DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH, VA 22042

BUMEDINST 6710.71B
BUMED-N4
6 Oct 25

BUMED INSTRUCTION 6710.71B

From: Chief, Bureau of Medicine and Surgery

Subj: NAVY MEDICINE PHARMACEUTICALS SHELF-LIFE EXTENSION PROGRAM

Ref: (a) DoD Instruction 6430.02 of 23 August 2017
(b) DoD Manual 4140.27, Volume 1, DoD Shelf-Life Management Program: Program Administration, 6 July 2016
(c) Statement of Work between Defense Health Agency and Naval Medical Readiness Logistics Command Detachment Fort Detrick for DoD/FDA Shelf-Life Extension Program (SLEP) DHA-2023-S-2584 (NOTAL)
(d) 21 CFR 4-205.50
(e) DHA-PM 6430.05, Shelf-Life Extension Program, 5 October 2021
(f) 10 U.S.C.
(g) NAVMED P-117

1. Purpose. To issue policies and guidelines for the management, disposal, and relabeling of dated pharmaceuticals per references (a) through (e), reference (f), section 1073c, and reference (g), Manual of the Medical Department, chapter 18. This instruction is a complete revision and should be reviewed in its entirety.

2. Cancellation. BUMEDINST 6710.71A.

3. Scope and Applicability. This instruction applies to all Navy and Marine Corps activities having Shelf-Life Extension Program (SLEP) pharmaceuticals.

4. Background. The Department of Defense (DoD) administers the SLEP in cooperation with the Food and Drug Administration (FDA) as a key component of the force protection strategy against endemic and pandemic diseases, and the threat of chemical, biological, radiological, and nuclear weapons. The program's focus is to defer replacement costs of military significant medical materiel by extending its useful life while assuring that only safe and effective drugs are provided to personnel during war or other contingencies. The organizations listed in subparagraphs 4a through 4c participate in the subject program:

a. The FDA evaluates candidate pharmaceuticals under the SLEP by testing samples submitted from the Services.

b. The Defense Health Agency (DHA) Medical Logistics Division (MEDLOG) is the executive manager for the DoD and FDA SLEP and oversees the program, per reference (a). DHA MEDLOG acts as the single interface between SLEP and the FDA.

c. The FDA, DHA MEDLOG, Army, Navy, Air Force, Marine Corps, Coast Guard, Defense Logistics Agency Troop Support, and other Federal agency participants fund and manage the program and receive the benefit of deferred pharmaceutical replacement costs.

5. Guidelines. All ships, stations, and Navy Medicine activities with pharmaceuticals must enter their on-hand inventory of chemical, biological, radiological, nuclear pharmaceutical, pandemic influenza, and anti-malaria pharmaceuticals into the SLEP Web-based program upon receipt.

a. For activities using the Assemblage Management module in Defense Medical Logistics Standard Support, inventories are automatically sent to LogiCole SLEP. All others required to post inventories must do so directly in LogiCole SLEP available at: https://logicole.health.mil/login/loginForm.

b. Upon verification of the user's System Authorization Access Request form and LogiCole training certificates, the user will receive an invitation link via e-mail to create an account.

c. All activities must register at least two Unit Monitors in the LogiCole SLEP system. Unit Monitors are required to complete training, per reference (b), and maintain current contact information.

d. Ensure all on-hand inventories of pharmaceuticals are accurately entered into the LogiCole SLEP database. Per reference (c), verify that inventory records are marked as current in LogiCole SLEP every 90 days, even if on-hand quantities have not changed. Users are required to upload digital images of a new lot number into LogiCole Reporting. The photo must clearly show the following data:

(1) Manufacturer

(2) Product Nomenclature or Name

(3) Lot Number

(4) Expiration Date

(5) National Drug Code

(6) Product Quantity

e. Review the currently approved eligible National Stock Numbers in the SLEP section: https://militaryhealth.sharepoint-mil.us/sites/ADS-MEDLOG/SitePages/Logistics-Plans-%26-Readiness.aspx. If the new lot number has an inventory value of less than $10,000.00 per lot, it is retained in the system of record until the total SLEP aggregate value of the lot number reaches the $10,000.00 threshold. The lot number will be included in the data refresh. If the new lot number has an inventory value of greater than or equal to $10,000.00 per lot, an automated notification will be sent to the DoD SLEP Program Manager for new lot number approval.

f. Maintain all SLEP pharmaceuticals in a controlled environment under conditions recommended by the manufacturer and per reference (d). Lots stored outside of the manufacturers recommended storage parameters must be immediately disclosed to the Navy SLEP Team at Naval Medical Readiness Logistics Command Detachment Fort Detrick via e-mail: usn.detrick.nmrlc-detftdmd.list.slep@health.mil

g. When physical samples are requested, ship them to the designated locations. The Navy SLEP Team will provide specific details and shipping address for each lot number.

h. The FDA will send a project results notification letter to DoD SLEP Program Manager. SLEP test results are listed in the LogiCole SLEP system along with the test result messages. Extensions are granted to SLEP participants with declared inventory only. If inventory is not declared in the LogiCole SLEP database, extension labels will not be generated, and pharmaceuticals will need to be replaced. Only pharmaceutical grade extension labels are authorized for use on extended inventories.

(1) If testing failed, the DoD SLEP Program Manager will change lot status in LogiCole to "Failed Testing – Return for credit or destroy." Upon receipt of an automated alert message, SLEP participants will dispose of expired pharmaceuticals according to Service or agency-specific policies and procedures, and update inventory in applicable system of record (i.e., LogiCole, Defense Medical Logistics Standard Support, Theater Enterprise-Wide Logistics System).

(2) If shelf-life is extended, the DoD SLEP Program Manager will change lot status in LogiCole to "Tested - Extended" and enter new expiration date. An automatic alert message will be sent to SLEP participants. Upon receipt, SLEP participants will update inventory in applicable system of record.

i. Items that have reached their expiration date should be marked to show the reason for suspension and secured to prevent use or loss. Dispose of all medical items that have reached their expiration date or end of the estimated storage life and are not extendable, per references (d) and (e). The facility should adhere to applicable Service or agency requirements in disposing of the pharmaceuticals subject to this document. Coordinate disposals according to Federal, state, and local agencies guidelines and policies. Class I Perishable Subsistence, Class II Chemical, Biological, Radiological, and Nuclear, and Class VIII Medical shelf-life items are not eligible to be returned to distribution centers.

6. Action

a. Relabeling is required for all declared inventories that are extended under the DoD and FDA SLEP. Items with expired dates will not be dispensed at any time. Extension labels must show the lot number, current expiration date, and FDA test project number.

(1) The SLEP system will automatically request labels based on the on-hand quantity declared by each site's inventory records when extensions are granted. Label orders will be suspended for SLEP participants that have not updated their inventory within the past 90 days.

(2) Labels will be mailed directly to the address listed in the SLEP database for each site. Unit mailing addresses must be kept current. SLEP Unit Monitor will confirm receipt of extension labels via e-mail.

b. The FDA permits SLEP participants to label only the outer cartons of products with updated information while they remain in centralized storage. Pharmaceuticals must be completely relabeled by local medical staff, down to the individual units of issue, before being distributed, issued, or dispensed outside centralized storage or to individuals.

c. Commanding officers (CO) or officers in charge (OIC) will appoint at least two SLEP unit monitor representatives and generate a designated appointment letter, per reference (e). Unit monitors will accurately enter all on-hand inventories of stockpiled pharmaceuticals into the SLEP database and ensure that inventory records are updated every 90 days.

d. Navy Medicine COs and OICs will submit appointment letters to:

Navy Shelf-Life Extension Program
Naval Medical Readiness Logistics Command Detachment Fort Detrick
Operational Forces Support Division
693 Neiman Street
Fort Detrick, Maryland 21702
usn.detrick.nmrlc-detftdmd.list.slep@health.mil
Phone: (301) 619-3068 or (301) 619-8054

e. U.S. Fleet Forces Command and U.S. Pacific Fleet COs and OICs will submit appointment letters to:

Fleet Medical Logistics Officer
U.S. Fleet Forces Command
1562 Mitscher Avenue, Suite 250
Norfolk, Virginia 23551-2487
Phone: (757) 836-6027 or Defense Switched Network: 836-6027
Fax: (757) 836-5520
USFFSLEP@navy.mil

f. Marine Corps COs and OICs will submit appointment letters to:

United States Marine Corps Medical Logistics Officer
Logistics Policy and Capabilities Branch (LPC-2)
Headquarters United States Marine Corps, Installation and Logistics
3000 Marine Corps Pentagon: Room 2E211
Washington, District of Columbia 20350-3000
Office: (571) 256-7115; (Defense Switched Network: 260-7115)

7. Points of Contact. If assistance is needed with the Navy's SLEP System, please refer any questions to the Naval Medical Readiness Logistics Command Detachment Fort Detrick SLEP Manager at (301) 619-3068 or via e-mail at usn.detrick.nmrlc-detftdmd.list.slep@health.mil. For assistance with the Marine Corps' SLEP System, please refer any questions to the U.S. Marine Corps Medical Logistics Officer at (571) 256-7115.

8. Records Management

a. Records created as a result of this instruction, regardless of format or media, must be maintained and dispositioned per the records disposition schedules located on the DON Assistant for Administration, Directives and Records Management Division portal page at https://portal.secnav.navy.mil/orgs/DUSNM/DONAA/DRM/Records-and-Information-Management/Approved%20Record%20Schedules/Forms/AllItems.aspx

b. For questions concerning the management of records related to this instruction or the records disposition schedules, please contact the local records manager or the OPNAV Records Management Program (DNS-16).

9. Review and Effective Date. Per OPNAVINST 5215.17A, Director, Logistics, Supply, and Support (BUMED-N4) will review this instruction annually around the anniversary of its issuance date to ensure applicability, currency, and consistency with Federal, DoD, Secretary of the Navy and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will be in effect for 10 years, unless revised or cancelled in the interim and will be reissued by the 10-year anniversary date if it is still required, unless it meets one of the exceptions in OPNAVINST 5215.17A, paragraph 9. Otherwise, if the instruction is no longer required, it will be processed for cancellation as soon as the need for cancellation is known following the guidance in OPNAV Manual 5215.1 of May 2016.

10. Information Management Control. Reports required in subparagraph 5d of this instruction are exempt from reports control per Secretary of the Navy Manual 5214.1 of December 2005, part IV, subparagraph 7k.

D. K. VIA

This instruction is cleared for public release and is available electronically only via the Navy Medicine Web site, https://www.med.navy.mil/Directives/