

**REMOVAL OF RECALLED MEDICAL PRODUCTS, DRUGS, AND FOOD FROM VA
MEDICAL FACILITIES**

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive maintains policy for the removal of recalled products including drugs, food, and medical products from use in VA medical facilities.
- 2. SUMMARY OF MAJOR CHANGES:** This VHA directive maintains policy for the removal of recalled products including drugs, food, and medical products from use in VA medical facilities. The directive title now emphasizes the key action as removal of recalled products. Definitions have been updated (see paragraph 3). Responsibilities have been added for the Under Secretary for Health, Consolidated Mail Outpatient Pharmacy National Director, and expanded to all Contracting Officers (see paragraph 5).
- 3. RELATED ISSUES:** VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook, dated March 4, 2011; VHA Directive 1069, National Pharmacy Benefits Management Drug Safety Alert Distribution, dated November 24, 2014; VHA Directive 1761(2), Supply Chain Inventory Management, dated October 24, 2016; and VHA Directive 1439 Food Service Management, dated October 21, 2019.
- 4. RESPONSIBLE OFFICE:** The VHA National Center for Patient Safety Office (10E2E) is responsible for the contents of this directive. Questions may be addressed to 734 - 930 -5890.
- 5. RESCISSIONS:** VHA Directive 1068, Recall of Defective Medical Devices and Medical Products, Including Food and Food Products, dated July 22, 2014, is rescinded.
- 6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before last working day of June 2025. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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

/s/ Gerard R. Cox MD, MHA
Deputy Under Secretary for Health
for Organizational Excellence

June 19, 2020

VHA DIRECTIVE 1068

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

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REMOVAL OF RECALLED MEDICAL PRODUCTS, DRUGS AND FOOD FROM VA MEDICAL FACILITIES

1. PURPOSE

This Veterans Health Administration (VHA) directive maintains policy for the removal of recalled products including drugs, food, and medical products from use in VA medical facilities. **AUTHORITY:** Title 38 United States Code (U.S.C.) § 7301(b).

2. BACKGROUND

a. The National Center for Patient Safety (NCPS) receives product-related safety information from a wide variety of internal and external sources, including VHA's patient safety event reporting system, manufacturers, distributors, and other Federal agencies (e.g., U.S. Food and Drug Administration (FDA), U.S. Department of Defense (DoD), and U.S. Department of Agriculture (USDA)). This information is analyzed and, if appropriate, communicated to VA medical facilities for action in the form of a product recall. Product recalls are issued via the VHA Alerts and Recalls Web application when defective or potentially harmful products must be removed from use by VA medical facilities to safeguard the life or health of VHA patients or staff. **NOTE:** *This directive does not apply to products in the patient's personal possession, or repairable medical devices that may be removed from use for corrective action including repair or scheduled maintenance. The VHA Alerts and Recalls website is: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>. This is an internal VA website that is not available to the public.*

b. FDA is the Federal agency that is responsible for protecting public health by regulating human drugs and biologics, animal drugs, medical devices, tobacco products, food (including animal food), cosmetics, and electronic products that emit radiation. Product Types regulated by the FDA that have the potential for recall to which this policy applies are the following:

(1) Animal and veterinary products including animal foods and veterinary drugs and devices.

(2) Biologics synthesized from living organisms or their products and used as a diagnostic, preventive, or therapeutic agent. Biological products include a wide range of products such as vaccines, drugs, antitoxins, blood and blood components, allergenics, somatic cells, gene therapies, and recombinant therapeutic proteins.

(3) Tissue and tissue products comprised of human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient, and are regulated by FDA as human cells, tissues, and cellular and tissue-based product (HCT/P). Examples of such tissues are bone, skin, corneas, ligaments, tendons, dura matter, heart valves, hematopoietic stem or progenitor cells derived from peripheral and cord blood, oocytes, and semen.

(4) Cosmetics intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof. Cosmetic items are products used for cleansing, beautifying, promoting attractiveness, or altering the appearance, and intended for use as a component of any such articles such as: lotions, creams, shampoos, toothpastes, and deodorants.

(5) Drugs (pharmaceuticals) identified as a finished dosage form of medication (e.g., tablet, capsule, solution) that contains an active chemical ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(6) Food or drink for humans or other animals, chewing gum, and articles used for components of any such article.

(7) Dietary supplements taken by mouth that contain a dietary ingredient intended to supplement the diet. The dietary ingredients in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ or glandular tissues, and metabolites. Dietary supplements can also be extracts or concentrates and may be found in many forms such as tablets, capsules, soft gels, gel caps, liquids, or powders.

(8) Medical device is any instrument, apparatus, implement, machine, implant, in vitro reagent, or other similar or related article, including a component part or accessory that is intended to be used in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or other animals.

(9) Implants and Prosthetics. Implants and prosthetics are medical implants or devices or tissues that are placed inside or on the surface of the body. Many implants are prosthetics intended to replace missing body parts. Other implants deliver medication, monitor body functions, or provide support to organs and tissues.

3. DEFINITIONS

The following definitions are applicable within this directive:

a. **Class I Product Recall.** A Class I Product Recall will remove a dangerous or defective product that could cause serious health problems or death.

b. **Class II Product Recall.** A Class II Product Recall will remove a product that might cause a temporary health problem or pose a slight threat of a serious nature.

c. **Class III Product Recall.** A Class III Product Recall will remove a product that is unlikely to cause any adverse health reaction, but that violates FDA labeling or manufacturing laws. ***NOTE: A Class III Product Recall is typically issued where there is no immediate or perceived danger of any health issues, but where items have been released that are in violation of FDA regulations.***

d. **Firm.** A firm, as used in this directive, is a manufacturer, wholesaler, distributor, or marketer of a product or service.

e. **Internal Product Recall.** An Internal Product Recall is a product removal action that is initiated and issued by NCPS, in consultation with VHA subject matter experts and relevant stakeholders, in response to identified product quality or safety issues where the risk of continued use is determined to be greater than its benefit.

f. **Product Recall.** A product recall is a method for removing products from use that are in violation of laws administered by the FDA or otherwise deemed defective or potentially harmful to patients. Product recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. NCPS may conduct a VHA Internal Product Recall in response to product quality or safety issues where the risk of continued use is determined to be greater than its benefit.

4. POLICY

It is VHA policy that NCPS administer product recalls and notify Veterans Integrated Service Networks (VISNs) and VA medical facility staff to remove recalled products determined to be in violation of laws administered by the FDA or otherwise deemed defective or potentially harmful.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the VISNs.

(2) Ensuring that each VISN Director has sufficient resources to implement this directive in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to assure compliance with this directive, relevant standards, and applicable regulations.

(4) Ensuring that appropriate product recall actions are completed within assigned due dates using the VHA Alerts and Recalls web application, available at <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>. **NOTE:** This is an internal VA website that is not available to the public.

b. **Deputy Under Secretary for Health for Organizational Excellence.** The Deputy Under Secretary for Health for Organizational Excellence is responsible for supporting the implementation and oversight of this directive across VHA.

c. **Executive Director, National Center for Patient Safety.** The Executive Director, NCPS is responsible for:

- (1) Monitoring internal VA and external sources for product recall information.
- (2) Researching, classifying, and prioritizing potential product recall information to determine the required removal actions.
- (3) Assigning and posting due dates for all actions involving product recalls on the VHA Alerts and Recalls Web application. **NOTE:** *NCPS may assign different due dates to a product recall action as circumstances warrant for Class I Product Recalls and all other recalls (Class II and III Product Recalls).*
- (4) Maintaining the national Email groups for Network Recall Coordinators (NRCs) and Facility Recall Coordinators (FRCs).
- (5) Coordinating between NCPS staff and Designated Service Area Specialists (DSAS) on product recalls that may require clinical action or other resolution as necessary.
- (6) Providing monthly product recall compliance reports to the VISN and VA medical facilities.
- (7) Providing business ownership of the VHA Alerts and Recalls Web application, available at <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>. **NOTE:** *This is an internal VA website that is not available to the public.*

d. **VHA Program Office Director.** Each VHA Program Office Director (or equivalent) who manages programs with responsibilities associated with NCPS product recall process is responsible for:

- (1) Appointing a DSAS and a back-up DSAS for each service or program under their supervision.
- (2) Providing NCPS with contact information including name, department and service, phone number, and Email address of the DSAS and back-up and updating this information whenever staff changes occur.

e. **VHA Program Office Designated Service Area Specialist.** The VHA Program Office DSAS is responsible for:

- (1) Serving as the primary contact and subject matter expert (SME) for all product recalls within their assigned area of expertise or specialty.
- (2) Responding to informational requests submitted by NCPS.
- (3) Informing NCPS if additional actions beyond a product recall are deemed necessary.

(4) Reporting to NCPS any product issues identified as potentially impacting patient safety that may necessitate a product recall as well as providing all product recall notifications received directly from firms.

f. **VA Contracting Officer.** *NOTE: The VA Contracting Office is responsible for distribution of workload across regions, networks, and facilities.* The VA Contracting Officer is responsible for:

(1) Serving as the primary point of contact for VA's Federal Supply Schedule, national blanket purchase agreements, and other product-related contracts.

(2) Ensuring that all contracts administered by the Contracting Office have standardized language in contracts requiring firms to notify the appropriate Contracting Officer and NCPS of any product safety issues or recalls.

(3) Contacting NCPS following receipt of product safety or other relevant information from the firm.

g. **Consolidated Mail Outpatient Pharmacy National Director.** The Consolidated Mail Outpatient Pharmacy (CMOP) National Director is responsible for:

(1) Ensuring all CMOP facilities comply with this directive.

(2) Implementing the product recall process at each CMOP location, for Direct to Patient (DTP) Contractors (i.e., contracted provision of medical/surgical supplies to patients' residences, contracted provision of enteral nutrition/supplies to patients' residences), and for the CMOP Pharmaceutical Repackaging Contractor, in accordance with this directive.

(3) Designating a National CMOP NRC and back-up NRC, and ensuring this information is kept current and transmitted to NCPS.

(4) Ensuring each CMOP location identifies and designates a primary FRC and back-up FRC, identifying and designating CMOP staff to serve as the primary FRCs and back-up FRCs for the CMOP DTP Contractors and the CMOP Pharmaceutical Repackaging Contractor, and ensuring this information is kept current and transmitted to NCPS.

h. **Consolidated Mail Outpatient Pharmacy Chief Supply Chain Officer.** The Consolidated Mail Outpatient Pharmacy (CMOP) Chief Supply Chain Officer is responsible for:

(1) Serving as the NRC within the CMOP for all product recalls.

(2) Coordinating with FRCs to implement product recall processes in accordance with this directive.

(3) Providing training to new FRCs and refresher training as needed.

(4) Monitoring and ensuring that the requirements of this directive are met.

(5) Creating and maintaining an Outlook Email group containing all FRCs and back-up FRCs within their CMOP and notifying NCPS of the Email group name.

(a) This Email group must follow the display naming convention: "VHA Product Recalls FRC CMOP."

(b) This Email group must be kept current by adding and deleting members to reflect changes made to FRCs and FRC back-ups at the individual CMOP facilities.

(c) NCPS will utilize this Email group as the primary means of contacting FRCs and back-up FRCs regarding matters involving recalls.

(6) Ensuring the VHA Alerts and Recalls Web application is utilized for responding to product recall actions.

(7) Reporting identified product issues to NCPS.

(8) Sharing with NCPS all product recall notices that may impact VHA and are not yet published by NCPS on the VHA Alerts and Recalls Web application.

(9) Monitoring product recall activities and following up with any CMOP facilities that have not responded by the due date, as identified by the VHA Alert and Recalls Web application: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>. **NOTE:** *This is an internal VA website that is not available to the public.*

(10) Establishing a process for auditing CMOP facility product recall programs and correcting any issues found. A minimum of three product recalls per CMOP facility per fiscal year is required and documentation maintained by NRC.

(11) Ensuring that product recalls are executed as directed and NCPS guidance followed.

i. **Veterans Integrated Service Network Director.** VISN Director is responsible for:

(1) Ensuring all facilities within the VISN comply with this directive.

(2) Implementing product recall processes in accordance with this directive.

(3) Designating the VISN Chief Supply Chain Officer as the NRC, identifying a back-up NRC, and ensuring this information is kept current and transmitted to NCPS.

j. **Veterans Integrated Service Network Chief Supply Chain Officer.** The VISN Chief Supply Chain Officer is responsible for:

(1) Serving as the NRC within the VISN for all product recalls.

(2) Coordinating with FRCs to implement product recall processes in accordance with this directive.

(3) Providing training to new FRCs and refresher training as needed.

(4) Monitoring and ensuring that the requirements of this directive are met.

(5) Creating and maintaining an Outlook Email group containing all FRCs and back-up FRCs within their VISN and notifying NCPS of the Email group name.

(a) This Email group must follow the display naming convention: "VHA Product Recalls FRC Vxx (xx represents the two-digit VISN number, ex: 01, 12, 23)."

(b) This Email group must be kept current by adding and deleting members to reflect changes made to FRCs and FRC back-ups at the individual VA medical facilities within the VISN.

(c) NCPS will utilize this Email group as the primary means of contacting FRCs and back-up FRCs regarding matters involving recalls.

(6) Ensuring the VHA Alerts and Recalls Web application is utilized for responding to product recall actions.

(7) Reporting identified product issues to NCPS.

(8) Sharing with NCPS all product recall notices that may impact VHA and are not yet published by NCPS on the VHA Alerts and Recalls Web application.

(9) Monitoring product recall activities and following up with any VHA facilities that have not responded by the due date, as identified by the VHA Alert and Recalls Web application: <http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>. **NOTE:** *This is an internal VA website that is not available to the public.*

(10) Establishing a process for auditing VA medical facility product recall programs and correcting any issues found. A minimum of three product recalls per VA medical facility per fiscal year is required and documentation maintained by NRC.

(11) Ensuring that product recalls are executed as directed and NCPS guidance followed.

k. **VA Medical Facility Director.** Each VA medical facility Director is responsible for:

(1) Providing oversight to ensure that VA medical facility staff support and comply with this directive.

(2) Ensuring removed and sequestered products are not used at any VA medical facility under their jurisdiction.

(3) Ensuring a primary FRC and back-up FRC are designated and appointed.

(4) Ensuring that all product recall actions are documented and completed by the due date specified on the VHA Alerts and Recalls Web application:

<http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>. **NOTE:** *This is an internal VA website that is not available to the public.*

l. **VA Medical Facility, Facility Recall Coordinator.** Each VA medical facility FRC is responsible for:

(1) Coordinating and maintaining a facility-wide network of Facility Designated Area Specialists (FDASs), to include multiple representatives from each specialty area, who can respond accurately and authoritatively to product recall information provided to the VA medical facility.

(2) Creating FDAS user accounts and updating FDAS user access, as needed, on the VHA Alerts and Recalls Web application:

<http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>. **NOTE:** *This is an internal VA website that is not available to the public.*

(3) Verifying that the appropriate product recall actions have been taken by FDASs, which include ensuring all appropriate areas of the VA medical facility were assigned and thoroughly checked for recalled products; identifying numbers and locations of recalled products; and, that all recalled products were found, removed, sequestered, and returned for credit, refund, or replacement if applicable.

(4) Documenting the completion of all required product recall actions and uploading relevant attachments (e.g., response forms, credit memos, refund verifications, replacement stock invoices) within the VHA Alerts and Recalls Web application.

(5) Contacting NCPS and the NRC with all product recall notifications received and important product issues that are locally identified as potentially impacting patient safety.

m. **VA Medical Facility Designated Area Specialist.** A VA medical facility FDAS is responsible for:

(1) Serving as the point of contact at the VA medical facility for the FRC, in a specific area of service.

(2) Serving as the subject matter expert within that specific area of service and responding to assigned product recalls.

(3) Completing product recall actions in coordination with the FRC, which include thoroughly checking for recalled products in assigned area; identifying numbers and locations of recalled products; ensuring all recalled products were found, removed, sequestered, and returned for credit, refund, or replacement if applicable; and, notifying the FRC if a product recall was incorrectly assigned.

(4) Documenting completion of product recall actions on the VHA Alerts and Recalls Web application and providing any relevant attachments (e.g., response forms, credit memos, refund verifications, replacement stock invoices) to the FRC for upload to the VHA Alerts and Recalls Web application:

<http://vaww.recalls.ncps.med.va.gov/WebRecalls/Recalls.html>. **NOTE:** *This is an internal VA website that is not available to the public.*

(5) Communicating to the FRC any product recall notifications received.

6. TRAINING

There are no formal training requirements associated with this directive.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 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. § 7301(b).
- b. 21 CFR parts 7, 107, 803, 806, 810 and 1270.
- c. VHA Directive 1069, National Pharmacy Benefits Manager Drug Safety Alert Distribution, dated October 24, 2019.
- d. VHA Directive 1105.04, Fluoroscopy Safety, dated June 21, 2018.
- e. VHA Directive 1439, Food Service Management, dated October 21, 2019.
- f. VHA Handbook 1050.01, VHA National Patient Improvement Handbook, dated March 4, 2011.
- g. Food and Drug Administration. Office of Regulatory Affairs' Office of Enforcement. Guidance for Industry: Product Recalls, including Removals and Corrections, found at website: www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm.
- h. Healthcare Technology Management. HTM Service Bulletin SB2016-010: Repairable Medical Device Safety Alerts and Recalls Management; available at <https://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/HTM/CommResource/Lists/HTM%20Service%20Bulletins/Attachments/41/Repairable%20Medical%20Device%20Safety%20Alerts%20and%20Recalls%20Management.pdf>. **NOTE:** *This is an internal VA website that is not available to the public.*

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