

# Exhibit 4



## DoD INSTRUCTION 6205.02

### DoD IMMUNIZATION PROGRAM

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**Originating Component:** Office of the Under Secretary of Defense for Personnel and Readiness

**Effective:** July 23, 2019

**Releasability:** Cleared for public release. Available on the Directives Division Website at <https://www.esd.whs.mil/DD>

**Incorporates and Cancels:** DoD Directive 6205.02E, "Policy and Program for Immunizations to Protect the Health of Service Members and Military Beneficiaries," September 19, 2006

DoD Directive 6205.3, "DoD Immunization Program for Biological Warfare Defense," November 26, 1993

DoD Instruction 6205.4, "Immunization of Other Than U.S. Forces (OTUSF) for Biological Warfare Defense," April 14, 2000

**Approved by:** James N. Stewart, Assistant Secretary of Defense for Manpower and Readiness, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

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**Purpose:** In accordance with the authority in DoD Directive (DoDD) 5124.02, this issuance:

- Establishes policy, assigns responsibilities, and provides procedures to establish a uniform DoD immunization program, in accordance with the authority in DoDD 6200.04 and DoD Instruction (DoDI) 1010.10.
- Reflects the cancellation of the Secretary of the Army as the DoD Executive Agent for the DoD Immunization Program, including the functions of the former Military Vaccine Agency, in accordance with the July 9, 2014 Deputy Secretary of Defense Memorandum.

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## **SECTION 1: GENERAL ISSUANCE INFORMATION**

### **1.1. APPLICABILITY.** This issuance applies to:

a. 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 (CJCS) and the Joint Staff, the Combatant Commands (CCMDs), 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”).

b. DoD Immunization Program support to other than U.S. forces (OTUSF) in regions designated as high-threat by the CJCS in consultation with the geographic Combatant Commanders (CCDRs) and the Director, Defense Intelligence Agency.

### **1.2. POLICY.** It is DoD policy that:

a. All DoD personnel and other beneficiaries required or eligible to receive immunizations will be offered immunizations in accordance with recommendations from the Centers for Disease Control and Prevention and its Advisory Committee on Immunization Practices.

b. All health-care personnel (HCP) working in DoD medical treatment facilities are required to receive the annual seasonal influenza immunization or obtain an exemption (i.e., medical or administrative). During an outbreak, pandemic influenza immunizations will be required or recommended for HCP, as appropriate, depending on the immunization’s regulatory status at the time of the outbreak. Pandemic influenza immunization is an additional requirement or recommendation during an outbreak, regardless of seasonal influenza immunization status.

(1) The Military Health System (MHS) will provide influenza vaccines for DoD employees and volunteers who are eligible for medical care in the MHS and for OTUSF as approved or directed by the Secretary of Defense.

(2) For HCP working under contract to any DoD Component, seasonal influenza immunizations may be provided by the DoD medical treatment facilities, if stated in the contract agreement. Otherwise, contracting companies will provide influenza vaccines to their employees.

c. All Active Duty and Selected Reserve (including 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. During an outbreak, pandemic influenza immunizations will be required or recommended as appropriate, depending on the immunization’s regulatory status at the time of the outbreak.

d. As part of the total force, DoD civilian employees are highly encouraged to receive the annual seasonal influenza vaccine.

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e. Designated at-risk individuals among the total force and other eligible beneficiaries will be provided the best available immunizations against biological hazards; infectious diseases of military or national importance; and other health threats.

(1) The DoD Components will make preferential use of immunizations approved by the U.S. Food and Drug Administration (FDA) and, when applicable, recommended by the Advisory Committee on Immunization Practices for their intended use, when available, to provide the needed medical protection.

(2) Under certain circumstances, the DoD may administer medical products for force health protection purposes that are not FDA-approved, or not approved for the particular use involved, in accordance with DoDI 6200.02.

(3) Smallpox and anthrax immunizations, when used as a force health protection measure, are restricted to DoD personnel or groups identified by the Office of the Secretary of Defense, in consultation with the CJCS, the Under Secretary of Defense for Intelligence, and the geographic CCDRs. This identification is based on information received from the CJCS, in consultation with the DoD Components.

(4) When there is a threatened or actual use of biological warfare agents, or naturally occurring infectious diseases of military or national significance, geographic CCDRs, in consultation with the CJCS, will recommend to the Secretary of Defense immunization requirements for OTUSF category 1-3 personnel. Coordination with the Secretary of State is required before providing immunization to OTUSF category 4 personnel.

## SECTION 2: RESPONSIBILITIES

**2.1. ASD(HA).** Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness (USD(P&R)), and in accordance with DoDD 5136.01, the ASD(HA):

a. Serves as the principal advisor to the Secretary of Defense and the USD(P&R) for all DoD health policies, programs, and force health protection activities.

b. Oversees the DoD Immunization Program and addresses requests from the DoD Component heads for changes to guidance or exceptions via the procedures in Section 3.

c. In coordination with the Under Secretary of Defense for Policy (USD(P)) and the General Counsel of the Department of Defense, recommends the initiation, modification, or termination of immunizations for deliberately released biological agents or naturally occurring infectious diseases of military or national importance beyond CCMD-defined requirements and associated Service-specific implementation plans to the Secretary of Defense. Depending on the scope of the intended changes to immunization activities against such health threats, and in coordination with the Office of the General Counsel of the Department of Defense, the ASD(HA) may recommend the approval be made by the USD(P&R) or the Secretary of Defense.

**2.2. DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS POLICY AND OVERSIGHT (DASD(HRP&O)).** Under the authority, direction, and control of the ASD(HA), the DASD(HRP&O):

a. Identifies the military-unique clinical needs for immunization-related medical products against deliberately released biological agents and naturally occurring infectious disease threats that impact force health protection, in coordination with the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD(NCB)), in accordance with DoDD 6200.04 and DoDD 5160.05E.

b. Reviews, evaluates, and provides policy and execution management oversight of the DoD Immunization Program.

c. Serves as the DoD representative for interagency efforts related to immunization policy.

d. Develops, in collaboration with the Secretaries of the Military Departments; the Commandant, U.S. Coast Guard (USCG); the CJCS; and the Director, Defense Health Agency (DHA), operational use guidance that reflects mandatory immunization requirements and availability of immunizations against deliberately released biological agents and naturally occurring infectious diseases of military or national importance.

**2.3. DIRECTOR, DHA.** Under the authority, direction, and control of the USD(P&R), through the ASD(HA), and in accordance with DoDD 5136.13, the Director, DHA:

- a. Serves as the manager for the DoD Immunization Program.
  - (1) Develops standardized clinical and implementation guidance for the DoD Immunization Program.
  - (2) Publishes procedural instructions necessary to implement the DoD Immunization Program.
- b. Synchronizes, integrates, and coordinates immunization policies and guidelines for the DoD Components, including applicable DoD civilian personnel and eligible health care beneficiaries.
- c. Oversees DoD Components' post-immunization patient safety surveillance procedures and publishes guidance on the detection, reporting, investigation, and management of immunization-associated adverse events.
- d. Develops and implements DoD-wide immunization communication strategies and activities.
- e. In conjunction with the Secretaries of the Military Departments, provides recommendations to the ASD(HA) through the DASD(HRP&O) on DoD immunization policy and operational use guidance necessary to protect the total force, eligible beneficiaries, and OTUSF listed in this issuance against diseases affecting public health.
- f. Serves as the primary medical consultation resource for clinical immunization healthcare issues including suspected immunization-associated adverse events and fatalities.
- g. Maintains and centrally manages a comprehensive program for DoD healthcare providers and beneficiaries to provide worldwide, continuously accessible, military, travel, and routine immunization healthcare-specific information, educational resources, training support, and specialized consultative services, and complete case management for immunization-associated adverse events.
- h. Collects and maintains historical DoD vaccine usage data, including quantities of vaccines acquired, administered, and unused, and supports the Secretaries of the Military Departments; the Commandant, USCG; and the CCDRs in identifying and defining future immunization requirements.
- i. Serves as the primary coordinator between DoD and commercial immunization-related medical product manufacturers for all applicable immunization safety studies following FDA approval or when otherwise authorized for use.
- j. Publishes procedural instructions requiring MHS enterprise-level immunization information management systems to meet national standards for storage of individual immunization data to facilitate safe and effective administration of immunization-related medical products.

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k. In collaboration with the Secretaries of the Military Departments, the Defense Agencies, and DoD Field Activities operating medical clinics, and the Commandant, USCG:

(1) Establishes clinical standards for the quality delivery of immunizations, including education and training of individuals involved in immunization healthcare.

(2) Establishes procedures for, and monitors compliance with, mandatory annual seasonal influenza immunization of HCP at DoD medical treatment facilities, and provides a consolidated report to the ASD(HA) no later than May 1st of each year.

(3) Establishes standards for the Military Departments for immunization-related product distribution and administration; risk communication; clinical services; patient safety surveillance; research; and program evaluation.

(4) Publishes procedural instructions and other supporting DHA execution guidance required for immunization healthcare operations to include immunization procedures and processes for MHS-eligible beneficiaries under DHA jurisdiction and OTUSF. See Section 3 for immunization guidance.

(5) Establishes an immunization distribution schedule to reduce impacts on operational requirements during periods of immunization shortage.

(6) Develops pandemic vaccination prioritization guidance in coordination with the Department of Health and Human Services, tailored to DoD operational requirements.

(7) Assesses the DoD Immunization Program no less than annually, and provides recommendations for improvement to the ASD(HA) through the DASD(HRP&O).

l. Identifies and defines requirements, and provides resources, including logistical support, through the DoD planning, programming, budgeting, and execution process for immunizations required to protect eligible beneficiaries.

m. Manages a single, standardized DoD immunization registry compliant with DoDIs 5400.11 and 6025.18, and coordinates health information exchange with state and territorial immunization registries.

n. Serves as primary coordinator for DoD support of the U.S. Government (USG) efforts to modernize influenza vaccine manufacturing.

**2.4. ASSISTANT SECRETARY OF DEFENSE FOR MANPOWER AND RESERVE AFFAIRS.** Under the authority, direction, and control of the USD(P&R), the Assistant Secretary of Defense for Manpower and Reserve Affairs:

a. Requires that immunization policy, operational use, clinical and administrative guidance, and related plans and programs pertaining to all Reserve Component forces are consistent with the immunization policies of the Active Components.



b. Develops, in coordination with the ASD(HA), immunization policy and clinical and administrative guidance pertaining to the Reserve Component forces that enhance the readiness and capabilities of Reserve Component units and personnel.

c. In conjunction with the ASD(HA) and the Secretaries of the Military Departments, develops operational use guidance and related plans and programs pertaining to the Reserve Component forces that enhance the readiness and capabilities of Reserve Component units and personnel.

**2.5. ASSISTANT SECRETARY OF DEFENSE FOR READINESS.** Under the authority, direction, and control of the USD(P&R), the Assistant Secretary of Defense for Readiness develops medical guidance for the Military Departments' occupational and environmental health programs in coordination with the Director, DHA, pursuant to DoDI 6055.05. This guidance may include providing immunizations to prevent or lessen the effects of diseases associated with occupational and environmental exposures to biological hazards.

**2.6. UNDER SECRETARY OF DEFENSE FOR INTELLIGENCE.** In coordination with the CJCS, provides required intelligence support necessary for the validation of deliberately released biological agents, and the validation and assessment of infectious diseases of military or national importance, as well as biological agent threats to DoD personnel, pursuant to DoDD 5160.05E and DoDD 6490.02E.

**2.7. ASD(NCB).** Under the authority, direction, and control of the Under Secretary of Defense for Acquisition and Sustainment, the ASD(NCB):

a. Coordinates and integrates the DoD Immunization Program with all acquisition-related elements of the DoD Chemical and Biological Defense Program, in accordance with DoDD 5160.05E.

b. Coordinates the development of chemical, biological, radiological, and nuclear defense concepts of operation and proposes immunization concepts for medical products under development for use as immunizations against deliberately released biological agents, in coordination with the ASD(HA).

**2.8. USD(P).** The USD(P):

a. Reviews and approves the implementation guidance for immunization of OTUSF.

b. Approves requests for exceptions to policy for immunization of OTUSF, in coordination with the CJCS, the Under Secretary of Defense for Acquisition and Sustainment, and the USD(P&R).

c. Coordinates with the ASD(HA) on the recommendation to immunize OTUSF.

d. Represents the Secretary of Defense and DoD with the National Security Council, USG departments and agencies, and other countries requesting vaccine, immunization assistance, or other related capabilities, in coordination with the USD(P&R), the ASD(HA), the CJCS, other senior DoD officials, and the Department of State.

**2.9. ASSISTANT SECRETARY OF DEFENSE FOR HOMELAND DEFENSE AND GLOBAL SECURITY.** Under the authority, direction, and control of the USD(P), the Assistant Secretary of Defense for Homeland Defense and Global Security receives, coordinates with the ASD(HA) and other DoD officials, and responds to USG department or agency requests for DoD vaccine, immunization assistance, or related capabilities in accordance with DoDD 3025.18, DoDD 5111.13, and DoDI 3025.24.

**2.10. ASSISTANT SECRETARY OF DEFENSE FOR SPECIAL OPERATIONS AND LOW-INTENSITY CONFLICT.** Under the authority, direction, and control of the USD(P), the Assistant Secretary of Defense for Special Operations and Low-Intensity Conflict:

- a. Serves as the DoD representative for international requests for vaccine, immunization assistance, or related capabilities.
- b. Evaluates and advises the USD(P) on interagency support requests for use of DoD immunizations in special operations or low-intensity conflict.
- c. In consultation with the Office of the General Counsel of the Department of Defense, monitors interagency use of DoD immunizations in such activities, in accordance with DoDD S-5210.36.
- d. Provides input to recommendations to the Secretary of Defense for immunization of OTUSF.

**2.11. SECRETARIES OF THE MILITARY DEPARTMENTS, DIRECTORS OF DEFENSE AGENCIES AND DOD FIELD ACTIVITIES THAT OPERATE MEDICAL CLINICS, AND THE COMMANDANT, USCG.** The Secretaries of the Military Departments, Directors of Defense Agencies and DoD Field Activities that operate medical clinics, and the Commandant, USCG:

- a. Develop, implement, and maintain immunization procedures or processes for personnel and beneficiaries under their jurisdiction. See Section 3 for immunization guidance.
- b. Comply with procedural instructions published by the Director, DHA.
- c. Require that properly identified and defined mandatory immunization requirements are provided in operational use guidance.
- d. In conjunction with the Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense and CCMDs, develop risk assessments and impact projections for

deliberately released biological agents and unique CCMD requirements to inform Service-specific immunization policies.

e. Identify and define requirements, and provide resources, including logistical support through the planning, programming, budgeting, and execution process for immunizations required to protect eligible beneficiaries.

f. Provide requested information to the Director, DHA, to support annual status reviews of the DoD Immunization Program.

#### **2.12. CHIEF, NATIONAL GUARD BUREAU.** The Chief, National Guard Bureau:

a. Serves as a channel of communications for matters pertaining to immunization readiness of National Guard personnel, coordination of resources, and decisions regarding priorities of immunization activities for National Guard personnel.

b. In coordination with the Adjutants General of the States, and consistent with Service regulations and policies, ensures National Guard personnel pre-designated for immediate response missions or deployment receive required immunizations. This includes provision of smallpox, anthrax, and other appropriate immunizations to chemical, biological, radiological, and nuclear response personnel.

#### **2.13. CJCS.** The CJCS:

a. Validates and prioritizes chemical, biological, radiological, and nuclear threats to DoD personnel, equipment, and weapon systems in coordination with the DoD Components in accordance with DoDD 5160.05E.

b. Requires that current geographic CCDR threat and risk assessments for deliberately released biological agents and infectious diseases of military or national importance are coordinated with the ASD(NCB), the ASD(HA), and the Assistant Secretary of Defense for Homeland Defense and Global Security.

c. Provides CCMD-specific immunization requirements to the Secretaries of the Military Departments and the ASD(HA).

d. Forwards CCMD requests for use of medical products and changes to immunization activities against deliberately released biological agents or naturally occurring infectious diseases of military or national concern to the ASD(HA) for approval.

e. Reviews geographic CCDRs' implementation guidance for immunizations of OTUSF.

#### **2.14. CCDRS.**

a. Geographic CCDRs:

(1) Use Defense Intelligence Agency assessments and Armed Forces Health Surveillance Branch-Integrated Biosurveillance Section updates to continually identify and reduce risk to the force and other eligible beneficiaries from infectious diseases of military or national importance, as well as deliberately released biological agents.

(2) Identify and define mandatory immunization requirements and establish policy and programs for the protection of Service members and deployable civilian employees within each respective CCMD in accordance with DoDD 6200.04. These requirements will apply to:

(a) Individuals assigned to the CCMD.

(b) Individuals pre-designated for immediate deployment (e.g., crisis response) to the CCMD.

(c) Individuals identified and scheduled for deployment on an imminent or ongoing contingency operation to the CCMD.

(d) OTUSF personnel within the CCMD, as defined by CCMD-specific guidance, and in accordance with procedures outlined in Section 3.

(3) Submit requests through the CJCS to the ASD(HA) for approval to initiate, modify, or terminate mandatory immunizations of personnel and voluntary immunizations of other eligible beneficiaries determined to be at risk from the effects of deliberately released biological agents or naturally occurring infectious diseases of military or national importance.

(4) Determine, at least every 3 years, the estimated quantity of vaccines required to immunize DoD non-uniformed beneficiaries or other individuals should there be a deliberate release of, or significantly elevated threat of release of, a biological agent or a naturally occurring infectious disease of military or national importance. Non-U.S. military personnel include, but are not limited to, DoD civilian and contractor support employees, including associated family members, and USG agency employees and family members. Include estimated total quantities of individuals in operational plans along with distribution and mass immunization contingency plans.

b. Functional CCDRs:

(1) Identify and define mandatory immunization requirements in addition to those of the geographic CCDRs for specific occupations or billets within their commands.

(2) Submit requests through the CJCS, through the ASD(HA) to the Secretary of Defense for approval to initiate, modify, or terminate mandatory immunizations of personnel and voluntary immunizations of other eligible beneficiaries determined to be at risk from the effects of deliberately released biological agents.

## SECTION 3: PROCEDURES

**3.1. IMMUNIZATION GUIDANCE.** Individual immunization delivery decisions will be based on nationally recognized standards of U.S. medical care or clinical practice guidelines to customize care or respond to specific clinical situations for each individual. All immunization programs must include, at a minimum, procedures that:

a. Provide clinical immunization services for vaccine-preventable diseases, including occupation-specific immunizations for personnel exposed to preventable hazards as part of their work environment.

b. Implement patient safety surveillance following immunizations that detects, evaluates, reports, investigates, and clinically manages vaccine-associated adverse events.

c. Document all immunizations electronically with systems interfacing with the DoD Immunization Registry.

d. Assess individual and unit medical readiness and effectiveness, in accordance with DoDI 6025.19.

e. Implement clinical guidelines and quality of care for the delivery of immunizations, including education and training of personnel involved in immunization healthcare.

f. Monitor and keep Service member and deployable civilian employee immunization requirements current.

g. To the maximum extent practicable, provide for the immunization of personnel for protection against deliberately released biological agents and naturally occurring infectious diseases of military or national importance, in time to develop sufficient immunity before deployment. These programs will provide specific immunizations identified by CCDRs and the Services.

h. When the types of immunizations provides indications of an impending deployment, especially to a sensitive location, the five-step operations security process will be used to protect this information in accordance with DoDD 5205.02E. Use of the operations security process helps planners develop measures to prevent exposing critical information and indicators associated with a deployment to our adversaries.

i. Advise eligible DoD beneficiaries of the availability and uses of immunizations for disease prevention, including the personal and collective (e.g., military or community) benefits, potential health risks, and the indications for providing an immunization.

j. Identify the overseas locations where beneficiaries are subject to Service- and CCMD-specific immunization requirements and recommendations and provide the immunizations in accordance with these recommendations.

### **3.2. IMMUNIZATIONS AGAINST BIOLOGICAL WARFARE AGENTS AND NATURALLY OCCURRING INFECTIOUS DISEASES OF MILITARY OR NATIONAL IMPORTANCE FOR OTUSF.**

a. The Secretary of Defense, upon the advice of the geographic CCDRs, the CJCS, and senior officials within the Office of the Secretary of Defense, will decide whether or not to provide immunizations for OTUSF.

b. All immunizations provided or supported in accordance with this section will be consistent with the medical procedures, requirements, and standards defined in Paragraph 3.1.

c. For all immunizations carried out by the DoD Components in accordance with this issuance, a full information and communications program must be implemented to ensure that recipients receive accurate and complete information regarding the vaccine or other immunization product and the immunization program involved. With the exception of those personnel for whom the immunization is determined to be mandatory, information provided must include a clear explanation that the immunization is voluntary.

d. For all immunizations carried out by entities other than the DoD Components in accordance with this issuance, the DoD will provide all necessary information to the receiving entity to allow it to carry out a comparable information and communication program for the benefit of its immunization recipients.

e. The responsibility for record-keeping rests with the DoD Component, other USG agency, allied or coalition government agency, or other organizational entity that receives the immunization and has responsibility for providing it. Record-keeping requirements will be consistent with the standards defined in Paragraph 3.1.

f. OTUSF Categories.

(1) **Category 1: Emergency-Essential and Combat-Essential DoD Civilian and Contractor Personnel.** This category includes emergency-essential and combat-essential U.S. national civilian employees of the DoD, in accordance with DoDI 1400.32 and DoD contractors (or subcontractors) or employees of DoD contractors (or subcontractors) performing mission essential DoD contractor services, in accordance with DoDI 3020.41.

(2) **Category 2: Other DoD or U.S. National Personnel and Other U.S. Citizens.** This category includes U.S. military family members; non-emergency-essential DoD civilian employees; non-combat essential DoD civilian employees; family members of DoD civilian employees; DoD contractor and subcontractor employees not covered by Paragraph 3.2.f.(1); family members of DoD contractor and subcontractor employees; employees of other USG agencies; family members of employees of other USG agencies; other USG contractor and subcontractor employees; and family members of other USG contractor and subcontractor employees.

(3) **Category 3: Non-U.S. National Civilian Personnel Supporting U.S. Military Operations.** This category includes non-U.S. national personnel who are employees of the DoD or a DoD contractor or subcontractor not included in categories 1 or 2 and their family members;

and foreign personnel employed by the host-nation government or contractors of the host-nation government and their family members.

(4) **Category 4: Allied/Coalition Nation Personnel.** This category includes host-nation and third-country personnel the United States may assist pursuant to an international agreement or as directed by the Secretary of Defense, such as allied or coalition military forces, government officials, and emergency response personnel.

g. Immunization Guidance for OTUSF.

(1) Unless otherwise directed by the ASD(HA), immunization requirements, tracking, and documentation applicable under Paragraph 3.1. apply to category 1 personnel assigned or designated to be deployed with those military personnel in a high-threat area.

(2) The Secretary of Defense, may direct immunizations as mandatory for category 1 personnel. DoD Components that employ emergency-essential DoD U.S. national civilian employees or that maintain contracts performing mission essential DoD contractor services, will comply with all administrative and procedural actions necessary to implement such a requirement. When immunizations are mandatory for DoD contractors (or subcontractor) employees, components will modify contracts as necessary to implement this requirement.

(3) Category 2 personnel will be removed from threat areas in accordance with standard inter-agency procedures for crisis situations. If there is an imminent threat of hostilities, the USG will attempt to evacuate category 2 personnel from the threat area. Evacuation, rather than immunization, is the primary means of addressing the threat for category 2 personnel.

(4) CCDRs may request authority to provide immunization for one or more designated groups of category 2, 3, or 4 personnel. The Secretary of Defense reserves the authority to approve such a request. The decision will be based on the feasibility of evacuation, availability of vaccine, impact on mission and other pertinent factors. For category 2, 3, and 4 personnel to whom immunization is offered, the following additional requirements apply:

(a) Receipt of immunization will be on a voluntary basis.

(b) For category 2 personnel, the DoD Component is responsible for implementation, including administering the vaccine and maintaining medical and other records. The medical records will be updated, maintained, and stored in accordance with DoD Component policies and procedures for medical records of DoD personnel.

(c) For category 3 personnel, implementation of the immunization initiative will be the responsibility of the DoD Component for DoD employees, contractors, and family members; and the host-nation for foreign personnel and family members employed by the host-nation government.

(d) For category 4 personnel, the foreign government is responsible for implementation of the immunization initiative. Coordination with the U.S. Secretary of State is required before providing immunization to category 4 personnel.

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(5) Heads of other USG agencies may decide to immunize their employees and family members. When another USG agency requests vaccine, immunization assistance, or other relevant capabilities, the Secretary of Defense reserves the authority to approve such a Defense Support of Civil Authorities request in accordance with DoDDs 5111.1, 5111.13, 3025.18, and DoDI 3025.24. In cases under this policy in which vaccine, immunization assistance, or other related capability is provided to another USG Agency pursuant to Section 1535 of Title 31, U.S.C (the Economy Act), the receiving agency will agree to indemnify the DoD for any DoD liability arising from personal injury, death, or other damage associated with the use of the vaccine, immunization assistance, or related capabilities provided.

(6) In cases where vaccine, immunization assistance, or other related DoD capability is provided to a foreign government, in accordance with DoDDs 5111.1 or 5111.10, or under the Arms Export Control Act (Chapter 39 of Title 22, United States Code), or the Foreign Assistance Act (Chapter 32 of Title 22, United States Code), the receiving government, absent a contrary requirement under treaty or international agreement, agrees to indemnify the DoD and the USG for any liability of the DoD arising from personal injury, death, or other damage associated with the use of the vaccine, immunization assistance, or other DoD capabilities provided.

**3.3. EXCEPTIONS TO POLICY.** The following procedures apply to initiate or increase immunizations against deliberately released biological agents beyond those specified by the geographic CCDRs:

a. FDA-approved immunizations.

(1) The requested use must be consistent with product's labeling. This includes indications, route of administration, dosing schedule, and dose of immunization.

(2) A risk/benefit analysis must accompany the request to justify use as a general readiness measure (i.e., use beyond geographic CCDR-identified threats). In addition to the justification, the request must include the units or unit types, personnel or personnel types, or individuals, and the number of such personnel or other individuals affected by the request.

(3) Requests will be routed from the requesting component to the ASD(HA) for approval or disapproval.

b. Requests to use non-FDA-approved immunizations will be processed as outlined in DoDI 6200.02.

c. Requests will be routed from the geographic CCDR through the CJCS to the Secretary of Defense for OTUSF.

(1) Requests that include non-DoD category 2 personnel will be coordinated with the head of the appropriate USG agency.

(2) Requests that include category 4 personnel will be coordinated with the U.S. Secretary of State.



d. For changes to immunization activities that terminate such measures, the request must justify the reason for termination and a risk/benefit analysis must accompany the request. The request must also state the unit or unit types, personnel or personnel types, or individuals to no longer be immunized and the number of such personnel or other individuals affected by the request.

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## GLOSSARY

### G.1. ACRONYMS.

ASD(HA)	Assistant Secretary of Defense for Health Affairs
ASD(NCB)	Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
CCDR	Combatant Commander
CCMD	Combatant Command
CJCS	Chairman of the Joint Chiefs of Staff
DASD(HRP&O)	Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight
DHA	Defense Health Agency
DoDD	DoD directive
DoDI	DoD instruction
FDA	U.S. Food and Drug Administration
HCP	health-care personnel
MHS	Military Health System
OTUSF	other than U.S. forces
USCG	U.S. Coast Guard
USD(P)	Under Secretary of Defense for Policy
USD(P&R)	Under Secretary of Defense for Personnel and Readiness
USG	U.S. Government

**G.2. DEFINITIONS.** Unless otherwise noted, these terms and their definitions are for the purpose of this issuance.

**beneficiaries.** Designated Active and Reserve Component military personnel, including the National Guard, U.S. Army, Navy, Air Force, Marine Corps, and USCG; non-military persons under military jurisdiction; selected federal employees; eligible DoD civilian employees and DoD contractor personnel, as specified by operational use guidance and subject to applicable civilian personnel system or acquisition system procedural requirements, respectively; dependents, retirees, and other individuals eligible for care within the MHS; and family members of contracted workers under military sponsorship in foreign-duty settings.

**biological agent.** Defined in the DoD Dictionary of Military and Associated Terms.

**dependent.** Defined in Section 1072 of Title 10, United States Code.

**DoD Immunization Program.** A single, uniform program, administered by the DHA, that the DoD Components will use to provide educational, public health, and clinical services to deliver and assess the effect of immunizations for eligible beneficiaries.

This program includes immunizations to protect the total force and other eligible beneficiaries against both naturally occurring diseases and biological threats.

Clinical services include disease surveillance, vaccine supply monitoring, pre-immunization education and screening, clinical administration of immunizations, post-immunization follow-up, and patient safety surveillance for effectiveness, and patient advocacy and care following adverse events following immunization.

**force health protection.** Defined in the DoD Dictionary of Military and Associated Terms.

**HCP.** 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. HCP required to receive annual influenza vaccination will be identified by the Director, DHA, and published in procedural instructions.

**immunization.** The process by which a person becomes protected or resistant to an infectious disease, typically by the administration of a vaccine.

**infectious diseases of military or national importance.** Naturally occurring infectious diseases with high potential to adversely affect U.S. or coalition forces, particularly during deployment. This term may also be called infectious diseases of operational concern.

**OTUSF.** Collectively refers to noncombatant, non-uniformed U.S. citizens, as well as other select non-U.S. citizens. The specific categories of OTUSF covered by this issuance are defined in Paragraph 3.2.

**Reserve Components.** Refers collectively to the Army National Guard of the United States, the Army Reserve, the Navy Reserve, the Marine Corps Reserve, the Air National Guard of the United States, the Air Force Reserve, and the Coast Guard Reserve at all times, including when the Coast Guard is operating as a Service of the Department of the Navy or when it is a Service in the Department of Homeland Security by agreement with that Department.

**total force.** The organizations, units, and individuals that comprise DoD resources for implementing the National Security Strategy. It includes DoD Active and Reserve Component military personnel, military retired members, DoD civilian personnel (including foreign national direct- and indirect-hire, as well as non-appropriated fund employees), contractor personnel, and host-nation support personnel.

**vaccination.** The administration of a vaccine to an individual for inducing immunity.

*DoDI 6205.02, July 23, 2019*

**vaccine.** A preparation that contains one or more components of a biological agent or toxin and induces a protective immune response against that agent when administered to an individual.

*DoDI 6205.02, July 23, 2019*

## REFERENCES

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- DoD Instruction 3020.41, “Operational Contract Support (OCS),” December 20, 2011, as amended
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- DoD Instruction 5400.11, “DoD Privacy and Civil Liberties Programs,” January 19, 2019
- DoD Instruction 6025.18, “Privacy of Individually Identifiable Health Information in DoD Health Care Programs,” March 13, 2019
- DoD Instruction 6025.19, “Individual Medical Readiness (IMR),” June 9, 2014
- DoD Instruction 6055.05, “Occupational and Environmental Health (OEH),” November 11, 2008, as amended
- DoD Instruction 6200.02, “Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs,” February 27, 2008

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