the first question that I wanted to ask—and anybody from the VA can answer it—is the Strategic National Stockpile has deployed for almost every national emergency since Hurricane Katrina. They can rarely respond in the, you know, two-day time-frame and it is my understanding that the VA's cache has never, since its inception, has never been deployed, when part of its mission, its fourth mission, is to fill that gap between an event and when the stockpiles arrival shows up at the disaster point.

So, can somebody tell me why a cache has never been deployed since its inception?

Mr. RATCHFORD. Thank you, Madam Chairwoman for that question.

The mission of the VA All-Hazards Emergency Cache program is a little bit different than the SNS. The SNS is designed to deploy somewhere, whereas the AHEC, which is our cache, is designed to support the medical delivery system of the VAMC that it is assigned to, so it is pretty much static. One of the contributing factors to the VA not having to deploy the cache is that the number of supplies we keep on hand at the VA Medical Center.

Referencing the San Juan Medical Center, for instance, in Puerto Rico during Hurricane Maria, we had on average, several weeks of medical supplies to include pharmaceuticals to support the operation there. In addition, we deployed mobile pharmacy assets to the island so that the cache would not be broken into, to support a more important mission that may come up later on down the line.

Ms. BROWNLEY. But isn't the purpose of the cache, in the case of Puerto Rico, to provide medical supplies immediately?

Mr. RATCHFORD. If we exceed our operational load that we have at the medical center—

Ms. BROWNLEY. If you exceed what? I'm sorry.

Mr. RATCHFORD. The operational load that each hospital has, the number of countermeasures they have on hand already, if it exceeded that, then, yes, the cache would be something that would be used to treat personnel.

Ms. BROWNLEY. So, are you saying that you didn't exceed it and, therefore, you didn't need to deploy the cache?

Mr. RATCHFORD. Yes, ma'am, that is correct. Based on the supplies that we had on hand and that we moved to the island, there was no need to break into the cache.

Ms. BROWNLEY. Okay. It just—I understand each location is a different set of circumstances, but it is clear from the Inspector General's report that you used cache to supplement drugs that you don't have and so, you have used the cache in that capacity. You have never deployed, and I just can't imagine with, you know, given all of the disasters, particularly natural disasters since 9/11, there has been—there has just been no deployment whatsoever.

And, you know, it is clear within the Inspector General's report, as well, is that there is a lack—in my mind, there is a lack of accountability, you know, who ultimately is responsible, who makes the call. My understanding is that the medical director—in the case of Puerto Rico, the medical director of the hospital in that area would make the call one way or the other. Or if there was an earthquake in Los Angeles, the medical director in West LA, which is my area, is the person who makes that call. But it is, you know, in some cases, the medical director is not even requiring that there be drills to make sure that, you know, the inspections are conducted correctly so forth and so on.

But the way it is currently set up—I just need a confirmation here—is that it is the medical director is the person who is responsible for the deployment of the cache?

Mr. RATCHFORD. Yes, that is correct.

Ms. BROWNLEY. Okay. So, I guess we need all the medical directors across the country, we need to survey them.

The Inspector General, can you comment on that at all? Did you survey, at all, medical directors in terms of their decision-making capacity?

Mr. REINKEMEYER. We did not survey them to get an understanding of what goes into their decision-making capacity. But it was surprising to me as well, that the caches had never been deployed. We do know that the caches have been used, occasionally, where there have been shortages, outside of the emergency arena.

But it is our understanding as well, that it has never been deployed, and it has never been denied to be deployed, either; in other words, a medical facility director never requested or tried to deploy it and was told no.

Ms. BROWNLEY. Thank you. My time is expired, so I yield back to, and, Dr. Dunn.

Mr. DUNN. Thank you so much, Madam Chair.

So, I went through this drill with the Army Medical Corps in the 80s and what we found was that it was a phenomenally expensive and wasteful way to try to forward place medications and supplies, that we were wasting a large—I think we have reinvented a problem and not a solution here.

And with that in mind, I went back and read the original statute, as enacted in 2002, to see what it requires of the VA, and I will briefly quote from it. "The Secretary of Veterans Affairs shall maintain a stockpile or stockpiles of drugs, vaccines, and other biological products, medical devices, and supplies to provide for the emergency health security of the United States."

Fast-forward to today's VA. The CMOP program, the Consolidated Mail Order Pharmacy program is now serving the entire country from just 7 locations. Eighty percent of all prescriptions are filled through the CMOP program in those locations.

Additionally in 2007—that is 12 years ago—the Department of Veterans Affairs Emergency Pharmacy Service has begun maintaining a fleet of mobile pharmacy vehicles to assist veterans, VA staff, as well as civilians during emergencies. These mobile pharmacies are strategically positioned around the country and they are self-contained units who are just a few hours away from driving every place in the country. Standard equipment includes satellite dishes, generators, teleconference capabilities, faxes, VOIP protocol, two-way radios, laptops, prescription printers, and secured connectivity with the VA. They are manned by pharmacists and pharmacy technicians recruited from the—system.

Currently, the VA is attempting to maintain 141 caches, not 7—141—and, you know, that is a difficult thing to do. I am not castigating somebody for not being able to do that. I am merely pointing out that we have set ourselves a very, very difficult bar and it seems to be duplicative.

It seems to me that the CMOP emergency programs actually do an admirable job of doing that. And with that in mind, I want to start this question, first to Dr. Kim: Given all these advancements and the progress that we have made since the first enactment of the law, is there really still a need for 141 medication caches and the various—around our country?

Dr. KIM. Thank you for that question. I do believe there is a need. As Mr. Ratchford had pointed out, the cache is designed for those events that we normally wouldn't have the pharmaceuticals available.

One quick example, we recently had an exposure to Americium in the Buffalo, New York, area. We had those drugs available in a cache in Syracuse. It was a veteran and a non-veteran. We were able to mobilize—

Mr. DUNN. What kind of drugs are we talking about?

Dr. KIM. Chelating agents. The Americium was inhaled, so it was a pretty significant dose for both victims and we were able to deploy those chelating agents in order to treat those two individuals successfully. Those drugs would not normally be available.

Mr. DUNN. So, I read the 38 drugs that are on the emergency list and I don't remember any chelating agents.

Dr. KIM. I would like to defer to Dr. Steinwandt.

Mr. DUNN. Please do.

Dr. STEINWANDT. Yes, sir. In that case, it was the calcium DTPA that was deployed for that incident.

Mr. DUNN. Was that in an emergency cache or just in the hospital?

Dr. STEINWANDT. No, that was part of the emergency care, sir.

Mr. DUNN. All right. Is it your impression that a few hours later, if that had come by these mobile CMOP, emergency trucks, that would have made a difference in life or death? I am putting you on the spot here. You aren't the doctor in the room, you know, I apologize for that. I withdraw that question.

I have to tell you, you know, we are wasting \$6.8 million a year in drugs. It is literally going out of date and if it is out of date, you can't resurrect it; although though, I see that you have an experimental program for extending shelf life. That just extends your liability. I mean, we all—medical liability being what it is, once a drug is expired, it is expired.

So, I would urge you, very strongly to go back and re-look at this. And with the 16 seconds remaining to me, I also want to call attention to the fact that having these drugs in the caches, especially the controlled medications—and there were 3, I believe, in the Schedule 2 drugs in the emergency caches—exposes you to risk. And we talked about missing drugs. Is it possible that those were the missing drugs?

I mean, this is a liability in anybody's hands, and I am well-familiar with having to control many, many controlled drugs. So, I would ask you to reconsider 141 medication caches at the expense that we are spending. And with that, I yield back.

Ms. BROWNLEY. Thank you, Dr. Dunn.

Mr. Cisneros, you have 5 minutes.

Mr. CISNEROS. Thank you, Madam Chairwoman.

Mr. Ratchford, I want to ask you about the inventories that are being conducted. So, the wall-to-wall inventory of the cache facilities, are they being done now on an annual basis?

Mr. RATCHFORD. There were many things that the IG identified that we were not doing prior to the audit that we are absolutely doing now, and for that we, I would like to defer to Dr. Paul Kim.

Dr. KIM. What we have done since the audit is, we have expanded the accountability. We now have 3 levels of accountability: My office, the Office of Emergency Management, the police and security folks, and the pharmacy individuals. So, what Dr. Steinwandt's team does is they do the wall-to-wall inventory and it is for all caches for that year.

What we didn't have before was this accountability. It was primarily on the Office of Emergency Management and we ran into issues not being able to do the inspections, as needed.

Now, with my colleagues' help, we are able to do those inspections. We have automated the system, and we feel pretty confident that we have solved that issue.

Mr. CISNEROS. So, when are the wall-to-wall inventories expected to be done?

Dr. KIM. I would like to defer to Dr. Steinwandt.

Dr. STEINWANDT. Yes, sir. So, that was recognized early on when we took over the program. The first wall-to-wall was done before December 31st of 2018, and it will be done annually going forward.

Mr. CISNEROS. So, in 2018, we did 141 facilities, complete the inventory?

Dr. STEINWANDT. Yes, sir.

Mr. CISNEROS. Was it all documented?

Dr. STEINWANDT. Yes, sir.

Mr. CISNEROS. And so, then, coming here in the end of December 2019, all 141 facilities will complete that inventory again?

Dr. STEINWANDT. Absolutely.

Mr. CISNEROS. And is there now a documented paper trail? I guess that was one of the things that didn't happen before, that

some of the facilities were saying that they conducted an inventory, but had no way of proving that.

Dr. STEINWANDT. Yes, sir. That is now documented electronically through a SharePoint site to where the pharmacy chief attests that this has taken place.

Mr. CISNEROS. Okay. And it goes up to the VA to whom? So, who has the ultimate responsibility for making sure that that is done?

Dr. STEINWANDT. So, I would like to go ahead and defer that to Dr. Mole.

Dr. MOLE. Thank you. So, we have begun our move towards the future state of how we are doing these inspections and audits. And so, the various members of the team complete their section of the audit, that then goes to the local medical center director to address any issues that were identified through the audit inspections and then it ultimately comes to me for approval through my office to say that they meet the standard.

Mr. CISNEROS. Okay. So, changing subjects now, I do have a question about the cache activation. You know, one of the things—I went and visited the VA hospital down there in Puerto Rico and they talked about what they did down there during Maria, but one of the things you kind of said that kind of makes me want to ask this question is, you know, when they were explaining the situation and when they were activating and what they were doing was not just for our veterans, but also for the surrounding community out there.

And so, if we are having these natural disasters where—are the VAs being activated to go and assist the community outside of the veterans that they are serving, and if so, why haven't the caches been activated for that reason if they are serving a larger community than just the veterans that they would normally serve?

Mr. RATCHFORD. Thank you for that question, sir.

When you look at the various authorities that the VA has to respond to a crisis, it ranges based upon the situation going on. Under Title 38, Section 1784, the Secretary has the authority to provide humanitarian care to people impacted on a humanitarian basis. Under Section 1785 of the same title, the Secretary has the authority to provide medical care to anyone impacted by a natural disaster. So, based upon those parameters, care can be provided to the local populous.

When you look at the normal stock—the normal stores that the VA maintains on hand at any given basis, we are not—inventory management. We have a large supply of resources on hand that adds to our resilience and also enables us to operate for a very long period of time.

Mr. CISNEROS. So, during these disasters like Hurricane Maria and others, did the Secretary actually authorize activation to provide humanitarian aid?

Mr. RATCHFORD. Activation of emergency support services?

Mr. CISNEROS. Yes.

Mr. RATCHFORD. Yes, he did.

Mr. CISNEROS. And for natural disasters?

Mr. RATCHFORD. Absolutely.

Mr. CISNEROS. Okay. I yield back my time.

Ms. BROWNLEY. Thank you, Mr. Cisneros.

Mr. Meuser, you have 5 minutes.

Mr. MEUSER. Thank you, Madam Chair.

Thank you all. Good to see you.

So, my first question would be for Mr. Ratchford. Sir, were you surprised by the IG report? Was it revealing to you and surprising?

Mr. RATCHFORD. Yes, it was surprising to me. Prior to the IG report, my organization was not part of the actual cache management program. I believe everyone at the table was surprised by the results of the audit because relatively everyone here is new in our positions, for a matter of speaking.

Once we did recognize and were aware of the challenges identified in the IG audit, we wasted no time to come together as one organization and come up with a strategy to make this better, so it doesn't happen again.

Mr. MEUSER. Right. Were some of the problems, were they IT-related? You know, it says here that there was a—within the report, there was a lack of authority to enforce the annual cache exercise requirement and monitor and compliance. Is that a piece that was surprising to you or was that one of the procedures that was causing the problem?

Mr. RATCHFORD. I am not really sure if that was one of the procedures causing the problem. As I stated before, sir, once we realized what the problem was, we spent more time focusing on a solution, rather than—on a problem.

Mr. MEUSER. No, I understand that makes sense. I am just—let me ask Mr. Reinkemeyer, you had stated that progress has been made. The recommendations were provided and listened to. Can you be specific on the progress made on the drug cache situation, as far as appropriate inventories being taken and as far as responsiveness for emergencies?

Mr. REINKEMEYER. Right now all 7 recommendations we made remain open. I can tell you though, as I mentioned in my statement, on Friday they provided us a document requesting closure of 3 of the recommendations, to include, I think, the wall-to-wall inventories and several of those items.

The team has not reviewed them. We will not close that recommendation until we are assured that the action has been implemented and that there is a plan in place. For example, we do see evidence that they conducted the wall-to-wall inventory, but we want to make sure it is a perpetual thing or a recurring thing, not just a one-time thing. So, we want to make sure that there is some document or some directive that establishes that requirement so that we have some assurance that it is going to occur in the future.

Mr. MEUSER. And Mr. Ratchford, really the same question, specifically, what progress have you made on those two categories, the drug cache as well as the emergency responsiveness?

Mr. RATCHFORD. Based upon the drug cache, I would defer that question to Dr. Steinwandt, based upon he has the logistical team member that put all of this together for that.

Dr. STEINWANDT. Okay. Thank you very much.

So, to that end, the Emergency Pharmacy Service, EPS, has provided the training for the pharmacy cache manager and pharmacy chief on how to conduct an annual wall-to-wall inventory, and as

stated earlier, that has taken place in 2018 and we are on target to get that finished in 2019, as well.

We have also gone ahead and provided training to the pharmacy chiefs and the cache managers, concerning what to do with the excess, missing, or expired items. And we went ahead and provided that training and they went ahead and did as instructed, and attested back to us that they had completed either removing or notifying EPS of the fact that they had missing medications.

Mr. MEUSER. All right. Thank you.

Has the circumstance where lacking the authority to enforce the annual cache exercise requirement and monitoring compliance, Mr. Reinkemeyer, has that been corrected at this point? Is the authority there.

Mr. REINKEMEYER. I am not aware that it is.

Mr. MEUSER. All right. Mr. Ratchford?

Mr. RATCHFORD. We have gone through a complete policy renovation and how the policy is and who can do what and the roles and responsibility of all Cache Program managers and support personnel. I will defer the specifics of that question to Dr. Larry Mole to talk specifically what the policy states.

Dr. MOLE. And if I could just ask for a clarification, what, in particular, sir?

Mr. MEUSER. Well, it seems to me that the IG report offered that one of the problems has been or lack of effectiveness and efficiency is that there is not enough authority for those on the ground to make the emergency decisions.

Dr. MOLE. So, I think in the policies that we had in place that were in place for almost a decade, actually had conflicting language, and it, to some extent, confused who the authoritative individual was, including things like the medical center director. Those are items that, as Mr. Ratchford mentioned, we have been working through all the policies to streamline it and make it very clear and concise about where those authorities reside.

Mr. MEUSER. Thank you. And I know I am over my time, but one last question: Are you continuing to work together or not just come together at extended intervals between the IG and the VA, Mr. Ratchford?

Mr. RATCHFORD. Yes, we are.

Mr. MEUSER. All right. Okay. Great.

I yield back, Ms. Chairwoman. Thank you.

Ms. BROWNLEY. Thank you, Mr. Meuser.

I will follow up and give myself another 5 minutes to follow up on some questions. So, in the event of an emergency, the medical director makes the decision to deploy a cache. There is this big emergency going on—I am going to use the hypothetical of an earthquake in Los Angeles—big emergency coming on. There are, you know, the City of Los Angeles, the County of Los Angeles, there is FEMA, there is Fire, there is, you know, all kinds of agencies involved.

And so, a medical director, although probably that cache is because the medical facility isn't necessarily been built to survive a big earthquake, it might not even be accessible, but in this scenario that I am building, then the medical director in his or her isolation decides whether to deploy this. Is there any coordination? Do these

agencies know that a cache exists? That this is a place that can look to?

I mean, how—in my district, we have had two of the biggest fires in California over the last 15 months and, you know, there are a gazillion agencies both, at the local, state, and Federal level who are addressing this issue, and they know what the drill is. They know how they are going to team up and coordinate to provide, you know, the best resources and the best results.

Is there any integration to this program with the rest of the community and how does that work?

Mr. RATCHFORD. Thank you for that question.

As you know, VA has both, a Federal and a local presence of being part of the community. So, we constantly work with the community to make sure that we have plans to—as the community, first, because all disasters are local.

When you think about the All-Hazards Cache Program, you have to keep in mind to why it was created. And its primary purpose was to bridge the gap between an event happens and the SNS arrival to that location, we can ensure a high-level continuity of care to the veterans that is resident at a local VAMC, that is been impacted by a disaster.

To speak a little bit more importantly on how VHA emergency medical teams tie into community and maybe even provide support through the cache and other programs that we have at the medical centers, I would like to defer to Dr. Paul Kim.

Dr. KIM. Thank you, Lewis, for the question.

I have staff deployed across the country. I have area emergency managers and regional emergency managers that are in just about every medical center across the country. And their primary role in emergency management is coordination and liaising with the community, and that means the local, state, and county emergency managers.

So, if there is a disaster, as you described, our emergency managers would be not only in the emergency operation center of that county, state, or local, but they would be actively planning and telling those folks what VA can do, what we can bring to the table, and making sure that we are aware, and it goes up to the secretary. And, invariably, he says, Let's do it, let's get there, and let's help.

Ms. BROWNLEY. Yeah, it seems to me that in reality, what is happening, since historically the cache has never been deployed, that in a disaster like that, you go straight to the secretary and you start to deploy what you can deploy in the area. I don't know if you have a grand plan for that separate from, you know, the cache plan—perhaps you do—but it sounds like—I mean, I, personally, I don't want to be too critical here, but I, personally, would feel it would be irresponsible for you to tell a local community that we had a cache that you know is not up to par and is not crisis ready, and so, therefore, you are going to go someplace else to find out where the VA can help.

And I understand with Hurricane Maria, there was a, you know, very noble response that the VA made, but it had nothing to do with the Cache Program whatsoever. And so, it is just—you know, it is set up for a purpose. It is set up because we have facilities

in the areas and they should be ready to respond in a very fast, quick way, which in many cases, will save lives, and yet, we are just kind of, Well, we aren't doing drills, we are not doing inspections, we are not even sure what the medical supplies are, we don't reassess on an annual basis to see if we need oxygen or other kinds of things that we might need in a particular type of disaster that we are experiencing, whether it is hurricanes or fires. It just doesn't seem like there is any real attention to this issue, which I find—I am sorry—but I find to be extraordinarily frustrating when, particularly, a community or an island like Puerto Rico is really depending on every single possible resource that we can supply them.

So, I will yield to Dr. Dunn.

Mr. DUNN. Thank you. Let me start by saying, I think this is a duplicative program. We have the VA emergency pharmacy program, so I am just going to frame it that way.

You talked about deploying a cache with a chelating agent in Syracuse, and did I hear you right, did you say DTPA or is it potassium iodide? Who said that? Who gave—I think it was you, Dr. Kim, that gave the example of a chelating agent being used in Syracuse, New York, out of the cache?

Dr. KIM. Yes, sir, that was me. And the issue was—

Mr. DUNN. Wait, what was the chelating agent?

Dr. KIM. Steve?

Dr. STEINWANDT. So, the medication that was deployed in that incident was the calcium DTPA.

Mr. DUNN. Oh, calcium iodide or potassium iodide, right? That is the normal chelating—I mean this, is for—so, normally you are treating radiation poisoning, right?

Dr. STEINWANDT. Correct.

Mr. DUNN. What else would you use besides potassium iodide for radiation poisoning?

Dr. STEINWANDT. I would have to get back with you on that, sir.

Mr. DUNN. All right. But you deployed a cache but then we read that no caches have ever been deployed. But somebody dipped into a cache; it wasn't deployed.

That is confusing to Members of Congress. It is confusing to doctors, as well, by the way.

I would also say that that chelating agent had to be available at every hospital in the city. We all have it. Everybody has it for—if you do isotope testing, you know, you have got potassium iodide somewhere in your pharmacy.

So, that cache, it was nice that it had it there. It is appropriate that it is there if you are going to treat radiation poisoning, but I don't believe that that was the only source of potassium iodide in Northern New York State. And I wonder if a 6.8—well, actually a forty-four million-dollar a year program is worth two doses of chelating agent.

General Reinkemeyer, you are the Inspector General, right?

Mr. REINKEMEYER. I am not. I am the Assistant Inspector General.

Mr. DUNN. Oh, you aren't? I'm sorry. Please go on.

Mr. REINKEMEYER. I am the Assistant Inspector General. Mr. Mike Missal is the Inspector General.

Mr. DUNN. So, I mean, do you make value-based judgments on programs—well, so this program, you know, it saves a life every now and then, but it is \$44 million a year and we think that we could also save that life in a downtown hospital or by sending for the trucks.

Mr. REINKEMEYER. So, we will certainly look at the cost and benefit of programs.

Mr. DUNN. Okay. Cost-benefit ratio, exactly.

And this is a hugely expensive program that hasn't really—you know, it is only been dipped into sort of, not strategically, but tactically over the years. And I think, again, let me say, you have this program, you have a much more thorough backup program and you have it all over the country, although, as I looked at the 7 locations, none of them was Puerto Rico—maybe you could add an eighth location or something like that. So, that is a good example of an isolated area where you aren't going to get down to in an hour or two.

I would say that the chelating agent example was not a mass—it was an example of a shortage of medication someplace that the VA made up for. Hurrah, I mean, I have been saved like that. My patients have been saved like that over the years, too, one by one, but it is not a mass—and it is not part of the system, not part of Section 121 of the Strategic National Stockpile that was passed by Congress.

And I would say, also, that it is much easier to maintain and control a system like the CMOP system where you have pharmacists who work with it every day. That is what they do. They count drugs. They account for drugs. They make sure they are controlled drugs.

And, finally, I guess I want to get to the question about the potential for controlled medications hitting the streets. We have controlled medications in these caches. We see that drugs are missing. Inspector General, can you assure me that none of the missing drugs were controlled substances?

Mr. REINKEMEYER. Yes.

Mr. DUNN. Okay. That would have been good to have in the report. I have been tossing and turning over that all night.

Mr. REINKEMEYER. And, let me add to that. The missing drugs were missing from—the records did not reconcile with the on-hand quantities. We did additional legwork and found that a lot of times, the records—it was really just a poor record—

Mr. DUNN. Poor recordkeeping. Usually when we find poor recordkeeping around morphine and Valium and temazepam, there is a reason. You know, that just happens in hospitals and clinics; that is why we have such controls in place for compliance.

I am going to echo Chairwoman Brownley's concern with the program, but I am also going to say that it looks like you have another program that works, and I would encourage you to think about falling back on that program and using it more robustly.

And with that, I yield back, Madam Chair.

Ms. BROWNLEY. Thank you, Dr. Dunn.

I just have a few more questions. I want to say that you are getting off sort of easy today because we had to change the timing of the Committee which has messed up everybody's schedule, so lots

of Members are not here, but I can assure you that every single Committee Member here is very concerned about this issue and has a keen eye on it.

But I just have to get this off my chest, and that is in your opening comments, you said that you are going to respond to all of the recommendations that the IG made, that you had gotten an update last Friday on how you were going to do that, and you are reviewing that this week, is what you said in your opening statement.

So, this is where my frustration lies. You know, we have a Committee hearing to ask you about, you know, this particular mission, the fourth mission of the VA, which you have had some kind of report and update in terms of how you were going to improve upon it, but yet, you can't share any of that. I mean, you have had Monday, Tuesday, and Wednesday, and I am not expecting to have, you know, a 25-page report and an entire program ironed out—I get that; that takes time—but it seems like you should be able to respond in some sense about how you are going about, you know, addressing and responding. You could give us some sense of certainty that, you know, that you are working on this, that you have got your arms around all of these issues.

It just seems to me that you would be able to do that. So, I am just getting that off my chest. You know, I don't want to come to the conclusion that you said that because you don't want to report to us about it, but I can assure you that we are going to be following up on that, too, because it is our responsibility to make sure that any program, and particularly a program that is set up and designed to save lives in an emergency is up to snuff, that we are ready.

And so, it is very important to us and we will be making sure that the VA is in a place to be responsive. So, if you have any comments towards my comment, I would be happy to hear them. No comment? Okay.

So, the last couple of questions, on the emergency refill program where in an emergency situation, a veteran can go to a local pharmacy to get their prescriptions filled, is that—do we have a common understanding of that?

Mr. RATCHFORD. Yes, ma'am, that is correct.

Ms. BROWNLEY. Okay. So, was this done during Hurricane Sandy, Irene, and was this program utilized during Hurricane Maria at all?

Mr. RATCHFORD. Thank you for the question, again, Madam. As far as my tenure here with the VA, I can confirm that the program was used during Hurricane Maria.

As far as Hurricane Sandy and Irene, I would like to defer to Dr. Paul Kim to respond to that portion of it.

Dr. KIM. We have activated the Heritage contract for all of the responses that I have been involved in, over the last several years, to include the wildfires in California and other flooding and disasters that we have been involved in where the veterans could not get to the medical center or the mail delivery system was interrupted. So, they could go to their local pharmacy and get what they needed.

Ms. BROWNLEY. Okay. And was this an option for veterans during flooding in the Midwest this spring and, you know, who is re-

sponsible for establishing these relationships with facilities and raising awareness among veterans that can do this? How do you educate veterans?

Dr. KIM. Yes, ma'am. It is up to the local medical center and they do a very active advertising campaign, if that is the right term, to let veterans know that that is available, and they work directly with the community pharmacies.

Ms. BROWNLEY. Okay. So, in my district where we had two fires, we don't have a medical center, so there wouldn't be anybody to tell us about that, so who would, in lieu of not having a medical center?

Dr. KIM. I can take that back and we will make sure that that gets done.

Ms. BROWNLEY. Okay. Last question and then we can adjourn, unless Dr. Dunn, you have some more questions, but the VA report made it very, very clear that we had—you had—the VA had one person who was responsible for properly supplying VA for all of its drugs in every single center across the country in a timely manner. One person was responsible for that.

So, it is my understanding, as I said in my opening remarks, that that person is no longer with the VA. Can somebody nod their head to say if I have that assumption correct? Okay. So, this person is no longer there, and the responsibilities have been shifted to the Consolidated Mail Outpatient Pharmacy; is that correct?

So, now, given that transfer, what assurances can you give this Committee that this change ensures that the caches will be stocked properly and, in a mission-ready status?

Mr. RATCHFORD. Thank you, again, for that question, Madam Chairwoman.

It is always bad to have a single point of failure and that is one of the things we recognized as we received the report and we reviewed it. For that question answer, specifically, I would like to defer to Dr. Steinwandt to give more specifics as to how we have improved thank you through the CMOP process.

Dr. STEINWANDT. So, since we took the Emergency Pharmacy Service underneath the wing of the CMOP program, at the Heinz facility itself, I have got logistics experts that are there on-site that can go ahead and spearhead to make sure that we get the drugs ordered in a timely fashion.

We also have a national CMOP logistics program, so if we run through any difficulties or if we need any assistance, they will be able to provide that assistance with us, as well.

Ms. BROWNLEY. Okay. And it is my understanding, too, the IG was just pointing out that when they did their audits, in terms of the accounting of the drugs, you know, the paperwork didn't add up to what was physically on the site. And so, you know, how are you keeping care of that inventory database?

Dr. STEINWANDT. So, with the inventory database, a couple of problems that we were having, number one was—is that there was assumptions by the individual that was putting the data in there that we would be seeing, for instance, the shelf life extension program, we would be seeing the data back within a certain timeframe and they would actually put in that projected timeframe as an expiration date, which, of course, is not correct. The other issue was that we were not having an open book to the field. We were not

showing them, at the time, what their master inventory list looked like.

So, what we have done is we have created a folder for each site that they can access securely for their site, and every day it is uploaded with the master file for them to go ahead and bounce against to make sure that what we say that they have at their site is actually what they can confirm for.

Ms. BROWNLEY. So, do you have confidence now in the process, in the system?

Dr. STEINWANDT. Yes, ma'am.

Ms. BROWNLEY. All right. Well, I will stop here.

Dr. DUNN, if you have any more questions?

Mr. DUNN. I just want to thank the chairwoman for calling this hearing. Left to my own devices, I might not have ever wandered into this particular subject.

But I hope this gives the VA reasons to go back and reflect on the concerns that you have today from the Members of Congress who are concerned about this, and also, perhaps, to reflect on the system and whether or not it is actually needed with your CMOP system. I think you could save us all a lot of money and save yourself a lot of work and embarrassment by simplifying the program a little bit.

But that is just my thought, and thank you very much, Madam Chair.

Ms. BROWNLEY. Thank you, Dr. Dunn.

And I want to thank all of you for joining us today and being here. I know I have expressed some frustration. I really do want to be a partner. This is a very important program and mission for the VA, but as I said before, this Committee will be very diligent in terms of our oversight to make sure that this program gets—you know, I don't know what grade we would give it, but we need to be—you know, there is great improvement that needs to be done; let me frame it that way. And we will be following your progress.

And with that, all Members will have 5 legislative days to revise and extend their remarks and include extraneous material, and, without objection, the Subcommittee stands adjourned.

[Whereupon, at 11:51 a.m., the Subcommittee was adjourned.]



# A P P E N D I X

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## **Prepared Statement of Lewis Ratchford**

Good morning Chairwoman Brownley, Ranking Member Dunn, and Members of the Subcommittee. Thank you for the opportunity to discuss the VA Emergency Response and All Hazards Emergency Cache (AHEC) program. I am accompanied today by my colleagues from the Veterans Health Administration (VHA): Dr. Larry Mole, the Chief Consultant for Population Health Services; Dr. Steve Steinwandt, the Hines Consolidated Mail Outpatient Pharmacy Director and Emergency Pharmacy Director; and Dr. Paul Kim, Director of VHA Office of Emergency Management.

### **Introduction**

In response to the terror attacks of 9/11, the United States (U.S.) Government took on a herculean task to overhaul homeland security efforts across all sectors of Government. On November 7, 2002, the VA Emergency Preparedness Act of 2002 (Public Law 107-287) became law and began the transformation of VA's preparedness mission. This Act not only enhanced VA's role as part of the Federal response effort aimed at preventing events like 9/11 and the anthrax attacks of 2001, it also served as a catalyst for VA to develop resilient capabilities that would support continuous delivery of services to Veterans in an all hazards environment.

Simultaneously, the Department of Health and Human Services (HHS) was in the process of implementing the Public Health and Bioterrorism Preparedness and Response Act of 2002, which enhanced the viability and capability of the Nation's Strategic National Stockpile (SNS) designed to aid in mitigating the consequences of a Chemical, Biological, Nuclear, or Radiological (CBRN) event or other public health emergency within the U.S. To complement these efforts, VA, on its own, established the All Hazards Emergency Cache (AHEC) program to bridge the gap until the SNS is operational in the local area impacted by a CBRN event or public health emergency. This capability was primarily designed to preserve VA's health care delivery infrastructure to ensure the continued delivery of services to our Nation's Veterans under the care of their local VA Medical Center (VAMC). AHEC included Medical Countermeasures that were either not stocked in the local VA pharmacy's inventory or quantities that would augment what was on hand to enable a rapid response to a public health emergency or CBRN event.

Today, the mission of the AHEC program remains the same as when it was created. And as a direct result of the VA Office of the Inspector General (OIG) audit dated October 31, 2018, VA continues to implement improvements to increase and ensure the readiness of AHEC to support consequence management operations and ensure the continued delivery of services to our Nation's Veterans.

### **VA Mission Readiness**

The establishment of the AHEC program was just the beginning of the evolution of VA's mission readiness and assurance programs.

One of VA's proudest moments occurred during the 2017 Hurricane response season was when the Department was identified as a major contributor to the overall Federal response while sustaining local VA operations. As a testimony to VA's preparedness and emergency response capabilities, the San Juan VAMC was the only hospital that remained operational throughout the response phase of Hurricane Maria and served as the initial base of operations for several Federal response entities. In partnership with HHS, the Department of Defense, and the Federal Emergency Management Agency, VA evacuated 423 personnel from the Caribbean; cared for over 6,500 personnel at the Manati Federal Medical Station; and provided emergency dialysis support to 76 non-Veteran personnel. To ensure a successful response to Hurricane Maria, VA transported 128 short tons of critical resources and response equipment to Puerto Rico and deployed 1,039 personnel to support both VA and Federal mission needs. In addition, VA deployed mobile canteen services that

provided over 100,000 at-cost meals to disaster survivors and Mobile Vet Centers that provided readjustment counseling services to over 4,500 disaster survivors.

In response to Hurricanes Florence and Michael in 2018, VA again demonstrated its agility to rapidly respond to crisis by establishing Veteran support sites that were one-stop shops for Veteran disaster survivors to receive nutritional, mental health, pharmaceuticals, medical care, and other services to aide in their recovery. The ability to respond with the breadth and depth of capabilities identified above does not happen by accident. This type of response capability is only achievable by having dedicated personnel and long-term investment strategies in response systems that are designed to support day-to-day operations, and during crisis, decisively equip response personnel with the resources necessary to manage the consequences associated with a disaster.

### **OIG Report on the Emergency Cache Program**

VA appreciates the OIG review as it has led to strengthening VA's AHEC program. Since the publication of the report, VA has implemented improvements to the inventory management and internal controls for the All Hazard Emergency Cache program. In response to the OIG recommendations, VA's Emergency Pharmacy Service (EPS) conducted training and aided medical facilities with their first annual wall-to-wall inventory of all cache drugs and supplies. The training provides the foundation for a reliable, efficient, and accurate cache formulary management process. Based on the training, all sites conducted the first enterprise-wide inventory of every facility AHEC. Because of the recent inspections, the individual cache inventories have been reconciled with the master inventory file. Cache sites now receive updated inventory sheets for use during wall-to-wall inventories. Additionally, the agency has developed a SharePoint file folder system for each site in which the existing master inventory file as entered in the software system is sent daily to the folder. Access to the folder is site specific.

Additionally, EPS developed processes to re-label all expired or excess inventory of drugs that are purposefully maintained to respond to drug shortages or for potential Shelf Life Extension program (SLEP) testing, and to remove and rectify cases of other expired, missing, or excess inventory of drugs. The Department of Defense administers SLEP, a program through which the Food and Drug Administration conducts periodic stability testing of certain drug products to extend the expiration date of such products to help defer their replacement costs in critical Federal stockpiles, with the goal of helping to ensure public health preparedness for U.S. military and civilian populations. VHA is coordinating a comprehensive policy that will modernize processes, clearly assign responsibilities among the many program offices with emergency management responsibilities and set requirements that ensure the AHEC program is always mission ready.

VHA provided training on the processes to ensure that expired, excess, incorrect, or missing items discovered during any inventory activity are handled appropriately. Sites were required to remove all expired, excess, and incorrect items from the caches and certify removal. Any items identified as missing are being replaced at affected sites. EPS has sent signage for any items that are expired but purposefully kept in the AHEC because the item is either being tested for SLEP or on national backorder without the availability of a suitable substitute. Sites have certified that signage is appropriately affixed to the expired items. All these requirements will be reviewed by the VHA Office of Emergency Management personnel during their cache inspections.

VHA has assessed the continued use of SLEP in conjunction with stock rotation and returns to a contracted vendor for appropriate disposition from a combined perspective of cost savings and patient safety. The justification to use SLEP varies by Federal agency. VHA participates in SLEP using pharmaceuticals with the following characteristics:

1. Little use in routine care of Veterans;
2. Limited availability from manufacturer; and
3. Excessive replacement cost (>\$500,000)

Importantly, all three characteristics must be considered for a given drug since one may outweigh (or minimize) another. For example, an expensive product may not be appropriate for SLEP if the volume normally used by VHA is large enough to permit cost-effective, stock rotation. Using this model, VHA determined that 12 pharmaceuticals should remain in SLEP; 6 for cost versus stock rotation; and 6 others with no clinical use in VHA. There are 13 additional pharmaceuticals that would not qualify for SLEP, most falling under a stock rotation program. SLEP- extended pharmaceuticals should not be used in routine patient care settings. VHA policy will be updated to reflect the appropriate use of SLEP.

The agency conducted a comprehensive assessment and feasibility analysis of drugs that can be readily used in a medical facility operation. EPS, with the oversight of the AHEC Committee, developed criteria for each medication based on the usage patterns of the VA medical facilities, the ability of a medication to be successful in the SLEP program; the availability of the medication through the manufacturers; and replacement cost of the medication. The AHEC Committee approved the assessment and feasibility analysis.

A comprehensive review of VHA Directives 1047(1) All-Hazards Emergency Cache Program and 0320.10 Inspection of VA All-Hazards Emergency Caches by the VHA Office of Emergency Management is underway which includes an assessment of roles and responsibilities for VHA Central Office program offices and Veterans Integrated Services Networks and field leadership. In December 2018, there was an organizational realignment of 6 program offices in VHA Patient Care Services including Public Health. This realignment was part of VHA Modernization and brought together program offices with similar functions and activities. An Integrated Program Team has been meeting since July 2018 to create the new vision, mission, strategy, and goals for a re-envisioned national Population Health program. One of the eight focus areas of this new program is emergency management. As the VHA Directives mentioned above are revised, responsibilities related to emergency management and Population Health will include clarifying the roles and responsibilities in the AHEC.

### **Conclusion**

We appreciate this opportunity to share our efforts to strengthen VA's preparedness to respond to public health or CBRN emergencies and our continued commitment to develop resilient capabilities to respond to crisis. Our objective is to give our Nation's Veterans the top-quality care they have earned and deserve, even in an all hazards environment.

Chairwoman Brownley, we appreciate this Subcommittee's continued support and encouragement in identifying and resolving challenges as we find new ways to care for Veterans. This concludes my testimony. My colleagues and I are prepared to respond to any questions you may have.

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### **Prepared Statement of Larry Reinkemeyer**

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 health care services to veterans and others is vital. In October 2018, the OIG published a report, the Emergency Cache Program: Ineffective Management Impairs Mission Readiness.<sup>1</sup> 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

<sup>1</sup>Emergency Cache Program: Ineffective Management Impairs Mission Readiness, October 31, 2018.

of a terrorist attack, or biological or natural disaster.<sup>2</sup> 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.

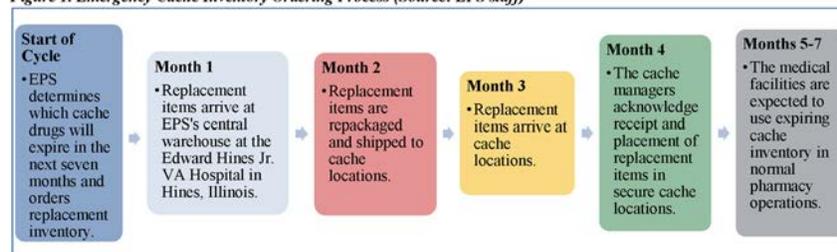
As of January 2018, there were emergency caches at 141 VA medical facilities, with a standard supply of 38 drugs (three are controlled substances) and 44 medical supplies, collectively worth about \$44 million. One of the caches in each Veterans Integrated Service Network also carries two drugs to treat 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.

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.

<sup>2</sup>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).

### **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.<sup>3</sup> The OIG's examination of the same 25 drugs at each site, for a total of 650 drug inspections, yielded seven key findings:<sup>4</sup>

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

<sup>3</sup> 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.

<sup>4</sup> 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.

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.<sup>5</sup>

### **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 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;
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.

<sup>5</sup> 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.

## **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.

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## **STATEMENT FOR THE RECORD**

### **HERITAGE HEALTH SOLUTIONS**

Heritage Health Solutions (Heritage) welcomes the opportunity to submit this Statement for the Record to the House Committee on Veterans' Affairs Subcommittee on Health. While Heritage does not work directly with the Department of Veterans Affairs (VA) Emergency Response and Pharmaceutical Cache Program, we have had significant experience working with the VA before, during, and after disasters across the country.

#### **INTRODUCTION**

Heritage is an integrated health care solutions provider located in Coppell, Texas. Heritage has more than a decade of experience providing first and emergent pharmacy services to the Department of Veterans Affairs and veterans.

Since 2005, Heritage has provided the VA with a cost effective solution to ensure that veterans have access to urgent and emergent medications when a VA pharmacy is unable to fill a prescription. Most often, the services are used when veterans are unable to reach a VA pharmacy due to the distance from the clinic to the closest VA pharmacy. When a veteran is in need of medications, Heritage is able to work with that veteran to pick up a 10–14 day supply of his or her prescription medications at one of the 65,000 retail pharmacy locations in our pharmacy network. When a veteran receives a prescription from an authorized prescriber, the veteran presents the VA authorized prescription and a voucher at a retail pharmacy and receives his or her medications with no out of pocket expense. This solution provides veterans with immediate access to needed medications while the remaining supply of medication is processed and delivered through VA's mail order system.

These services allow the VA to exercise appropriate controls related to which medications on the VA National Formulary qualify as first and emergent, and only prescriptions from VA authorized prescribers can be filled at the retail locations.

#### **DISASTER RESPONSE PLANNING**

Several years ago, we recognized the need to develop a disaster response plan that would be ready for implementation in the case of a natural or other type of disaster. With this disaster response plan, Heritage works with the VA to provide veterans access to medications during a natural disaster or other disruptions to the pharmaceutical supply chain and distribution system. In some instances, the infrastructure that exists after a natural disaster is the roadblock to care. When there is disruption in the power supply, pharmacies are unable to keep medications, such as some insulins, at the appropriate temperature. When roads are washed away or littered with debris, the pharmacies may be inaccessible. Planning around these types of uncertainties is critical to the success of the disaster response plan. Having a well-managed cache of medication is important. But that is just one part of the solution. The ability to distribute these medications can be impacted in a disaster, and appropriate planning needs to be in place to address those types of challenges.

Often, during a natural disaster, veterans are displaced from their homes and are unable to access a VA pharmacy or receive necessary medications from the VA mail order system. It is not uncommon that veterans are forced to quickly evacuate their homes, and they often leave without an adequate supply of medication. Furthermore, when veterans are displaced from their homes for an extended period of time

because the natural disaster prevents them from getting back to their homes, they are unable to rely on VA's mail order system for their prescription re-fills.

Under these circumstances, it is important that a process be in place to provide veterans with a seamless system to help identify what medications are needed and ensure veterans can gain access to emergent medications such as insulin, inhalers, and antibiotics. Utilizing our disaster response plan allows the VA to ensure that veterans have access to their VA authorized prescriptions at a retail pharmacy during the disaster response.

For example, during our work with the VA after recent disasters, we encountered a situation where an elderly veteran was forced to quickly evacuate his home and was unable to remember what medications he was taking. We were able to work with the VA, the veteran, and family members to identify the veteran's medications and then provide the family caregiver with information on where to fill a new prescription.

Heritage has also worked with retail pharmacy chains to identify and communicate to the VA which retail pharmacy locations are open in the disaster response area. With this information, the VA and Heritage are able to direct veterans to locations that are operational and have the needed medication in stock.

The Heritage disaster response plan is an adjunct to the VA's Emergency Cache Program and serves as an augmentation to the VA's own Disaster Response Plan. Either upon notification of an impending event by the VA, or Heritage's own vigilance, we start an internal disaster response scenario. Our response includes advising VA leadership on the potential impact of the event, tailoring options to manage both patient risk and cost control, notification of participating pharmacies, and consistent reporting of utilization back to the VA. The constant flow of communication provides key leaders with the data required to make more informed decisions regarding the appropriate access to medications depending upon the severity and extent of the disaster.

#### **DISASTER RESPONSE DETAILS**

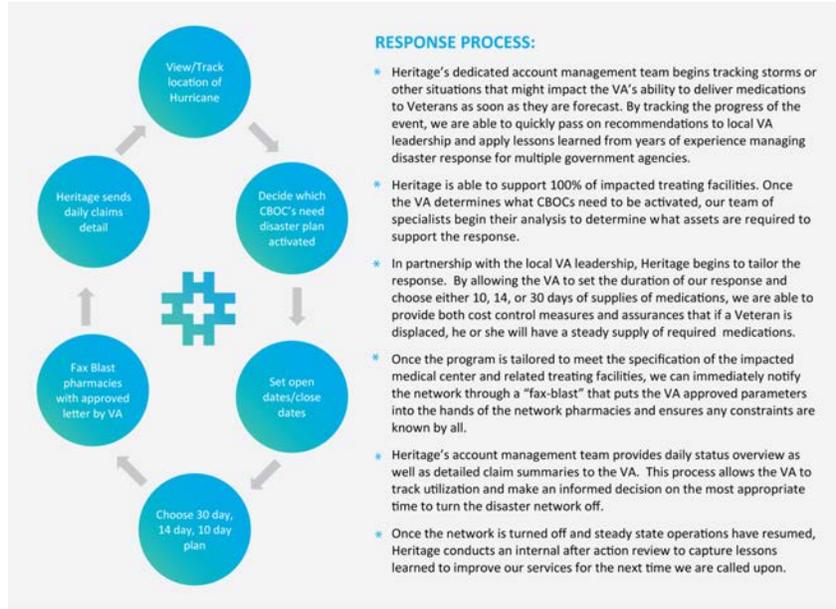
Heritage has activated its disaster response plan many times in recent years. In 2018, Heritage successfully assisted the VA with their responses to Hurricanes Helene (Pacific Islands), Florence and Michael. 2017 was also a very active year for hurricanes with Harvey, Irma, Jose, and Maria devastating many parts of the Gulf Coast, Puerto Rico and the Virgin Islands.

In addition to hurricanes, Heritage has also assisted the VA after the wildfires in California and throughout the Western states. And more recently, we have helped manage the responses to flooding in Arkansas and Oklahoma. We are well aware of how disruptive and damaging these kinds of natural disasters can be for those impacted by them, and we are grateful to be a small part of the efforts to assist veterans in the aftermath.

The VA also used our program to fill prescriptions in Colorado as the VA updated critical IT infrastructure in their pharmacies, which caused a temporary disruption to the VA's ability to fill prescriptions for veterans.

Our disaster response plan has been incorporated into the VA's requirements for the first and emergent pharmacy program, and it currently serves as the basis for the statement of work on many first and emergent prescription program contracts within the VA today.

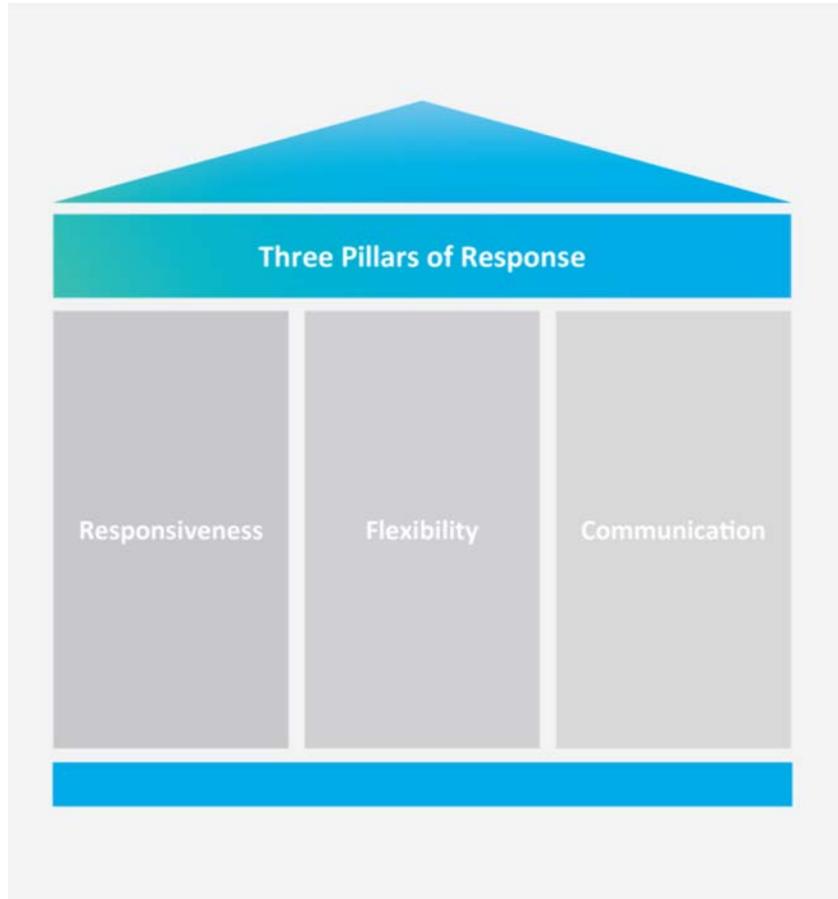
The following is an example of the response process Heritage implements to respond to natural disasters:



### LESSONS LEARNED AND RECOMMENDATIONS

Heritage continues to be impressed with the VA's commitment to caring for veterans during disasters. The VA's graduated disaster response scenarios allow for a scalable solution that capitalizes on the availability of contractor inventories for smaller more regional events through the establishment of emergency caches of critical medications for more wide scale, catastrophic events.

As part of our work with the VA, we have continually strived to improve the disaster response process. In our experience, the success of our disaster response plan rests on three pillars: Responsiveness, Flexibility, and Communication.



Because each disaster has its own unique set of circumstances, we have identified the following lessons learned and make the following recommendations for Congress and the VA to consider in the future:

- Responsiveness is key. The ability to quickly and effectively activate a disaster network can assist the VA leadership with their strategic messaging efforts to inform veterans of available resources in a timely manner. Development of a step-by-step guide for the VISN's to utilize might be a useful tool to provide the details necessary to effectively plan and respond to disasters.
- As part of our disaster response plan, Heritage expands our business hours and the availability of our staff at no cost to the VA. We also provide the VA with 24 hour POC information in case of emergency. These steps help provide for a seamless response system for veterans and the VA.
- As part of our disaster response plan, we partner with both the VA's mobile medical unit and national retail pharmacies to establish a dedicated service line for veterans filling prescriptions. This type of process has improved communications between the retail pharmacy and Heritage and ensured that veterans received immediate access to their medications. Replicating this type of approach more broadly may further improve disaster responses.
- Increased use of Social Networking can directly impact the number of calls that our Customer Care Center receives during a disaster. Providing veterans, their family members and other caregivers with a number they can call to assist them in filling a veteran's prescription helps take a concern off their agenda during a high stress event in their lives.

- Assisting veterans with their medication needs can become more complicated in a disaster setting. Having a disaster response plan already developed and ready to be implemented at a moment's notice can reduce both financial and medication compliance risks for both the VA and their patients. The disaster response plan needs to be precise enough to target impacted populations yet flexible enough to shift as an event matures and migrates through the country.
- It is possible that the VA's Emergency Response and Pharmaceutical Cache Program could benefit from pursuing a private-public partnership that would take advantage of industry's agility while adhering to the complex mission and requirements of the program. Increasing the use of contractor management of the program would, if structured properly, encourage the appropriate use of the FDA's Service Life Extension Program. The use of contracted management could also alleviate the VA's concern about using reverse distribution services by combining those services as a requirement in a single contract vehicle.
- Veterans are not the only population impacted by disasters. Patients on other government insurance plans such as Medicare and Medicaid could similarly benefit from this type of system. We believe the disaster response plan we have developed is tailorable to other agencies and scalable to meet the demands of large and small agencies - thus useful as a possible guide to other Federal agencies.

### **CONCLUSION**

Throughout our work responding to disasters on behalf of the VA, Heritage has been able to use creative and innovative solutions to assist veterans. In certain situations, private sector Industry has an unparalleled ability to provide agile procedures that can quickly adapt and respond to changing demands and situations on the ground during a disaster.

Heritage is committed to working with the VA to help them find solutions to their most challenging health care problems. We firmly believe that private-public partnerships, under certain conditions, can be a tremendous asset and we are honored to be one of the VA's service providers.

