Department of Veterans Affairs Veterans Health Administration Washington, DC 20420

Amended January 10, 2023 VHA DIRECTIVE 1047(1)
Transmittal Sheet
April 21, 2020

ALL-HAZARDS EMERGENCY CACHE PROGRAM

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policy for oversight, configuration, maintenance, activation, audit, and inspection of national and local cache programs. These programs involve the use of potentially life-saving pharmaceuticals and medical supplies in response to catastrophic chemical, biologic, radiation, nuclear, explosion, and public health emergencies which overwhelm existing health care resources.

2. SUMMARY OF MAJOR CHANGES:

Amendment dated January 10, 2023 updates the language in Appendix B, paragraph 1.b.

Major changes as of April 21, 2020 include: VHA directive clarifies the purpose of the All-Hazards Emergency Cache in paragraph 1, establishes new lines of authority and responsibility in paragraph 5, uses an updated definition of All-Hazards Emergency Cache Program in paragraph 3, and consolidates multiple policies into a single directive.

- **3. RELATED ISSUES:** VA Handbook 0730(5), Security and Law Enforcement, dated July 11, 2014; VHA Directive 0320, Comprehensive Emergency Management Program, dated April 12, 2013; VHA Directive 1108.02(1), Inspection of Controlled Substances, dated November 28, 2016; and VHA Directive 1108.07, Pharmacy General Requirements, dated March 10, 2017; VHA Handbook 1108.01(1), Controlled Substances Management, dated May 1, 2019.
- **4. RESPONSIBLE OFFICE:** The Office of Population Health (10P4V) is responsible for the contents and oversight of this directive. Questions may be directed to the Department of Veterans Affairs Office of Population Health at VHA ALL-HAZARD EMER CACHE (VHAALLHAZARDEMERCACHE@VA.GOV).
- **5. RECISSIONS:** VHA Directives 1047(1) All-Hazards Emergency Caches, dated December 30, 2014; and VHA Directive 0320.10, Inspection of VA All-Hazard Emergency Caches by the VHA Office of Emergency Management, dated July 26, 2017, are rescinded.
- **6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of April 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Lucille B. Beck, PhD.
Deputy Under Secretary for Health
for Policy and Services

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publication Distribution List on April 22, 2020

Amended January 10, 2023

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ALL-HAZARDS EMERGENCY CACHE PROGRAM

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy for national and local emergency pharmacy caches comprised of life-saving pharmaceuticals and medical supplies for use in response to catastrophic public health emergencies. These caches are known as Department of Veterans Affairs (VA) All-Hazards Emergency Caches (AHEC). Veterans Integrated Service Network (VISN) or VA medical facility supplies used for emergency operations related to manmade disasters or emergencies and natural disasters (e.g., floods, hurricanes, earthquakes) are covered under this directive. **AUTHORITY:** Title 38 United States Code (U.S.C.) 1785, 7301(b); 42 U.S.C. 300hh-11(b), 5170a(1), 5170b, 5192, 8117; and Title 38 Code of Federal regulations (CFR) 17.86.

2. BACKGROUND

- a. The Department of Veterans Affairs Emergency Preparedness Act of 2002 (Public Law 107-287) served as a catalyst for VA to develop resilient capabilities that would support continuous delivery of services to Veterans in an All-Hazards environment. The law established the requirement for emergency preparedness and readiness for VA medical facilities, the tracking of pharmaceutical and medical supplies, participation in the National Disaster Medical System (NDMS), and it amended the authority to furnish health care during major disasters and medical emergencies. The law references preparedness for Chemical, Biological, Radiological, Nuclear, and Explosive weapons (CBRNE), and other public health emergencies including pandemic events.
- b. The U.S. Departments of Homeland Security (DHS) and Health and Human Services (HHS) are responsible for identifying specific high-priority CBRNE threats. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), a Federal Government interagency group led by HHS, publishes an annual list of the

high-priority threats that is used to guide the development, procurement, and stockpiling of pharmaceuticals and medical supplies for the Strategic National Stockpile (SNS).

The SNS is designed to respond to CBRNE events with delivery goals of 12 hours or less to the States impacted by the event. The States, in turn, distribute assets to designated hospitals or other facilities in accordance with established agreements and protocols. In a catastrophic public health emergency, most hospitals will need to function with on-hand stock and limited re-supply for at least 24 to 48 hours.

c. The VA AHEC has been designed to complement the SNS and local pharmacy formulary and stock levels to ensure short-term preservation of the VA health care infrastructure until other resources can be made available in the immediate area. VISNs and VA medical facilities may find themselves receiving casualties from a CBRNE emergency or natural disaster that overwhelms local inventory of medications and supplies and replacement stock from prime vendors or the VHA Consolidated Mail Outpatient Pharmacy (CMOP). As part of a VA medical facility's emergency operations plan, VA medical facilities must prepare to provide care on a humanitarian basis

these victims and provide necessary support and protection to Veterans and VA staff. The AHEC does not provide all emergency supplies that may be required for a local disaster such as a flood, earthquake, hurricane, or fire. The AHEC may be used in response to an epidemic that arises from a local disaster. See Appendix A for further details.

3. DEFINITIONS

- a. <u>After Action Review.</u> The After Action Review (AAR) summarizes key exercise-related evaluation information, including the exercise overview and analysis of objectives and core capabilities.
- b. <u>All-Hazards Emergency Cache.</u> AHEC is a stock of specific pharmaceuticals and medical supplies required to administer the pharmaceuticals stored under specific guidelines at specific VA medical facilities. The AHEC serves a limited population of local facility Veterans and staff during the initial 48 hours of a major catastrophic emergency. *NOTE:* The list of specific pharmaceuticals is confidential, and access is only granted to individuals who need it to perform approved duties.
- c. <u>All-Hazards Emergency Cache Stock Rotation</u>. AHEC stock rotation is a cost-savings measure that refers to the planned, timely transfer of pharmaceuticals and medical supplies from the AHEC to VA medical facilities normal stock for use prior to product expiration.
- d. <u>Casualties.</u> Casualties include individuals directly injured by an event and those individuals requiring intervention to prevent potential illness or injury.
- e. <u>Catastrophic Public Health Emergency.</u> Catastrophic public health emergencies include CBRNE events that result in the uncontrolled release of chemicals, biological agents, or radioactive contamination into the environment or explosions that cause widespread damage. CBRNE events can be intentional (terrorist acts) or unintentional. Unintentional CBRNE events include accidents as well as naturally occurring epidemic or pandemic events of high-consequence infectious diseases such as pandemic influenza. Catastrophic natural disasters such as massive earthquakes, floods, hurricanes, and fires can result in a public health emergency.
- f. Emergency Management Capability Assessment Program. The VHA Office of Emergency Management conducts assessments of the Comprehensive Emergency Management Programs (CEMP) at VA medical facilities called the Emergency Management Capability Assessment Program (EMCAP). This program exists to ensure resiliency and continuity of functions essential to the delivery of health care services for VA patients, military personnel, and the public, as appropriate, in the event of a disaster, emergency or other contingency.
- g. <u>Emergency Operations Plan.</u> An Emergency Operations Plan (EOP) provides the structure and processes that the organization utilizes to respond to and initially recover from an incident/event. The EOP is implemented through the Incident Command System. It refers to the documentation that addresses all hazards through

the "Basic Plan", "Functional Annexes", and "Incident Specific Appendices." For more information, please refer to VHA Directive 0320, Comprehensive Emergency Management Program, dated April 12, 2013, and VHA Directive 0320.01, Veterans Health Administration Comprehensive Emergency Management Program (CEMP) Procedures, dated April 6, 2017.

- h. <u>Point of Dispensing.</u> Point of Dispensing (POD) locations are places where medical countermeasures such as vaccines, antiviral drugs, antibiotics, antitoxins, and chemical antidotes are dispensed and administered. In the event of a large-scale CBRNE event, the medications from the AHEC would be distributed through PODs.
- i. Shelf Life Extension Program. The Shelf Life Extension Program (SLEP) extends the expiration dates for specific medications and supplies stored in Federal stockpiles. SLEP is coordinated through multiple agencies. The Defense Health Agency (DHA), in coordination with the Food and Drug Administration (FDA), the Military Departments, the Defense Logistics Agency, CDC SNS, the State Department, the Federal Bureau of Investigation, VA, and several other Federal agencies, administers a comprehensive SLEP in order to avoid replacement costs for potency-dated pharmaceuticals in pre-positioned stockpiles. The FDA also 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.
- j. <u>Strategic National Stockpile.</u> SNS is the Nation's largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out. The SNS is separate from the VA AHEC.

4. POLICY

It is VHA policy that VISN and VA medical facility Directors create a local emergency operation's plan in collaboration with local and State authorities that includes the potential use of an AHEC. It is VHA policy that VA medical facilities designated by the Under Secretary for Health to house an AHEC must have plans to securely store, maintain, inspect, and audit a cache of pharmaceuticals and medical supplies reserved specifically for the prevention or treatment of casualties from a catastrophic public health emergency.

5. RESPONSIBILITIES

- a. <u>Under Secretary for Health.</u> The Under Secretary for Health is responsible for:
- (1) Approving the contents and stock levels of items in the national and local AHEC formulary.
- (2) Assigning which VA medical facilities house a cache and the size (large, small) of that cache at the initial cache approval and as needed.

- (3) Ensuring funding for implementation, maintenance, and oversight of AHEC.
- (4) Ensuring that the contents or locations of the AHEC are proprietary for VA and are not released to any person or agency external to VA without approval of the Under Secretary for Health.
 - (5) Reviewing the annual report on AHEC activities from the AHEC leadership team.
 - (6) Ensuring overall compliance with this directive.

NOTE: VA personnel who need to know the contents and locations of AHECs can receive this information if it is essential to perform their disaster-related duties as outlined below.

- b. <u>Deputy Under Secretary for Health for Operations and Management.</u> The Deputy Under Secretary for Health for Operations and Management is responsible for:
 - (1) Communicating the contents of this to each VISN.
- (2) Ensuring that each VISN Director has sufficient resources to fulfill the terms of this directive at all VA medical facilities within that VISN.
- (3) Providing oversight of VISNs to ensure compliance with all applicable statutes, regulations, and VA and VHA policies.
- c. <u>Deputy Under Secretary for Health for Policy and Services.</u> The Deputy Under Secretary for Health for Policy and Services is responsible for:
- (1) Collaborating with the Deputy Under Secretary for Health for Operations and Management regarding communication of the contents of this directive to each of the VISNs.
- (2) Collaborating with the Deputy Under Secretary for Health for Operations and Management regarding oversight of VISNs to ensure compliance with all applicable statues, regulations, and VA and VHA policies.
- d. <u>Director</u>, <u>Office of Population Health</u>. The Director of the Office of Population Health is responsible for:
 - (1) Providing subject matter expertise on public health and cache contents.
- (2) Ensuring currency of the AHEC contents through annual and ad hoc review and comparison with the SNS.
- (3) Making recommendations to modify the contents and locations of the AHEC to the Under Secretary for Health.
- (4) Initiating and providing final approval of annual audit and inspection of regional and local AHEC programs.

- (5) Ensuring the completion of the annual audit of the cache.
- (6) Reporting annually to the Under Secretary for Health and VISN Directors on cache use, audit and inspection results, and cost of the cache program.
- (7) Approving temporary exemptions to AHEC policy in cases where supplies are destroyed, or security is compromised. **NOTE:** Temporary exemptions in AHEC policy are stored with AHEC Leadership.
- (8) Serving as chair and setting schedules and timelines for the AHEC leadership team and AHEC Program Committee.
- (9) Summarizing important findings from metrics and reports prepared by the AHEC leadership team and providing recommendation to send to the Under Secretary for Health.
- e. <u>Lead, All-Hazards Emergency Cache Leadership Team.</u> The AHEC leadership team is comprised of representatives from the Offices of Emergency Management, Pharmacy Benefits Management/Emergency Pharmacy Service (EPS), and the Office of Population Health (lead). The AHEC leadership team is responsible for:
- (1) Establishing a process for reviewing and recommending modifications to the cache to the Under Secretary for Health including products, quantity, location and size.
 - (2) Reviewing the following metrics and reports for the Under Secretary for Health:
 - (a) Quarterly assessments of cache activations.
 - (b) Annual summaries of AHEC audit and inspection.
- (c) Annual assessments of inventory management including stock rotation and cost avoidance utilizing SLEP.
 - (d) Annual AHEC formularies and stock level reviews.
 - (e) Annual costs of the AHEC program.
 - (3) Evaluating AHEC activations.
 - (4) Reviewing local requests to modify a cache readiness status.
- (5) Assessing findings from AHEC audits, initiated by the Office of Population Health.
- (6) Determining items to be maintained in the SLEP, in accordance to guidance from SNS.
 - (7) Appointing subject matter experts to the AHEC Program Committee.

- f. Chair, All-Hazards Emergency Cache Advisory Committee. The AHEC Advisory Committee Chair is responsible for convening the AHEC committee annually and as needed as determined by the Director of the Office of Population Health. The committee is responsible for conducting reviews of existing and proposed AHEC program policies, procedures, training and education outlined in paragraph 6 of this directive and advising the AHEC Leadership team. Membership of this committee is comprised of subject matter experts from these disciplines and services:
 - (1) The Office of Population Health (lead).
 - (2) The Office of Pharmacy Benefits Management/EPS.
 - (3) The Office of Emergency Management (OEM).
 - (4) VA Office of Security and Law Enforcement or VHA Chief of Police.
 - (5) VHA Medical Emergency Radiological Response Team (MERRT).
 - (6) VHA National Director for Emergency Medicine.
 - (7) VHA National Infectious Diseases Service (NIDS).
 - (8) VHA Support Service.
 - (9) Nursing Services.
 - (10) VISN and VA medical facility governance.
- (11) The Department of Human Health Services Assistant Secretary of Preparedness and Response (ASPR).
- (12) Additional subject matter experts as required by topic area including but not limited to CBRNE, natural disasters, and expertise in operations emergency preparedness and response.
- g. <u>Director</u>, <u>Office of Emergency Management</u>. The Director of the OEM is responsible for:
- (1) Providing representation on AHEC leadership team and AHEC program committees.
- (2) Designating an Area Emergency Manager (AEM) to inspect and provide direct support and guidance to the VISNs and VA medical facilities on development of plans, procedures, training, and exercises.
- (3) Establishing a program to train VISN and VA medical facility emergency managers on AHEC associated policy, roles, and responsibilities.

- (4) Reviewing and addressing deficiencies in local disaster plans identified during OEM EMCAP assessments by AEM as they relate to AHEC activation and use.
- (5) Providing subject matter expertise in response planning and linkage with VHA Directive 0320.06, First Receivers Decontamination Program, dated October 27, 2016.
 - (6) Assisting the VISN and VA medical facility with the annual audit of AHEC plans.
- (7) Developing and deploying a solution and maintaining AHEC software which tracks AHEC audits and inspections nationwide within the VA Performance Improvement Management System (PIMS).
- (8) Providing training or education and sustainment support for PIMS. See paragraph 6 for PIMS training information.
- (9) Providing training and education on the local POD plan, team and exercise development, and documentation.
- (10) Notifying the AHEC Leadership team via Email of any cache activations or issues reported to the VHA Watch Officer including activations during emergency preparedness exercises. Please see VHA Directive 0320 and VA Directive 0322, VA Integrated Operations Center, dated April 29, 2010, for additional information about VHA Watch Officers.
- h. <u>Area Emergency Manager, Office of Emergency Management.</u> The AEM is responsible for:
- (1) Providing support and guidance to VA medical facility leadership and field-based emergency management staff regarding the incorporation of the AHEC program into their local emergency preparedness, response, recovery, and exercise plans.
- (2) Developing a corrective action plan in coordination with the VA medical facility to address VA medical facility disaster plan deficiencies identified by OEM EMCAP assessments and providing technical assistance to the VA medical facility during implementation of the corrective action plan.
- i. <u>Director, Emergency Pharmacy Service.</u> The Director of the EPS is responsible
 for:
- (1) Providing representation on AHEC leadership team and AHEC program committees.
- (2) Creating a standardized AHEC configuration for efficient storage and transport of large and small pharmaceutical caches including space for accessing the cache and controlled substances. **NOTE:** Standardized AHEC configurations are confidential and accessible only to authorized individuals.

- (3) Providing subject matter expertise for procurement, logistics, storage, and pharmacy-cache related issues.
- (4) Maintaining a centralized inventory management system for all pharmaceutical caches and centralized warehouse.
- (5) Ensuring a centralized procurement of products, standardization of AHEC CBRNE, shipping cache related stock (initial and replacement) and equipment to designated VA medical facilities.
- (6) Training pharmacy staff responsible for cache oversight including notification requirements, stock rotation, replacement, and participation in SLEP.
- (7) Procuring and shipping replacement products, as appropriate, to each cache site in advance of product expiration dates.
- (8) Managing SLEP. More information on SLEP can be found at https://vaww.cmopnational.va.gov/CR/eps/SitePages/Home.aspx. **NOTE:** This is an internal VA Web site that is not available to the public.
- (9) Notifying the AHEC Leadership Team via Email correspondence of product outages including recommendations for alternative course of action.
- (10) Reviewing and approving waiver requests from VA medical facilities for storage and inventory requirements of controlled substances, or storage of non-AHEC emergency items inside the AHEC room. More information can be found at https://vaww.cmopnational.va.gov/CR/eps/SitePages/Home.aspx. **NOTE:** This is an internal VA Web site that is not available to the public.
- j. <u>Veteran Integrated Service Network Director</u>. The VISN Director is responsible for:
- (1) Ensuring that Network Emergency Managers develop VISN Emergency

 Operations Plans (EOPs) that incorporate access, distribution, and use of the caches located within their VISN.
- (2) Ensuring each VA medical facility within the VISN maintains compliance with cache program requirements through information provided in the Annual Cache Inspection report prepared by the Office of Population Health.
- (3) Addressing deficiencies identified during the annual AHEC audit or at other times.
- k. <u>Veterans Integrated Service Network Emergency Manager</u>. The VISN (Network) Emergency Manager is responsible for development, maintenance, training, and exercise of VISN EOPs.

- I. **<u>Director</u>**, **VA Medical Facility**. The VA medical facility Director is responsible for:
- (1) Incorporating use of the AHEC into local emergency preparedness plans. Appendix B provides a list of the items to include in the local plan.
- (2) Designating staff from Pharmacy Service, OSLE, and Emergency Management to implement and oversee the local AHEC plan.
- (3) Activating the cache when a local, regional, or national emergency warrants its use. **NOTE:** Drug shortages are not a valid reason for activating the cache; however, the VA medical facility Director may activate the cache and use up to 50 percent of the stock of a drug during a shortage when patients are in a life-threatening situation. Activation of the cache for this purpose must follow the normal process with required notifications. The VA medical facility Director may also delegate this authority to other VHA staff. The VA medical facility's EOP must document any positions with delegated authority such as the Incident Commander and VA medical facility Chief of Staff.
- (4) Notifying the VHA Watch Office immediately upon activation of a cache in contacting 202-461-0268 or at the Email WatchOfficer-VHA@va.gov, followed by a detailed Issue Brief no later than 12 hours after activation. Please see Appendix B for additional information about notifying the VHA Watch Officer. Please see VHA Directive 0320 and VA Directive 0322 for additional information about VHA Watch Officers.
- (5) Conducting a full AAR no later than 5 working days post real world activation or exercise. The AAR is loaded into PIMs and reviewed by the AHEC Committee within 30 days.
- (6) Conducting an annual inspection and review of AHEC and local AHEC procedures with the appropriate local expertise (VA Police, Pharmacy, Emergency Manager), and recording the results including deficiencies in the designated PIMS system. Part of this inspection is to ensure that all cache items are not expired (per SLEP, where applicable).
- (7) Developing a corrective action plan in coordination with AEM and implementing the corrective actions.
- (8) Addressing any deficiencies identified during the annual audit and inspection or at any other time.
- (9) Ensuring cache readiness and mitigation plans for damaged cache contents or loss of secure environment.
- (10) Maintaining the cache so as to remain ready-for-use through ongoing routine inspection and oversight.
- (11) Ensuring that VA Police conduct routine security checks on the cache area consistent with VA and VHA policies: VA Handbook 0730, Security and Law Enforcement, dated August 11, 2000; VHA Handbook 1108.01(1), Controlled

Substances Management, dated May 1, 2019; and VHA Directive1108.02(1), Inspection of Controlled Substances dated November 28, 2016.

- (12) Ensuring that VA medical facility Pharmacy Service, in conjunction with the National EPS, conducts oversight and rotate stock, perform re-labeling of products as part of the SLEP, and update the cache inventory as directed by EPS.
- (13) Addressing any acute loss of integrity to the cache contents or storage location (e.g., water pipe burst, floods, hurricane, earthquake) and developing a plan to mitigate the issue as quickly as possible and inform the VISN through standard communication channels. If the cache is expected to be offline for more than 2 weeks, the VA medical facility Director must contact the VHA Watch Officer (see paragraph 5.h.(4)).
- (14) Ensuring the POD team and plan is developed, exercised, trained on an annual basis in accordance with OEM standards (see paragraph 5.g.(9)).
- (15) Ensuring the design, execution, and evaluation of an annual exercise that includes the activation and physical movement of the AHEC and deployment of the POD team.
- (16) Ensuring VA personnel comply with requirements for disclosure and public discussion of the VA cache which outlines publicly releasable information. See Appendix A for additional information.
- (17) Providing all necessary training for emergency and medical personnel, as appropriate, on use of pharmaceuticals, medical supplies, and equipment contained in the cache.
- (18) Ensuring that the VA medical facility Chief of Police provides security inspections for locations proposed for AHEC storage, conducts annual and routine security inspections for the local cache storage areas, and documents the results of the annual cache inspection in the PIMS system. The report must include any deficiencies along with the standard that was not met at the time of inspection.
- (19) Ensuring that State and local authorities are included in the development of preparedness plans that include the AHEC.
- (20) Providing oversight to ensure that VA medical facility staff comply with this directive.
- m. **VA Medical Facility Chief of Pharmacy.** The VA medical facility Chief of Pharmacy is responsible for:
- (1) Ensuring all inspections and inventories are completed, documented, and attested to in accordance with this directive, annual PIMS inspection of AHEC, annual wall-to-wall inventory of the AHEC, and annual (VHA) and biennial (DEA) inventory of controlled substances.

- (2) Ensuring management of controlled substances in the AHEC in accordance with FDA regulations (21 CFR part 1301 et seq.); VHA Handbook 1108.01(1) and VHA Directive 1108.02(1).
- (3) Requesting any needed waivers for storage of schedule II or schedule III-controlled substances in the AHEC room's vault or storage of non-AHEC emergent items within the AHEC room. See VHA Handbook 1108.01(1) and VHA Directive
- 1108.02(1) for additional information on CII and CIII controlled substances and waivers.
- (4) Creating and maintaining an AHEC Email group for communication and notification between the VA medical facility and national EPS.
 - (5) Participating in annual cache simulation exercises.
- (6) Notifying EPS via the EPS SharePoint site (https://vaww.cmopnational.va.gov/CR/eps/EPS%20Survey%20Page/Home.aspx) and utilizing the survey functions when the VA medical facility has completed an assigned task or receipt. These include notifications of confirmation of receipt of supplies, signage for purposefully kept supplies that are past their expiration date, and SLEP labels. **NOTE:** This is an internal VA Web site that is not available to the public.
- (7) Designating an AHEC Pharmacy Manager, ensuring the completion of their responsibilities, with responsibilities written into the position description or functional statement.
 - (8) Ensuring fulfillment of the AHEC Pharmacy Manager responsibilities.
- n. <u>All-Hazards Emergency Cache Pharmacy Manager</u>. The AHEC Manager is responsible for:
 - (1) Ensuring the accurate completion of cache product rotation and inventory.
 - (2) Ensuring rotated stock is available for VA medical facility or within VISN use.
 - (3) Appropriately re-labeling stock managed in the SLEP as required.
- (4) Processing expired items in the most cost-effective manner, which may include utilizing the contracted reverse distributor or other vendor which can manage pharmaceutical waste.
- (5) Ensuring all cache items are stored separately from pharmacy inventory. Any cache-controlled substances which are stored within the facility pharmacy vault must be kept in sealed totes and not intermingled with other controlled substances at the facility.
- (6) Ensuring that all cache items are stored in a manner consistent with VHA Directive 1108.07, Pharmacy General Requirements, dated March 10, 2017, and manufacturer's recommendations.

- (7) Ensuring the AHEC room temperature (20-25°C) and humidity (20-60 percent relative humidity) is monitored.
 - (8) Ensuring direct communication with EPS regarding the following:
- (a) Cache activation including the products used with lot numbers during activation, exercise, or drill.
 - (b) Drill dates and training waivers if AHEC products are removed from AHEC.

6. TRAINING

The following training is required:

- a. VHA PIMS: PIMS training is provided by VHA OEM and the PIMS contractor and is conducted via webinar. The contractor also provides on-line user guides for all functions and they are updated each time the system is updated or new functions added. This provides the user with access to step-by-step instructions, frequently asked questions (FAQs), and additional resources that are easily accessed within the system.
- b. Job-specific training for VHA staff involved with emergency management, pharmacy service, security and law enforcement, and staff that would use the cache when activated (i.e., Emergency Medicine, Nursing). Training covers appropriate use of pharmaceuticals, medical supplies, and equipment contained in the cache.
- c. Job-specific training for VHA pharmacy staff with responsibilities related to the AHEC content management, covering appropriate signage and labeling for SLEP program, and notification procedures.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created pursuant to this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule (RCS) 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

8. REFERENCES

- a. 38 U.S.C 1785 and 7301(b).
- b. 42 U.S.C. 300hh-11(b), 5170a(1), 5121, 5170b, 5192, and 8117.
- c. 21 CFR 1301 et seq.
- d. 38 CFR 17.86.

- e. Executive Order 13527, Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack, dated December 30, 2009.
 - f. VA Directive 0322, VA Integrated Operations Center, dated April 29, 2010.
 - g. VA Handbook 0730, Security and Law Enforcement, dated August 11, 2000.
- h. VA Handbook 0730/4 Appendix B, Security and Law Enforcement, dated March 29, 2013.
 - i. VA Handbook 0730(5), Security and Law Enforcement, dated July 11, 2014.
- j. VHA Directive 0320, Comprehensive Emergency Management Program, dated April 12, 2013.
- k. VHA Directive 0320.01, Veterans Health Administration Comprehensive Emergency Management Program (CEMP) Procedures, dated April 6, 2017.
- I. VHA Directive 0320.06, First Receivers Decontamination Program, dated October 27, 2016.
- m. VHA Directive 0320.10, Inspection of VA All-Hazard Emergency Caches by the VHA Office of Emergency Management, dated July 26, 2017.
 - n. VHA Handbook 1108.01(1), Controlled Substances dated May 1, 2019.
- o. VHA Directive 1108.02(1), Inspection of Controlled Substances, dated November 28, 2016.
 - p. VHA Directive 1108.07 Pharmacy General Requirements, dated March 10, 2017.
 - q. EPS Web site: https://vaww.cmopnational.va.gov/CR/eps/SitePages/Home.aspx.

NOTE: This is an internal VA Web site that is not available to the public.

- r. Federal Emergency Management Agency. Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans. November 27, 2017 https://www.fema.gov/media-library/assets/documents/152894.
 - s. National Fire Protection Association (NFPA) 101 Life Safety Code.
- t. U.S. Department of Health and Human Services, Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) web site: https://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx.

OFFICE OF GENERAL COUNSEL ADVISORY OPINION

On May 4, 2012, the Office of General Counsel issued an advisory opinion detailing Department of Veterans Affairs' (VA's) authority to provide medical countermeasures during a disaster or emergency. Key points from the opinion are summarized below.

- a. VA's authority to provide emergency and disaster assistance to non-Veterans must be authorized by statute, and VA's appropriation must authorize the expenditure.
- b. The primary source of VA's authority to respond to disasters and emergencies is the Stafford Act, which sets forth the Federal government's authority to respond to major disasters and emergencies. Following a declaration of a major disaster or emergency, the President may direct any Federal agency to use its authorities and resources in support of state and local assistance efforts (see Title 42 United States Code (U.S.C.) 5170a(1), 5170b(1), and 5192). VA also has a role in providing care and services through the National Disaster Medical System (42 U.S.C. 300hh11(b)). VA's authority to provide care and services during disasters and emergencies is codified at 38 U.S.C. 1785. Implementing regulations are at Title 38 Code of Federal Regulations (CFR) 17.86.
- c. VA's authority to provide assistance pursuant to section 1785 should be evaluated within the context of the National Response Framework (NRF), which guides the Federal government in responding to disasters and emergencies and managing incidents. The NRF includes a series of Incident Annexes developed to provide specialized, incident-specific implementation of the NRF. The *Biological Incident Annex* outlines the actions, roles and responsibilities associated with response to a human disease outbreak of known or unknown origin requiring Federal assistance and describes the anticipated role of cooperating agencies (including VA).
- d. In addition to the NRF, Executive Order 13527 directed the Secretaries of Homeland Security and Health and Human Services, in coordination with the Secretary of Defense, to develop a concept of operations and establish requirements for a federal rapid response to dispense medical countermeasures to an affected population following a large-scale biological attack. There is applicable guidance for VA based on these discussions.
- e. Outside the circumstances when VA is authorized to act under section 1785 pursuant to a Stafford Act tasking or declared public health emergency, several additional statutes (below) authorized VA to provide care to non-VA beneficiaries.
- f. Pursuant to 5 U.S.C. 7901, VA has authority to provide certain health services to employees. Further, employee health maintenance and the prevention of patient-

threatening conditions is an integral part of providing health care and medical services to eligible Veterans. VA, therefore, has authority to provide medical countermeasures to employees.

- g. With regard to family members of Veterans, VA has authority to provide medical care and services to certain family members eligible for Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA) care (38 U.S.C. 1781).
- h. Pursuant to 38 U.S.C. 8111A, VA is authorized to provide care to members of the Armed Forces during a time of war or national emergency.
- i. VA also has broad authority, pursuant to 38 U.S.C. 1784, to furnish hospital care and medical services as a humanitarian service in emergency cases.
- j. Pursuant to 38 U.S.C. 8153, VA may enter into sharing agreements with other health care providers, entities, or individuals. These agreements can be used to secure health care resources that otherwise might not be feasibly available, or to effectively utilize health care resources by furnishing such resources to these parties on a reimbursable basis.

In summary, the opinion advised that VA is authorized to provide care to individuals responding to, involved in, or otherwise affected by a disaster or emergency, as described in 38 U.S.C. 1785 and 38 CFR 17.86, the NRF and other guidance. VA has additional authority to furnish hospital care and medical services as a humanitarian service in emergency cases but is required to charge for such care (see 38 U.S.C. 1784 and 38 CFR 17.102). Pursuant to 5 U.S.C. 7901, VA has authority to provide certain health services to employees, and pursuant to 38 U.S.C. 1781, VA has authority to provide care to certain family members of Veterans. Pursuant to 38 U.S.C. 8111A, VA is also authorized to provide care to members of the Armed Forces during a time of war or national emergency. Finally, 38 U.S.C. 8153 authorizes VHA to enter into sharing agreements with other health-care providers, entities, or individuals to secure health-care resources that otherwise might not be feasibly available, or to effectively utilize health-care resources by furnishing such resources to these parties on a reimbursable basis.

ITEMS TO INCLUDE IN THE FACILITY EMERGENCY RESPONSE PLAN COVERING THE ALL-HAZARDS EMERGENCY CACHE

The following contains a list of mandatory items for inclusion in a Department of Veterans Affairs (VA) medical facility emergency operations plan.

1. PERSONS AUTHORIZED TO ACTIVATE THE CACHE

- a. The All-Hazards Emergency Cache (AHEC) can be activated when a local, regional, or national emergency warrants its use. **NOTE:** Drug shortages are not a valid reason for activating the cache; however, the VA medical facility Director may activate the cache and use up to 50 percent of the stock of a drug during a shortage when patients are in a life-threatening situation. Activation of the cache for this purpose must follow the normal process with required notifications.
- b. The VA medical facility Director is authorized to activate the cache. This authority is delegated when the VA medical facility Director is out of contact and has designated authority to cover their position. Local AHEC experts inform newly designated persons of responsibilities. The VA medical facility's Emergency Operations Plan should document any positions with delegated authority such as the Incident Commander and Chief of Staff. The Veterans Health Administration (VHA) National Watch Officer must be notified when a cache is activated (202-461-0268 or 202-461-0269 or WatchOfficer-VHA@va.gov).

 **NOTE: The decision to activate a cache is the responsibility of the VA Medical Facility Director or designee and does not require approval from VISN or VHA leadership. During a response to a CBRNE event that is regional, national, or international in scope, the VHA Under Secretary for Health (VHA USH) or designee may establish and deploy special criteria for cache activation.

The USH may redefine the requirements for AHEC activations upon an "emergency declaration" (authorized under Stafford Act Section 501) or a "major disaster declaration" (authorized under Stafford Act Section 401).

A memorandum from the USH defining the new parameters for an AHEC activation will be sent via email to all relevant parties— including medical facility directors and pharmacy chiefs— from the AHEC Committee within 3 business days from the declaration of the emergency or disaster. This enhanced AHEC activation criteria will be incorporated into the Watch Officer documentation procedures.

- c. The VA medical facility should provide the following information when notifying the VHA Watch Officer of a cache activation.
 - (1) VA medical facility name.
 - (2) Person reporting activation.
 - (3) Reason for activating cache.

(4) Description, quantity, and lot number of items removed from cache.

2. VA MEDICAL FACILITY ALL-HAZARDS EMERGENCY CACHE PROGRAM CONTACT INFORMATION

- a. Emergency cache team lead.
- b. Facility Emergency Manager.
- c. OEM Area Emergency Manager.
- d. OEM Regional Emergency Manager.
- e. EPS.
- f. VA Police.
- g. VHA Watch Office: 202-461-0268 or 202-461-0269 or WatchOfficer-VHA@va.gov.
- h. State and Local Strategic National Stockpile (SNS).

3. LOCATION OF THE CACHE

[Insert facility name] has been designated as a location for a [large/small] all-hazards emergency cache. The contents of the cache can be found on [campus] in the following locations.

Controlled substances:

Non-controlled substances:

NOTE: The dimensions for the cache can be provided by the National EPS at [VHAPBMEPSTeam@va.gov]. Ideally, the cache is stored separate from other pharmaceuticals, supplies, and other storage items. A facility may prefer to locate controlled substances in a centralized vault to achieve controlled substance inspection requirements. It may be acceptable to store other emergency supplies in the cache area (i.e., personal protective equipment, patient transport equipment, etc.) if the overall space required can maintain easy access to the cache including space required to activate (access) it.

Enterprise

4. ACCESS TO THE CACHE

Only those staff who provide direct oversight (e.g., Pharmacy Services) or those trained on the use of the cache can have access to the cache. These individuals are responsible for directing the distribution of any cache contents once activated by the facility's authorized staff.

5. LIST OF STAFF TRAINED AND RESPONSIBLE FOR DEPLOYING THE CACHE

The staff with roles to access the cache, distribution of its contents, and use specific contents in response to an emergency as well as those who would be authorized to receive cache contents are listed below.

<u>Title</u> <u>Responsibilities</u> <u>Contact information</u>

6. STATE AND LOCAL EMERGENCY MANAGEMENT

A plan is in place to coordinate with local state public health and emergency officials to delineate [VA medical facility] potential roles in planning and response activities in an emergency disaster including the use of the VA's cache and SNS. This plan is located and stored at each VA medical facility. **NOTE:** Refer to Appendix A for guidance from the VA Office of General Counsel regarding VA roles in preparedness and response.

7. CACHE INSPECTIONS

On an annual basis, the cache will be physically inspected, and all emergency operations policies will be reviewed for inclusion of cache related activities. The inspection is initiated by the National Population Health program through the Performance Improvement Management System (PIMS). The National Population Health office maintains records and results of inspections. Inspections should be coordinated with medical facility leadership to ensure all areas of the inspection are completed, entered in PIMS, and communicated to the facility. There are three areas of focus for this inspection:

- a. **Physical Security.** VA Police will inspect the cache storage facilities for compliance with current policy for the storage of pharmacy drugs and AHEC specific security requirements.
- b. **Pharmaceutical Inventory.** Pharmacy Service will inspect the contents of the cache for expiration dates, adherence to Shelf Life Extension Program (SLEP) requirements, and adherence to other VHA pharmacy policy.
- c. <u>Emergency Plan Audit.</u> The VHA OEM will perform an audit of all local documents covering emergency operations including the all-hazards cache. The audit will include but not limited to documentation and after-action reports on all cache activation exercises and Emergency Management Committee meeting minutes.

8. CACHE EXERCISE

An annual exercise of cache activation and deployment will be included in at least one facility-wide emergency operations training exercise. This exercise must include physical movement of cache contents and deployment of the POD team. An inventory of the items opened in the exercise will be conducted by appropriate staff following the exercise. EPS will be notified of any replacement stock needed post exercise.

9. PUBLIC AFFAIRS

VHA may disclose the contents of the cache to individuals with the need to know in local and State emergency operations for emergency preparedness planning or during a cache activation event.