THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

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HEALTH AFFAIRS

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (MANPOWER AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE NAVY (MANPOWER AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE (MANPOWER AND RESERVE AFFAIRS)
DIRECTOR, DEFENSE HEALTH AGENCY

SUBJECT: U.S. Food and Drug Administration Licensure and Registration of Department of Defense Blood Collection and Transfusion Facilities

Pursuant to the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) memorandum, "Alignment of Operational and Installation-Specific Medical Functions and Responsibilities with Section 702 of the National Defense Authorization Act for Fiscal Year 2017, and Sections 711 and 712 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019" dated March 27, 2019, (Attachment One), the Military Department (MILDEP) Surgeons General will coordinate with the Director, Defense Health Agency (DHA), to transfer their respective U.S. Food and Drug Administration (FDA) licenses and registrations for Department of Defense (DoD) blood collection and transfusion facilities. The transfer will be completed no later than 60 days following signature of this memorandum and will include updating the existing Memorandum of Understanding between the DoD and FDA to reflect this realignment (Attachment Two). This transfer is applicable to all blood collection and transfusion facilities funded through the Defense Health Program (DHP), to include those operating within military medical treatment facilities (MTFs) under the authority, direction, and control of the DHA and all Armed Services Blood Bank Centers.

Upon transfer, the Director, DHA, will assume responsibility for ensuring all Armed Services Blood Program (ASBP) activities are FDA-compliant. The Director, DHA, as the "FDA responsible person," will execute this responsibility in coordination with the MILDEP Surgeons General. More specifically, "FDA alternate responsible persons" designated by the MILDEP Surgeons General will coordinate with the DHA to maintain FDA compliance for designated facilities as outlined in Attachment Three.

Department of Defense Instruction (DoDI) 6480.04, "Armed Services Blood Program (ASBP) Operational Procedures," will be revised to reflect these updates and is tentatively scheduled for publication the last quarter of Calendar Year 2020. Your collective support in completing this transfer of responsibilities will reduce the MILDEPs' regulatory requirements associated with in-garrison MTF operations funded through the DHP appropriation, streamline coordination between the DoD and FDA, and facilitate compliance with congressional mandates and USD(P&R) guidance.

As outlined in Attachment One, the MILDEPs, in coordination with the Joint Staff and Combatant Commands, will continue to exercise responsibility for policy involving "deployability, assignability, and employability" for all blood bank activities in the deployed setting. Although these deployed activities may not be licensed by the FDA, FDA requirements will be followed to the maximum extent possible. The DHA, as the DoD Component responsible for the operational management and support of the ASBP, will continue to support the MILDEPs and Combatant Commands in the execution of these responsibilities.

The point of contact for the revision of DoDI 6480.04 is the Director, Operational Medicine, Office of the Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight, at (703) 681-8310 or DSN 761-8310. The point of contact for this memorandum is the Chief, ASBP, DHA, at (703) 681-8026, or DSN 761-8026.

Tom McCaffery

Attachments:
As stated

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Director, Joint Staff
Medical Officer of the Marine Corps