

United States of America

BEFORE THE FEDERAL SERVICE IMPASSES PANEL

In the Matter of

UNITED STATES DEPARTMENT OF DEFENSE
BROOKE ARMY MEDICAL CENTER
FT SAM HOUSTON, TX

And

AMERICAN FEDERATION OF GOVERNMENT
EMPLOYEES, LOCAL 1004

Case No. 19 FSIP 059

DECISION AND ORDER

This request for assistance, concerning the requirement that bargaining unit employees maintain current immunizations and vaccinations while employed at the Brooke Army Medical Center (BAMC), was filed by the Department of Defense, Brooke Army Medical Center, Fort Sam Houston, Houston, Texas (Agency or Management).

The Agency provides safe, quality care to military service members, their families, veterans and civilian emergency patients. The American Federation of Government Employees, Local 1004 (Union) represents just over 2000 bargaining unit employees in non-professional positions. Approximately 167 positions, occupied by approximately 693 bargaining unit employees (or 35% of the bargaining unit) are impacted by the change in this policy. The parties are governed by a national collective bargaining agreement (CBA) that expired in September 2019.

BACKGROUND, BARGAINING AND PROCEDURAL HISTORY

In June 2018, the Agency submitted notification to the Union regarding the Agency's desire to change the immunization and vaccination requirements for

employees employed at the Brooke Army Medical Center (BAMC). The parties conducted negotiations, both in-person and via email. The parties originally filed this case jointly in May 2019, but having not pursued mediation services, withdrew the filing. In June 2019, the parties engaged with a Mediator from the Federal Mediation and Conciliation Services (FMCS). The parties were unable to resolve the matter with the Mediator. In July 2019, the Agency filed this request for FSIP assistance. The Panel asserted jurisdiction over the impasse concerning the requirement that all personnel in the medical center be subject to immunization (including influenza) requirements. The Panel ordered the parties to engage in written submission procedures, with an opportunity to submit rebuttals. Both parties provided written submissions and timely rebuttals.

RELEVANT AUTHORITIES

Army Regulation – 2013

As background, the Army Regulation 40-562 (October 2013) established the Military Vaccination Program and the program requirements. Included with that regulation was an acknowledgement that bargaining unit employees would be exempt from the requirements consistent with their bargaining agreements. (Army Regulation 40-562, Section 2-6(c)). As such, the requirement has not historically applied to this bargaining unit under their CBA.

DHA Guidance - 2019

The Army regulation operates under the guidance and approval of the Defense Health Agency (DHA), a component of DoD. Annually, DHA issues procedural guidance on the Annual Influenza Vaccination Program (IVP), which is adopted and followed by each component of the DoD. The latest version of their annual memo is Interim Procedural Memorandum 19-006, 2019-2020 Seasonal Influenza Vaccination Program. Under the DHA memo, the immunization policy applies to:

All civilian healthcare personnel (HCP), as identified by the CDC¹, working in healthcare setting who have potential exposure to patients or to infectious materials; including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces or contaminated air. HCPs include both persons who provide direct or indirect care to patients and those not directly involved in patient care, but potentially exposed to infectious agents that can be transmitted to and from other HCPs and patients.

¹ CDC website - Healthcare workers include physicians, nurses, emergency medical personnel, dental professionals and students, medical and nursing students, laboratory technicians, pharmacists, hospital volunteers, and administrative staff.

DOD Instruction – 2019

The DoD Instruction 6205.02 (DoDI 6205.02) establishes the Department of Defense's (DoD) uniform immunization policy for DOD personnel. The latest version of that Instruction was issued effective July 23, 2019. The latest version of the instruction reflects the cancellation of the functions of the former Military Vaccine Agency. Under the latest DoDI 6205.02, the Assistant Secretary for Health (ASH), through the Deputy Assistant Secretary of Defense (DASD) for Health Readiness Policy and Oversight (HRP&O), are authorized to work in collaboration with the Defense Health Agency (DHA) to develop guidance that reflects the mandatory immunization requirements.

The DoDI 6205.02 policy includes the requirement that all health-care personnel (HCP) working in a DoD medical treatment facility be required to receive annual season influenza immunization or obtain an exemption (i.e., medical or administrative). The instruction defines HCP as defined above by the 2019 DHA guidance. Specifically, in that DoD Instruction, unlike in the prior guidance, DoD civilian employees who are not HCPs, but who could be potentially exposed to infectious agents that can be transmitted to and from HCP and patients, are required to be immunized. (DoDI 6205.02, Section 1.2(d)).

BAMC Guidance – 2019

As a follow up to the revised DoDI policy, the Brooke Army Medical Center drafted its own guidance on the immunization requirements for employees working in BAMC; BAMC Memo D40-235. That memo is the subject of this negotiation impasse. Under that memo, ALL personnel categories, whether they are involved in direct (e.g., physician and nurse) or non-direct patient care (administrative and logistical), are subject to mandatory immunizations and vaccinations. That policy makes no distinction for the non-HCPs that are potentially exposed or not potentially exposed. It simply applies to all BAMC employees. Appendix D includes all impacted positions, which includes the bargaining unit impacted by this negotiation.

POSITIONS OF THE PARTIES

AGENCY POSITION

The Agency's position is that the welfare of employees, patients, and visitors is best served by very high rates of staff immunization to early childhood diseases, potential occupational exposures, and evolving outbreaks. The Agency's policy includes a process for exemptions on the basis of adverse medical reaction and requests for exemption on the basis of religious affiliation. The Agency's policy also establishes non-DoD beneficiaries will not be charged for any required vaccine if received at BAMC.

The Agency argued that the Union provided no counter proposals during bargaining regarding the negative impact, other than to reiterate employees who are engaged in non-direct patient care should not be required to maintain proof of receiving immunizations/vaccinations. The Agency argued in its submission that the Union merely asserting that bargaining unit employees "do not want to take shots" does not constitute an appropriate arrangement to address adverse effects of the Agency exercising their rights under 5 U.S.C. 71 of the Statute. As background to the Agency's argument, in its initial filing with the Panel, the Agency cited the management rights section of the Statute, Section 7106 (a)(1), which establishes the right of the Agency to determine internal security practices, including the policies and practices that are necessary to safeguard its personnel, physical property, or operations against internal and external risks. The Agency argued at that time that safeguarding the public from transmitting childhood diseases, preventing potential occupational exposures, and protection from evolving outbreaks falls within internal security practices. The Agency argued that eliminating and reducing the number of potential outbreaks that could adversely affect military preparedness and medical care is well within the Agency's management right to determine its internal security practices.

During the investigation, the Agency was asked about their position that subjecting all BAMC personnel to the mandatory immunization policy is within its management rights – internal security. The FLRA has ruled on the negotiability of an agency's mandatory vaccination program in AFGE Local 1345 and Department of Army, Army Medical Department Agency, Army Dental Activity, Fort Carson, Colo, 64 FLRA 949 (June 30, 2010) (Ft. Carson). In *Ft. Carson*, the agency implemented a policy requiring all civilian HCPs who had direct contact with patients to be immunized annually against influenza. The policy provided exceptions for those workers with documented medical or religious reasons for not wanting to be immunized. The agency in that case provided the same reasoning for wanting a mandatory program. The union was seeking exemptions from the program for personal reasons. The FLRA determined in *Ft. Carson* that the plan was targeted and specific, applying only to health care workers with patient responsibilities, and the union's proposal affected management's right to deal with health risks associated with the influenza virus. Therefore, in that case, it was determined that the Agency's limited, mandatory policy was within management rights.

As the Agency in this case seemed to be making the same negotiability arguments that were made in *Ft. Carson* for why it was rejecting the Union's proposal to exempt some employees that are not HCP, during the investigation, the Agency was asked to provide their position on the negotiability of the Union's proposal in writing. The Agency then amended its position during the investigation and asserted that they believed that the matter is negotiable and properly before the Panel for resolution. In its written submission, the Agency continued to assert that the Commanding General is vested with the full authority and command to set a policy that encompasses all BAMC employees, as proposed by the Agency, and, therefore, the Panel should adopt the policy as written because it is the most effective in protecting employees, patients and visitors. The Agency did not go so far as to assert that the policy is non-negotiable

because it is a management right to set this policy. However, in its rebuttal statement, the Agency once again asserted that the Union's proposals restrict and preclude the Agency from exercising its right under 5 U.S.C. 7106. Although the Agency was the party to file the request for Panel's assistance to resolve this matter, the Agency appeared to be flirting with making a management rights argument.

UNION POSITION

The Union proposed that the immunizations become a condition of employment only for Health Care Professionals (HCPs). The Union offered evidence of Agency findings that the immunization is not required for this bargaining unit (i.e., Email from Agency representative). The Agency argued that the evidence cannot be relied upon because the drafter of the email, an agency representative, didn't explain in the email how she reached her conclusion. The Union also offered evidence of past practice of not requiring the immunizations for non-direct patient care employees under the DOD guidance².

The Union argued that the proposed policy change would negatively impact the non-HCP employees in such a way that experienced BAMC employees may be subject to termination after years of service. Specifically, in its rebuttal statement, the Union argued that the exemption provisions (both for religious reasons and for medical reasons) are unworkable because with ALL positions subject to the policy, there is no other position to reassign the exempt employee to, leaving no choice except to be terminated.

PANEL DECISION

The lack of agreement is over the Union's position that the bargaining unit employees, who are not HCPs and have no direct contact with patients, should be allowed to opt out of the program. The BAMC policy goes beyond the DOD or Army policy. The Union argued that the policy is overreaching (goes beyond that which is required by DOD or the Army) and could result in some employees losing their job. The Agency argued that the BAMC Commander has the management right to go beyond the DOD and Army policy. The Agency provided no authority to support that argument. Assuming the BAMC policy could go beyond the DOD or Army policies, this negotiation will determine if that extension is appropriate and agreeable for the BAMC facility.

The Agency presented evidence that maximizing immunization ("herd immunity") would benefit the employees, the patients, and visitors, in general. However, neither party presented evidence to show the benefit of the immunization of non-direct patient

²See DHA-IPM 18-005 – August 14, 2018 – the list of HCP positions where immunization is required does not include the bargaining unit positions impacted in this negotiation. See DHA-IPM 19-006 – August 29, 2019 – which could apply to positions not directly involved in patient care, but only if potentially exposed to infectious agents that can be transmitted to and from HCP and patients; no list provided.

care employees, particularly those who occupy positions that cannot potentially be exposed to an infectious agent that can be transmitted to and from other HCP and patients (the extent of the application of the DOD policy). In other words, both parties failed to make a substantive argument addressing the extension of the program, or not, beyond that which is provided for throughout the rest of DOD. The Union asked the Agency to provide evidence that the immunization requirement went through the proper procedures and approval established by OPM for substantiating a condition of employment. The Agency denied the Union's information request. Without a demonstration of the need for or impact of extending the application of the DOD policy, the Panel has determined that the BAMC policy should be consistent with the intent and guidance provided under the DOD and Army policy.

The Union also expressed concern that in addition to the policy being overreaching, the exemptions (both medical and religious) may not be available in practice. That argument was unpersuasive. The Union presented no evidence that exemptions have been or will be improperly denied. The Agency acknowledges that their immunization policy must be flexible enough to provide for medical and religious exemptions, which it has provided. Both parties understand that improper denials of exemptions for medical or religious purposes could result in a grievance or an EEO complaint.

ORDER

Pursuant to the authority vested in the Federal Service Impasses Panel under 5 U.S.C. §7119, the Panel hereby orders the parties to adopt the terms of the BAMC Memorandum No 040-235, with the following modification:

The policy will to apply to all HCP, including non-direct positions that can be potentially exposed to an infectious agent that can be transmitted to and from other HCP and patients or where the requirement has been established as is a condition of employment.



Mark A. Carter
FSIP Chairman

November 14, 2019
Washington, D.C.

Attachments:

- Union Submission and Rebuttal
- Agency Submission and Rebuttal

15614650.1

19059

Union Submission

September 29, 2019

AFGE Local 1004 position on case No. 19 FSIP 059, that immunizations become a condition of employment (COE) only for Health Care Personnel (HCP). This has been a past practice per guidance from BAMC OCIA Attorney Advisor Kristina A. Letcher (attachment #1); consistent with the guidelines of the "References for Immunization" sent to AFGE Local 1004 from Labor Relations Officer Robert Anthony Rodriguez (Attachment #2) and the Interim Procedures "Memorandum 19-006 2019-2020" (attachment #3)—See 6b (Highlighted) Influenza vaccination is a required condition of employment for all civilian HCP. The proposed policy change will negatively impact to non-HCP employees; such that the well experienced employee at Brooke Army Medical Center may face termination after so many years of service and resource investment.

Steven N. Connolly
AFGE Local 1004
Chief Steward

Moseley, Kimberly

From: Rodriguez, Robert A CIV USARMY CHRA-NC (USA) <robert.a.rodriguez44.civ@mail.mil>
Sent: Friday, March 1, 2019 9:43 AM
To: Connolly, Steven N CIV USARMY MEDCOM BAMC (USA)
Cc: Guerra, Catherine M CIV USARMY CHRA-NC (USA); Arroyo, Milna I CIV USARMY CHRA-NC (USA); Jacks, Samantha T CIV USARMY MEDCOM BAMC (USA); Douglas, Sharon D MAJ USARMY MEDCOM BAMC (USA)
Subject: FW: References for Immunization
Attachments: SIGNED DHAIPM 1800x Seasonal Influenza Vaccination Program.pdf; Guidance for the 20182019 Annual Influenza Immunization Program_Redacted....pdf; DoD Guidance for the 2017-2018 Annual Influenza Immunization Program.pdf

Good morning Steve,

Attached are the references that were discussed when the Parties met to discuss the immunization issue. During the discussion the AFGE made reference to documents they had in possession or they referenced information and data from. At this time the Agency is requesting copies of these documents in order to address the impact questions you raised during our last meeting.

V/R

Robert Anthony Rodriguez
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DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

DHA-IPM 18-005
August 14, 2018

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 OF THE JOINT STAFF
DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH READINESS POLICY AND OVERSIGHT)
DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH SERVICES POLICY AND OVERSIGHT)
DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH RESOURCES MANAGEMENT AND POLICY)
DIRECTORS OF THE DEFENSE AGENCIES
DIRECTORS OF THE DOD FIELD ACTIVITIES
ASSISTANT COMMANDANT FOR HUMAN RESOURCES,
U.S. COAST GUARD

SUBJECT: Interim Procedures Memorandum 18-005, 2018–2019 Seasonal Influenza Vaccination Program (IVP)

References: See Attachment 1.

Purpose. This Defense Health Agency-Interim Procedures Memorandum (DHA-IPM), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (p):

- Provides guidance for the Seasonal IVP. Please disseminate this message to all military activities to include, but not limited to, Commanders of Medical Treatment Facilities (MTFs), immunization clinics, patient-centered medical homes, public health offices, pharmacy services, ships, aid stations, and medical logistics/supply sections that administer or order/receive/store influenza vaccine.
- This DHA-IPM is effective immediately and will expire 12 months from the date of issue.

Applicability. This DHA-IPM applies to OSD, the Military Departments (including the Coast Guard at all times, including when it is a Service in the Department of Homeland Security by agreement with that Department), the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of DoD, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the

DoD (referred to collectively in this DHA-IPM as the "DoD Components").


Policy Implementation. It is Defense Health Agency (DHA) policy, pursuant to References (g) and (i), that all Active Duty (AD) and Reserve Component personnel will be vaccinated against influenza. Individual Ready Reserve and Retired Reserve personnel are not subject to this DHA-IPM.

Responsibilities

- Director, DHA. The Director, DHA, will track, collect, and analyze immunization data and all confirmed vaccine compromises in coordination with the DoD Components.
- Surgeons General of the Military Departments. The Surgeons General of the Military Departments will monitor influenza immunization compliance data.

Procedures. See Attachment 2.

Releasability. **Cleared for public release.** This DHA-IPM is available on the Internet from the Health.mil site at: www.health.mil/DHAPublications.


R. C. BONE
VADM, MC, USN
Director

Attachments:

As stated

cc:

Acting Assistant Secretary of Defense for Health Affairs
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Medical Officer of the Marine Corps
Joint Staff Surgeon
Director of Health, Safety, and Work-Life, U.S. Coast Guard
Surgeon General of the National Guard Bureau
Director, National Capital Region Medical Directorate

ATTACHMENT 1

REFERENCES

- (a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA)),
September 30, 2013, as amended
- (b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
- (c) DHA-Procedural Instruction 5025.01, "Publication System," August 21, 2015
- (d) Assistant Secretary of Defense for Health Affairs Memorandum, "Department of Defense
Influenza Pandemic Preparation and Response Health Policy Guidance," January 25, 2006
- (e) United States Code, Title 42, Sections 300aa-1-300aa-34
- (f) Centers for Disease Control and Prevention, "Vaccine Information Statements (VIS),
Influenza (Flu) Vaccine: Inactivated or Recombinant; Live, Intranasal," August 7, 2015
- (g) Army Regulation 40-562, BUMEDINST 6230.15B, AFI 48-100_IP, CG COMDTINST
M6230.4G, "Immunizations and Chemoprophylaxis for the Prevention of Infectious
Diseases," October 7, 2013
- (h) Assistant Secretary of Defense for Health Affairs Policy 08-005, "Policy for Mandatory
Seasonal Influenza Immunization for Civilian Health Care Personnel Who Provide Direct
Patient Care in Department of Defense Military Treatment Facilities," April 4, 2008
- (i) Assistant Secretary of Defense for Health Affairs Memorandum, "Guidance for the 2018-
2019 Annual Influenza Immunization Program," July 5, 2018
- (j) DoD Instruction 4000.19, "Support Agreements," April 25, 2013, as amended
- (k) Navy Aeromedical Reference and Waiver Guide, April 9, 2018
- (l) Official Air Force Aerospace Medicine Approved Medications, June 13, 2017
- (m) Centers for Disease Control and Prevention, "Immunization of Health-Care Personnel:
Recommendations of the Advisory Committee on Immunization Practices (ACIP),"
Morbidity and Mortality Weekly Report Recommendations and Reports,
November 25, 2011; 60(RR07); 1-45
- (n) Code of Federal Regulations, Title 5, Part 339
- (o) Coast Guard Medical Manual, COMDTINST M6000.1 (series)
- (p) Coast Guard Occupational Medicine Manual, COMDTINST M6260.32

ATTACHMENT 2

PROCEDURES

1. 2018–2019 SEASONAL INFLUENZA INFORMATION

a. Influenza or “flu” has the potential to adversely impact force readiness and mission execution. The Centers for Disease Control and Prevention (CDC) estimates that influenza has resulted in between 9.2 million and 35.6 million illnesses; between 140,000 and 710,000 hospitalizations; and between 12,000 and 56,000 deaths annually since 2010 in the United States. Vaccination is the primary method for preventing influenza and its complications.

b. In accordance with Reference (g), the DoD and the Coast Guard generally follow the CDC and Advisory Committee on Immunization Practices (ACIP) vaccine recommendations, requirements, and guidance of the U.S. Food and Drug Administration (FDA), while considering the unique needs of military populations. The most current CDC and ACIP recommendations can be found at <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html>. The DoD uses only FDA-approved vaccines. Information on the DoD Seasonal IVP can be found on the Defense Health Agency-Immunization Healthcare Branch (DHA-IHB) seasonal influenza website: <https://www.health.mil/flu>.

c. The CDC and the ACIP recommend seasonal influenza vaccine for all people 6 months of age and older. Special efforts should be made to vaccinate those at high risk from influenza complications to include pregnant women, children under 5 years of age, adults 65 years and older, and those with certain medical conditions outlined in the ACIP guidelines.

d. 2018–2019 U.S. trivalent influenza vaccines will contain A/Michigan/45/2015 (H1N1) pdm09-like virus, A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage). Quadrivalent vaccines will also include B/Phuket/3073/2013-like virus (Yamagata lineage). The 2018–2019 vaccine represents a change in the influenza A (H3N2) and the B/Colorado virus strains. The ACIP has not expressed a preference for quadrivalent or trivalent vaccine in any age group, nor has it expressed a preference for “High-Dose” vaccine or any other licensed influenza vaccine for use in persons 65 years and older. Vaccinate all individuals with available product in accordance with the package insert. Influenza vaccinations will continue until all required personnel have received the vaccine, or the vaccine expires.

e. Additional influenza vaccine formulations, not available through the Defense Logistics Agency (DLA) bulk purchase contract (e.g., specific vaccines for adults age 65 years and older, egg protein free etc.) are available for purchase through the Defense Logistics Agency-Troop Support Medical (DLA-TSM) Direct Vendor Delivery (DVD) program, as described in paragraph 2d. Clinics must contact their supply/logistics support personnel for more details. The ACIP included live attenuated influenza vaccine, or Flumist®, in the 2018–2019 Influenza Vaccine Recommendations after the DoD’s annual contract was initiated. For this reason, live attenuated influenza vaccine will only be available through the DLA-TSM DVD program.

2. ORDERING, DISTRIBUTION, AND COLD CHAIN MANAGEMENT

a. For the 2018–2019 influenza season, DoD purchased 3.4 million doses of influenza vaccine. This amount will ensure that all Service members and beneficiaries have access to protection against influenza. Additional information about ordering influenza vaccine can be found in the Service-specific appendices at the end of this DHA-IPM. Activities should expect several deliveries to fulfill requirements.

b. The following vaccines have been contracted for by DoD for the 2018–2019 season:

NDC	Name	Presentation	Price/package/vial
19515-0909-52	Flulaval®	PFS	138.20
19515-0900-11	Flulaval®	MDV	129.18
58160-0898-52	Fluarix®	PFS	138.20
33332-0318-01	Afluria®	PFS	110.78
33332-0418-10	Afluria®	MDV	121.68

c. The manufacturers will ship to the DLA Distribution Depot per the following delivery schedule (% is of total DoD and USCG order):

Contracted Delivery Schedule	17 AUG	30 AUG	31 AUG	14 SEP	28 SEP	30 SEP	19 OCT	15 NOV
6505-01-670-7649, Peds, FluLaval® PFS			50%		30%		20%	
6505-01-670-7372, FluLaval®, MDV			50%		30%		20%	
6505-01-670-8188, Fluarix®, PFS						50%		50%
6505-01-670-7769, Afluria®, PFS	40%	25%		25%	10%			
6505-01-670-8005, Afluria®, MDV	40%	25%		25%	10%			

d. Influenza vaccines not purchased through the annual DoD contract may be available through the DLA-TSM DVD program, via Military Standard Requisitioning and Issue Procedures (MILSTRIP). Requisitions may be submitted via the Defense Medical Logistics Standard Support (DMLSS) or via the DoD-FEDMALL system. Information on the DoD-FEDMALL system can be located at: <https://www.fedmall.mil/index.html>.

e. Logistics and immunization personnel should register to receive influenza vaccine updates by way of the DoD Medical Materiel Quality Control (MMQC) messages. Personnel can register at: <http://www.usamma.army.mil/SitePages/MMQCMsgSubscriber.aspx>

f. DoD Components will ensure that logistics and immunization personnel are properly trained in the storage and handling of influenza vaccines, and are present to receive and store vaccines upon arrival. These vaccines will be promptly posted in the facilities' requisition processing system.

g. To ensure proper receipt, DLA-TSM will ship vaccine to Outside Continental United States (OCONUS) locations on Mondays and Fridays, and to Continental United States (CONUS) locations on Mondays, Tuesdays, and Wednesdays. DLA-TSM does not ship on holidays or weekends, and will only ship on Thursdays on a case-by-case basis.

h. All vaccine shipments will include temperature monitoring devices. These items should be returned to DLA-TSM as soon as possible after receipt, per instructions included in each vaccine shipment. All DoD activities that receive and administer influenza vaccine will use the pre-paid/pre-addressed Federal Express materials provided with shipping containers to physically return the temperature monitors to DLA-TSM.

(1) No-Alarm temperature monitors: The material is released for immediate use. Disposition is not needed from DLA-TSM, but the temperature monitor must be returned for audit purposes.

(2) Alarmed temperature monitors: Activity will segregate the vaccine in the refrigerator with a sign saying, "DO NOT USE," return temperature monitor to DLA-TSM, and await disposition instructions.

(3) Un-started or malfunctioning temperature monitors: Activity will treat the shipment as alarmed.

(4) If an activity currently has the Template Monitor Software loaded on a computer and is using Version 7.2, please contact your Service/Information Technology point of contact for the updated version (7.4), as Version 7.2 is not compatible with Windows 10.

i. Influenza vaccines will be stored and transported correctly within the temperature parameters of 2° to 8°C (36° to 46°F), at all times. If the vaccine is not stored correctly within the correct temperature parameters, it may lose potency. Any time a temperature compromise is suspected:

(1) The vaccine will be placed immediately in a refrigerator approved for vaccine storage and marked "DO NOT USE."

(2) Notify your DHA-IHB Immunization Healthcare Specialist (<http://health.mil/ContactYourIHS>), and complete the Potentially Compromised Vaccine/Temperature Sensitive Medical Products response worksheet, dated on or after August 1, 2018, located on the DHA-IHB website at www.health.mil/coldchain. The worksheet must be submitted online to DLA-TSM, United States Army Medical Materiel Agency-Distribution Operations Center (USAMMA-DOC), and to your local medical logistics directorate.

(3) Do not assume the vaccine is unusable, and do not discard potentially compromised vaccine(s) until directed by DLA-TSM and/or USAMMA-DOC.

(4) An Executive Summary for all confirmed compromises will be submitted through the Service medical headquarters (if required by Service policy) and to the Director, DHA.

j. All DoD Components, Coast Guard activities, as well as other organizations eligible to participate in DLA-TSM's Pharmaceutical Prime Vendor programs, will participate in the DLA-TSM Pharmaceutical Reverse Distribution Program for returning unused, expired, and/or compromised influenza vaccines, at the end of the season, June 30, 2019. This program provides

a safe option for the disposal of unused, expired, and/or compromised influenza vaccines while maintaining full compliance with Federal regulations. Credit for returned vaccines will be posted to the activity's Pharmaceutical Prime Vendor credit account. Credits can be used for future purchases or to cover disposal costs. DoD activities should make every effort to return influenza vaccine in its original box. Pharmacies or logistics activities can provide more guidance on the use of this program.

3. FUNCTIONAL CONSIDERATIONS

a. The Assistant Secretary of Defense for Health Affairs (ASD(HA)) has directed that all uniformed personnel receive an annual influenza vaccination, with a recommended goal of greater than 90% of personnel immunized by January 15, 2019, per Reference (i). The Services may designate earlier dates for the 90% completion goal in the Service specific appendices at the end of this IPM.

b. In the event of an influenza pandemic, target populations will be prioritized per Reference (d). Should unanticipated shortage of vaccine or unforeseen distribution delays occur, the ASD(HA) will provide direction regarding priority tiers, consistent with CDC and ACIP guidelines.

4. VACCINE ADMINISTRATION

a. In accordance with Reference (g), only appropriately trained and qualified medical personnel working within their scope of practice, upon the order (including standing orders) of an appropriately privileged healthcare provider, will administer the influenza vaccine.

b. The DHA-IHB will provide online training modules via Joint Knowledge Online, which will include patient screening, documentation, administration, and cold chain management procedures. The 2-hour Influenza Vaccination Training (DHA-US069) and 1-hour Cold Chain Management of the Influenza Vaccine for Logistical Personnel (DHA-US070) can be found at <https://jkosupport.jten.mil/Atlas2/page/login/Login.jsf>. This online training may be incorporated into local or regional training programs.

c. Prior to vaccination, all potential vaccine recipients will be screened utilizing locally-approved or current standardized screening questions available via the CDC or DHA-IHB website. In accordance with Reference (e), individuals receiving a vaccine will be provided the current influenza Vaccine Information Statement (VIS), in accordance with Reference (f), for the inactivated, injectable, or intranasal influenza vaccines. When minors are vaccinated, the VIS will be provided to their legal representative.

d. Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Any licensed and recommended influenza vaccine that is otherwise appropriate for the recipient's age and health status may be used. Persons who report having had reactions to egg involving symptoms other than hives, such as angioedema,

respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, may similarly receive any licensed and recommended influenza vaccine that is otherwise appropriate for the recipient's age and health status. The selected vaccine should be administered in an inpatient or outpatient medical setting (including, but not necessarily limited to, hospitals, clinics, health departments, and physician offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic conditions.

e. Patients reporting an allergic reaction to an excipient of the influenza vaccine (example: neomycin) should be referred to an allergist/immunologist for further evaluation and to identify risk of reaction to other vaccines with similar excipients. The Medical, Temporary (MT) exemption code should be entered into the Service-specific Immunization Tracking System (ITS) when vaccination is deferred in these cases.

5. DOCUMENTATION

a. Documentation of immunization for Service members is required in the appropriate Service-specific ITS: Medical Protection System (MEDPROS) for Army, Medical Readiness Reporting System (MRRS) for Navy, Marine Corps, and Coast Guard, and Aeromedical Services Information Management System (ASIMS) for the Air Force, in accordance with Reference (g). When documenting immunizations in the Armed Forces Health Longitudinal Technology Application (AHLTA), the immunization module will be used. For locations that have transitioned from AHLTA to Military Health System (MHS) GENESIS, influenza immunizations will be documented in MHS GENESIS, and the data will transfer to the Service-specific ITS.

b. In accordance with Reference (e), proper documentation of an immunization includes: patient identification, date vaccine was administered; vaccine name or CVX code, manufacturer and lot number, dose administered, route of administration, anatomic site of vaccination, date the VIS was provided; and VIS version date.

c. Due to the number of vaccine products available each year, staff should verify all product names and CVX codes before documentation. CVX codes 15 (influenza, split), 16 (influenza, whole), 111 (influenza, live, intranasal), and 153 (influenza, MDCK, PF) are inactive and should NOT be used to document vaccines administered this season. CVX code 88 (influenza unspecified) should be used for historical documentation only when vaccine specifics are not known. The CVX codes for the DoD purchase 2018–2019 vaccine include:

(1) CVX Code 150: For documenting single dose, injectable quadrivalent, preservative free. (Afluria®, FluLaval®, and Fluarix® pre-filled syringes)

(2) CVX code 158: For documenting multi-dose injectable, quadrivalent, containing preservative. (Afluria® and FluLaval® multi-dose vials)

d. Service members who receive influenza vaccinations from non-military facilities will provide immunization data to their unit's ITS point of contact for transcription no later than close of business the next duty day (next drill weekend/battle assembly for Reserve Component members), following the immunization. All available information should be transcribed into the ITS. Contract providers will document immunization information, as noted in Section 5.b., into the ITS at the time of immunization delivery. Personnel who receive the seasonal influenza vaccine through the Reserve Health Readiness Program (RHRP) may not (or do not) need to provide immunization data directly to their unit's ITS point of contact; the RHRP contractor will update the ITS.

e. Do not use exemption codes "Medical, immune (MI)," "Medical, assumed (MA)," "Medical, declined (MD)," "Not required (NR)," "Medical, permanent (MP)", or "Medical, reactive (MR)" to defer seasonal influenza vaccinations for military personnel. Due to the variety of influenza vaccines available each year and scientific evidence providing options for those individuals previously identified as having a contraindication to influenza vaccine, the risk/benefit of influenza vaccine should be reviewed on an annual basis by a treating physician. The MT exemption code should have an expiration date of no later than June 30, 2019.

6. ADVERSE EVENTS

a. Local swelling, soreness at the injection site, and headache are common side effects that are self-limiting, resolve quickly, and do not constitute an allergic reaction. Soreness at the immunization site lasting up to 2 days, fever, malaise, myalgia, and other systemic symptoms may occur. These begin 6–12 hours after immunization and can persist for 1–2 days. Immediate allergic reactions including hives, angioedema, allergic asthma, and systemic anaphylaxis are rare.

b. All suspected serious or unexpected vaccine-related adverse events (e.g., events resulting in hospitalization, life-threatening events, one or more duty shifts lost due to illness, or an event related to suspected contamination of a vaccine vial) must be reported through the Vaccine Adverse Event Reporting System at: <https://vaers.hhs.gov/reportevent.html>. The DHA-IHB Immunization Healthcare Support Center is available at: 1-877-GET-VACC (1-877-438-8222) to answer questions regarding vaccine screening and potential vaccine-related adverse events.

7. INFLUENZA VACCINATION REQUIREMENTS AND RECOMMENDATIONS

a. Influenza vaccinations are mandatory for all Active and Reserve Component members, in accordance with Reference (g), and Service-specific guidance (see Appendices 1–4). Exemptions can be granted on a case-by-case basis for medical or administrative (such as religious) reasons in accordance with Reference (g).

b. Influenza vaccination is a required condition of employment for all civilian healthcare personnel (HCP), in accordance with Service-specific guidance, who provide direct patient care

in DoD MTFs, unless there is a documented medical or administrative reason not to be immunized, in accordance with References (g) and (h) and (n).

(1) Service points of contact will provide Service-level civilian HCP compliance reports to DHA-IHB no later than February 15, 2019, including the total number of the following: HCPs, HCPs immunized, and medical and administrative exemptions.

(2) The DHA-IHB will provide the ASD(HA) with the consolidated annual report detailing DoD HCP influenza immunization compliance, in accordance with Reference (h), no later than March 1, 2019.

c. Activities should advise all DoD civilian employees that the influenza vaccination is available without cost or copay as a benefit of the Federal Employee Health Benefit program.

d. Activities are authorized to use DoD purchased influenza vaccine for the immunization of:

(1) Active/Reserve Component members;

(2) DoD beneficiaries;

(3) Contracted HCPs in accordance with the terms of their contract;

(4) DoD civilian personnel who are employed under the Defense Health Program (DHP). (DHP-funded civilian employees provide for the delivery of medical and dental care to DoD Service members and beneficiaries); and

(5) Non-DHP-funded DoD civilian personnel (including DoD Education Activity and Non-Appropriated Fund (NAF) employees), on a reimbursable basis.

(a) Activities may waive reimbursement, in accordance with Reference (j), if it is determined that the reimbursement process would be impractical or prohibitively expensive.

(b) Activities may direct specific limitations associated with the vaccination of non-DHP-funded employees (e.g., only at mass vaccination events or during set times).

8. RESOURCES. The Influenza Resource Center located on the DHA-IHB website (<http://www.health.mil/flu>) contains templates and additional documents for the management of the Seasonal IVP to include standing orders, suggested screening questions, staff competency forms, dosing algorithms, vaccine cold chain management tools, and vaccine product guides. Product package inserts (e.g., ACIP guidelines, Service policies, and other references) to support the Seasonal IVP are posted on the website upon publication.

DHA-IPM 18-005
August 14, 2018

9. QUESTIONS. For DoD Seasonal IVP questions, please contact the DHA-IHB at: 1-877-GET-VACC (1-877-438-8222), or via email: DoDVaccines@mail.mil.



APPENDIX 1

ARMY

1. VACCINE ORDERING AND DISTRIBUTION

a. USAMMA-DOC is the Army's inventory control point for the influenza vaccine which is an Acquisition Advice Code Service regulated item. DLA contracts with manufacturers, acquires the vaccine, and distributes it to activities based on the priorities submitted to them by USAMMA. USAMMA follows all requisitions until they are fulfilled. USAMMA-DOC will notify units of the quantities ordered and the document numbers being used when vaccine is being shipped. Additional quantities required must be coordinated with USAMMA-DOC, Defense Switched Network (DSN) 343-4128/4318, Commercial 301-619-4128/4318.

b. Questions or concerns, including ordering influenza vaccines which are not centrally contracted by DoD should be directed to USAMMA-DOC: Email: usarmy.detrick.medcom-usamma.mbx.vaccines@mail.mil; Commercial: (301) 619-4128/4318; DSN: 343-4128/4318; Fax: (301) 619-4468, or call the after-hour number at (301) 676-1184.

2. FUNCTIONAL CONSIDERATIONS

a. All locations will initiate seasonal immunization operations upon receipt of influenza vaccine in accordance with national guidelines as outlined in the most recent ACIP recommendations on the Prevention and Control of Influenza, <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html>.

b. Exemptions for civilian employees based on the need for accommodation will be documented in the Civilian Employee Medical Record (CEMR).

c. Logistics personnel will verify their DoD Activity Address Code (DODAAC) with the Army Influenza Manager at USAMMA-DOC prior to the start of the influenza vaccine season.

d. Organizations/units will report vaccine loss and destruction. Complete and submit DA Form 3161 for any influenza vaccine that is lost or destroyed in excess of 1% of the total order received (due to expiration, validated compromise due to temperature excursion, or other reasons requiring destruction). Completion of the loss/destruction report is a cost saving tool that aids in assessing program vaccine requirements. Email these forms to usarmy.detrick.medcom-usamma.mbx.vaccines@mail.mil. Email subject is: Influenza Loss and Destruction report.

e. Regional Health Commands (RHCs) will provide their civilian HCP compliance reports to Deputy Chief of Staff-Public Health (DCS-PH), Public Health Directorate, using the following format.

RHC Name	Total # of mandatory HCP	Total # of mandatory HCP vaccinated	Total # of mandatory HCP with exemptions
RHCA(P)	0	0	0

f. Civilian employees who choose to receive an influenza vaccine outside of an MTF or Army occupational health clinic may bring vaccination documentation to the occupational health clinic to be filed in their CEMR.

3. INFLUENZA VACCINATION REQUIREMENTS AND RECOMMENDATIONS

a. In order to increase efforts to protect the workforce, patients and beneficiaries, all MTF personnel, as defined below, should receive influenza immunization, with the exception of those medically or administratively exempt. Medical exemptions will be validated by a health care provider and documented in the MEDPROS, AHLTA, MHS-GENESIS, and the CEMR as appropriate. An exemption excusing a healthcare worker from a mandatory vaccination may impose additional infection control practices on the worker as a result, such as wearing a mask. While an employer may not impose such practices for discriminatory or retaliatory reasons, it may do so for legitimate, non-discriminatory and non-retaliatory reasons.

b. HCPs are defined as all paid and unpaid persons working in healthcare settings who have the potential for exposure to patients and/or infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCPs might include (but are not limited to), physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients.

c. The table below references mandatory immunization employees per Reference (h). RHC Commanders retain the flexibility and authority to add to the minimum list.

Occupational Title	Job Series
Psychologists	0180
Social Workers	0185
Chiropractors	0601
Physicians	0602
Physician Assistants	0603
Registered Nurses	0610
Licensed Practical Nurses/Licensed Vocational Nurses	0620
Nursing Assistants	0621
Nutritionists/Dietitians	0630
Occupational Therapists	0631
Physical Therapists	0633
Physical Therapy Assistants	0636
Health Technicians	0640
Nuclear Medicine Technicians	0642
Medical Technologists	0644
Medical Technicians	0645
Diagnostic Radiologic Technicians	0647
Therapeutic Radiologic Technicians	0648
Medical Instrument Technicians	0649
Medical Technician Assistants	0650
Respiratory Therapists	0651
Pharmacists	0660
Pharmacy Technicians	0661
Optometrists	0662
Audiologists	0665
Speech Pathologists	0665
Orthotists and Prosthetists	0667
Podiatrists	0668
Medical Support Assistants	0679
Dentists	0680
Dental Technicians	0681
Dental Hygienists	0682
Dental Lab Aids	0683

APPENDIX 2

NAVY

1. VACCINE ORDERING AND DISTRIBUTION

a. The Naval Medical Logistics Command (NAVMEDLOGCOM) is responsible for ordering and distributing influenza vaccine for all Navy and Marine Corps activities. Additional quantities required must be coordinated with the NAVMEDLOGCOM Influenza Vaccine Manager, Ms. Barbra Rosenthal, email: barbra.r.rosenthal.civ@mail.mil, Commercial: (301) 619-8054, DSN: 343-8054 or the VIALS helpdesk at: usn.detrick.navmedlogcomftdmd.list.vialhelp@mail.mil.

b. Vaccine Information and Logistics System (VIALS) is the online requisition system for seasonal influenza vaccines. VIALS is used to electronically track requisitioned vaccines via Military Standard Requisitioning and Issuing Procedures, and simplify vaccine requisitions to enable electronic tracking of vaccine orders from requisition to receipt. Activities submit requirements into the VIALS found at https://gov_only.nmlc.med.navy.mil/int_code03/vials/.

c. Navy influenza vaccine is batch-ordered by NAVMEDLOGCOM from the DLA using command requirements in VIALS. Navy influenza vaccine is centrally funded.

d. Questions or concerns, including ordering influenza vaccines which are not centrally contracted by DoD should be directed to the Navy Influenza Vaccine Manager noted above in section 1a.

2. FUNCTIONAL CONSIDERATIONS

a. Personnel in an active flying status will observe the grounding period guidance provided in section 18.5 of Reference (k). For Service members in an active flying status exposed to altitude as part of their career field, injectable vaccine is preferred for its shorter post-administration grounding period (12 hours versus 72 hours) and milder side effect profile.

b. Service members in an active diving status are authorized to receive intranasal vaccine; however, injectable vaccine remains the preferred vaccine.

c. Previous influenza seasons have been used to exercise and evaluate mass vaccination scenarios. These coordinated mass vaccination campaigns provide rapid and efficient vaccinations to protect the maximum number of susceptible persons. Based on lessons learned, process improvements are made to delivery and reporting procedures.

d. Vaccination administration compliance will be monitored via the MRRS. Designated command personnel will access MRRS to track their personnel to ensure compliance.

Shore-based commands will request access to MRRS based on their unit identification code by calling the MRRS program office at the number below. Ship-based commands may utilize Navy Medicine Online (NMO) or the Shipboard Non-Tactical Automated Data Processing Program (SNAP) Automated Medical System (SAMS) to populate MRRS. All commands requesting MRRS access must submit a System Access Authorization Request (SAAR) form. MRRS can be accessed at: <https://mrrs.dc3n.navy.mil/mrrs> (note: MRRS web address is case sensitive). Point of contact/MRRS program office/email: mrrspo@navy.mil/ (800) 537-4617/ (504) 697-7070/ DSN: 647-7070.

3. INFLUENZA VACCINATION REQUIREMENTS AND RECOMMENDATIONS

a. In order to maximize force medical readiness before peak influenza season, the Navy's seasonal influenza vaccination goal will remain to exceed 90 percent immunization of all active and reserve component personnel by December 15, 2018.

b. Mandatory influenza vaccination is a condition of employment for all civilian HCPs providing direct patient care in a DoD MTF, per Reference (h). Influenza vaccination is mandatory for all civilians where it is written in their position description as a condition of employment. Other Navy civilian personnel are highly encouraged to receive influenza vaccinations.

APPENDIX 3

AIR FORCE

1. VACCINE ORDERING AND DISTRIBUTION

a. Air Force Medical Operations Agency, Medical Force Health Protection Manpower Equipment Force Package (AFMOA/SGMX) is responsible for ordering and distributing influenza vaccine for Air Force activities. AFMOA/SGMX will notify units of the quantities ordered and the document numbers being used. Additional quantities required must be coordinated with AFMOA/SGMX, DSN 343-4170, Commercial (301) 619-4170.

b. Questions or concerns, including ordering influenza vaccines which are not centrally contracted by DoD should be directed to TSgt Adrienne Kramer: Email: adrienne.m.kramer2.mil@mail.mil, Commercial: (301) 619-4164; DSN: (312) 343-4164; Fax: (301) 619-2557; or Mr. Scotti Smith: Email: scotti.j.smith.civ@mail.mil, Commercial: (301) 619-4183; DSN: 343-4183.

2. FUNCTIONAL CONSIDERATIONS

a. Aeromedical impact: Aircrew are in duties not to include flying status for 4 hours following influenza vaccination in accordance with Reference (l): "Access to medical care on the ground is recommended for a period of 4 hours for all personnel after immunization unless operational needs dictate otherwise."

b. Individual Mobilization Augmentees should be immunized at their first opportunity, or by their supporting MTF and should be included in requirements for the MTF. Alternatively, they can provide full information about the immunization received to be transcribed into the ASIMS at <https://asims.afms.mil/WebApp2/MainMenu.aspx>.

3. INFLUENZA VACCINATION REQUIREMENTS AND RECOMMENDATIONS

a. In order to maximize force medical readiness before peak influenza season, the Air Force seasonal influenza vaccination goal will remain to exceed 90 percent immunization of all active and reserve component personnel by December 17, 2018.

b. All civilian HCP will be immunized annually against influenza virus in accordance with recommendations of the CDC and the ACIP. Local bargaining obligations will need to be satisfied prior to full implementation of this program guidance.

c. The Air Force endorses the CDC's definition of HCP found in Reference (m) in which HCPs are defined as "all paid and unpaid persons working in health-care settings who have the potential for exposure to patients and/or to infectious materials, including body substances,

contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP might include (but are not limited to); physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers), not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients.”

APPENDIX 4

COAST GUARD

1. VACCINE ORDERING AND DISTRIBUTION

a. The Health, Safety, and Work-Life Service Center (HSWL SC) is responsible for ordering and monitoring influenza vaccine distribution to Coast Guard units. The HSWL SC will notify unit points of contact of forthcoming shipments that will include estimated quantity, date of arrival, and tracking number supplied by DLA. The receiving unit point of contact will contact the HSWL SC upon receipt of shipment to verify the quantity received and the status of the alarm.

b. For questions or concerns about ordering, distribution, and the receipt of influenza vaccine, the HSWL SC contact is CAPT Daniel Hasenfang.

2. FUNCTIONAL CONSIDERATIONS

a. Influenza vaccination is mandatory for all Coast Guard AD and Selected Reserve (SELRES) personnel to ensure force medical readiness and avoid disruption of Coast Guard missions. In accordance with References (g), (o), and (p), the seasonal influenza vaccine is also mandatory for Child Development Services personnel (including certified Family Child Care Providers); civilian, contract, and Auxiliary HCP who provide direct patient care; and recreation personnel in the youth programs at Borinquen, Cape Cod, Kodiak, and Petaluma.

b. Influenza vaccinations are available at Coast Guard clinics for AD personnel and for Auxiliary health care personnel assigned to Coast Guard clinics. Contract personnel will obtain the flu vaccine according to the terms of their contract.

c. Remotely located AD and SELRES personnel may receive their influenza vaccination via the RHRP through an RHRP contracted clinic or the RHRP Walgreens Walk-In option. Personnel desiring to use RHRP for their influenza vaccination must request an order from the Coast Guard clinic responsible for their unit; a list can be found at https://www.reserve.uscg.mil/Portals/2/Resources/USCG-Clinic_Lookup.PDF?ver=2018-05-11-110428-050. The RHRP contractor will ensure the vaccination is properly recorded in MRRS.

d. Coast Guard civilian employees enrolled in the Federal Employees Health Benefits Program (FEHBP) can be immunized through their health plan at no out-of-pocket cost. Many FEHBP health plans make the influenza vaccine available in pharmacies and other convenient community locations. Coast Guard civilian employees who are not insured through the FEHBP and who are required to be immunized against influenza shall complete the Claim for Reimbursement for Expenditures on Official Business, Form OF 1164, to obtain reimbursement

from COMDT (CG-832). Ms. Regina Cash and Mr. Felix Edozie are the COMDT (CG-832) points of contact regarding the reimbursement process. Civilian employees who are required to have the influenza vaccine must provide the following information to the cognizant clinic administrator no later than January 17, 2019: the date the vaccine was administered, the vaccine name or code, the manufacturer and lot number, the dose administered, route and anatomic site of vaccination, the date the VIS was provided, and the VIS version date.

e. NAF employees should obtain the influenza vaccination through their NAF health insurance or other health insurance coverage available. Those employees who are not part of the NAF health benefits plan and are mandated to obtain the influenza vaccine may complete the Claim for Reimbursement for Expenditures on Official Business, Form OF 1164, and submit the form and the immunization receipt to their supervisors for approval and submission to Ms. Virginia Cameron, Human Resources Director in the Community Services Command, for payment. NAF employees who are required to have the influenza vaccine must provide appropriate documentation as described in Paragraph 2.d above to their supervisor no later than January 17, 2019.

APPENDIX 5

INFLUENZA VACCINE PRODUCT LIST AND AGE GROUPS – UNITED STATES, 2018-2019

Influenza Vaccine Product List and Age Groups – United States, 2018-2019 Season*
(DOD contracted vaccines are highlighted in yellow; Direct Vendor Delivery (DVD) available vaccines are highlighted in orange)

Manufacturer	Trade Name (Vaccine abbreviation)	NDC	Presentation	Miscellaneous (Units/box)	Dose (mL)	Age Group	CUV	CPT
Seqirus, Inc.	Afluria [®] (IV4)	33332-0318-01	0.5 mL single-dose syringe	0	<1	2-5 yrs	150	90686
	Afluria [®] (IV4)	33332-0418-10	5.0 mL multi-dose vial [†]	24.5	<1	≥ 65 yrs	150	90688
	Flucelvax [®] (cellV4)	70461-0018-03	0.5 mL single-dose syringe	0	<0.4	≥ 65 yrs	166	90653
	Flucelvax [®] (cellV4)	70461-0318-03	0.5 mL single-dose syringe	0	††	2-4 yrs	171	90674
GlaxoSmithKline	Fluarix [®] (IV4)	70461-0418-10	0.5 mL single-dose vial	25	††	2-6 mos	186	90756
	Fluarix [®] (IV4)	58103-0808-52	0.5 mL single-dose syringe [‡]	0	‡‡	2-6 mos	150	90685
	Fluarix [®] (IV4)	19515-0909-32	0.5 mL multi-dose syringe [‡]	0	‡‡	2-9 mos	150	90696
	Fluarix [®] (IV4)	19515-0909-11	5 mL multi-dose vial (M)	0	‡‡	6-35 mos	158	90688
Sanofi-Pasteur, Inc.	Fluzone [®] (IV4)	49281-0518-25	0.5 mL single-dose syringe	0	§§	2-3 yrs	150	90686
	Fluzone [®] (IV4)	49281-0418-50	0.5 mL single-dose vial	0	§§	6-35 mos	150	90687
	Fluzone [®] (IV4)	49281-0829-15	5 mL multi-dose vial (0.25 mL dose)	0	§§	2-3 yrs	158	90688
	Fluzone [®] (IV4)	49281-0829-15	5 mL multi-dose vial (0.50 mL dose)	0	§§	2-3 yrs	158	90688
Protein Sciences Corp.	Fluzone [®] High-Dose [®] (IV3-HD)	49281-0718-10	0.5 mL single-dose syringe	0	§§	≥ 65 yrs	135	90692
	Fluzone [®] High-Dose [®] (IV4)	49281-0718-10	0.5 mL single-dose syringe	0	§§	≥ 65 yrs	135	90692
MedImmune	FluMist [®] (LAIV4)	166019-0305-10	0.2 mL single-use intranasal sprayer	0	≤ 0.024	2-49 yrs	149	90672

1. Immunization providers should check Food and Drug Administration approved prescribing information for 2018-19 seasonal influenza vaccines at www.fda.gov/biologics/bloodvaccines/vaccines/default.htm for the most complete and up-to-date information, including (but not limited by) indications, contraindications, warnings, and precautions.

2. If IV4/IV4-egg-based (inactivated) influenza vaccine (injectable); where (cellV4) refers to refer to cell culture-based vaccine. The prefix "cc" is used (e.g., cellV4) where applicable.

3. The Fluarix[®] (IV4) and Fluarix[®] (IV3) 0.5 mL dose is the same for adults and pediatric.

4. Once the stopper of the multi-dose vial is pierced the vial must be discarded within 28 days.

5. Afluria[®] is licensed for administration by Pharmacia[®] Stratis[®] Needle-Free Injection System for persons aged 38 through 64 years only.

6. Fluarix[®] includes the MF59[®], a squalene based oil-in-water emulsion.

7. Trivalent inactivated vaccine high-dose (0.5 mL dose contains 60 µg of each vaccine antigen (180 µg total).

8. Recommendation of the CDC's Advisory Committee on Immunization Practices (ACIP) for the 2018-19 influenza season, providers may choose to administer any licensed, age appropriate influenza vaccine (IV4, recombinant influenza vaccine (RIV4), or LAIV4). LAIV4 (FluMist[®]) is an option for those for whom it is otherwise appropriate. In addition, LAIV4 is acceptable for persons with a history of egg allergy. No preference is expressed for any influenza vaccine product. ACIP will continue to review data concerning the effectiveness of LAIV4 as they become available.

†† Information not included in package insert. Although cellV4 viruses are propagated in mammalian cells rather than in eggs, some of the viruses provided to the manufacturer are egg-derived, and therefore egg proteins may potentially be introduced at the start of the manufacturing process. Dilutions at various steps during manufacturing result in a theoretical maximum of 50.0 µg/0.5 mL dose of total egg protein.

§§ Available upon request from Sanofi Pasteur, 1-800-332-2463 or US.enquiries@sanofi-pasteur.com.

* Direct Vendor Delivery (DVD) vaccines are available for purchase by medical treatment facilities. Refer to the 2018-2019 Seasonal Influenza DHA-IPM for information on the ordering process.

www.health.mil/vaccines

(877) GET-VAOC

DHA-IPM (01 Aug 18)

GLOSSARY

ABBREVIATIONS AND ACRONYMS

ACIP	Advisory Committee on Immunization Practices
AD	Active Duty
AFMOA	Air Force Medical Operations Agency
AHLTA	Armed Forces Health Longitudinal Technology Application
ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASIMS	Aeromedical Services Information Management System
CDC	Centers for Disease Control and Prevention
CEMR	Civilian Employee Medical Record
DHA-IHB	Defense Health Agency-Immunization Healthcare Branch
DHA-IPM	Defense Health Agency-Interim Procedures Memorandum
DHP	Defense Health Program
DLA	Defense Logistics Agency
DLA-TSM	Defense Logistics Agency-Troop Support Medical
DSN	Defense Switched Network
DVD	Direct Vendor Delivery
FDA	U.S. Food and Drug Administration
FEHBP	Federal Employees Health Benefits Program
HCP	healthcare personnel
HSWL SC	Health, Safety, and Work-Life Service Center
ITS	Immunization Tracking System
IVP	Influenza Vaccination Program
MA	Medical, assumed
MD	Medical, declined
MEDPROS	Medical Protection System
MHS	Military Health System
MI	Medical, immune
MP	Medical, permanent
MR	Medical, reactive
MRRS	Medical Readiness Reporting System
MT	Medical, temporary
MTF	Medical Treatment Facility
NAF	Non-Appropriated Fund
NAVMEDLOGCOM	Naval Medical Logistics Command

NR	Not required
RHC RHRP	Regional Health Command Reserve Health Readiness Program
USAMMA-DOC	United States Army Medical Materiel Agency-Distribution Operations Center
VIALS VIS	Vaccine Information and Logistics System Vaccine Information Statement



THE ASSISTANT SECRETARY OF DEFENSE

**1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200**

JUL -5 2018

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)
DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH
SERVICES POLICY AND OVERSIGHT)
DEPUTY ASSISTANT SECRETARY OF DEFENSE (MILITARY
COMMUNITY AND FAMILY POLICY)
DIRECTOR, DEFENSE HEALTH AGENCY
DIRECTOR, JOINT STAFF**

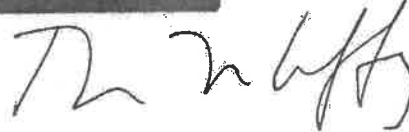
SUBJECT: Guidance for the 2018–2019 Annual Influenza Immunization Program

The forthcoming Department of Defense (DoD) Instruction 6205.02, "DoD Immunization Program," will require that all Active Duty and Reserve Component personnel, and DoD civilian health care personnel be immunized annually against influenza with vaccines approved for use by the U.S. Food and Drug Administration and in accordance with the recommendations of the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. Accordingly, addressees should assure that their members receive their annual influenza vaccinations. The annual program will be administered in accordance with Defense Health Agency instructions augmented by Service-specific guidance.

The Department orders more than 3 million doses of influenza vaccine annually. Military medical treatment facilities (MTFs) should expect multiple deliveries starting in August and continuing for several months. MTFs should begin immunization immediately upon receipt of the vaccine. Commanders are responsible for establishing policies and procedures to maximize usage and minimize loss of vaccine to prevent avoidable waste of government resources.

We applaud the efforts of the Services and the Combatant Commands in preparing for seasonal influenza. Our goal is to exceed 90 percent immunization of military Service members and health care personnel by January 15, 2019.

My point of contact for this memorandum is [REDACTED] . [REDACTED] may
be reached at [REDACTED] , or [REDACTED] .



Tom McCaffery
Acting

cc:

Assistant Secretary of Defense (Reserve Affairs)
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Director, Defense Logistics Agency Troop Support
Director of Health, Safety and Work-Life, U.S. Coast Guard
Director, Marine Corps Staff



**OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200**

HEALTH AFFAIRS

MAY 26 2017

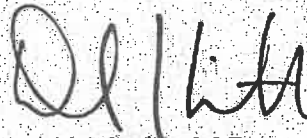
**MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (MANPOWER
AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE NAVY (MANPOWER
AND RESERVE AFFAIRS)
ASSISTANT SECRETARY OF THE AIR FORCE (MANPOWER
AND RESERVE AFFAIRS)
DIRECTOR OF THE JOINT CHIEFS OF STAFF
DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH
SERVICES POLICY AND OVERSIGHT)
DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR
MILITARY COMMUNITY AND FAMILY POLICY
DIRECTOR, DEFENSE HEALTH AGENCY**

SUBJECT: Guidance for the 2017–2018 Annual Influenza Immunization Program

The forthcoming Department of Defense (DoD) Instruction 6205.02, "DoD Immunization Program," will require that all Active Duty and Reserve Component personnel, and DoD civilian health care personnel be immunized annually against influenza with vaccines approved for use by the U.S. Food and Drug Administration and in accordance with the recommendations of the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. Accordingly, addressees should assure that their members receive their annual influenza vaccinations. The annual program will be administered in accordance with Defense Health Agency instructions augmented by Service-specific guidance.

The Department orders more than 3 million doses of influenza vaccine annually. Military medical treatment facilities (MTFs) should expect multiple deliveries starting in August and continuing for several months. MTFs should begin immunization immediately upon receipt of the vaccine. Commanders are responsible for establishing policies and procedures to maximize usage and minimize loss of vaccine to prevent avoidable waste of government resources.

We applaud the efforts of the Services and the Combatant Commands in preparing for seasonal influenza. Our goal is to exceed 90 percent immunization of military Service members and health care personnel by December 15, 2017.



David J Smith, M.D.
Performing the duties of the Assistant Secretary
of Defense for Health Affairs

cc:

Assistant Secretary of Defense (Reserve Affairs)
Director, Defense Health Agency
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Director, Defense Logistics Agency Troop Support
Director of Health, Safety and Work-Life, U.S. Coast Guard
Director, Marine Corps Staff

Army Regulation 40-562
BUMEDINST 6230.15B
AFI 48-110_IP
CG COMDTINST M6230.4G

Medical Services

Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases

Headquarters
Departments of the Army,
the Navy,
the Air Force,
and the Coast Guard
Washington, DC
7 October 2013

UNCLASSIFIED

SUMMARY of CHANGE

AR 40-562/BUMEDINST 6230.15B/AFI 48-110_IP/CG COMDTINST M6230.4G
Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases

This major revision, dated 7 October 2013--

- o Changes the regulation title to "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases" (cover).
- o Describes the responsibilities of the privileged physician with medical oversight of any clinic or activity that administers immunizations (para 1-4c(2)).
- o Describes the responsibilities of the privileged health care provider, who is under the direction of the privileged physician of any clinic or activity that administers immunizations (para 1-4c(3)).
- o Changes a reference to five-injection thresholds to reflect current evidence-based practices (para 2-1e(1)).
- o Adds a description of procedures for vaccine storage and handling (para 2-3).
- o Adds a description of military indications for required and recommended vaccines (paras 4-2 through 4-19).
- o Makes changes to chemoprophylaxis recommendations (chap 5).
- o Adds a description of procedures for documenting immunizations and immunization recordkeeping (para B-5).
- o Establishes and recommends immunization personnel training (para B-6 and table B-1).
- o Establishes criteria for determining required immunizations for military personnel (app D).
- o Makes administrative revisions (throughout).

Headquarters
Departments of the Army,
the Navy,
the Air Force,
and the Coast Guard
Washington, DC
7 October 2013

*Army Regulation 40-562
*BUMEDINST 6230.15B
*AFI 48-110 IP
*CG COMDTINST M6230.
4G

Medical Services

Effective 7 November 2013

Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases

By Order of the Secretary of the Army, Navy, Air Force, and Coast Guard:

RAYMOND T. ODIERNO
General, United States Army
Chief of Staff

Official:



GERALD B. O'KEEFE
Administrative Assistant to the
Secretary of the Army

M. L. NATHAN
Vice Admiral, Medical Corps
United States Navy
Surgeon General of the Navy

THOMAS TRAVIS
Lieutenant General, U.S. Air Force
Surgeon General

MAURA K. DOLLYMORE
Rear Admiral, U.S. Coast Guard
Director, Health, Safety and Work-Life

History. This publication is a major revision.

Summary. This regulation for immunization and chemoprophylaxis updates quality standards for immunization delivery; establishes electronic immunization tracking systems as the preferred immunization record; provides guidance for lost immunization records, immunization credit for pre-existing immunity, and complying with regulations for vaccines and other products administered in investigational, new drug status or in accordance with emergency use authorization; describes dividing initial entry immunization into two clusters; and describes the role of the Military Vaccine Office.

Applicability. This regulation applies to the Active Army, the Army National Guard/Army National Guard of the United States, and the U.S. Army Reserve, unless otherwise stated. It also applies to the following: uniformed Departments of the Navy, Air Force, and Coast Guard (including the active and reserve components of each Service); nonmilitary persons under military jurisdiction; selected Federal employees; selected employees of Department of Defense contractors; and Family members and other health care beneficiaries eligible for care within the

military health care system. This regulation is applicable during mobilization.

Proponent and exception authority. The proponent of this regulation is The Surgeon General. The proponent has the authority to approve exceptions or waivers to this regulation that are consistent with controlling law and regulations. The proponent may delegate this approval authority, in writing, to a division chief within the proponent agency or its direct reporting unit or field operating agency, in the grade of colonel or the civilian equivalent. Activities may request a waiver to this regulation by providing justification that includes a full analysis of the expected benefits and must include formal review by the activity's senior legal officer. All waiver requests will be endorsed by the commander or senior leader of the requesting activity and forwarded through their higher headquarters to the policy proponent. Refer to AR 25-30 for specific guidance.

Army internal control process. This regulation contains internal control provisions and identifies key internal controls that must be evaluated (see appendix E).

Supplementation. Supplementation of this regulation and establishment of command and local forms are prohibited without prior approval from The Surgeon

General (DASG-ZA), 7700 Arlington Blvd., Falls Church, VA 22041-5143.

Suggested improvements. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) directly to The Surgeon General (DASG-ZA), 7700 Arlington Blvd., Falls Church, VA 22041-5143. Air Force users are invited to send comments and suggested improvements on AF Form 847 (Recommendations for Change of Publication) through channels to Headquarters, AFMSA/SGOP, 7700 Arlington Blvd., Falls Church, VA 22041-5143.

Distribution. This publication is available in electronic media only and is intended for command levels A, B, C, D, and E for the Active Army, the Army National Guard/Army National Guard of the United States, and the U.S. Army Reserve. Navy/Marine Corps: Ships, units, and stations having medical department personnel. Air Force: Active Air Force, the Air National Guard, and Air Force Reserve. Coast Guard: Active Coast Guard and Coast Reserves.

*This regulation supercedes AR 40-562/BUMEDINST 6230.15A/AFJI 48-110/CG COMDTINST M6230.4F, dated 29 September 2006.

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Glossary

Chapter 1 Introduction

1-1. Purpose

This publication provides directive requirements for the Military Vaccination Program; establishes general principles, procedures, policies, and responsibilities for the immunization program; and implements military and international health regulations and requirements.

1-2. References

Required and related publications and prescribed and referenced forms are listed in appendix A.

1-3. Explanation of abbreviations and terms

Abbreviations and special terms used in this regulation are explained in the glossary.

1-4. Responsibilities

a. Command medical authority. The command medical authority will prescribe specific immunization and chemoprophylactic requirements for their units per requirements established by this publication and additional guidance provided by the appropriate surgeon general or the U.S Coast Guard (USCG), Director of Health, Safety, and Work-Life (USCG, CG-11).

b. Command leaders. Combatant commanders, major command commanders, unit commanding officers, commanders of special operations and forces, and officers-in-charge will:

(1) Ensure military and nonmilitary personnel under their jurisdiction receive required immunizations and chemoprophylaxis. Ensure immunizations and immunization exemption codes (medical or administrative) are documented in an approved Department of Defense (DOD) or USCG Service Immunization Tracking System (ITS), as described in paragraph 2-7a.

(2) Maintain appropriate international, Federal, State, and local records of all immunizations and chemoprophylaxis.

(3) Ensure personnel transferred to another command or unit, including advanced instructional training or technical school, receive proper screening for, and administration of, appropriate immunizations and chemoprophylaxis for the area assigned, and are timed to provide immunity before deployment or exposure or to complete a vaccine series.

(4) Ensure immunization exemptions are documented in the Service ITS.

(5) Ensure vaccine doses or boosters are administered to complete a started series or maintain immunity.

(6) Ensure deviations from specified immunizations are cleared or authorized by the appropriate combatant commander; surgeon general; or USCG, CG-11.

(7) Observe international military standardization agreements (STANAGs).

c. Medical commanders, commanding officers, and command surgeons. Medical commanders, commanding officers, and command surgeons will:

(1) Ensure individuals administering immunizations are properly trained in accordance with DOD, Service, and Centers for Disease Control and Prevention (CDC) guidelines and act within their scope of practice as determined by each Service. A training checklist is found in appendix B, paragraph B-6 and table B-1.

(2) Appoint, in writing, a privileged physician with medical oversight over any clinic or activity that administers immunizations. This physician will:

(a) Complete appropriate training in immunization science in residence or via distance learning.

(b) Be available to address immunization issues, although it is not required that the privileged physician be present for administration of vaccines. The USCG requires a privileged health care provider to administer immunizations to civilians who are eligible for care in a medical treatment facility.

(c) Establish and sign vaccine and chemoprophylaxis standing orders for clinics or other locations where immunizations or chemoprophylaxis medications are administered.

(d) Ensure standard operating procedures (SOPs) are established that implement current national standards for adult and pediatric immunizations and chemoprophylactic practices and promote appropriate quality improvement mechanisms. Incorporate local practices and requirements of policies contained in references listed at appendix A.

(3) Appoint, in writing, a privileged health care provider, who is under the direction of the privileged physician appointed in paragraph 1-4c(2), to have oversight over the daily activities of any clinic or activity that administers immunizations. The privileged physician may serve as the health care provider if no one is available to assume the position of privileged health care provider.

(4) Ensure patients are evaluated for preexisting immunity, screened for administrative and medical exemptions, and/or evaluated for the need for medical exemptions to immunizations or chemoprophylaxis medications. Exemptions are granted per paragraph 2-6; document any exemptions.

(5) Monitor the immunization status of personnel and ensure compliance with policies and procedures for creating and maintaining immunization records in accordance with Title 42, United States Code, Chapter 300aa-25.

(6) Ensure emergency medical response is available and that personnel who administer immunizations receive

training on: basic cardiopulmonary resuscitation, administration of epinephrine, and emergency response to immunization-adverse events, at a minimum.

(7) Ensure health care providers are available to respond to and report adverse events resulting from immunization.

(8) Ensure patients needing evaluation of adverse events after immunization are referred to appropriate health care providers, such as medical subspecialists (including specialists in immunization health care) for evaluation, consultation, or indicated intervention.

d. The Army, as Executive Agent for the Military Vaccination Program. The Army, as Executive Agent for the Military Vaccination Program and in cooperation with the Military Services, will:

(1) Operate a Military Vaccine (MILVAX) Office to provide the Military Services with a coordinated source for information and education of vaccine-related activities needed in order to implement Department of Defense Directive (DODD) 6205.3, DODD 6205.02E, and Department of Defense Instruction (DODI) 6205.4.

(2) Synchronize, integrate, and coordinate immunization policies and other immunization-related activities for all DOD components.

(3) Facilitate and promote the quality of immunization policy, implementation, education, distribution, risk communication, administration, clinical services, safety surveillance, research, and program evaluation.

(4) Provide a comprehensive access point to provide information, education resources, safety surveillance, and uniform procedures to identify, report, and evaluate vaccine-associated adverse events.

(5) Maintain historical vaccine usage data as well as identify future vaccine requirements as needed.

(6) Provide primary coordination between DOD and vaccine manufacturers for all applicable post-licensure vaccine studies.

(7) Coordinate with other Secretaries of the Military Departments and the Commandant, USCG to:

(a) Establish joint clinical quality standards for immunization delivery and education and training to personnel involved in immunization healthcare. The goals of these standards are to promote clinical excellence and decrease practice variability.

(b) Assess the DOD Immunization Program by developing metrics to measure individual medical readiness, vaccine effectiveness and safety, and compliance with overall immunization policies.

(c) Regularly update the Joint Regulation on Immunization and Chemoprophylaxis for the Prevention of Infectious Diseases.

(8) Promote scholarly immunization study activities through the Army's Medical Infectious Disease Research Program using funds both from the Defense Health Program and the Research, Development, Test, and Evaluation.

e. Each of the Military Services. Each of the Military Services will provide an immunization health care capability to deliver medical specialty consultation, case management, and clinical investigation. The U.S. Navy provides medical services for the U.S. Marine Corps.

Chapter 2 Program Elements and Clinical Considerations

2-1: Standards

a. Department of Defense and U.S. Coast Guard policy. The Military Service policy concerning immunizations follows the recommendations of the CDC and the Advisory Committee on Immunization Practices (ACIP) and the prescribing information on the manufacturer's package inserts, unless there is a military-relevant reason to do otherwise. Any vaccine or drug licensed by the U.S. Food and Drug Administration (FDA) or the U.S. Department of Health and Human Services (DHHS) may be used, as well as vaccines or drugs compliant with applicable DOD investigational new drug (IND) or emergency use authorization (EUA) processes. Privileged health care providers may make clinical decisions for individual beneficiaries to customize medical care or to respond to an individual clinical situation that is compliant with IND or EUA processes.

b. Standards for delivery of military vaccines. Standards for delivery of military vaccines are provided in appendix B. Military Services will abide by these standards in routine immunization delivery.

c. Expiration date. Vaccines or drugs will not be used beyond the manufacturer's potency expiration date, unless the appropriate surgeon general or USCG, CG-11, authorizes extension in exceptional circumstances.

d. Screening for contraindications. Screen all potential vaccines for contraindications, precautions, or warnings per the prescribing information on the manufacturer's package insert.

e. Immunization schedules and intervals.

(1) *Initial series.* Once an immunization series has been started, it must be completed, unless a medical or administrative exemption exists. Restarting an immunization series or adding extra doses is not necessary when an initial series of a vaccine or toxoid is interrupted; instead, give delayed doses as soon as feasible.

(2) *Doses.* Vaccine doses in an initial series will not be administered at intervals less than the recommended minimum intervals or earlier than the minimum age unless the doses are part of a CDC catch-up schedule or during an

outbreak. Doses in an initial series administered 5 or more days earlier than the minimum interval should not be counted as valid doses. The next valid dose is calculated after the last invalid dose.

(3) *Booster doses.* After the initial series of a vaccine is complete, a booster dose may be recommended for specific vaccines. For vaccines that do not provide lifetime immunity, the booster dose is usually recommended or required to increase immunity back to protective levels.

f. Simultaneous immunizations.

(1) When simultaneous vaccine injections are necessary, administer vaccines in different limbs. The anatomical site may depend on the age of the individual, and the degree of muscle development. If different anatomical sites are not possible, then separate the injections by at least 1 inch. Refer to the ACIP General Recommendations on Immunizations for proper needle lengths.

(2) Priority of immunization is based on the relative likelihood of various microbial threats and the existence of any vaccine-vaccine, vaccine-antibody, or vaccine-drug interactions and is best performed by the health care provider. In military training centers, contagious diseases typically represent the most imminent threats.

(3) Spacing of live and inactivated vaccines.

(a) Two or more inactivated vaccines can be administered simultaneously or at the prescribed interval and restrictions indicated in the package insert for each vaccine.

(b) Inactivated and live vaccines can be administered simultaneously or at the prescribed interval and restrictions indicated in the package insert for each vaccine.

(c) Two or more live virus vaccines must be administered simultaneously or separated by at least 28 days (4 weeks). Refer to ACIP guidelines for exceptions.

g. Screening for immunity. For some vaccine-preventable diseases, serologic or other tests can be used to identify pre-existing immunity from prior infections or immunizations that may eliminate unnecessary immunizations.

h. Live virus vaccines and tuberculosis testing. Vaccinations with live vaccines may affect tuberculosis (TB) testing. This includes both the Mantoux tuberculin skin test and the Interferon-Gamma Release Assays test whole-blood test. To avoid interference:

- (1) Administer live virus vaccines and TB test on the same day.
- (2) Perform TB test 4 to 6 weeks after administration of live virus vaccines, or
- (3) Administer live virus vaccines, once the TB test is read.

2-2. Logistics

a. Requisitioning of immunizing and chemoprophylaxis agents. Immunizing and chemoprophylaxis agents are requisitioned in accordance with medical supply procedures. However, vaccinia immune globulin—also known as VIG-intravenous—is available only by ordering through the MILVAX Office.

b. Transportation, storage, and handling. All personnel will maintain the cold chain in vaccine delivery during transportation, storage, and handling. Shipping and storage advice is available from Services medical logistics centers.

c. Small stations, ships, and cutters. To minimize the shipment of vaccines that must be stored at frozen temperatures, small stations, ships, and cutters may requisition these items from a nearby military medical activity stocking the items. Requisitioning procedures and reimbursement are prescribed by the supplying activity.

2-3. Storage and handling

a. Safety and efficacy of vaccines. Failure to adhere to recommended specifications for storage and handling of vaccines may reduce potency, resulting in inadequate immune responses in the recipients and inadequate protection against disease. To maintain the safety and efficacy of vaccines, ensure immunizing and chemoprophylaxis agents are stored, shipped, and handled in accordance with the pharmaceutical manufacturer's instructions as outlined in the product package insert or other guidance.

b. Policies for maintaining vaccines. All locations that maintain and administer vaccines will develop and implement policies and procedures for maintaining cold chain management of vaccines.

c. Shelf-life after opening.

(1) Administer vaccines shortly after withdrawal from single-dose or multi-dose vials, in accordance with the manufacturer's package insert.

(2) Single dose vials are meant for one-time use only. At the end of the clinic day, discard all single-dose vials without protective caps.

(3) For multi-dose vaccine vials that do not require reconstitution, doses that remain after withdrawal of a dose can be administered until the expiration date printed on the vial or vaccine packaging, so long as the vial has been stored correctly and the vaccine is not visibly contaminated and the manufacturer has not specified otherwise.

(4) Multi-dose vials that require reconstitution must be used within the interval specified by the manufacturer. After reconstitution, the new expiration date should be written on the vial.

d. Diluents.

- (1) Diluents are not interchangeable, unless specified by the manufacturer.

- (2) Transport diluents at room temperature in validated containers, but not in direct contact with shipping gel packs.
- (3) Store diluents according to the manufacturer's package insert.
- (4) Discard diluents when stored inappropriately or expired.

e. Filling syringes and attaching needles.

- (1) Never mix individual vaccines in the same syringe. Different vaccines should never be mixed in the same syringe unless specifically licensed for such use. Do not transfer vaccine between syringes.
- (2) Use a separate needle and syringe for each injection.
- (3) Label filled syringes with the type of vaccine, lot number, and date of filling, unless the vaccine is administered immediately after being drawn into the syringe by the same person administering the vaccine.
- (4) Attach needles to manufactured filled syringes just prior to administration. Discard needle and syringe if the vaccine is not administered before the end of the clinic day or vaccination session in accordance with the manufacturer's package insert. If no time line is provided, discard after 8 hours.

f. Prefilling syringes.

(1) Prefilling syringes is highly discouraged because of the increased risk of administration errors and possible bacterial growth in vaccines that do not contain preservatives. Syringes other than those filled by the manufacturer are designed for immediate use and not for vaccine storage.

(2) In certain circumstances in which a single vaccine type is being used, such as during an influenza vaccination campaign, filling a small number of syringes may be considered.

(3) Discard unused syringes filled by the end user (that is, not filled by the manufacturer) in accordance with the manufacturer's package insert. If no time line is provided, discard after 8 hours.

g. Storing vaccine.

(1) Ensure that only vaccines are stored in the vaccine storage unit (refrigerator or freezer).

(2) Store refrigerated vaccines at temperatures of 35°F to 46°F (2°C to 8°C). Do not expose refrigerated vaccines to freezing temperatures.

(3) Store frozen vaccines at temperatures of 5°F (-15°C) or lower.

(4) Store all reconstituted lyophilized (freeze-dried) vaccines in accordance with the manufacturer's temperature and light condition parameters.

h. Vaccine storage equipment. Ensure that vaccine storage units are carefully selected, used properly, and consistently monitored to maintain recommended vaccine storage temperatures.

(1) Stand-alone refrigerators and freezers are recommended for storage of vaccines. A combination refrigerator/frost-free freezer for home use is acceptable if only the refrigerator compartment of the combination unit is used to store refrigerated vaccines. A separate stand-alone freezer should then be used to store frozen vaccine. Dormitory style refrigerators are not authorized for vaccine storage.

(2) Use certified and calibrated thermometers in all vaccine storage units. Uncertified liquid (mercury or alcohol) thermometers and uncertified dial-type household refrigerator/freezer thermometers are not authorized.

(3) Ensure alarm systems are incorporated as part of the vaccine storage unit to alert staff of power failures or indicate whether or not vaccine temperatures have been maintained.

i. Temperature tracking.

(1) Ensure temperatures are documented for each vaccine storage unit. Physically confirm the temperature of all vaccine refrigerators and freezers at a minimum of two times per day. Document the date, time, and temperature of the vaccine storage unit on a temperature log. Vaccine outside of a refrigerator or freezer must have the temperature checked and documented every hour.

(2) Keep temperature logs for at least 3 years. State and/or local requirements may require longer recordkeeping.

(3) Record date and time of any mechanical malfunction or power outage on the temperature log or on another equipment-tracking document.

j. Vaccine storage alarms.

(1) Ensure alarm systems are capable of monitoring vaccine storage 24 hours a day, 7 days per week. Ensure the system either notifies an accountable person when a failure is detected, or the system is capable of indicating that the vaccine temperature integrity was maintained during the storage period (or notes any deviations).

(2) Ensure current personnel contact information exists on auto-dialers, and that appropriate coverage occurs during periods of leave, holiday weekends, and so forth.

(3) Monitor alarms electronically and physically 24 hours a day, 7 days per week.

(4) Test the entire alarm system, to include refrigerator-freezer-unit sensor to the remote monitoring station and telephone or pager, at least monthly. Maintain test records for at least 3 years.

(5) For vaccine storage units within restricted access areas, ensure the temperature can be checked and a light or audible alarm is installed to indicate when the storage unit temperature is out of range without having to physically enter the restricted area.

k. Transporting vaccines.

- (1) Always transport vaccines in properly insulated containers to maintain the recommended temperatures.
- (2) Ensure containers used for transporting vaccines are capable of maintaining the vaccine at the correct temperatures. Validated storage devices include the Vaxicool, Vaxipac, manufacturer shipping containers, Styrofoam(tm) coolers with at least 2-inch thick walls, or Endurotherm insulating shipping containers.
- (3) Pack containers to appropriately maintain the proper temperature while vaccine is transported or shipped. Refrigerated or frozen packs are authorized for use to maintain the cold chain when used according to the U.S. Army Medical and Materiel Agency (USAMMA) Distribution Operations Center instructions.
- (4) Include calibrated thermometers to track temperatures in all transportation and off-site storage containers.
- (5) Pack vaccines in their original packaging. Do not remove vaccine vials from boxes.
- (6) Document vaccine type, quantity, date, time, and originating facility on the outside of the transportation containers.

(7) Ensure temperatures are tracked during transportation and any deviations in temperature are readily identifiable.

1. Vaccine disposal or disposition.

- (1) Discard syringes or vials that contain live virus vaccines per installation policy.
- (2) Contact the pharmacy or logistics office for specific policies regarding the disposition of unopened vials, expired vials, unused doses, and potentially compromised vaccine.
- (3) Label potentially compromised vaccines with the words "Do not use" and place in the refrigerator or freezer based on the manufacturer's instructions as if they were not compromised. Report all compromised anthrax, smallpox, and influenza vaccines to USAMMA for validation before destruction. Contact the manufacturer for all other potentially compromised vaccines for disposition or destruction instructions.
- (4) Report all confirmed compromised vaccine losses through Service-specific channels to the Military Vaccine Office. The report must include the following: description of the reason for the loss, vaccines compromised, total vials/doses lost, and cost of lost or compromised vaccines.

2-4. Hypersensitivity or allergy

a. Before administration of any medication, including vaccines, determine if the individual has previously shown any unusual degree of adverse reaction or allergy to it or any specific component of the vaccine or its packaging (for example, eggs, gelatin, preservatives, latex). Review the manufacturers' package inserts and reference materials for product-specific information.

b. Defer individuals with reported hypersensitivity to a particular vaccine or its components from immunization.

c. Refer individuals with a hypersensitivity to an appropriate medical specialist for evaluation, unless the health record contains documentation of a prior consultation or a specialist's recommendations. Document hypersensitivity and any recommended exemption(s) in the electronic ITS and the appropriate sections of the health record.

2-5. Immunizing women of childbearing potential

A pregnancy screening test for women of childbearing potential is not routinely required before administering vaccines, including live virus vaccines. Take the following precautions to avoid unintentional immunization with contraindicated products during pregnancy—

a. Display signs asking pregnant women to identify themselves. Discreetly ask her if she is, or might be, pregnant. Document responses in the health record. If the answer is "yes," and the ACIP does not recommend the vaccine for use in pregnancy, then defer her from immunization or refer to an obstetric healthcare provider to determine whether the benefits of immunization outweigh risks in pregnancy. If the vaccine is recommended for use in pregnancy by ACIP, the vaccine may be administered. If pregnancy status is uncertain, defer immunization until after a negative pregnancy evaluation (for example, urine, or serologic test).

b. With regard to smallpox (vaccinia) vaccine, a specific pre-immunization screening form (available at <http://www.smallpox.mil/resource/forms.asp>) that assesses the date of the last menstrual period is required. For women whose last menstrual period was more than 28 days ago, a pregnancy test is recommended.

c. Breastfeeding women may be immunized in accordance with the current ACIP guidelines. At present, no immunization products are medically contraindicated in breastfeeding women. Smallpox vaccine is withheld from breastfeeding women, except in an outbreak, primarily due to the potential for contact transmission of vaccinia virus to the child.

d. If a live virus vaccine is administered, counsel her to avoid becoming pregnant for the appropriate interval as recommended by CDC or the vaccine manufacturer. Document the counseling in the health record.

e. If she is pregnant and immunization is indicated, immunize in consultation with her obstetric health care provider.

f. If a contraindicated vaccine is inadvertently administered to a pregnant woman, report the event upon discovery to the preventive medicine point of contact and obstetric services and complete appropriate quality assurance documents. Report such cases to any applicable registry. For assistance with registry referral procedures, contact the preventive medicine service or MILVAX.

2.6 Exemptions

There are two types of exemptions from immunization—medical and administrative. Granting medical exemptions is a medical function. Granting administrative exemptions is a nonmedical function.

a. Medical exemptions. A medical exemption includes any medical contraindication relevant to a specific vaccine or other medication. Health care providers will determine a medical exemption based on the health of the vaccine candidate and the nature of the immunization under consideration. Medical exemptions may be temporary (up to 365 days) or permanent. Standard exemption codes appear in appendix C.

(1) General examples of medical exemptions include the following—

(a) Underlying health condition of the vaccine candidate (for example, based on immune competence, pharmacologic or radiation therapy, pregnancy and/or previous adverse response to immunization).

(b) Evidence of immunity based on serologic tests, documented infection, or similar circumstances.

(c) An individual's clinical case is not readily definable. In such cases, consult appropriate medical specialists, including specialists in immunization health care.

(2) Providers who are assessing medical exemptions may seek a second opinion from a provider experienced in vaccine adverse event management, such as specialists in immunization health care at a medical center, or seek additional consultation from MILVAX.

(3) Annotate electronic ITS and paper-based service treatment records with exemption codes denoting evidence of immunity, severe adverse event after immunization (except for the Medical Readiness Reporting System), other temporary or permanent reasons for medical exemption, and other appropriate categories.

(4) Report cases warranting permanent medical exemptions due to a vaccine related adverse event to the Vaccine Adverse Events Reporting System (VAERS) at the Web site at <http://www.vaers.hhs.gov> and as discussed in paragraph 2-10.

(5) Revoke medical exemptions when they are no longer clinically warranted.

b. Administrative exemptions. Standard exemption codes appear in appendix C.

(1) *Separation or retirement.* Within 180 days before separation or retirement, Service personnel may be exempt from deployment (mobility) immunizations, if one of the following conditions are met:

(a) They are not currently assigned, deployed, or scheduled to perform duties in a geographical area where an immunization is indicated.

(b) The commander has not directed immunization because of overriding mission requirements. Personnel who meet separation or retirement requirements and desire an immunization exemption must identify themselves to their commander. The member must have approved retirement or separation orders. Active duty personnel continuing duty in the reserve component are not exempted on this basis.

(2) *Thirty days or fewer of service remaining.* Applies to civilian employees and contractor personnel who will leave a permanent (other than OCONUS deployments) assignment subject to immunization within 30 days or fewer.

(3) Religious exemptions.

(a) *Servicemembers.* Immunization exemptions for religious reasons may be granted according to Service-specific policies to accommodate religious beliefs of a Service member. This is a command decision made with medical, judge advocate, and chaplain input.

1. Requests for religious exemption must comply with the provisions of the applicable policy and/or regulation for the Servicemember requesting religious accommodation. For the Army, religious accommodation policy is provided in AR 600-20. For the Navy and Marine Corps, waivers are granted on a case-by-case basis by the Chief, Bureau of Medicine, and Surgery. For the Air Force, permanent exemptions for religious reasons are not granted; the MAJCOM commander is the designated approval and revocation authority for temporary immunization exemptions. For the Coast Guard, CG-122 is the designated approval and revocation authority for religious immunization exemptions. USCG requests must be forwarded through the appropriate chain to Commandant CG-122 via CG-112.

2. A military physician must counsel the applicant. The physician should ensure that the Servicemember is making an informed decision and should address, at a minimum, specific information about the diseases concerned; specific vaccine information including product constituents, benefits, and risks; and potential risks of infection incurred by unimmunized individuals.

3. The commander must counsel the individual that noncompliance with immunization requirements may adversely impact deployability, assignment, or international travel.

4. Per DODI 1300.17 and applicable service regulations will be provided whether Servicemembers with pending active requests for religious exemption are temporarily deferred from immunizations, pending outcome of their request.

5. Religious exemptions may be revoked, in accordance with Service-specific policies and procedures, if the individual and/or unit are at imminent risk of exposure to a disease for which an immunization is available.

(b) *Civilian employees.* Civilian employees submit requests for immunization exemption for religious reasons to their supervisors. Civilian requests are processed in accordance with Part 1605, Title 29, Code of Federal Regulations and component policies.

(c) *Bargaining units.* Civilian personnel affected by this document who are members of bargaining units will be

~~considered for exemption consistent with applicable personnel management policies and applicable labor relations obligations.~~

(d) *Other exemption categories.* Administrative or medical personnel will appropriately annotate electronic ITS with exemption codes denoting separation, permanent change of station, emergency leave, missing or prisoner of war, deceased, and other appropriate categories.

2-7. Immunization and chemoprophylaxis records

a. *Electronic immunization tracking systems.*

(1) Document all immunizations in a DOD and USCG-approved ITS. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, Vaccine Information Sheet (VIS) date, and the identification of the person administering the vaccine.

(2) Electronic ITS must—

(a) Comply with the requirements of the National Vaccine Injury Compensation (NVIC) Program as provided in 42 USC 300aa-25, Report and Recording of Information, and 42 USC 300aa-26. NVIC information is outlined in paragraph 2-7d.

(b) Incorporate DOD-directed levels of security, certification, and redundancy, and the requirements of the Health Insurance Portability and Accountability Act to preclude unauthorized access to personal medical information and to survive hardware or software malfunction.

(c) Be capable of generating printed reports of immunization status and exemption information on both an individual and unit basis.

(3) A printed report from the electronic ITS, in CDC Form 731 (International Certificate of Vaccination or Prophylaxis) 731, SF 601 (Health Record-Immunization Record), or DD Form 2766C (Adult Preventive and Chronic Care Flowsheet) (Continuation Sheet) format, accompanied by an official clinic stamp and the authorized signature and printed name of an authenticating official, will qualify as an official paper immunization record.

(4) A printed report as identified in preceding paragraph 2-7a(3) will suffice as a valid certificate of vaccination for international travel (except for yellow fever which is documented on the CDC Form 731) for active duty members of the Armed Forces as outlined in Article 36 (Annex 6) of the World Health Organization (WHO) International Health Regulations.

b. *Non-electronic immunization and chemoprophylaxis records.*

(1) *Deployment records.* Transfer information regarding immunizations and chemoprophylaxis including date, product given, dose, and initials of person administering to the deployable health record (DD Form 2766) or comparable approved form, either by computer-generated report or by hand. Upon return from deployment, transfer entries on the deployment record into the appropriate ITS or other electronic record system.

(2) *Abbreviations.* Use abbreviations for vaccines and their manufacturers conforming to the nomenclature adopted by the CDC Vaccine Identification Standards Initiative. When annotating the date a vaccine is administered, the day, month, and year are listed in that order. The day is expressed in Arabic numerals, the month spelled out or abbreviated using the first three letters of the word, and the year expressed in Arabic numerals either by four digits or by the last two digits (for example, 14 June 1994 or 14 Jun 94).

(3) *Transcribed records.* Entries based on prior official records will include the following statement: "Transcribed from official records." Alternately, the statement may cite the specific source (for example, "Transcribed from SF 601"). When entries are transcribed onto paper records, include the initials of the transcriber on each entry.

(4) *SF 601 (Navy, Marine Corps, and U.S. Coast Guard).* Prepare SF 601 in accordance with this directive and chapter 16 of NAVMED P-117.

(5) *DD Form 2766C.* Initiate DD Form 2766C for all personnel at the time of entry into Military Service.

(6) *Paper-based immunization and chemoprophylaxis records.* Individuals preparing paper-based immunization and chemoprophylaxis records will ensure that paper records match the electronic ITS. If paper-based immunization or chemoprophylaxis records are used, electronic ITS will be updated within 24 hours.

(7) *CDC Form 731.* Required for yellow fever documentation and or prepared upon request for each member of the Armed Forces and for nonmilitary personnel receiving immunizations, including date, immunization given, dose, and the initials of the person administering the vaccine. The form contains valid certificates of immunization for international travel and quarantine purposes in accordance with WHO international health regulations. CDC Form 731 remains in the custody of the individual who is responsible for its safekeeping and for keeping it in his or her possession when traveling internationally. Data are entered by hand, rubber stamp, or by typewriter.

(a) *Supply.* CDC Form 731 is obtained through normal publication supply channels.

(b) *Stamps.* Use in accordance with instructions received from the Division of Global Migration and Quarantine; the appropriate surgeon general; Chief, Bureau of Medicine and Surgery; or CG-11.

1. *Army.* USAHRC (AHRC-PDR), 1600 Spear Head Division Avenue, Fort Knox, KY 40122.

2. *Navy.* Bureau of Medicine and Surgery (BUMED), Washington, DC 20372.

3. *Air Force.* HQ AFPC/DPMDB, Randolph AFB, TX 78148.

4. *Marine Corps*. Headquarters, U.S. Marine Corps, Washington, DC 20380.
5. *Coast Guard*. Commandant, CG-11, USCG Headquarters, 2100 Second Street SW, Washington, DC 20593-0001.

(c) *Written signatures*. Written signatures must appear in appropriate spaces on each certificate; signature stamps are not valid.

c. *Lost immunization records*. If an individual's immunization records are lost, assume the individual received standard immunizations administered at entry into Military Service by the individual's accession source (for example, enlisted, Service academy, direct commission) unless there is an objective reason to believe otherwise. Do not repeat such immunizations. Base decisions for future immunizations on assumed date of last immunization (for example, individual assumed to have received tetanus-diphtheria toxoid in July 1995 would next be immunized in July 2005).

d. *National Vaccine Injury Compensation Program*.

(1) The statute 42 USC 300aa-1 to 300aa-34 (The National Childhood Vaccine Injury Act of 1986) and other regulations set standards for certain immunizations. These requirements apply to U.S. vaccines as indicated by the CDC after the DHHS Secretary publishes a notice of coverage. Document the patient's name; identifying number (for example, sponsor's SSN); type of vaccine; date of administration; manufacturer; lot number; and the name, address, and title of person administering the vaccine in a permanent health record or permanent office log or file, in either paper or electronic format. The electronic immunization tracking systems are the primary method of immunization documentation. Other records and management reports may be generated from the electronic immunization database, as described above.

(2) Personnel who administer any vaccine covered under the NVIC program, to either children or adults, will provide a written copy of the VIS to the vaccinee and allow sufficient opportunity to read the most recent VISs provided by the DHHS and an opportunity to ask questions about the vaccine. Copies of VISs are available through the CDC Web site (<http://www.cdc.gov/vaccines>). The VIS should be supplemented with an oral explanation or video presentation, or in the appropriate language, when the patient or guardian does not appear to be literate in English. Provide printed copies to any individual who requests one. Translations of VISs into languages other than English are available from nongovernmental organizations.

(3) Personnel who administer vaccines are not required to obtain the signature of the military member, patient, or legal representative acknowledging receipt of a VIS. However, to create a record that the materials were provided, health care personnel who administer vaccines will annotate each patient's health record that the VISs were provided at the time of immunization.

(4) The statute 42 USC 300aa-1 to 300aa-34 (The National Childhood Vaccine Injury Act of 1986), requires that the following events be reported to VAERS, a public health activity administered by the FDA and CDC:

(a) Any event listed in the NVIC program's vaccine injury table (at <http://www.hrsa.gov/vaccinecompensation/table.htm>) occurring within the time period specified.

(b) Any contraindicating event listed in a vaccine's package insert (product labeling).

(5) The VAERS accepts all reports by any interested party of real or suspected adverse events occurring after the administration of any vaccine.

(6) All DOD and USCG health care beneficiaries are eligible to file claims with the NVIC program, according to the program's procedures.

2-8. Jet-injection immunization devices

These devices must be used in accordance with FDA-approved manufacturer's recommendations. Only vaccines with FDA approval for jet injectors use may be used in these devices.

2-9. Emergency response requirements

a. *Written plan*. Clinics or activities administering immunizations will develop and maintain a written plan for emergency response, including standing orders for the management of anaphylaxis and fainting.

b. *Training*. Whenever vaccines are administered, at least one person present must be trained and current in basic cardiopulmonary resuscitation, oropharyngeal airway management, and recognition and initial treatment of anaphylaxis with epinephrine.

c. *Anaphylaxis management*. For the medical management of an anaphylaxis event whenever vaccines are administered, the following must be immediately accessible on scene: stethoscope, blood pressure cuff (sphygmomanometer), minimum of three adult doses of epinephrine (1:1000), oral airway, bag valve mask or equipment to administer oxygen by positive pressure, and the equipment and ability to activate an emergency medical system. Other equipment and/or medications (for example, injectable antihistamines, corticosteroids, vasopressors, glucagon, albuterol, and IV fluids with administration sets), depending on the clinical setting and local policy, may be included beyond the minimum requirements listed above.

d. *Observation*. The ACIP general recommendations suggest that persons be observed for 15 to 20 minutes after

being immunized. Manufacturer's guidance must be followed when the manufacturer's package insert exceeds this requirement.

2-10. Adverse events

a. Describe in the individual's health record a detailed account of adverse events after administering immunizing agents or other medications. Mandatory information consists of identification, lot number, and manufacturer of the vaccine or other medication; date of administration; name and location of the medical facility; the type and severity of the event; treatment provided; and any exemption from additional doses. Consultation through MILVAX's Vaccine Healthcare Centers network is available 24 hours a day, 7 days a week, for providers who require additional support for clinical evaluation of possible vaccine adverse events.

b. Health care providers will report adverse events involving vaccines via the VAERS Web site <http://www.vaers.hhs.gov> or by faxing or mailing a VAERS-1 form. Obtain VAERS forms and information by calling 1-800-822-7967 or by accessing the VAERS Web site.

c. Health care providers will report adverse events involving chemoprophylaxis agents to MedWatch via the Web site at <http://www.fda.gov/Safety/MedWatch/default.htm> or on FDA Form 3500. MedWatch forms and information are available by calling 1-888-463-6332 or on the MedWatch Web site.

d. Reporting requirements are as follows:

(1) Report adverse events resulting in hospitalization, a life-threatening event (for example, anaphylaxis), time lost from duty more than one duty shift, or an event related to suspected contamination of a vaccine vial. Reports are also required for all events listed on the VAERS Table of Reportable Events Following Vaccination (available at <http://vaers.hhs.gov/resources/vaersmaterialspublications>).

(2) Further, health care providers are encouraged to report other adverse events considered unexpected in nature or severity.

(3) Reports of mild expected reactions are not required (for example, low-grade, self-limited fever of less than 24 hours duration, temporary local soreness, redness, or minor swelling at the site of immunization), but such reports may be submitted if the clinician or patient wishes.

e. Patients may also submit a VAERS or MedWatch report directly. If a patient wishes to submit a VAERS report, health care personnel will assist the patient in completing the form, regardless of professional judgment about causal association to immunization.

f. Record pertinent information from the recipient's health record on the VAERS or MedWatch report. Submit copies of the report within 7 days of adverse event recognition as follows:

(1) Send the original report form to the VAERS or MedWatch office.

(2) File a copy of the VAERS or MedWatch report in the patient's individual health record or annotate the relevant information on the report within the health record.

g. Immediately notify USAMMA or the vaccine manufacturer if contamination or other serious problem with a vaccine vial or lot is suspected. Suspend usage, but quarantine and retain all such opened or unopened vials or lots under appropriate storage conditions pending further investigation and disposition instructions.

h. An adverse reaction to a DOD-directed immunization in Service personnel is a line-of-duty condition.

(1) Medical treatment facility (MTF) commanders will provide full access to reserve component (National Guard and Reserve) members for evaluation and treatment of adverse events potentially related to DOD-directed immunizations.

(2) Reserve component (National Guard and Reserve) unit commanders will inform their members that they may seek medical care for such adverse events, with the unit providing assistance and information related to pay status and compensation issues. Any necessary documentation, including line-of-duty determinations, will be completed after the Reserve component Servicemember is evaluated and, if required, treated. In no case will such evaluation or treatment be denied or delayed pending line-of-duty determination. If additional health care is required after the initial visit and a line-of-duty determination has established a Service connection, a notice of eligibility must be completed in accordance with DODD 1241.01.

(3) DOD will provide an immunization health care capability to deliver medical specialty consultation, case management, and clinical investigation.

2-11. Program evaluation

MTF facilities and commands storing service treatment records will review immunization and chemoprophylaxis practices at least annually to ensure compliance with current standards of care and documentation and as a measure of medical readiness and health promotion. Program evaluation includes internal and external assessments of the standards for military immunization (see app B). Program evaluation is focused at the clinic level, regardless of Service, to include both fixed facilities and field units. The Continuous Quality Immunization Improvement Process Tool is one of several tools available to assist with program evaluation and is described at <http://www.vaccines.mil/cqiip>. MILVAX

can assist with guidance and implementation of the Continuous Quality Immunization Improvement Process Tool. Other tools may be available depending on the Service.

2-12. Blood donation

For timing of immunization with regard to blood donations, clinicians will consider the policies of the Armed Services Blood Program Office (<http://www.militaryblood.DOD.mil>) and the specific Service Blood Program Offices. In some situations, such as accession sites where blood donations are scheduled, regularly coordinate the administration of live vaccine immunizations after scheduled blood donation activities, when possible.

Chapter 3 Personnel Subject to Immunization

3-1. Military accessions

a. Military accessions. Accessions include Service personnel in enlisted initial entry training, Reserve Officers Training Corps (ROTC), Officer Candidate School, academy preparatory school, Service academy, Officer Indoctrination School, other officer accession programs, and officers who are directly commissioned.

(1) When determining the immunization needs of accessions, give credit for immunizations appropriately documented earlier in life (for example, data from electronic immunization registries maintained by State health departments).

(2) Immunize if the primary series is incomplete, if a booster immunization is needed, or if the Service personnel has no serologic or documented evidence of immunity. Complete multiple-dose immunization series according to the recommended schedule as soon as possible.

(3) Before immunizing, conduct serologic testing where available. At a minimum, conduct serologic testing for antibodies for measles, rubella, hepatitis A, hepatitis B, and varicella. Document medical exemptions for immunity (MI) in Service ITS. Documented medical exemptions for immunity will be accepted as evidence of immunity in lieu of vaccination.

(4) Except in an outbreak setting or for individual clinical purposes, immunization records will not be screened after completion of initial training with regard to measles, mumps, and rubella (MMR), poliovirus, or varicella vaccines.

(5) Document immunizations and immunization exemption codes (medical or administrative) in a DOD-approved Service ITS.

b. Enlisted accessions. Enlisted accessions may be scheduled for immunizations in two or more clusters, as long as all appropriate immunizations are administered or seroimmunity is determined. Pregnancy screening or testing for female accessions must be verified prior to administration of any live virus vaccines.

(1) *First cluster.* The first cluster of immunizations is administered, if susceptible, before or at the beginning of collective training (initial entry training, basic military training) to protect against pathogens that represent an imminent risk of contagious disease in settings of close contact: adenovirus; influenza; meningococcal; MMR; tetanus-diphtheria-pertussis; and varicella. Pneumococcal vaccine may be administered if warranted epidemiologically. Ensure live virus vaccines are given on the same day or at least 28 days apart (see ACIP guidelines for exceptions).

(2) *Second cluster.* The second cluster of immunizations may be administered, if susceptible, in the first or second half of basic military training, during advanced individual training, or upon arriving at the first duty station to protect against travel and other military risks. These immunizations include hepatitis A, hepatitis B, influenza (if not administered in first cluster), and poliovirus. Live virus immunizations follow at least 28 days after earlier live virus immunizations (see ACIP guidelines for exceptions).

c. Reserve Officers' Training Corps cadets and midshipmen. ROTC cadets and midshipmen and similar officer candidates who are ordered or called to active duty or active duty for training will require immunizations. Cadets and midshipmen may be scheduled for immunizations in two or more clusters:

(1) *First cluster.* Assess immunization or immunity status and administer immunizations, if susceptible, before or at the beginning of collective training to protect against pathogens that represent an imminent risk of contagious disease in settings of close contact. These immunizations include: influenza; meningococcal; MMR; tetanus-diphtheria-pertussis; and varicella. Ensure live virus vaccines are given on the same day or at least 28 days apart (see ACIP guidelines for exceptions).

(2) *Second cluster.* The second cluster of immunizations may be administered, if susceptible, in the first or second half of collective training to protect against travel and other military risks. These immunizations include hepatitis A, hepatitis B, influenza (if not administered in first cluster), and poliovirus. Live virus immunizations follow at least 28 days after earlier live virus immunizations (see ACIP guidelines for exceptions). ROTC cadets or midshipmen who travel overseas as part of their training will receive immunizations according to geographic risk assessments.

d. Service academy cadets and midshipmen. Service academy cadets and midshipmen will require immunizations as follows:

(1) *First cluster.* Assess immunization or immunity status and administer immunizations, if susceptible, before or at the beginning of collective training to protect against pathogens that represent an imminent risk of contagious disease in settings of close contact. These immunizations include: influenza, meningococcal, MMR, tetanus-diphtheria-pertussis, and varicella. Ensure live virus vaccines are given on the same day or at least 28 days apart (see ACIP guidelines for exceptions).

(2) *Second cluster.* The second cluster of immunizations may be administered, if susceptible, in the first or second half of collective training to protect against travel and other military risks. These immunizations include hepatitis A, hepatitis B, influenza (if not administered in first cluster), and poliovirus. Live virus immunizations follow at least 28 days after earlier live virus immunizations (see ACIP guidelines for exceptions). Cadets and midshipmen who travel overseas as part of their training will receive immunizations according to geographic risk assessments.

e. Entry-level officers. Upon accession, screen commissioned and warrant officers for immunization or immunity status and vaccinate as required.

3-2. Military personnel

a. Active duty personnel. Immunize active duty personnel in accordance with appendix D or as supplemented in official notices posted at the Military Vaccine Office Web site, <http://www.vaccines.mil>. During Military Service, active duty personnel will receive or be up-to-date on adult routine immunizations.

b. Reserve component (National Guard and Reserve). Immunize Reserve component Servicemembers in accordance with appendix D or as supplemented in Service-specific policies and notices posted at <http://www.vaccines.mil>. Reserve component Servicemembers receive the same immunizations as active duty personnel, but must be in a duty status to receive required immunizations.

c. Aviation personnel. Typically, aviation personnel are grounded for 12 hours (Air Force: access to medical care 4 hours post vaccination unless operational needs dictate otherwise; Navy: refer to "Aeromedical Reference and Waiver Guide" (ARWG) for vaccine specific information) after immunization, or as specified by their flight surgeon. No formal grounding documents are required for uncomplicated immunization. Personnel who previously experienced urticaria, hypersensitivity phenomena, or other unusual phenomena after an immunization are restricted from flying duty for an appropriate interval (for example, 72 hours) as determined by the flight surgeon. Additional temporary grounding may be necessary until significant side effects resolve.

d. Occupational risk. Military members at occupational risk for specific disease threats will receive appropriate vaccines per appendix D or as supplemented in Service-specific policies posted at <http://www.vaccines.mil>. Immunize special populations at occupational risk for vaccine-preventable diseases not listed in appendix D per Service, Federal, State, or local occupational medicine guidance.

e. Geographic travel requirements.

(1) Each Service's preventive medicine authority maintains current health threat assessments based on disease prevalence in specific geographical regions using Federal, DOD, USCG, and other relevant sources of information. These assessments are disseminated to units within their respective jurisdictions. Special Operations may determine additional area-specific immunization requirements.

(2) Installations and deployed units report disease occurrence through appropriate unit and/or medical lines of communication.

(3) Combatant commanders, in coordination with the appropriate surgeons general or CG-11, establish specific immunization requirements based on a disease threat assessment. These requirements may differ from standard Service immunization policies for personnel entering their area of responsibility to participate in exercises or other operational missions. Immunize personnel on official deployment or travel orders in accordance with the specific guidance established by the combatant commander before departure.

(4) For short notice travel or deployments requiring vaccines given in a multi-dose series, administer the first dose of the basic series. Administer as many of the subsequent doses as time permits. Completion before departure is the goal. If the series cannot be completed before departure, complete it upon arrival. Inform the patient that in order to obtain optimal immunity, the series must be completed by receiving all the required doses at the recommended intervals.

(5) For quarantine, entry, and reentry requirements, follow the provisions of the CDC, Division of Global Migration and Quarantine regulations concerning entry or reentry of military and nonmilitary personnel into the United States or its commonwealths, territories, and possessions.

f. Other uniformed Service personnel. Members of other uniformed Services are authorized immunizations according to their occupation, official duties, travel plans, health status, or other relevant factors.

3-3. Certain civilian employees

a. Federal civilian employees

(1) *General.* Federal civilian employees will receive country-specific immunizations without charge at military activities upon presentation of official orders or authorization. Area preventive medicine authorities are consulted for recommendations applicable to specific areas. People declining immunizations required for entry into foreign countries

are referred to the appropriate authority for counseling. Document counseling in the health record and note that omission of certain immunizations may have consequences under host country policies, which could include compulsory immunization, detention, quarantine, or denial of entry.

(2) *Civilian employees at occupational risk for vaccine-preventable disease.* Federal civilian employees who are at risk of exposure to an infectious disease associated with their occupation may receive appropriate immunizations without charge at military activities. Administer immunizations upon recommendation of the responsible occupational medicine authority.

(3) *Civilian health care employees.* Susceptible or occupationally exposed health care employees (including volunteers) who are at risk of exposure to an infectious disease (for example, influenza) associated with their occupation may receive appropriate immunizations without charge at military activities. This policy applies to all health care settings, regardless of age or sex of the health care employee. Employees, including volunteers, who have contact with or potential exposure to human blood or blood products (whether from patient care, laboratory, or other health care settings) are provided hepatitis B virus vaccine in accordance with the local bloodborne pathogen exposure control plan. Refer to the Occupational Safety and Health Administration standards (29 CFR 1910.1030) for additional information. Immunizations or immune status may be a condition of employment.

(4) *Employees with potential occupational exposure to wastewater or sewage.* Employees at occupational risk of exposure to wastewater or sewage will receive tetanus-diphtheria toxoids (preferably with pertussis vaccine) per ACIP recommendations. Other vaccines are not routinely required based solely on occupational exposure for wastewater treatment system workers, including sewage generated by medical facilities.

(5) *Individuals immunized per categories above.* Individuals immunized per the civilian personnel categories above are authorized treatment and necessary medical care related to adverse events after immunization, consistent with applicable occupational health program requirements.

b. *Civilian Expeditionary Workforce.* Civilian employees and others in the Civilian Expeditionary Workforce may receive, without charge, appropriate immunizations at military activities. In accordance with DODD 1404.10, components should ensure emergency-essential and non-combat essential employees are aware of potential deployment immunizations as a condition of employment. Components should also ensure the employee completes and signs a record of notification with a signed DD Form 2365 (DOD Civilian Employee Overseas Emergency-Essential Position Agreement). Applicable vacancy announcements and position descriptions will note obligations to receive immunizations. Emergency-essential and non-combat essential employees have the same access as military personnel to treatment and necessary medical care related to adverse events after immunization, consistent with applicable occupational health program requirements.

c. *Bargaining units.* For Federal employees in a bargaining unit, local management must meet applicable labor relations obligations before implementing any changes to the bargaining unit employees' conditions of employment. Civilian personnel advisory centers provide guidance on these matters.

d. *Biological warfare defense.* Immunization of civilian employees and contracted workers for biological warfare defense are addressed in DODI 6205.4.

e. *Emergency situations.* In emergency situations, the provisions of DODD 6200.03 apply.

3-4. Contracted workers

a. Provide immunizations to contracted workers according to the terms of the contract and as stated in the contract agreement. If the contract does not provide for provision of immunizations by the government, contractors are responsible for providing appropriate immunizations to their employees. For vaccines with limited distribution (for example, anthrax, smallpox), DOD or USCG may provide the immunizations, regardless of the terms of the contract. The contractor is responsible for work-related illnesses, injuries, or disabilities under worker-compensation programs, supplemented by existing Secretarial designee authority.

b. Contracted health care workers are eligible for immunizations required or offered to health care employees and are provided as stated in the contract agreement. Contracts will include specifications describing immunizations required of contracted health care workers.

c. Family members of contracted workers in foreign-duty settings under military sponsorship will receive country-specific immunizations without charge at military activities upon presentation of official orders or authorization. People declining immunizations required for entry into foreign countries are referred to the appropriate authority for counseling. Document counseling in the health record and note that omission of certain immunizations may subject them to adverse action according to host country policies, which could include compulsory immunization, detention, quarantine, or denial of entry.

3-5. Department of Defense, U.S. Coast Guard schools, childcare centers and youth programs

a. As a condition of employment, schoolteachers, childcare center workers, youth program workers, and volunteers are administered appropriate vaccines against communicable diseases in accordance with ACIP adult immunization schedule recommendations, unless already immune, based on seroimmunity, physician diagnosed illness, or documented proof of immunization.

b. Children attending DOD and USCG-sponsored primary and secondary schools, childcare centers, or similar facilities are required to be up to date on all age appropriate ACIP-recommended vaccines for children unless there is documentation of previous immunization, religious exemption, or medical contraindication. For foreign-national children outside the United States, observe host country recommendations or requirements.

3-6. Other populations

a. *Department of Defense and U.S. Coast Guard beneficiaries.*

(1) *Family members of military personnel.* Family members receive immunizations according to current ACIP recommendations. In addition, Family members may be subject to Service-specific requirements and recommendations for immunizations applicable to the country in which they will reside while accompanying military members under military sponsorship.

(2) Family members or sponsored individuals of other Federal civilian employees in foreign-duty-settings under military sponsorship. These Family members will receive country-specific immunizations without charge at military activities upon presentation of official orders or authorization. People declining immunizations required for entry into foreign countries are referred to the appropriate authority for counseling. Document counseling in the health record and note that omission of certain immunizations may have consequences under host country policies, which could include compulsory immunization, detention, quarantine, or denial of entry.

b. *Foreign nationals.* Foreign nationals who come to the United States, its territories, commonwealths, or possessions under Armed Forces sponsorship receive immunizations required for entry into the United States and by local jurisdictions. When returning to their country of origin, foreign nationals receive immunizations required by international health regulations or their country of origin. These immunizations are administered without charge at military activities upon presentation of official orders or authorization.

c. *Detainees.* The installation or activity commander, upon the recommendation of the appropriate medical authority, will provide immunizations against diseases that may be a significant cause of death or illness among detainees. Such immunizations are voluntary and are administered without charge to the detainee. Annotate all immunizations and chemoprophylactic medications in the detainee's health record. Before immunization, inform detainees in their own language about the relative benefits and risks of the specific immunizations offered. Factors to consider in deciding which immunizations to offer detainees include their likely preexisting immunity, the anticipated length of detention, seasonal threat of infection, and other risk factors related to personal health status and living conditions. (Refer to DODI 2310.08E for additional guidance.)

d. *Overseas commander authority.* The overseas commander, commanding officer, or officer-in-charge, upon the recommendation of the appropriate medical authority, will provide immunizations against communicable diseases judged to be a potential hazard to the health of the command; such vaccines are administered without charge.

e. *Other than U.S. Forces.* Immunization of other than U.S. Forces for biological warfare defense are addressed in DODI 6205.4.

f. *Emergency situations.* In emergency situations, the provisions of DODD 6200.03 apply.

Chapter 4

Specific Immunization Requirements for Department of Defense and U.S. Coast Guard Personnel

(Also see appendix D for a chart on the required immunizations for military personnel.)

4-1. Civilian applicability

Certain civilian employees may be required to receive immunizations as a condition of their employment or participation in a particular assignment. In such cases, failure to voluntarily receive the immunizations may result in a personnel action being taken (see chap. 3), but in no case will immunizations be involuntarily administered.

4-2. Adenovirus types 4 and 7

a. *Military indication.* To prevent adenovirus infection, an acute febrile respiratory disease caused by adenovirus serotypes 4 and 7. Direct contact and fecal oral transmission of the virus may result in a respiratory disease infection or outbreak of disease among an unvaccinated recruit population.

b. *Basic trainees.* Administer adenovirus vaccine to military enlisted basic trainees before or at the beginning of collective training at the same time the first live virus vaccines are administered. Routine administration in other populations is not generally recommended except when directed by preventive medicine guidance, based on disease incidence and severity.

4-3. Anthrax

a. *Military indication.* To prevent anthrax, an acute infectious disease caused by the spore forming bacterium

Bacillus anthracis. Direct exposure to anthrax spores may result in cutaneous, gastrointestinal, or inhalational infection. *Bacillus anthracis* has been identified as a potential biological warfare agent.

b. *Military and civilian personnel*. Administer anthrax vaccine to military personnel and applicable civilians according to DOD or USCG policy for the Anthrax Vaccine Immunization Program and Service-specific implementation plans. Immunize personnel based on geographical areas at higher risk for release of anthrax as a weapon or in occupational roles as designated by the Services, Chairman of the Joint Chiefs, or the Office of the Secretary of Defense.

c. *Occupational risk*. Administer anthrax vaccine to at-risk veterinary and laboratory workers and others at occupational risk of exposure.

4-4. Haemophilus influenzae serotype b, commonly called Hib

a. *Military indication*. To prevent invasive *Haemophilus influenzae* serotype b (Hib). The disease is transmitted via respiratory droplets. The most common types of invasive Hib disease are: meningitis, epiglottitis, pneumonia, arthritis, and cellulitis.

b. *Military and civilian personnel*. Administer Hib vaccine to those who are immunocompromised, have sickle cell disease, or do not have a spleen or a functioning spleen.

4-5. Hepatitis A

a. *Military indication*. To prevent hepatitis A, an acute infection of the liver that is acquired by consuming food or water contaminated with hepatitis A virus, particularly during deployment or travel to areas with poor food, water, and sewage sanitation. It can range in severity from a mild illness lasting a few weeks to a severe illness lasting several months. Hepatitis A infections occur worldwide.

b. *Basic trainees and other accessions*. Unless seroimmune, administer hepatitis A vaccine to trainees and accessions during initial entry training.

c. *Military and civilian personnel*. Unless seroimmune, or evidence of appropriate complete vaccination, administer hepatitis A vaccine to all military personnel, and civilian personnel when indicated.

d. *Occupational risk*. Hepatitis A vaccine is indicated per ACIP guidelines and locally designated food handlers.

4-6. Hepatitis B

a. *Military indication*. To prevent hepatitis B, an acute or potentially chronic infection of the liver that is acquired through percutaneous, sexual, and other mucosal exposure to blood and body fluids from people infected with hepatitis B virus. Chronic infections may result in cirrhosis or cancer of the liver. Hepatitis B infections occur worldwide, and some infected people maintain a chronic carrier state.

b. *Basic trainees and other accessions*. Unless seroimmune, administer hepatitis B vaccine to basic trainees and accessions during initial entry training.

c. *Military and civilian personnel*. Unless seroimmune, or evidence of appropriate complete vaccination, administer hepatitis B vaccine to all military personnel, and civilian personnel, when indicated.

d. *Occupational risk*. Administer hepatitis B vaccine to susceptible personnel who are at risk of potential exposure to bloodborne pathogens per the Occupational Safety and Health Administration standards (29 CFR 1910.1030). For military purposes, this includes occupational specialties involving health care workers, emergency medical technicians, mortuary affairs personnel, search and rescue specialists, correctional facility staff, and designated special operations forces.

e. *Serologic testing*. Conduct serologic testing of health care workers who have direct contact with patients and those who have potential occupational risk for exposure to bloodborne pathogens 1 to 2 months after completion of the hepatitis B vaccine series to determine serologic response according to CDC and ACIP recommendations.

4-7. Influenza

a. *Military indication*. To prevent influenza, an acute febrile respiratory viral infection that can cause epidemics within military populations, especially under conditions of crowding, such as initial entry training, aboard ships, extended air transport, or deployment settings. Influenza has the potential for widespread transmission through person-to-person contact and fomites.

b. *Military personnel*. Administer influenza vaccine(s) annually or as indicated to all active duty, Reserve, and National Guard personnel.

c. *Occupational risk*. Administer influenza vaccine(s) annually or as indicated to personnel who work or volunteer in DOD MTFs.

4-8. Japanese encephalitis

a. *Military indication*. To prevent Japanese encephalitis, a mosquito-borne viral disease, during deployments and travel to endemic areas in Eastern Asia and certain western Pacific Islands. Japanese encephalitis virus (JEV) can cause

an acute infection of the brain, spinal cord, and meninges with high rates of complications, chronic disability, and death.

b. Military and civilian personnel. Administer the JEV vaccine to military personnel and civilian personnel who have a substantial risk of exposure to the virus based on their geographic location.

c. Temporary flying restrictions. Impose temporary flying restrictions post-JEV immunization for aircrew personnel per Service-specific policy.

4-9. Measles, mumps, and rubella (MMR)

a. Military indication. To prevent MMR, primarily by boosting immunity acquired from childhood immunization. These three acute viral infections are spread by the respiratory route or person-to-person contact. In military trainee populations, each can cause disease outbreaks. Rubella usually causes a mild infection, but infection during the first trimester of pregnancy puts the fetus at high risk of congenital rubella syndrome and birth defects. Young adults may experience more severe complications from mumps infection. All three diseases occur worldwide, primarily among children.

b. Basic trainees and other accessions. Unless seroimmune to both measles and rubella, administer MMR vaccine to susceptible basic trainees and accessions within the first 2 weeks of training.

c. Military and civilian personnel. Presume immunity through infection for persons born in 1957 or earlier. Ensure personnel born after 1957 have received two lifetime doses of MMR vaccine or have positive serologic test results. Immunity against mumps is not necessary as a military requirement, but may be appropriate in exceptional clinical circumstances such as outbreaks.

d. Occupational risk. Ensure health care workers have received two documented doses of MMR vaccine or have positive serologic test results.

4-10. Meningococcal

a. Military indication. To prevent meningococcal disease or meningitis and other systemic infections caused by the bacteria *Neisseria meningitidis* serogroups A, C, W-135, and Y. No vaccine against serogroup B meningococcus, another common pathogen, is currently licensed in the United States. Basic trainees and other military populations living in crowded conditions are at an increased risk for meningococcal infection. Historically, outbreaks have occurred in training populations. Meningococcal vaccine may be indicated for deployment and travel to areas with highly endemic meningococcal disease.

b. Basic trainees and other accessions. Administer meningococcal vaccine to basic trainees, cadets, and midshipmen at Service academies within the first 2 weeks of training, if no evidence of vaccination within the last 5 years.

c. Military and civilian personnel. Administer meningococcal vaccine to personnel traveling to countries in which *N. meningitidis* is hyperendemic or epidemic and other countries as required by DOD and USCG policy or recommended by the CDC.

d. Alert personnel. Administer meningococcal vaccine to personnel who are designated to deploy within 10 days of notification.

e. Other personnel. Administer one dose of meningococcal vaccine to persons who do not have spleens or functional spleens.

4-11. Pertussis

Tetanus, diphtheria, and pertussis guidance is in paragraph 4-16.

4-12. Pneumococcal

a. Military indication. To prevent pneumococcal disease due to *Streptococcus pneumoniae* in personnel who fall into a high-risk category due to age or underlying health conditions (for example, persons who smoke, have asthma, or have no spleen) or who are in high-risk situations, such as certain training populations. *Streptococcus pneumoniae* may result in pneumonia, bacteremia, and meningitis.

b. Basic trainees and other accessions. Routine administration of vaccine is not generally practiced, but may be directed by preventive medicine guidance, based on disease incidence and severity.

c. Military personnel. Administer pneumococcal vaccine to military personnel who are in a high-risk category per ACIP recommendations. Administer a second dose to persons without spleens or severely immunocompromised five years after the initial dose.

4-13. Poliomyelitis

a. Military indication. To prevent poliomyelitis, a viral infection that affects the central nervous system resulting in paralytic symptoms, primarily by boosting immunity acquired from childhood immunization. Poliomyelitis is acquired by person-to-person transmission through the fecal-oral route. Military and civilian personnel deploying or traveling to areas with poor sanitation are at increased risk, although international immunization efforts have decreased poliomyelitis incidence worldwide. Only inactivated poliovirus vaccine (IPV) is available in the US.

b. Basic trainees and other accessions. Administer a single booster dose of IPV to basic trainees and accessions. Personnel who have not received the primary series must complete the series using IPV. Unless there is reason to suspect otherwise (for example, childhood spent in a developing country, childhood immunizations not administered), receipt of the primary series of IPV may be assumed.

c. Military personnel. Because of the high level of childhood immunization against this disease, do not screen immunization records with regard to poliovirus immunity after completion of initial entry training except in an outbreak setting or for individual clinical purposes.

4-14. Rabies

a. Military indication. To prevent rabies, a life threatening viral disease caused by exposure to the saliva of animals or humans infected with the rabies virus, which includes bites.

(1) *Pre-exposure prophylactic immunization.* A pre-exposure immunization series may be indicated for people with potential occupational risk of exposure to rabid animals, or for forces assigned to locations where access to definitive care likely exceeds 24 hours. Pre-exposure prophylaxis should not be considered sufficient for the prevention of rabies; however, it reduces the need for human rabies immune globulin-better known as HRIG-and reduces the number of shots required for post-exposure prophylaxis.

(2) *Post-exposure prophylaxis.* Consult with a preventive medicine physician and veterinarian for guidance and to report the animal exposure. Post-exposure treatment includes immediate wound care, and may include the post-exposure vaccine series, and human rabies immune globulin in an unvaccinated patient. Post-exposure prophylaxis is safe and effective.

b. Military personnel. Administer pre-exposure rabies vaccine series to special operations personnel, including designated special operations enablers and the occupational risk groups listed below, in accordance with Service policy.

c. Occupational risk. Administer pre-exposure rabies vaccine series to veterinary workers, animal handlers, certain laboratory workers, and personnel who have animal control duties and personnel assigned long-term to regions with endemic rabies. Give booster doses every 2 years or when antibody concentrations indicate.

4-15. Smallpox

a. Military indication. To prevent smallpox disease due to the deliberate release or spread of the smallpox virus. In 1980, the WHO declared the global eradication of naturally occurring smallpox. Nonetheless, stocks of variola virus, the causative agent of smallpox, could be used as a biological warfare agent.

b. Military and civilian personnel. Vaccinate designated military and civilian personnel according to DOD and other designed personnel in accordance with USCG policy and Service-specific implementation plans. These include military personnel and applicable civilians who are smallpox epidemic response team members, assigned to medical teams at hospitals and clinics, or assigned to designated forces that constitute mission-critical capabilities. Immunize personnel based on geographical areas at higher risk for release of smallpox as a weapon or in occupational roles as designated by the Services, Chairman of the Joint Chiefs, or the Office of the Secretary of Defense.

c. Training and education. Before administering smallpox vaccine to military or civilian personnel who are eligible to receive smallpox vaccine, provide education on the criteria for exemption from immunization, expected response at the vaccination site, vaccination-site care, risks of spreading vaccinia to close contacts, adverse events following immunizations (AEFI) such as myopericarditis, and other relevant topics per Service implementation plans.

d. Screening. Use the DOD-specific screening form posted at <http://www.vaccines.mil> to identify persons with personal or household contraindications to smallpox vaccination (for example heart conditions, immunosuppressed conditions, pregnancy, skin conditions such as eczema and atopic dermatitis). Screening will include assessing pregnancy status and recency of testing for human immunodeficiency virus infection. In the event of a smallpox outbreak, "permanent" exemptions may be rescinded according to individual risk of exposure to variola virus.

e. Vaccination. Internal MTF and command clinical quality management programs will have mechanisms to confirm that vaccinators demonstrate proper vaccination technique.

f. Post-vaccination site care. Take appropriate care to prevent the spread of vaccinia virus from a vaccinee's vaccination site. MTFs will monitor the vaccination sites of vaccinated health care workers (for example, operating site-care stations), promote effective bandaging, and encourage scrupulous hand washing.

g. Post-vaccination evaluation ("take" check). Assessment and documentation of response (a "take") to vaccination is required for health care workers and members of smallpox response teams who would travel into a smallpox outbreak area. Evaluate and record the vaccination response of individuals receiving smallpox vaccine in a DOD and USCG-approved electronic ITS.

4-16. Tetanus, diphtheria, and pertussis

a. Military indication. To prevent tetanus, diphtheria, and pertussis, primarily by boosting immunity acquired from childhood immunization.

(1) Tetanus is an acute disease of the nervous system caused by the serotoxin produced by *Clostridium tetani*. The *C. tetani* spores enter the body through breaks in the skin, and the bacterium then grows at the wound site. A tetanus

infection results in generalized rigidity and convulsive spasms of the skeletal muscles. The *C. tetani* spores occur in the environment worldwide.

(2) Diphtheria is an acute disease caused by a cytotoxin of the bacteria *Corynebacterium diphtheriae*. *C. diphtheriae* is transmitted person-to-person via respiratory droplets and direct contact. Diphtheria can lead to airway obstruction, and more severe complications may result from toxin absorption into organs and tissues. Diphtheria occurs worldwide.

(3) Pertussis is a highly communicable acute respiratory illness caused by the bacteria *Bordetella pertussis*. Pertussis is spread via direct contact with respiratory secretions. Pertussis occurs worldwide.

b. Basic trainees and other accessions. For those individuals lacking a reliable history of prior immunization, administer one dose of Tetanus-diphtheria and acellular pertussis (Tdap) vaccine according to ACIP guidelines. Unless there is reason to suspect otherwise (for example, childhood spent in a developing country, childhood immunizations not administered), receipt of the basic immunizing series may be assumed.

c. Military and civilian personnel. Administer booster doses of Tetanus-diphtheria (Td) to all personnel every 10 years following the completion of the primary three-dose series. A one-time dose of Tdap in place of a Td booster during adulthood is required, regardless of interval.

d. All personnel. Following ACIP wound-management guidelines for the treatment of contaminated wounds. Tdap is preferred to Td for adults vaccinated 5 years earlier who require a tetanus toxoid-containing vaccine as part of wound management and who have not previously received Tdap. For adults previously vaccinated with Tdap, Td should be used if a tetanus toxoid-containing vaccine is indicated for wound care.

4-17. Typhoid fever

a. Military indication. To prevent typhoid fever, a systemic bacterial disease acquired by consuming food or water contaminated with *Salmonella typhi*, particularly during deployment or travel to typhoid-endemic areas and other areas with poor sanitation.

b. Military and civilian personnel. Administer typhoid vaccine before overseas deployment to typhoid-endemic areas.

c. Alert personnel. Administer typhoid vaccine to alert personnel, per Service policy, who are prepared for deployment to typhoid-endemic areas or who have potential risks of exposure to contaminated local food and drink. Administer booster doses per immunization schedule. For Air Force, only units specifically identified by the MAJCOM surgeon require initial and subsequent immunization against typhoid fever.

4-18. Varicella

a. Military indication. To prevent varicella (chickenpox), a generally mild and self-limiting viral infection caused by the varicella zoster virus. Although varicella is a common childhood disease, adults may experience more severe illness and have higher complication and case-fatality rates. Adolescents and adults are at higher risk for severe disease complications such as secondary skin infections, neurologic disease, and multi-organ involvement. Varicella zoster virus is transmitted by respiratory secretions, direct contact, and aerosolization of the virus from skin lesions. Military members at higher risk for infection include basic trainees, cadets/midshipmen at Service academies, officer trainees, and special operations personnel, and others living in military environments conducive to person-to-person spread of respiratory diseases (for example, barracks, ships).

b. Basic trainees and other accessions. Administer varicella vaccine to susceptible trainees and other accessions within the first 2 weeks of initial entry training. Serologic screening of trainees is the preferred means of determining those susceptible to varicella infection and in need of immunization. Identify those people who do not have a personal history of varicella disease, documentation of two prior varicella immunizations, or documentation of immunity based on serologic testing as susceptible. Document positive results of serologic testing in a DOD-approved electronic ITS. Adults and adolescents require two doses of varicella vaccine given 4 to 8 weeks apart.

c. Health care workers. Administer varicella vaccine to susceptible health care workers. Determine susceptibility as noted above for trainees, birth before 1980 should not be considered evidence of immunity for health care workers. Routine post-immunization testing for antibodies to varicella is not recommended.

d. Other susceptible adults. Offer varicella vaccine to other susceptible persons, especially nonpregnant women of childbearing age and men living in households with young children.

4-19. Yellow fever

a. Military indication. To prevent yellow fever disease, a viral infection that may result in severe systemic disease and organ failure. Yellow fever infection is transmitted via the bite of an infected mosquito. Documented vaccination status must be verified to meet international health requirements during deployment or travel to yellow-fever-endemic areas. Areas of greatest risk are sub-Saharan Africa and tropical South America.

b. Military personnel. Administer yellow fever vaccine to all Marine Corps accessions and military personnel traveling to or transiting through yellow-fever-endemic areas.

c. Alert personnel. Administer yellow fever vaccine to alert personnel prepared for deployment to yellow-fever-endemic areas. Administer booster doses per immunization schedule. For Air Force, only units specifically identified

by the MAJCOM surgeon require initial and subsequent immunization against yellow fever. For Navy, administer to those assigned to units subject to deployment within 10 days of notification into land areas where yellow fever is endemic.

d. Civilian and other personnel. Administer yellow fever vaccine to personnel traveling to, or transiting through, endemic areas.

Chapter 5 Chemoprophylaxis

5-1. General

a. Chemoprophylaxis. This section does not relate to the treatment of diseases but provides a brief review of military relevant diseases and associated chemoprophylaxis guidelines. Chemoprophylaxis is defined here as the administration of medication before, during, or after possible exposure to an infectious agent, to prevent either infection or disease. Most agents used for chemoprophylaxis are not FDA-approved for this indication and thus may not be administered to units under a force health protection strategy or policy; rather, these agents must be prescribed to individuals and documented accordingly by an appropriate health care provider. Follow instructions from the relevant combatant command surgeon who will consult with the appropriate preventive medicine authority for the use of chemoprophylactic agents. Command medical officers will review indications for use and potential adverse effects of specific chemoprophylactic medications before use. These recommendations for drugs or agents are current as of the date of this publication. Consult current information and guidance for appropriate drugs and dosing regimens (for example the CDC, the ACIP, the National Center for Medical Intelligence (NCMI), and the American Public Health Association's "Control of Communicable Diseases Manual"). The following classes of chemoprophylaxis are not addressed in this publication:

(1) Chemical warfare-related chemoprophylaxis. Consult the current version of "Medical Management of Chemical Casualties," published by the U.S. Army Medical Research Institute of Chemical Defense.

(2) Medical therapy for tuberculosis infection. Consult publications from CDC, the American Thoracic Society, the Advisory Council for the Elimination of Tuberculosis, and similar authorities.

(3) Radiation-related chemoprophylaxis (for example, potassium iodide, granisetron, or Prussian blue).

(4) Other forms of prevention involving nonbiological medications (for example, calcium, aspirin, or vitamins).

(5) Immunotherapy.

b. Packaging. Dispense chemoprophylaxis agents to individuals in child-resistant containers, consistent with 15 USC 1471-1476 (The Poison Prevention Packaging Act), or unit-of-use packaging. Use appropriate packaging to keep the medication clean and dry.

c. Labeling. Dispense chemoprophylaxis agents to individuals in packages that contain the name of the product, directions for proper use, and the name of the person to whom the medication was dispensed.

5-2. Anthrax

a. Military indication. The use of antibiotics and immunoglobulin following a possible exposure to anthrax is locally-directed and is prescribed by preventive medicine based on risk. The use of antibiotics and immunoglobulin have been shown to increase survival when used after exposure to anthrax and before onset of symptoms (post-exposure prophylaxis or empiric treatment).

b. Chemoprophylaxis. Recommended drugs include ciprofloxacin and doxycycline. Refer to Service-specific policies. Anthrax immunoglobulin is available through the CDC's Emergency Operation Center.

5-3. Group A streptococcus

a. Military indication. Outbreaks of group A streptococci can spread rapidly in groups in settings of close contact, such basic training and contingency operations.

b. Chemoprophylaxis. The primary drug used for prophylaxis is penicillin, specifically the long-acting injectable form, penicillin G benzathine. Oral penicillin VK and azithromycin have also been used effectively. Administer penicillin prophylactically, when required, to terminate disease transmission. Routine administration of penicillin for prophylaxis of basic trainees against group A streptococcal infection has been shown to be effective at some installations with historically high incidence of disease. This practice should be directed by local preventive medicine authority.

5-4. Influenza

a. Military indication. Influenza can be a significant cause of morbidity in a susceptible population and can degrade mission capability.

b. Chemoprophylaxis. Consider prophylactic use of antiviral therapy if available vaccine does not antigenically

match circulating strains or if an outbreak occurs early in the season before widespread immunization. For additional guidance, refer to CDC.

5-5. Leptospirosis

a. Military indication. Leptospirosis can cause morbidity in personnel exposed to contaminated water sources.

b. Chemoprophylaxis. Doxycycline is effective in preventing leptospirosis in exposed military personnel during periods of high risk of exposure. Consult an infectious diseases or preventive medicine authority for proper use and dosing.

5-6. Malaria

a. Military indication. Malaria has caused morbidity and mortality in military populations for centuries. It continues to be one of the most important disease threats to military and civilian personnel deployed to areas where the disease is endemic.

b. Chemoprophylaxis. The Services or the combatant command surgeon determine specific chemoprophylactic regimens, typically with guidance from the NCMI, for the area of operations based on degree and length of exposure and the prevalence of drug resistant strains of *plasmodia* in the area(s) of travel. Prescribe anti-malarials per package insert. Health care providers will screen individuals for contraindications to specific malaria chemoprophylaxis (for example G6PD deficiency and primaquine) and determine the appropriate malaria chemoprophylaxis. Health care providers must document malaria chemoprophylaxis prescriptions in the health record when anti-malarial medications are prescribed. Include the member's electronic medication profile (for example, Composite Health Care System II), whenever possible.

5-7. Meningococcal disease

a. Military indication. Meningococcal disease can result in morbidity and potential mortality in populations experiencing crowded conditions. Chemoprophylaxis has been shown to prevent disease when administered post-exposure to susceptible people.

b. Chemoprophylaxis. There are several drugs available for prophylaxis of close contacts of meningococcal disease cases. Consult an infectious diseases or preventive medicine authority for determination of individuals to offer prophylaxis and for assistance with drug selection and dosing.

5-8. Plague

a. Military indication. Plague has been identified as a potential biological warfare agent, especially if aerosolized to cause pneumonic plague. There is no licensed vaccine that is effective against pneumonic plague. Provide chemoprophylaxis to persons potentially exposed to cases of pneumonic plague.

b. Chemoprophylaxis. Consult an infectious diseases or preventive medicine authority for determination of individuals to offer prophylaxis and for assistance with drug selection and dosing.

5-9. Scrub typhus

a. Military indication. Spread by the bite of infective larval mites. Mite bites may be a source of morbidity in populations encountering field conditions.

b. Chemoprophylaxis. Doxycycline has been shown to be effective in preventing scrub typhus in exposed personnel. Consult an infectious diseases or preventive medicine authority for proper use and dosing.

5-10. Smallpox

a. Military indication. Various forms of vaccinia infections may develop following receipt of the smallpox vaccine. Chemoprophylaxis may be indicated to prevent morbidity in immunized Servicemembers or their contacts.

b. Chemoprophylaxis. VIG and vaccinia-specific antivirals are available through the DOD. Contact MILVAX to request and coordinate administration of these chemoprophylactic agents.

5-11. Traveler's diarrhea

a. Military indication. Diarrhea can cause morbidity in personnel exposed to contaminated food and water sources.

b. Chemoprophylaxis. Chemoprophylaxis for traveler's diarrhea is only recommended on rare occasions where diarrhea would compromise a mission. Prophylactic antibiotics may be considered for short-term travelers who are high-risk hosts (such as those who are immunosuppressed) or those taking critical trips during which even a short bout of diarrhea could significantly impact the purpose of the trip. Instead of prophylaxis travelers, should be prescribed appropriate medications and provided instructions for self-treatment of diarrhea. Consult an infectious diseases or preventive medicine authority for assistance.

Chapter 6 Biological Warfare Defense

6-1. Responsibilities

- a. The combatant commanders, annually and as required, provide the Chairman of the Joint Chiefs of Staff with their assessment of the biological warfare threats to their theaters.
- b. The President of the Defense Health Board, in consultation with the Secretaries of the Military Departments, annually and as required, identifies to the Assistant Secretary of Defense (Health Affairs) (ASD (HA)) vaccines available to protect against validated biological warfare threat agents and recommends appropriate immunization protocols and/or chemoprophylaxis.

6-2. Procedures

The DOD Immunization Program for Biological Warfare Defense is conducted as follows:

- a. The combatant commanders, annually and as required, provide the Chairman of the Joint Chiefs of Staff with their assessment of the biological warfare threats to their theater.
- b. The Chairman of the Joint Chiefs of Staff, in consultation with the combatant commanders; the chiefs of the Military Services; and the Director, Defense Intelligence Agency, annually validates and prioritizes the biological warfare threats to DOD personnel and forwards the threat list to the DOD Executive Agent through the ASD (HA).
- c. Within 30 days of receiving the validated and prioritized biological warfare threat list from the Chairman of the Joint Chiefs of Staff, the DOD Executive Agent, in consultation with the Secretaries of the military departments and the President of the Defense Health Board, provides recommendations to the ASD (HA) on vaccines and immunization protocols necessary to enhance protection against validated biological warfare threat agents.
- d. Within 30 days of receiving the coordinated recommendations of the DOD Executive Agent, the ASD (HA) directs the Secretaries of the military departments to begin immunization of the specified DOD and USCG personnel against specific biological warfare threat agents. The ASD (HA) will coordinate with and obtain approval from the Secretary or Deputy Secretary of Defense before issuing the appropriate direction.
- e. The Secretaries of the military departments will program and budget for required vaccinations, including the costs of the biological warfare defense vaccines.

Chapter 7 Vaccines and Other Products in Investigational New Drug Status

7-1. Purpose

For infectious disease threats for which the only available vaccine or chemoprophylaxis product is in an IND status, the IND product must be administered in full accordance with FDA regulations at 21 CFR Parts 50 and 312, as well as 10 USC 1107, Executive Order 13139, and DODD 6200.2. DOD may use products that have not been approved or licensed for commercial marketing as force health protection measures in combat settings, other military operations, peacekeeping, or humanitarian missions. DOD will provide comparable access to IND products to military personnel, civilian personnel, contracted workers, and beneficiaries based on the health risk to the people involved.

7-2. General guidance on investigational new drug products

Commanders, through the appropriate chain, must request approval from the Secretary of Defense to use INDs for force health protection. If the member's use of an IND product is voluntary, the product must be administered with documented informed consent in accordance with a protocol approved by the FDA for IND product use. A vaccine, antibiotic, or other product in an IND status may be mandatory for military members, if the President of the United States has approved a waiver of the requirement for informed consent. Under 10 USC 1107, only the President has the authority to grant a waiver of the requirement that a military member provide prior consent to receive an IND or a drug unapproved for its applied use in connection with the member's participation in a particular military operation. The President must determine, in writing, that obtaining consent (1) is not feasible, (2) is contrary to the best interests of the member, or (3) is not in the interests of national security. The requirement for informed consent may not be waived for civilian personnel, contracted workers, and beneficiaries.

7-3. Health recordkeeping requirements for investigational new drug products

All IND vaccines or chemoprophylaxis products that are administered, whether with the member's informed consent or with an approved waiver of informed consent, must be recorded in the individual's permanent health record or DOD and USCG-approved electronic ITS. For vaccines, the documentation is the same as that required for other vaccines with an annotation "IND" with the vaccine name. This recordkeeping requirement is in addition to any recordkeeping

requirements of the FDA-approved IND protocol. The requirement for recordkeeping applies to IND vaccines, antibiotics, and other medications in IND status.

7-4. Information requirements for investigational new drug products

Any recipient of an IND vaccine or chemoprophylaxis product must receive the information (for example, briefing, individual counseling, information statements) required by the FDA-approved IND protocol. Full compliance with this requirement is extremely important whether the IND product is voluntary or mandatory.

7-5. Coordination

The Army, as the Executive Agent for the Immunization Program for Biological Warfare Defense, maintains a program office at the U.S. Army Medical Materiel Development Activity (USAMMDA) to execute oversight and coordination of the use of IND products for Force Health Protection.

Chapter 8

Vaccines and Other Products Used Under Emergency Use Authorization

8-1. General

Under 21 USC 564 (The Food, Drug, and Cosmetic Act), some drugs, vaccines, or devices that have not been approved or licensed by the FDA through the regular drug approval process (or not approved for an intended use) may be used as medical countermeasures to chemical, biological, radiological, and nuclear (CBRN) agents or threats, if the FDA grants an EUA. This EUA authority is an alternative to the otherwise applicable requirement to file an IND application and follow IND rules (see chap. 7) to use such unapproved drugs as CBRN medical countermeasures.

8-2. Criteria

In general, the FDA may grant an EUA for up to 12 months, with potential renewal, based on the following:

- a. The Secretary of Defense or designee has determined that there is a military emergency or significant potential for a military emergency relating to a particular CBRN agent or threat.
- b. The Secretary of DHHS declares an emergency based on the Secretary of Defense's determination.
- c. The Secretary of DHHS determines—
 - (1) The vaccine or drug may be effective in diagnosing, treating, or preventing the disease or condition.
 - (2) The known and potential benefits of the vaccine or drug outweigh the known and potential risks.
 - (3) There is no adequate, approved, and available alternative medical countermeasure.
- d. The duration of authorization corresponds to the duration of the emergency or significant potential for an emergency.

8-3. Refusal options

The FDA may decide that potential recipients of a drug under an EUA should have the option to refuse it. The President may waive this option for military personnel.

8-4. Health recordkeeping requirements for emergency use authorization products

All EUA vaccines or chemoprophylaxis products that are administered must be recorded in the individual's permanent health record and/or DOD-approved electronic ITS.

8-5. Information requirements for emergency use authorization products

Any recipient of an EUA vaccine or chemoprophylaxis product must receive the information (for example, briefing, individual counseling, information statements) required by the FDA-approved EUA. Full compliance with this requirement is critical.

8-6. Department of Defense requests for emergency use authorizations

Requests for possible EUAs for military purposes must be submitted to ASD (HA) for consideration.

8-7. Coordination

The Army, as the Executive Agent for the Immunization Program for Biological Warfare Defense, maintains a program office at the USAMMDA. This office oversees and coordinates EUA product use for force health protection.

Appendix A References

Section I Required Publications

Unless otherwise stated, all publications are available at: <http://www.apd.army.mil/>. Department of Defense regulations are available at: <http://www.dtic.mil/>.

DODI 6200.03

Public Health Emergency Management within the Department of Defense (Cited in paras 3-3d, 3-6f.)

DODI 6205.4

Immunization of Other Than U.S. Forces (OTUSF) for Biological Warfare Defense (Cited in paras 3-3e, 3-6f.)

Section II Related Publications

A related publication is a source of additional information. The user does not have to read a related publication to understand this regulation. Unless otherwise stated, all publications are available at: <http://www.apd.army.mil/>. Department of Defense regulations are available at: <http://www.dtic.mil/>. The U.S. Code and the Code of Federal Regulations are available at: <http://www.gpoaccess.gov/fdsys/>.

AR 11-2

Managers' Internal Control Program

AR 25-30

The Army Publishing Program

AR 600-20

Army Command Policy

AFI 48-123

Medical Examination and Standards (Available at <http://www.e-publishing.af.mil/>.)

Control of Communicable Diseases Manual

Communicable disease control and the international health regulations (Available at <http://www.apha.org/>.)

COMDTINST M6000.1

Medical Manual

DODD 1241.01

Reserve Component Medical Care and Incapacitation Pay for Line of Duty Conditions

DODD 1404.10

DOD Civilian Expeditionary Workforce

DODI 6200.02

Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs

DODD 6205.02E

Policy and Program for Immunizations to Protect the Health of Service Members and Military Beneficiaries

DODD 6205.3

DOD Immunization Program for Biological Warfare Defense

DODI 1300.17

DOD Accommodation of Religious Practices Within the Military Services

DODI 1400.32

DOD Civilian Work Force Contingency and Emergency Planning Guidelines and Procedures

DODI 2310.08E

Medical Program Support for Detainee Operations

DODI 5010.40

Manager's Internal Control (MCIP) Program Procedures

Executive Order 13139

Improving Health Protection of Military Personnel Participating in Particular Military Operations (Available at <http://www.archives.gov/federal-register/executive-orders/disposition.html/>.)

NATO STANAG 2037

Vaccination of NATO Forces(Available at <http://www.nato.int/docu/standard.htm/>.)

NATO STANAG 2491

NBC/MED Policy for the Immunization of NATO Personnel Against Biological Warfare Agents(Available at <http://www.nato.int/docu/standard.htm/>.)

NATO STANAG 3474

Temporary Flying Restrictions Due to Exogenous Factors Affecting Aircrew Efficiency (Available at <http://www.nato.int/docu/standard.htm/>.)

10 USC 1107

Notice of use of an investigational new drug or a drug unapproved for its applied use

15 USC 1471

Definitions

15 USC 1472

Special packaging standards

15 USC 1473

Conventional packages, marketing

15 USC 1474

Regulations for special packing instructions

15 USC 1475

Repealed. Section 1205(c), Act of 13 August 1981, Public Law 97-35, Title XII, Volume 95, U.S. Statute at Large, p: 716.

15 USC 1476

Preemption of Federal standards

21 USC 360

Registration of producers of drugs or devices

42 USC 300aa

Public Health Service

42 USC 300aa-1 to 300aa-34

The National Childhood Vaccine Injury Act of 1986

42 USC 300aa-25

Recording and Reporting of Information

21 CFR 312

Investigational New Drug Application

29 CFR 1605

Guidelines on Discrimination Because of Religion

29 CFR 1910.1030.
Blood borne pathogens

Section III
Prescribed Forms

This section contains no entries.

Section IV
Referenced Forms

Except where otherwise indicated below, the following forms are available as follows: DA forms are available on the APD Web site, at <http://www.apd.army.mil>; DD forms are available from the OSD Web site, at <http://www.dtic.mil/whs/directives/infomgt/forms/index.htm>; standard forms (SFs) and optional forms (OFs) are available from the GSA Web site (<http://www.gsa.gov>).

DA Form 11-2
Internal Control Evaluation Certification

DA Form 2028
Recommended Changes to Publications and Blank Forms

DD Form 2365
DOD Civilian Employee Overseas Emergency-Essential Position Agreement

DD Form 2766
Adult Preventive and Chronic Care Flowsheet (Available through normal forms supply channel.)

DD Form 2766C
Adult Preventive and Chronic Care Flowsheet (Continuation Sheet) (Available through normal forms supply channel.)

FDA Form 3500
MedWatch: The FDA Safety Information and Adverse Event Reporting System (Available at <http://www.fda.gov/Safety/MedWatch/default.htm>).

Form VAERS-1
Vaccine Adverse Event Reporting System (Available at <http://vaers.hhs.gov/esub/index>)

CDC Form 731
International Certificate of Vaccination (Available through normal forms supply channel. Also available at <http://bookstore.gpo.gov>, or toll free at 1-866-512-1800.) (Marine Corps and Navy - S/ N 0108-LF-400-0706. Available from the Navy Supply System and may be requisitioned per NAVSUP P-2002D.)

SF 600
Medical Record - Chronological Record of Medical Care

SF 601
Health Record - Immunization Record

Appendix B Standards for Military Immunization

B-1. Standard #1: immunization availability

- a.* Ensure immunizations are available when required to minimize disruption of deployment or training schedules.
- b.* Ensure immunizations are available at convenient times, without unnecessary barriers and are available on a walk-in basis, as staffing permits. As clinically appropriate, administer any vaccine doses required simultaneously to avoid missed immunization opportunities.
- c.* Ensure immunization services are responsive to the needs of beneficiaries.
- d.* Review the vaccination status of all beneficiaries at every health care visit to determine which vaccines are indicated.
- e.* Implement standing orders if written orders are unavailable. Standing orders must address vaccine dosage and administration, contraindications and precautions, and documentation procedures. Ensure standing orders are signed by the privileged physician who has medical oversight of the clinic.

B-2. Standard #2: vaccine information and vaccinee education

- a.* Educate beneficiaries about the benefits and risks of vaccination in a culturally appropriate manner and at an appropriate education level.
- b.* Prior to vaccination, provide all parents/guardians and vaccinees the most current Vaccine Information Sheets (VISs) for each vaccine as mandated by Federal law (42 USC 300aa-26). Allow sufficient time to discuss any concerns or questions as noted by the vaccinee. Ensure VISs are accessible and visible in the patient waiting area of the clinic or activity that provides immunizations.
- c.* Prior to each vaccination provide all potential vaccinees the opportunity to read the current DOD and/or FDA mandated vaccine information brochure. Additional education requirements may be required as outlined in vaccination policy.
- d.* Ensure immunization personnel are readily available to accurately answer patients' immunization questions and concerns about vaccines. Ensure personnel have ready access to immunization information resources.

B-3. Standard #3: vaccine storage and handling

- a.* Ensure staff members adhere to cold-chain management principles during administration, transportation, and storage. Ensure up-to-date, written cold-chain management protocols are accessible at all locations where vaccines are stored.
- b.* Implement temperature monitoring processes at any clinic or activity that administers immunizations. All vaccine storage devices should have a calibrated thermometer and alarm systems that are visually monitored at a minimum of twice a day.
- c.* The CDC's National Center for Immunization and Respiratory Diseases strongly recommends that providers draw vaccine only at the time of administration to ensure that the cold chain is maintained and that vaccine is not inappropriately exposed to light. Do not pre-draw doses; draw them when they are needed.

B-4. Standard #4: indications and contraindications

- a.* Screen each patient for allergies, health status, recent vaccinations, and previous vaccine adverse events before immunization. Provide each patient an opportunity to ask questions about potential contraindications. Refer patients for appropriate medical evaluation, as needed.
- b.* Screen each patient's immunization record to determine vaccine needs or requirements.
- c.* Ensure staff members document any contraindication to an immunization in the health record and ITS. Screen all women for pregnancy status.

B-5. Standard #5: immunization recordkeeping

- a.* Record immunizations accurately in a DOD and USCG-approved electronic ITS according to Service-specific policy at the time of immunization, or no later than 24 hours after administration of immunization. Transcribe all historical immunizations into the immunization tracking system.
- b.* Recommend any clinic or activity that administers immunizations has one or more mechanisms for notifying patients when the next dose of an immunization series is needed (a reminder system) or when doses are overdue (recall system). Reminder and recall systems may be automated or manual and may include mailed, emailed, or telephone messages.
- c.* Record all military personnel immunization information in an electronic ITS immunization record. All Services must record military immunization data into an electronic database that communicates with a centralized DOD registry.

B-6. Standard #6: immunization personnel training

a. Ensure all persons who administer vaccines, including immunization augmentees, are appropriately trained and work within their appropriate scope of practice as determined by Service policies.

b. Immunization training must meet a standard acceptable to the MTF commander, command surgeon, or other appropriate medical authority. Training will include vaccine storage and handling; vaccine characteristics; recommended vaccine schedules; patient screening; contraindications; vaccine administration techniques; and treatment and reporting of adverse events to include anaphylaxis, vaccine benefit and risk communication, and documentation and management.

c. Ensure personnel who administer vaccines complete a comprehensive immunization orientation and annual continuing education that addresses training standards and competency of vaccine related topics based on an individual's role in administering and/or handling vaccines. Individuals who routinely administer vaccines should complete at least 8 hours of training annually. Training resources include resident courses, self-paced online training programs, and video training (see table B-1).

Table B-1
Training standards

Medical standard or procedure	Physicians and medical directors	Immunizers	Chapter and appendix paragraph locations
Quality patient care and delivery of immunizations			
Properly trained in accordance with DOD, Service, USCG, and Centers for Disease Control and Prevention (CDC) guidelines and act within their scope of practice as determined by each Service.	B ¹ , A ²	B, A	1-4c(1)
Understands standing order procedures for administering immunizations including dose, route, time indication, contraindications, and so forth.	B, A	B, A	2-1b and B-1
Demonstrates the ability and knowledge to screen individuals for contraindications, hypersensitivities, allergies, and so forth, before administering vaccines.	B	B, A	2-1d and B-4
Understands and adheres to immunization dosing and interval schedules.	B	B, A	2-1e and B-6
Understands how to properly document exemptions from further immunization in the ITS (DD Form 2766C), on the DD Form 2766 (Adult Preventive and Chronic Care Flowsheet), and/or in other relevant paper-based immunization records.	B	B, A	2-6, 2-7, and B-4
Patient information and education before immunization			
Understands the purpose of and legal requirements for making VISs available to vaccine recipients.	B	B, A	2-7d(2) and B-2
Understands how to document the date of the VIS in the ITS when documenting an immunization given.	B	B, A	2-7d(3) and B-2
Vaccine storage and handling			
Trained in cold-chain management principles and procedures.	B, A	B, A	2-3 and B-3
Demonstrates how to read a vaccine package insert for storage and handling requirements.	B	B, A	2-3 and B-3
Understands proper reporting procedures for vaccine storage and handling losses.	B, A	B, A	2-3f and B-3
Emergency care and adverse-event reporting			
Basic cardiopulmonary resuscitation and the administration of epinephrine.	B, R ³	B, R	2-9b and B-6
Knows how to use the emergency equipment available for treating an anaphylactic reaction. Ensures medications in kit are not expired.	B	B, A	2-9c and B-6
Demonstrates the ability to initiate anaphylactic reaction treatments per protocol.	B	B, A	2-9c and B-6
Understands the procedure for documenting an adverse event after an immunization.	B	B, A	2-10d and B-7

Table B-1
Training standards—Continued

Knows how to submit a Vaccine Adverse Event Reporting System (VAERS) Form 1.	B	B, A	2-10d and B-7
Comprehends DOD's Clinical Guidelines for Managing Adverse Events after Immunization.	B, A	B	2-10 and B-7
Understands how to handle and administer specific vaccines			
Military and civilian personnel eligible to receive smallpox vaccine will be educated before immunization regarding criteria for exemption from immunization, expected response at the vaccination site, vaccination-site care, risks of spreading vaccinia to close contacts, and other relevant topics.	B, A	B, A	4-15
Immunization record keeping (documentation)			
Trained to accurately document immunizations, historical immunization data, and medical exception codes in ITS.	B	B, A	2-6a and b, 2-7, and B-5
Training			
Demonstrates understanding of and ability to follow this multi-Service publication and other pertinent references such as DOD, USCG, and CDC guidance in the performance of duties.	B, A	B, A	1-5

Notes:

¹ B=baseline or initial training

² A=annually

³ R=as required

d. Ensure persons who administer vaccines have ready access to information resources regarding current recommendations for childhood, general adult, travel, and military-specific immunizations.

B-7. Standard #7: adverse events after immunization

a. Epinephrine (such as auto-injectable epinephrine) must be properly stored and readily available at all vaccination locations along with other supplies determined locally to manage adverse events (see para 2-9). Ensure all immunization personnel are trained to administer epinephrine.

b. Provide easy access to telephones or radios to persons who administer vaccines for summoning emergency medical personnel. Medical providers document adverse events in the health record at the time of the event or as soon as possible thereafter.

c. Report all clinically significant adverse events after vaccination to VAERS. Provide staff members with ready access to reporting options for the VAERS.

d. Develop a quality improvement process to assure adverse events are reported to VAERS promptly.

B-8. Standard #8: vaccine advocacy to protect the military Family

a. Develop a mechanism at the MTF level to determine the extent of influenza and pneumococcal immunization coverage among its high-risk patients. Develop a plan to optimize vaccination uptake and coverage.

b. Implement a plan to optimize immunization rates among cardiac, pulmonary, diabetic, asplenic, and other patient groups at elevated risk of complications from vaccine-preventable infectious diseases.

c. Conduct a quality improvement program to optimize the performance in immunizing children, adolescents, and adults against the preventable infections that most threaten them.

d. Ensure commanders use immunization databases to identify and resolve the vulnerabilities of their units.

e. All health care providers (not just those in any clinic or activity that administers immunizations) should routinely determine the immunization status of their patients, offer vaccines to those for whom they are indicated, and maintain complete immunization records.

Appendix C Medical and Administrative Exemption Codes

This appendix gives details about medical and administrative exemption codes, as well as information on duration.

C-1. Medical exemption codes

Medical exemption codes appear in table C-1.

Code	Meaning	Explanation of example	Duration
MD	Medical, declined	Declination of optional vaccines (not applicable to military required vaccinations).	Indefinite
MA	Medical, assumed	Prior immunization reasonably inferred from individual's past experiences (for example, basic military training), but documentation missing. Code used to avoid superfluous immunization. Code can be reversed upon further review.	Indefinite
MI	Medical, immune	Evidence of immunity (for example, by serologic antibody test); documented previous infection (for example, chickenpox infection); natural infection presumed (for example, measles, if born before 1957).	Indefinite
MP	Medical, permanent	HIV infection, prolonged or permanent immune suppression, upper age limit, other contraindication determined by physician. Can be reversed if the condition changes. For tuberculosis, positive tuberculosis test.	Indefinite
MR	Medical, reactive	Permanent restriction from receiving additional doses of a specific vaccine. Use only after severe reaction after vaccination (for example, anaphylaxis). Report such reactions to VAERS. Code can be reversed if an alternate form of prophylaxis is available. Do not code mild, transient reactions as MR. code events referred for medical consultation as MT.	Indefinite
MS	Medical, supply	Exempt due to lack of vaccine supply.	Up to 90 days
MT	Medical, temporary	Pregnancy, hospitalization, events referred for medical consultation, temporary immune suppression, convalescent leave, pending medical evaluation board, any temporary contraindication to immunization.	Up to 365 days

C-2. Administrative exemption codes

Administrative exemption codes appear in table C-2.

Code	Meaning	Explanation of example	Duration
AD	Administrative, deceased	Individual is deceased.	Indefinite
AL	Administrative, emergency leave	Individual is on emergency leave.	Up to 30 days
AM	Administrative, missing	Missing in action, prisoner of war.	Indefinite
AP	Administrative, PCS	Permanent change of station.	Up to 90 days
AR	Administrative, refusal	Personnel involved in actions under the Uniformed Code of Military Justice, religious waiver. (Indefinite and revocable. May be revoked at any time. See paragraph 2-6b(2).	Until resolution
AS	Administrative, separation	Pending discharge, separation (typically within 60 days), and retirement (typically within 180 days).	Until 180 days
AT	Administrative, temporary	Absent without leave, legal action pending (other than code AR).	Until 90 days
NR	Not required	Individuals who received immunization while eligible, subsequently changed occupational category and now serve as civilian employees or contract workers not otherwise required to be immunized.	Indefinite

Appendix D Immunizations for Military Personnel

D-1. Text citations

Paragraphs 4-2 to 4-19 provide additional information on immunizations for military personnel.

D-2. Required immunizations

This table provides a listing of required immunizations for military personnel.

Table D-1
Immunizations for military personnel

Name of vaccine	Army	Navy	Air Force	Marine Corps	Coast Guard
Adenovirus ¹	Acc ²	Acc	Acc	Acc	Acc
Anthrax	Risk	Risk	Risk	Risk	Risk
Haemophilus influenzae type b	Risk	Risk	Risk	Risk	Risk
Hepatitis A	Acc, Rou ³	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Hepatitis B	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Influenza	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Japanese encephalitis	Risk ⁴	Risk	Risk	Risk	Risk
Measles, mumps, rubella	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Meningococcal	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Pneumococcal	Risk	Risk	Risk	Risk	Risk
Poliovirus ⁵	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Rabies	Risk	Risk	Risk	Risk	Risk
Smallpox (vaccinia)	Risk	Risk	Risk	Risk	Risk
Tetanus-diphtheria (preferably with pertussis vaccine)	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Typhoid fever	Risk	Risk	Risk	Risk	Risk
Varicella	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Yellow fever	Risk	Risk	Risk	Acc, Risk	Risk

Notes:

¹ Initial entry and basic training accessions only

² Acc=accessions

³ Rou=adult routine

⁴ Risk=special, risk-based, and occupational

⁵ Refer to paragraph 4-13.

Appendix E Internal Control Evaluation Process

E-1. Function

The function covered by this checklist is immunization and chemoprophylaxis.

E-2. Purpose

The purpose of this checklist is to assist in evaluating key management controls and is not intended to address all controls. The evaluation is focused at the clinic level, regardless of Service, to include both fixed facilities (MTFs, TDA units) and TOE field units. The checklist serves as a clinical quality improvement tool and is described at <http://www.vaccines.mil/cqip>.

E-3. Instructions

Answers must be based on the actual testing of key management controls (for example, document analysis, direct observation, interviewing, sampling, or simulation). Answers that indicate deficiencies must be explained and corrective action indicated in supporting documentation. These key management controls must be formally evaluated at least once every 5 years. Certification that this evaluation has been conducted must be accomplished on DA Form 11-2-5 (Internal Control Evaluation Certification Statement).

E-4. Test questions

Test questions are available directly via a link at the Web site address in paragraph E-2, above.

E-5. Supersession

This evaluation replaces the evaluation for immunization and chemoprophylaxis previously published in AR 40-562, dated 29 September 2006.

Glossary

Section I Abbreviations

ACIP

Advisory Committee on Immunization Practices

AFI

Air Force Instruction

AFJI

Air Force Joint Instruction

ASD (HA)

Assistant Secretary of Defense (Health Affairs)

CBRN

chemical, biological, radiological, and nuclear

CDC

Centers for Disease Control and Prevention

CFR

Code of Federal Regulations

CG-11

Coast Guard, Director, Health, Safety, and Work-Life

COMDTINST

Commandant Instructions

DCJI

disposable-cartridge jet injectors

DD

Department of Defense Form

DHHS

Department of Health and Human Services

DODD

Department of Defense Directive

DODI

Department of Defense Instruction

EUA

emergency use authorization

FDA

Food and Drug Administration

G6PD

glucose-6-phosphate dehydrogenase

Hib

Haemophilus influenzae type b

HQ

headquarters

HQDA

Headquarters, Department of the Army

IND

investigational new drug

IPV

inactivated poliovirus vaccine

ITS

immunization tracking systems

JTF CapMed

Joint Task Force - National Capital Region/Medical

JEV

Japanese-encephalitis vaccine

MAJCOM

major command (Air Force)

MILVAX

Military Vaccine Office

MMR

measles, mumps, rubella

MTF

medical treatment facility

NCVIA

National Childhood Vaccine Injury Act

NVIC

National Vaccine Injury Compensation (Program)

OTUSF

other than U.S. Forces

RC

reserve component

ROTC

Reserve Officers' Training Corps

SF

Standard Form

SOP

standard operating procedure

SSN

social security number

STANAG

standardized agreement

TB

tuberculosis

Td

Tetanus-diphtheria

Tdap

Tetanus-diphtheria and acellular pertussis (vaccine)

USAMMDA

U.S. Army Medical Materiel Development Activity

USC

United States Code

USCG

United States Coast Guard

VAERS

Vaccine Adverse Events Reporting System

VIS

vaccine information statement

WHO

World Health Organization

Section II**Terms**

This section contains no entries.

Section III**Special Abbreviations and Terms****Accession**

The attainment of rank or dignity.

Alert personnel

Specified forces maintained (alert force) in a special degree of readiness.

Antigen

A substance that, when introduced into the body, stimulates the production of an antibody.

Contraindication

A factor that renders the administration of a drug or the carrying out of a medical procedure inadvisable.

Hyperendemic

Equally endemic, at a high level, in all age groups of a population.

Neisseria meningitidis

The bacteria that is the causative agent of cerebrospinal meningitis.

Plasmodia

A genus of apicomplexan protozoa, in the family Plasmodiidae parasitic, in the blood cells of animals and humans; the malarial parasite.

Primaquine

An ant malarial agent especially effective against Plasmodium vivax.

Seroimmunity

Immunity conferred by administration of an antiserum.

Serologic

The scientific study of blood serum and other bodily fluids.

Toxoid

A bacterial toxin (usually an exotoxin) whose toxicity has been weakened or suppressed either by chemical (formalin) or heat treatment, while other properties, typically immunogenicity, are maintained.

Urticaria

A skin condition characterized by intensely itching welts and caused by allergic reactions.

Variola virus

The causative agent of smallpox.



UNCLASSIFIED

PIN 000011-000

Moseley, Kimberly

From: Letcher, Kristina A CIV DODHRA DMOC (USA) <kristina.a.letcher.civ@mail.mil>
Sent: Friday, June 8, 2018 12:44 PM
To: Connolly, Steven N CIV USARMY MEDCOM BAMC (USA)
Subject: RE: Contact John Walsh ? (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

I talked to Occ Health and he can decline the Hepatitis vaccine (there is a declination form available at Occ Health). There will be no negative consequences.

Best,

Kristina A. Letcher
Attorney Advisor
BAMC OCJA
210-916-4433

This document may contain confidential information that is legally privileged under the Privacy Act, 5 USC 552(a), and/or the Health Insurance Portability and Accountability Act (PL 104-191) and its various implementing regulations. If this correspondence contains protected health information, it is being provided to you after appropriate authorization from the patient or under circumstances that do not require patient authorization. You, the recipient, are obligated to maintain it in a safe, secure and confidential manner. Unauthorized redisclosure or failure to maintain confidentiality subjects you to application of appropriate civil and criminal sanctions. If you have received this correspondence in error, destroy any copies you have made and notify the sender.

-----Original Message-----

From: Connolly, Steven N CIV USARMY MEDCOM BAMC (US)
Sent: Friday, June 8, 2018 8:40 AM
To: Letcher, Kristina A CIV USARMY MEDCOM BAMC (USA) <kristina.a.letcher.civ@mail.mil>
Subject: FW: Contact John Walsh ? (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Good Morning Kristina,

Anything new on the vaccination, see below they are asking for more, Attached is copy of the employees PD. I don't see anything about having to have Vaccination.

Respectfully

Steven N. Connolly
Chief Steward
AFGE Local 1004 -BAMC-
Phone: (210) 916-0825
Steven.n.connolly.civ@mail.mil

"I find that the Harder I work, the more luck I seem to have"
Thomas Jefferson

-----Original Message-----

From: Walsh, John M CIV USARMY MEDCOM BAMC (US)
Sent: Wednesday, June 06, 2018 8:54 AM
To: Connolly, Steven N CIV USARMY MEDCOM BAMC (US) <steven.n.connolly.civ@mail.mil>
Subject: RE: Contact John Walsh ? (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Anything yet ? OCH now wants me to take another vaccination .

John M. Walsh
Logistics Division FLO
San Antonio Military Medical Center
3851 Roger Brooke Dr.
Fort Sam Houston TX 78234
Phone 210-916-2196
Room # 713-16

-----Original Message-----

From: Connolly, Steven N CIV USARMY MEDCOM BAMC (US)
Sent: Thursday, May 31, 2018 8:09 AM
To: Walsh, John M CIV USARMY MEDCOM BAMC (US) <john.m.walsh52.civ@mail.mil>
Subject: RE: Contact John Walsh ? (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Nothing at this time!

Respectfully

Steven N. Connolly
Chief Steward
AFGE Local 1004 -BAMC-
Phone: (210) 916-0825
Steven.n.connolly.civ@mail.mil

"I find that the Harder I work, the more luck I seem to have"
Thomas Jefferson

-----Original Message-----

From: Walsh, John M CIV USARMY MEDCOM BAMC (US)
Sent: Thursday, May 31, 2018 8:05 AM
To: Connolly, Steven N CIV USARMY MEDCOM BAMC (US) <steven.n.connolly.civ@mail.mil>

Subject: RE: Contact John Walsh ? (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Have you heard anything from JAG/Logistics on this issue ?
Thanks,

John M. Walsh
Logistics Division FLO
San Antonio Military Medical Center
3851 Roger Brooke Dr.
Fort Sam Houston TX 78234
Phone 210-916-2196
Room # 713-16

-----Original Message-----

From: Walsh, John M CIV USARMY MEDCOM BAMC (US)
Sent: Wednesday, May 30, 2018 1:43 PM
To: Connolly, Steven N CIV USARMY MEDCOM BAMC (US) <steven.n.connolly.civ@mail.mil>
Subject: Contact John Walsh ? (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Steve -
If you try to reach me my voicemail is not working.
I also have an in-house cell phone 210-539-0713 Thanks,

John M. Walsh
Logistics Division FLO
San Antonio Military Medical Center
3851 Roger Brooke Dr.
Fort Sam Houston TX 78234
Phone 210-916-2196
Room # 713-16

CLASSIFICATION: UNCLASSIFIED
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CLASSIFICATION: UNCLASSIFIED
CLASSIFICATION: UNCLASSIFIED



DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

DHA-IPM 19-006
August 29, 2019

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)
DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH READINESS POLICY AND OVERSIGHT)
DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH SERVICES POLICY AND OVERSIGHT)
DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH RESOURCES MANAGEMENT AND POLICY)
ASSISTANT COMMANDANT FOR HUMAN RESOURCES,
U.S. COAST GUARD

SUBJECT: Interim Procedures Memorandum 19-006, 2019–2020 Seasonal Influenza Vaccination Program (IVP)

References: See Attachment 1.

Purpose. This Defense Health Agency-Interim Procedures Memorandum (DHA-IPM), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (o), implementing instructions, assigns responsibilities, and prescribes procedures for the seasonal influenza vaccination program.

- This DHA-IPM cancels and reissues DHA-IPM 18-005.
- This DHA-IPM is effective immediately and will expire 12 months from the date of issue.

Applicability. This DHA-IPM applies to: OSD, the Military Departments (including the Coast Guard at all times), the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the “DoD Components”)

Policy Implementation. It is DHA’s guidance, pursuant to Reference (g), that All Active Duty, Selected Reserve, and National Guard personnel are required to receive the annual seasonal influenza immunization or obtain an exemption (i.e., medical or administrative), with a goal of 90 percent immunized by January 15th of each year. The Services may indicate earlier dates for the 90% completion goal in the enclosed Service-specific appendices.

Responsibilities

- Director, DHA.
 - Review and approve requests for exceptions to this IPM.
 - Approve and submit the seasonal influenza vaccination Healthcare Personnel (HCP) compliance report to the Assistant Secretary of Defense for Health Affairs (ASD(HA)) no later than May 1, 2020.
- Secretaries of the Military Departments.
 - Will achieve 90% seasonal influenza vaccination of all military personnel no later than January 15, 2020.
 - Submit a seasonal influenza vaccination Healthcare Personnel (HCP) compliance report to DHA Immunization Healthcare Division no later than March 1, 2020.
- Director, DHA Immunization Healthcare Division (IHD).
 - Will consolidate and submit the DoD HCP seasonal influenza compliance report to Director DHA no later than April 1, 2020.

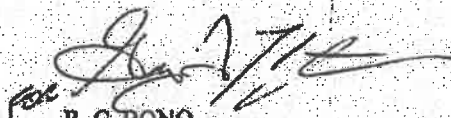
Procedures. See Attachment 2.

Forms.

- DD Form 2875, System Authorization Access Request can be found on the internet at <https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2875.pdf>.
- DHA Form 116, IHD Influenza Vaccine Screening Questions can be found on the internet at https://info.health.mil/cos/admin/DHA_Forms_Management/DHA_Forms1/DHA116_FluScreening_20190729.pdf.
- OF Form 1164, Claim for Reimbursement for Expenditures on Official Business can be found on the internet at <https://www.gsa.gov/reference/forms>.
- DA Form 3161, Request for Issue or Turn-in, can be found on the internet at <https://armypubs.army.mil/>.

DHA-IPM 19-006
August 29, 2019

Releasability. Cleared for public release. This DHA-IPM is available on the Internet from the Health.mil site at: www.health.mil/DHAPublications.



R. C. BONO
VADM, MC, USN
Director

Attachments:
As stated

cc:
Assistant Secretary of Defense for Health Affairs
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force
Medical Officer of the Marine Corps
Joint Staff Surgeon
Director of Health, Safety, and Work-Life, U.S. Coast Guard
Surgeon General of the National Guard Bureau
Director, National Capital Region

ATTACHMENT 1

REFERENCES

- (a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD(HA)),
September 30, 2013, as amended
- (b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013
- (c) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018
- (d) United States Code, Title 42, Sections 300aa-1-300aa-34
- (e) Centers for Disease Control and Prevention, "Vaccine Information Statements (VIS),
Influenza (Flu) Vaccine: Inactivated or Recombinant," August 15, 2019
- (f) Army Regulation 40-562, BUMEDINST 6230.15B, 48-110_IP, CG COMDTINST
M6230.4G, "Immunizations and Chemoprophylaxis for the Prevention of Infectious
Diseases," October 7, 2013
- (g) DoD Instruction 6205.02, "DoD Immunization Program," July 23, 2019
- (h) Medical Material Quality Control Message MMQC-19-1105, January 15, 2019
- (i) DoD Instruction 4000.19, "Support Agreements," April 25, 2013, as amended
- (j) Navy Aeromedical Reference and Waiver Guide, November 27, 2018
- (k) Official Air Force Aerospace Medicine Approved Medications, June 13, 2017
- (l) Centers for Disease Control and Prevention, "Immunization of Health-Care Personnel:
Recommendations of the Advisory Committee on Immunization Practices (ACIP),"
Morbidity and Mortality Weekly Report Recommendations and Reports,
November 25, 2011; 60(RR07); 1-45
- (m) Code of Federal Regulations, Title 5, Part 339
- (n) Coast Guard Medical Manual, COMDTINST M6000.1F, June, 2018
- (o) Coast Guard Occupational Medicine Manual, COMDTINST M6260.32

ATTACHMENT 2

PROCEDURES

1. 2019-2020 SEASONAL INFLUENZA INFORMATION

a. Influenza or “flu” has the potential to adversely impact force readiness and mission execution. The Centers for Disease Control and Prevention (CDC) estimates that influenza has resulted in between 9.2 million and 35.6 million illnesses; between 140,000 and 710,000 hospitalizations; and between 12,000 and 56,000 deaths annually since 2010 in the United States. Vaccination is the primary method for preventing influenza and its complications.

b. In accordance with Reference (f), the DoD and the Coast Guard generally follow the CDC and Advisory Committee on Immunization Practices (ACIP) vaccine recommendations, requirements, and guidance of the U.S. Food and Drug Administration (FDA), while considering the unique needs of military populations. The most current CDC and ACIP recommendations can be found at <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html>. The DoD uses only FDA-approved vaccines. Information on the DoD Seasonal IVP can be found on the Defense Health Agency-Immunization Healthcare Division (DHA-IHD) seasonal influenza website at: <https://www.health.mil/flu>.

c. The CDC and the ACIP recommend seasonal influenza vaccine for all people 6 months of age and older. Special efforts should be made to vaccinate those at high risk from influenza complications to include pregnant women, children under 5 years of age, adults 65 years and older, and those with certain medical conditions outlined in the ACIP guidelines.

d. 2019-2020 United States trivalent influenza vaccines will contain A/Brisbane/02/2018 (H1N1) pdm09-like virus, A/Kansas/14/2017 (H3N2)-like virus a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage). Quadrivalent vaccines will also include B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage). The 2019-2020 vaccine represents a change in the influenza A (H1N1) and influenza A (H3N2) virus strains. The ACIP has not expressed a preference for quadrivalent or trivalent vaccine in any age group, nor has it expressed a preference for “High-Dose” vaccine or any other licensed influenza vaccine for use in persons 65 years and older. Vaccinate all individuals with available product in accordance with the package insert. Influenza vaccinations will continue until all required personnel have received the vaccine, or the vaccine expires.

e. Additional influenza vaccine formulations, not available through the Defense Logistics Agency (DLA) bulk purchase contract (e.g., egg protein free etc.) are available for purchase through the DLA-Troop Support Medical (DLA-TSM) Direct Vendor Delivery (DVD) program, as described in paragraph 2d of Attachment 2. Clinics must contact their supply/logistics support personnel for more details.

2. ORDERING, DISTRIBUTION, AND COLD CHAIN MANAGEMENT

a. For the 2019-2020 influenza season, DoD purchased 3.3 million doses of influenza vaccine. This amount will ensure all AD and RC personnel and beneficiaries have access to protection against influenza. Additional information about ordering influenza vaccine can be found in the Service-specific appendices at the end of this DHA-IPM. Activities should expect several deliveries to fulfill requirements.

b. The following vaccines (in prefilled syringe (PFS) and multi-dose vial (MDV) presentations) have been contracted for by DoD for the 2019-2020 season:

NDC	Name	Presentation	Price/package/vial
33332-0219-20	Afluria®	PFS (0.25mL)	\$133.31
33332-0319-01	Afluria®	PFS (0.5mL)	\$133.31
33332-0419-10	Afluria®	MDV (5mL)	\$127.34
70461-0019-03	Fluad®	PFS (0.5mL)	\$373.27

c. Influenza vaccines not purchased through the annual DoD contract may be available through the DLA-TSM DVD program, via Military Standard Requisitioning and Issue Procedures (MILSTRIP). Requisitions may be submitted via the Defense Medical Logistics Standard Support (DMLSS) or via the DLA-FedMall system. Information on the DoD-FEDMALL system can be located at: <https://www.fedmall.mil/index.html> (LAIV, or Flumist® will not be available via the DVD program for the 2019 - 2020 season). Activities ordering flu vaccine via the DVD process need to coordinate their orders with their Service influenza vaccine logistics POC.

d. ECRI Institute is the primary source for all Medical Material Quality Control Message (MMQC) messages. MMQC messages will be known as Hazard Alerts and Recalls (HAR) notifications. Logistics and immunization personnel must validate or register for a current subscription for HAR notifications in accordance with Reference (h). Personnel can register at: <https://www.usamma.army.mil/Pages/MMQCMIMsgMgmt.aspx>

e. Heads of OSD Components that operate activities administering influenza vaccine will establish procedures requiring the proper storage and handling of influenza vaccines. Personnel will be present to receive and store vaccines upon arrival. These vaccines will be promptly posted in the facilities' requisition processing system.

f. To ensure proper receipt, DLA-TSM will ship vaccine to Outside Continental United States locations on Mondays and Fridays, and to Continental United States locations on Mondays, Tuesdays, and Wednesdays. DLA-TSM does not ship on holidays or weekends and will only ship on Thursdays on a case-by-case basis.

g. All vaccine shipments will include temperature monitoring devices. These items should be returned to DLA-TSM as soon as possible after receipt, per instructions included in each

vaccine shipment. All DoD activities that receive and administer influenza vaccine will use the pre-paid/pre-addressed Federal Express materials provided with shipping containers to physically return the temperature monitors to DLA-TSM.

(1) No-Alarm temperature monitors: The material is released for immediate use. Disposition is not needed from DLA-TSM, but the temperature monitor must be returned for audit purposes.

(2) Alarmed temperature monitors: Activity will segregate the vaccine in the refrigerator with a sign saying, "DO NOT USE," return temperature monitor to DLA-TSM, and await disposition instructions.

(3) Un-started or malfunctioning temperature monitors: Activity will treat the shipment as alarmed.

(4) If an activity currently has an outdated temperature monitor software package loaded on their computer, please contact DLA Troop Support for an updated version, as previous versions are not compatible with Windows 10. Also, please note if you do have the temperature monitor hardware and software, all temperature monitor data should be sent into DLA-TSM via email at: Dana.Dallas@dla.mil or nancy.collins@dla.mil. Temperature monitors that did not start or are malfunctioning should be physically returned.

h. Influenza vaccines will be stored and transported correctly within the temperature parameters of 2° to 8°C (36° to 46°F), at all times. If the vaccine is not stored correctly within the correct temperature parameters, it may lose potency. Any time a temperature compromise is suspected post receipt:

(1) The vaccine will be placed immediately in a refrigerator approved for vaccine storage and marked "DO NOT USE."

(2) Notify your DHA-IHD Immunization Healthcare Specialist (<http://health.mil/ContactYourIHS>) and complete the Potentially Compromised Vaccine/Temperature Sensitive Medical Products response worksheet, dated on or after August 1, 2019, located on the DHA-IHD website at: <http://www.health.mil/coldchain>. The worksheet must be submitted online to DLA-TSM, United States Army Medical Materiel Agency-Distribution Operations Center (USAMMA-DOC), and to your local medical logistics directorate.

(3) Do not assume the vaccine is unusable, and do not discard potentially compromised vaccine(s) until directed by DLA-TSM and/or USAMMA-DOC.

i. All DoD Components, Coast Guard activities, as well as other organizations eligible to participate in DLA-TSM's Pharmaceutical Prime Vendor programs, will participate in the DLA-TSM Pharmaceutical Reverse Distribution Program for returning unused, expired, and/or compromised influenza vaccines, at the end of the season, June 30, 2020. This program provides a safe option for the disposal of unused, expired, and/or compromised influenza vaccines while

maintaining full compliance with Federal regulations DoD activities should make every effort to return influenza vaccine in its original box. Pharmacies or logistics activities can provide more guidance on the use of this program.

3. VACCINE ADMINISTRATION

a. In accordance with Reference (f), only appropriately trained and qualified medical personnel working within their scope of practice, upon the order (including standing orders) of an appropriately privileged healthcare provider, will administer the influenza vaccine.

b. The DHA-IHD will provide online training modules via Joint Knowledge Online, which will include patient screening, documentation, administration, and cold chain management procedures. The 2-hour Seasonal Influenza Vaccination Training (DHA-US069) and 1-hour Seasonal Influenza Vaccine Cold Chain Management for Logistical Personnel (DHA-US070) can be found at: <https://jkosupport.jten.mil/Atlas2/page/login/Login.jsf>. This online training may be incorporated into local or regional training programs.

c. Prior to vaccination, all potential vaccine recipients will be screened utilizing locally-approved or current standardized screening questions available via DHA-IHD website (DHA Form 116). In accordance with Reference (e), individuals receiving a vaccine will be provided the current influenza Vaccine Information Statement (VIS) for inactivated or recombinant injectable influenza vaccines. When minors are vaccinated, the VIS will be provided to their legal representative.

d. When vaccinating persons with a history of egg allergy immunization personnel should refer to the current ACIP Recommendations for the Prevention and Control of Seasonal Influenza <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html>. Persons with a history of egg allergy of any severity may receive any licensed, recommended, and age-appropriate influenza vaccine (IIV, RIV4, or LAIV4) in accordance with the ACIP Recommendations. The selected vaccine should be administered in an inpatient or outpatient medical setting and be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

e. Patients reporting an allergic reaction to an excipient of the influenza vaccine (example: neomycin) should be referred to an allergist/immunologist for further evaluation and to identify risk of reaction to other vaccines with similar excipients. The Medical Temporary (MT) exemption code should be entered into the Service-specific Immunization Tracking System (ITS) when vaccination is deferred in these cases.

4. DOCUMENTATION

a. Documentation of immunization is required in the appropriate Service-specific ITS: Medical Protection System for Army, Medical Readiness Reporting System (MRRS) for Navy, Marine Corps, and Coast Guard, and Aeromedical Services Information Management System

(ASIMS) for the Air Force, in accordance with Reference (f). When documenting immunizations in the Armed Forces Health Longitudinal Technology Application (AHLTA), the immunization module will be used. For locations that have transitioned from AHLTA to Military Health System (MHS) GENESIS, influenza immunizations will be documented in MHS GENESIS, and the data will transfer to the Service-specific ITS.

b. In accordance with Reference (d), proper documentation of an immunization includes: patient identification, date vaccine was administered; vaccine name or CVX code, manufacturer and lot number, dose administered, route of administration, anatomic site of vaccination, date the VIS was provided; and VIS version date.

c. Due to the number of vaccine products available each year, staff should verify all product names and CVX codes before documentation. CVX codes 15 (influenza, split), 16 (influenza, whole), 111 (influenza, live, intranasal), and 153 (influenza, MDCK, PF) are inactive and should NOT be used to document vaccines administered this season. CVX code 88 (influenza unspecified) should be used for historical documentation only when vaccine specifics are not known. The CVX codes for the DoD purchase 2019-2020 vaccine include:

(1) CVX Code 150: For documenting single dose, injectable quadrivalent, preservative free (Afluria® pre-filled syringes).

(2) CVX code 158: For documenting multi-dose injectable, quadrivalent, containing preservative (Afluria® multi-dose vials).

(3) CVX code 161: For documenting single dose, injectable quadrivalent, preservative free, pediatric (Afluria® pre-filled syringes).

(4) CVX code 168: For documenting single dose, seasonal trivalent influenza vaccine, adjuvanted, preservative free (Fluad® multi-dose vials).

d. AD and RC personnel who receive influenza vaccinations from non-military facilities will provide immunization data to their unit's ITS point of contact for transcription no later than close of business the next duty day (next drill weekend/battle assembly for RC members), following the immunization. All available information should be transcribed into the ITS. Contract providers will document immunization information, as noted in Section 4.b., into the ITS at the time of immunization delivery. Personnel who receive the seasonal influenza vaccine through the Reserve Health Readiness Program (RHRP) may not (or do not) need to provide immunization data directly to their unit's ITS point of contact; the RHRP contractor will update the ITS.

e. Do not use exemption codes "Medical, immune (MI)," "Medical, assumed (MA)," "Medical, declined (MD)," "Not required (NR)," "Medical, permanent (MP)," or "Medical, reactive (MR)" to defer seasonal influenza vaccinations for military personnel. Due to the variety of influenza vaccines available each year and scientific evidence providing options for

those individuals previously identified as having a contraindication to influenza vaccine, the risk/benefit of influenza vaccine should be reviewed on an annual basis by a treating physician. The MT exemption code should have an expiration date of no later than June 30, 2020.

5. ADVERSE EVENTS

a. Local swelling, soreness at the injection site, and headache are common side effects that are self-limiting, resolve quickly, and do not constitute an allergic reaction. Soreness at the immunization site lasting up to 2 days, fever, malaise, myalgia, and other systemic symptoms may occur. These begin 6 - 12 hours after immunization and can persist for 1 - 2 days. Immediate allergic reactions including hives, angioedema, allergic asthma, and systemic anaphylaxis are rare.

b. All suspected serious or unexpected vaccine-related adverse events (e.g., events resulting in hospitalization, life-threatening events, one or more duty shifts lost due to illness, or an event related to suspected contamination of a vaccine vial) must be reported through the Vaccine Adverse Event Reporting System at: <https://vaers.hhs.gov/reportevent.html>. The DHA-IHD Immunization Healthcare Support Center is available at: 1-877-GET-VACC (1-877-438-8222) to answer questions regarding vaccine screening and potential vaccine-related adverse events.

6. INFLUENZA VACCINATION REQUIREMENTS AND RECOMMENDATIONS

a. Annual influenza vaccination is mandatory for all Active and RC members, in accordance with Reference (g), and Service-specific guidance (see Appendices 1 through 4). Exemptions can be granted on a case-by-case basis for medical or administrative reasons in accordance with Reference (f).

b. ~~Influenza vaccination is a required condition of employment for all civilian HCP,~~ as identified by the CDC, all paid and unpaid persons working in healthcare settings who have the potential for exposure to patients or to infectious materials; including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP include both persons who provide direct or indirect care to patients and those not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from other HCP and patients, in accordance with References (g) and (n).

(1) Service points of contact (POCs) will provide Service-level civilian HCP compliance reports to DHA-IHD no later than 1 Mar 2020, including the total number of the following: HCPs, HCPs immunized, and medical and administrative exemptions.

(2) The DHA-IHD will provide the Director, DHA with a consolidated annual report detailing DoD HCP influenza immunization compliance no later than April 1, 2020.

c. Activities should advise all DoD civilian employees that the influenza vaccination is available without cost or copay as a benefit of the Federal Employee Health Benefit program.

d. Activities are authorized to use DoD purchased influenza vaccine for the immunization of:

- (1) Active/RC members;
- (2) DoD beneficiaries;
- (3) Contracted HCPs in accordance with the terms of their contract;
- (4) DoD civilian personnel who are employed under the Defense Health Program (DHP). (DHP-funded civilian employees provide for the delivery of medical and dental care to DoD Service members and beneficiaries); and
- (5) Non-DHP-funded DoD civilian personnel (including DoD Education Activity and Non-Appropriated Fund (NAF) employees), on a reimbursable basis.

(a) Activities may waive reimbursement, in accordance with Reference (j), if it is determined the reimbursement process would be impractical or prohibitively expensive.

(b) Activities may direct specific limitations associated with the vaccination of non-DHP-funded employees (e.g., only at mass vaccination events or during set times).

7. RESOURCES. The Influenza Resource Center located on the DHA-IHD website (<http://www.health.mil/flu>) contains templates and additional documents for the management of the Seasonal IVP to include standing orders, dosing algorithms, vaccine cold chain management tools, and vaccine product guides. Product package inserts (e.g., ACIP guidelines, Service policies, and other references) to support the Seasonal IVP are posted on the website upon publication.

8. QUESTIONS. For DoD Seasonal IVP questions, please contact the DHA-IHD at: 1-877-GET-VACC (1-877-438-8222), or via email at: DoDVaccines@mail.mil.

APPENDIX 1

ARMY

1. VACCINE ORDERING AND DISTRIBUTION

a. USAMMA-DOC is the Army's inventory control point for the influenza vaccine which is an Acquisition Advice Code Service regulated item. DLA contracts with manufacturers, acquires the vaccine, and distributes it to activities based on the priorities submitted to them by USAMMA. USAMMA follows all requisitions until they are fulfilled. USAMMA-DOC will notify units of the quantities ordered and the document numbers being used when vaccine is being shipped. Additional quantities required must be coordinated with USAMMA-DOC, Defense Switched Network (DSN) 343-4128/4318, Commercial (301) 619-4128/4318.

b. Questions or concerns, including ordering influenza vaccines which are not centrally contracted by DoD should be directed to USAMMA-DOC: Email: usarmy.detrick.medcom-usamma.mbx.vaccines@mail.mil; Commercial: (301) 619-4128/4318; DSN: 343-4128/4318; Fax: (301) 619-4468, or call the after-hour number at (301) 676-1184.

2. FUNCTIONAL CONSIDERATIONS

a. All locations will initiate seasonal immunization operations upon receipt of influenza vaccine in accordance with national guidelines as outlined in the most recent ACIP recommendations on the Prevention and Control of Influenza, <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html>.

b. Exemptions for civilian employees based on the need for accommodation will be documented in the Civilian Employee Medical Record (CEMR).

c. Logistics personnel will verify their DoD Activity Address Code with the Army Influenza Manager at USAMMA-DOC prior to the start of the influenza vaccine season.

d. Organizations/units will report vaccine loss and destruction. Complete and submit DA Form 3161 and an Executive Summary for any influenza vaccine that is lost or destroyed in excess of one percent of the total order received (due to expiration, validated compromise due to temperature excursion, or other reasons requiring destruction). Completion of the loss/destruction report is a cost-saving tool that aids in assessing program vaccine requirements. Please submit both the completed DA Form 3161 and Executive Summary to usarmy.detrick.medcom-usamma.mbx.vaccines@mail.mil (email subject: "Influenza Loss and Destruction Report").

e. Regional Health Commands (RHCs) will submit civilian HCP compliance reports to the Deputy Chief of Staff-Public Health, Public Health Directorate, no later than February 1, 2020, using the following format:

RHC Name	Total # of mandatory HCP	Total # of mandatory HCP vaccinated	Total # of mandatory HCP with exemptions
RHC (X)	0	0	0

f. Civilian employees who choose to receive an influenza vaccine outside of an MTF or Army occupational health clinic may bring vaccination documentation to the occupational health clinic to be filed in their CEMR.

3. INFLUENZA VACCINATION REQUIREMENTS AND RECOMMENDATIONS

a. To maximize force medical readiness prior to peak influenza season, the Army seasonal influenza vaccination goal will remain to exceed 90% immunization of all Active and RC personnel no later than January 15, 2020.

b. To increase efforts to protect the workforce, patients, and beneficiaries, all MTF personnel should receive influenza immunization, with the exception of those medically or administratively exempt. Medical exemptions will be validated by a healthcare provider and documented in the Medical Protection System, AHLTA, MHS-GENESIS, and the CEMR as appropriate. An exemption excusing a healthcare worker from a mandatory vaccination may impose additional infection control practices on the worker as a result, such as wearing a mask. While an employer may not impose such practices for discriminatory or retaliatory reasons, the employer may do so for legitimate, non-discriminatory, and non-retaliatory reasons.

c. ~~Influenza vaccination is a required condition of employment for all civilian HCP.~~ HCP are identified by the CDC as all paid and unpaid persons working in healthcare settings who have the potential for exposure to patients or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care, but potentially exposed to infectious agents that can be transmitted to and from HCP and patients in accordance with References (f), (g), and (m). For contracted employees and those participating in healthcare-related activities with the American Red Cross, this requirement is to be specified in the respective employee contract and/or participation agreement. For DoD civilian (Title 5) employees, participation in this immunization program is a condition of employment under 5 CFR 339, but participation does not confer a requirement for a medical qualification examination beyond what is dictated by the immunization itself.

d. Activities are authorized to use DoD purchased influenza vaccine for the immunization of: DoD civilian Appropriated Funded personnel who are employed under the DHP; Non-DHP-funded DoD civilian personnel (including DoD Education Activity and NAF employees), on a reimbursable basis; and contracted HCPs in accordance with the terms of their contract.

August 29, 2019

e. Activities should advise all DoD AF civilian employees that the influenza vaccination is available without cost or copay as a benefit of the Federal Employee Health Benefit program. Activities may waive reimbursement for NAF personnel, in accordance with Reference (i), if it is determined that the reimbursement process would be impractical or prohibitively expensive. Additionally, activities may direct specific limitations associated with the vaccination of non-DHP-funded NAF employees (e.g., only at mass vaccination events or during set times).

APPENDIX 2

NAVY

1. VACCINE ORDERING AND DISTRIBUTION

a. The Naval Medical Logistics Command (NAVMEDLOGCOM) is responsible for ordering and distributing influenza vaccine for all Navy and Marine Corps activities. Additional quantities required must be coordinated with the NAVMEDLOGCOM Influenza Vaccine Manager, Ms. Barbra Rosenthal, e-mail: barbra.r.rosenthal.civ@mail.mil, Commercial: (301) 619-8054, DSN: 343-8054 or the Vaccine Information and Logistics System (VIALS) helpdesk at: usn.detrick.navmedlogcomftdmd.list.vialhelp@mail.mil.

b. VIALS is the online requisition system for seasonal influenza vaccines. VIALS is used to electronically track requisitioned vaccines via Military Standard Requisitioning and Issuing Procedures and simplify vaccine requisitions to enable electronic tracking of vaccine orders from requisition to receipt. Activities submit requirements into VIALS found at: https://gov_only.nmlc.med.navy.mil/int_code03/vials/.

c. Navy influenza vaccine is batch-ordered by NAVMEDLOGCOM from the DLA using command requirements in VIALS. Navy influenza vaccine is centrally funded.

d. Questions or concerns, including ordering influenza vaccines which are not centrally contracted by DoD, should be directed to the Navy Influenza Vaccine Manager noted above in paragraph 1a of appendix 2.

2. FUNCTIONAL CONSIDERATIONS

a. Personnel in an active flying status will observe the grounding period guidance provided in Section 18.5 of Reference (j).

b. Service members in an active diving status are authorized to receive intranasal vaccine; however, injectable vaccine remains the preferred vaccine.

b. Previous influenza seasons have been used to exercise and evaluate mass vaccination scenarios. These coordinated mass vaccination campaigns provide rapid and efficient vaccinations to protect the maximum number of susceptible persons. Based on lessons learned, process improvements are made to delivery and reporting procedures.

c. Vaccination administration compliance will be monitored via MRRS. Designated command personnel will access MRRS to track their personnel to ensure compliance. Shore-based commands will request access to MRRS based on their unit identification code by calling the MRRS program office at the number below. Ship-based commands may utilize Navy Medicine Online or the Shipboard Non-Tactical Automated Data Processing Program Automated

Medical System (SAMS) to populate MRRS. All commands requesting MRRS access must submit a DD Form 2875, System Access Authorization Request (SAAR). MRRS can be accessed at: <https://mrrs.dc3n.navy.mil/mrrs> (note: MRRS web address is case sensitive). Point of contact/MRRS program office/email: mrrspo@navy.mil / (800) 537-4617 / (504) 697-7070 / DSN: 647-7070.

3. INFLUENZA VACCINATION REQUIREMENTS AND RECOMMENDATIONS

a. In order to maximize force medical readiness before peak influenza season, the Navy's seasonal influenza vaccination goal will remain to exceed 90 percent immunization of all active and reserve component personnel by December 15, 2019.

b. Mandatory influenza vaccination is a condition of employment for all civilian HCPs providing direct patient care in a DoD MTF, per Reference (g). Influenza vaccination is mandatory for all civilians where it is written in their position description as a condition of employment. Other Navy civilian personnel are highly encouraged to receive influenza vaccinations.

APPENDIX 3

AIR FORCE

1. VACCINE ORDERING AND DISTRIBUTION

a. The Air Force Medical Readiness Agency (AFMRA) Medical Force Health Protection Manpower Equipment Force Package (AFMRA/SG4M) is responsible for ordering and distributing influenza vaccine for Air Force activities. AFMRA/SG4M will manage the influenza program utilizing the Air Force Vaccine Application located on the medical logistics website (<https://medlog.us.af.mil/apps/vaccine/>). Units will monitor and track the quantities ordered, and document transportation tracking numbers being used. Additional quantities required must be coordinated with AFMRA/SG4M, DSN 343-4183, Commercial (301) 619-4183.

b. Questions or concerns, including ordering of influenza vaccines which are not centrally contracted by DoD should be directed to: usaf.detrick.afmoa.mbx.sgm-readiness-vaccines@mail.mil

Alternatively, you may contact:

TSgt Ezequiel Villarreal Jr.: ezequiel.villarreal.mil@mail.mil, Commercial: (301) 619-9688; DSN: (312) 343-9688; Fax: (301) 619-2557

Mr. Scotti Smith via email at: scotti.j.smith.civ@mail.mil, Commercial: (301) 619-4183; DSN: 343-4183.

2. VACCINATION PROGRAM REQUIREMENTS

a. In order to maximize force medical readiness before peak influenza season, the Air Force goal is to immunize greater than 90% of all Active and RC personnel by December 15, 2019. Air Force personnel who are required to receive flu vaccine will become due (yellow) in ASIMS on September 1, 2019, and overdue (red) on December 15, 2019.

b. All civilian HCP will be immunized annually against influenza virus in accordance with recommendations of the CDC and the ACIP. Public health personnel will ensure Medical Employee Health Program employees at their installations are marked 'Required' for influenza vaccine, in ASIMS.

c. MTFs will begin vaccinating immediately on receipt of vaccine. Do not stockpile vaccine in anticipation of a mass-vaccination exercise; this results in missed opportunities for immunization, end-of-season vaccine waste, and unprotected beneficiaries.

d. Aeromedical impact: Adverse reactions are rare. Access to medical care on the ground is recommended for a period of 4 hours for all personnel, unless operational needs dictate otherwise (Reference (k)).

APPENDIX 4

COAST GUARD

1. VACCINE ORDERING AND DISTRIBUTION

a. The Health, Safety, and Work-Life Service Center (HSWL SC) is responsible for ordering and monitoring influenza vaccine distribution to Coast Guard units. The HSWL SC will notify unit POC of forthcoming shipments that will include estimated quantity, date of arrival, and tracking number supplied by DLA. The receiving unit point of contact will contact the HSWL SC upon receipt of shipment to verify the quantity received and the status of the alarm.

b. For questions or concerns about ordering, distribution, and the receipt of influenza vaccine, the HSWL SC contact is CAPT Daniel Hasenfang, daniel.l.hasenfang@uscg.mil Office: 757-628-4331 Cell: 757-615-2138.

2. FUNCTIONAL CONSIDERATIONS

a. Influenza vaccination is mandatory for all Coast Guard AD and Selected Reserve personnel to ensure force medical readiness and avoid disruption of Coast Guard missions. In accordance with References (f), (n), and (o), the seasonal influenza vaccine is also mandatory for Child Development Services personnel (including certified Family Child Care Providers); civilian, contract, and Auxiliary HCP who provide direct patient care; and recreation personnel in the youth programs at Borinquen, Cape Cod, Kodiak, and Petaluma.

b. Influenza vaccinations are available at Coast Guard clinics for AD personnel and for Auxiliary healthcare personnel assigned to Coast Guard clinics. Contract personnel will obtain the flu vaccine according to the terms of their contract.

c. Remotely located AD and Selected Reserve personnel may receive their influenza vaccination via the RHRP through an RHRP contracted clinic or the RHRP Walgreens Walk-In option. Personnel desiring to use RHRP for their influenza vaccination must request an order from the Coast Guard clinic responsible for their unit; a list can be found at: https://www.reserve.uscg.mil/Portals/2/Documents/PDF/HSWL_HRC_list_SELRES%232.pdf?ver=2018-08-17-135417-933. The RHRP contractor will ensure the vaccination is properly recorded in MRRS.

d. Coast Guard civilian employees enrolled in the Federal Employees Health Benefits Program (FEHBP) can be immunized through their health plan at no out-of-pocket cost. Many FEHBP health plans make the influenza vaccine available in pharmacies and other convenient community locations. Coast Guard civilian employees who are not insured through the FEHBP and who are required to be immunized against influenza shall complete OF Form 1164, to obtain reimbursement from COMDT (CG-832). Ms. Regina Cash and Mr. Felix Edozie are the COMDT (CG-832)

August 29, 2019

POCs regarding the reimbursement process. Civilian employees who are required to have the influenza vaccine must provide the following information to the cognizant clinic administrator no later than January 15, 2020: the date the vaccine was administered, vaccine name or code, manufacturer and lot number, dose administered, route and anatomic site of vaccination, date the VIS was provided, and VIS version date.

e. NAF employees should obtain the influenza vaccination through their NAF health insurance or other health insurance coverage available. Those employees who are not part of the NAF health benefits plan and are mandated to obtain the influenza vaccine may complete OF Form 1164, and submit the form and the immunization receipt to their supervisors for approval and submission to Ms. Virginia Cameron, Human Resources Director in the Community Services Command, for payment. NAF employees who are required to have the influenza vaccine must provide appropriate documentation as described in Paragraph 2.d of Appendix 4 to their supervisor no later than January 15, 2020.

APPENDIX 5

TRANSITIONAL INTERMEDIATE MANAGEMENT ORGANIZATION

1. VACCINE ORDERING AND DISTRIBUTION

a. DLA contracts with manufacturers, acquires the influenza vaccine, and distributes it to activities based on the priorities submitted to them by the Service immunization logistics POCs. tIMO MTFs should refer to their regular logistics POCs when requesting influenza vaccine. Your POC will follow all requisitions until they are fulfilled. The POC will notify units of the quantities ordered and the document numbers being used when vaccine is being shipped. Additional quantities required must be coordinated with your POC.

b. Questions or concerns, including ordering influenza vaccines which are not centrally contracted by DoD should be directed to your POC. Logistics POC contact information is located in the other Service specific appendices in this IPM.

2. FUNCTIONAL CONSIDERATIONS

a. All locations will initiate seasonal immunization operations upon receipt of influenza vaccine in accordance with national guidelines as outlined in the most recent ACIP recommendations on the Prevention and Control of Influenza, <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/flu.html>.

b. Organizations/units will report vaccine loss and destruction IAW paragraph 2(i) in attachment 2.

3. INFLUENZA VACCINATION REQUIREMENTS AND RECOMMENDATIONS

a. In order to maximize force medical readiness before peak influenza season, the DHA MTF seasonal influenza vaccination goal will remain to exceed 90 percent immunization of all active and reserve component personnel by December 15, 2019.

b. All civilian HCP will be immunized annually against influenza virus in accordance with recommendations of the CDC and the ACIP. Local bargaining obligations should be satisfied when indicated.

c. The DHA endorses the CDC's definition of HCP found in Reference (m) in which HCPs are defined as "all paid and unpaid persons working in health-care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP might include (but are not limited to); physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel,

pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers), not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients.”

APPENDIX 6

INFLUENZA VACCINE PRODUCT LIST AND AGE GROUPS—UNITED STATES
2019–2020

Influenza Vaccine Product List and Age Groups — United States, 2019–2020 Season*
 *DOD contracted vaccines are highlighted in yellow; †Direct Vendor Delivery (DVD) available vaccines are highlighted in orange;

Manufacturer	Trade Name (Vaccine abbreviation) [†]	NDC	Presentation	Mercury (thimerosal) mg/0.5 ml	Ovalbumin mg/0.5 ml	Age Group	CVX	CPT
Seqirus, Inc.	Afluria [®] (IV4)	33332-0319-20	0.25 mL single-dose syringe	0	<0.5	6-35 mos	161	90685
		33332-0319-01	0.5 mL single-dose syringe	0	<1	≥ 3 yrs	150	90686
		33332-0419-10	5 mL multi-dose vial (0.25 mL dose) [†]	12.25	<0.5	6-35 mos	158	90687
	33332-0419-10	5 mL multi-dose vial (0.5 mL dose) [†]	24.5	<1	≥ 3 yrs	158	90688	
GlaxoSmithKline	Flucelvax [®] (IV3)	70461-0019-03	0.5 mL single-dose syringe	0	<0.4	≥ 65 yrs	168	90653
		70461-0319-03	0.5 mL single-dose syringe	0	††	≥ 4 yrs	177	90674
	Flucelvax [®] (IV4)	70461-0419-10	5 mL multi-dose vial	25	††	≥ 6 mos	186	90756
		19515-0906-52	0.5 mL single-dose syringe [†]	0	<0.05	≥ 6 mos	150	90686
Sanofi Pasteur, Inc.	Fluzone [®] (IV4)	19515-0897-11	5 mL multi-dose vial [†]	<25	<0.3	≥ 6 mos	158	90688
		49281-0519-25	0.25 mL single-dose syringe [†]	0	§§	6-35 mos	161	90685
	Fluzone [®] (IV4)	49281-0419-50	0.5 mL single-dose syringe [†]	0	§§	≥ 6 mos	150	90686
		49281-0419-10	0.5 mL single-dose vial	0	§§	6-35 mos	158	90687
Protein Sciences Corp.	Fluzone [®] High-Dose [†] (H3-H4)	49281-0631-15	5 mL multi-dose vial (0.25 mL dose)	12.5	§§	≥ 6 mos	158	90687
		49281-0631-15	5 mL multi-dose vial (0.5 mL dose)	25	§§	≥ 6 mos	158	90688
	FluMist [®] (LAIV4)	49281-0719-10	0.5 mL single-dose syringe	0	§§	≥ 65 yrs	135	90662
		66019-0306-10	0.2 mL single-use intranasal sprayer	0	<0.024	2-49 yrs	149	90672

1. Check the Food and Drug Administration prescribing information for 2019-2020 seasonal influenza vaccines at www.fda.gov/Biologics/Blood/BloodProducts/Products/default.htm for the most complete and up-to-date information, including (but not limited to) indications, contraindications, warnings, and precautions.
 2. IV3 (IV4) is egg-based trivalent/quadrivalent inactivated influenza vaccine (injectable); where necessary to refer to cell culture-based vaccine, the prefix "cc" is used (e.g., ccIV3); IV4 is quadrivalent recombinant hemagglutinin influenza vaccine (injectable); all/3 = adjuvanted trivalent inactivated influenza vaccine.
 3. Fluzone[®] (IV4) and Fluzone[®] (IV3) 0.5 mL dose is the same for adults and pediatric.
 4. Once the stoppers of the Afluria[®] and Fluzone[®] multi-dose vials are pierced the vial must be discarded within 28 days.
 5. Afluria[®] is licensed for administration by Pharmed[®] Stratix[®] Needle-Free Injection System for persons aged 18 through 64 years only.
 6. Fluzone[®] Quadrivalent is licensed for persons 6 months of age and older. Persons 6 to 35 months of age can receive either the 0.25 mL or the 0.5 mL dose.
 7. Fluad[®] includes the MF59C.1 adjuvant (MF59[®]), a squalene based oil-in-water emulsion.
 8. Trivalent inactivated vaccine high-dose: a 0.5-mL dose contains 60 µg of each vaccine antigen (180 µg total).
 9. Recommendation of the CDC's Advisory Committee on Immunization Practices (ACIP) for the 2019-2020 influenza season, providers may choose to administer any licensed, age-appropriate influenza vaccine (IV, recombinant influenza vaccine (RIV), or LAIV4). No preference is expressed for any influenza vaccine product.
 †† Flucelvax[®] Quadrivalent was manufactured for the 2019-2020 influenza season using cell-based candidate vaccine virus (CVV) for all four influenza strains recommended by the World Health Organization (WHO); and is considered an egg-free product.
 §§ Available upon request from: Sanofi Pasteur (1-800-822-2465 or usmail@sanofipasteur.com).
 * Direct Vendor Delivery (DVD) vaccines are available for purchase by Medical Treatment Facilities. Refer to the 2019-2020 Seasonal Influenza DHA-IPM for information on the ordering process.

GLOSSARY

ABBREVIATIONS AND ACRONYMS

ACIP	Advisory Committee on Immunization Practices
AD	Active Duty
AFMRA	Air Force Medical Readiness Agency
AHLTA	Armed Forces Health Longitudinal Technology Application
ASIMS	Aeromedical Services Information Management System
CDC	Centers for Disease Control and Prevention
CEMR	Civilian Employee Medical Record
DHA	Defense Health Agency
DHA-IHD	Defense Health Agency-Immunization Healthcare Division
DHA-IPM	Defense Health Agency-Interim Procedures Memorandum
DHP	Defense Health Program
DLA	Defense Logistics Agency
DLA-TSM	Defense Logistics Agency-Troop Support Medical
DSN	Defense Switched Network
DVD	Direct Vendor Delivery
FDA	U.S. Food and Drug Administration
FEHBP	Federal Employees Health Benefits Program
HAR	Hazard Alerts and Recalls
HCP	healthcare personnel
HSWL SC	Health, Safety, and Work-Life Service Center
ITS	Immunization Tracking System
IVP	Influenza Vaccination Program
MA	Medical, assumed
MDV	multi-dose vial
MHS	Military Health System
MI	Medical, immune
MMQC	Medical Material Quality Control Message
MP	Medical, permanent
MR	Medical, reactive
MRRS	Medical Readiness Reporting System
MT	Medical, temporary
MTF	Military Medical Treatment Facility
NAF	Non-Appropriated Fund
NAVMEDLOGCOM	Naval Medical Logistics Command

NR	Not required
PFS POC	prefilled syringe points of contact
RC RHC RHRP	Reserve Component Regional Health Command Reserve Health Readiness Program
USAMMA-DOC	United States Army Medical Materiel Agency-Distribution Operations Center
VIALS VIS	Vaccine Information and Logistics System Vaccine Information Statement