OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

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HEALTH AFFAIRS

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MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE
(RESERVE AFFAIRS)
SURGEON GENERAL OF THE ARMY
SURGEON GENERAL OF THE NAVY
SURGEON GENERAL OF THE AIR FORCE
DIRECTOR, JOINT STAFF
DIRECTOR HEALTH AND SAFETY, U.S. COAST GUARD
DIRECTOR, DEFENSE LOGISTICS AGENCY

SUBJECT: Department of Defense Pandemic Vaccine Guidance for Novel Influenza A (H1N1)

Novel Influenza A (H1N1) was first recognized in April 2009. Since that time, it has spread internationally. The World Health Organization declared a pandemic on June 11, 2009. The severity of infections caused by this virus remains mild. A form of this strain will impact the 2009–2010 influenza season, the virulence of which is unknown. Immunization is the most effective method of preventing or limiting illness. This guidance describes how the Department of Defense (DoD) will receive novel Influenza A (H1N1) vaccine for operational requirements, as well as for the family member and retiree populations. Vaccine targeting, supply, and distribution strategies are described. The immunization program will begin without delay upon receipt of vaccine.

This policy applies to the Office of the Secretary of Defense, the Military Departments, 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 Field Activities, all other organizational entities in DoD and military beneficiaries. The term "Military Services," as used herein, refers to the Army, Navy, Air Force, Marine Corps, and the Coast Guard (but only when it is operating as a Service within the Navy).

This policy reflects two potential scenarios for the anticipated resurgence of this virus in the fall. The first is a pandemic that results in mild disease. Early indications suggest a mild disease is most likely. The second scenario is characterized by a more virulent virus causing severe disease. In either instance, vaccine to meet DoD mission requirements will be provided from both DoD and national stockpiles. Other segments of the DoD community, to include family members and retirees, will receive vaccine from national stockpiles with allocation based on the demographics and population of each

state. This policy supersedes previous guidance related to pandemic and pre-pandemic vaccine allocation and use.

For operational requirements, DoD acquired 2.7 million doses of novel Influenza A (H1N1) vaccine. This vaccine has been approved by the Food and Drug Administration (FDA), and is projected to be available in October 2009. Vaccine for operational requirements may be allocated to Active Duty members, Reservists, National Guard, DoD civilians, and essential contractors. This unadjuvanted vaccine will be mandatory for uniformed personnel and highly encouraged for all others. The goal is for all members of the DoD community, who wish to be immunized, to receive the vaccine. Vaccine will be available for DoD civilians. However, within the civilian community, there will be multiple sites offering the vaccine. DoD civilians and contractors may seek vaccination through non-DoD sources, when available, because this may result in quicker access to vaccine. Agencies that receive seasonal influenza vaccine through the Federal Occupational Health System (FOHS) will receive novel Influenza A (H1N1) vaccine through that system. Depending on the specifications of each seasonal influenza vaccine memorandum of understanding with FOHS, there may or may not be an additional charge for administration.

The Joint Staff will provide guidance for target groups to receive the available vaccine as described below to the Combatant Commands and Services based on operational requirements and this policy.

The Military Vaccine Agency (MILVAX), which coordinates and integrates immunization efforts for DoD, will issue implementation instructions to the Services for the novel Influenza A (H1N1) immunization program. Instructions will cover DoD priority operational forces identified by the Joint Staff, as well as immunization education and training. These implementation instructions will form a basis for Service-specific novel Influenza A (H1N1) immunization policies to follow.

Prioritization of immunization, Service policy synchronization, and distribution of DoD-purchased novel Influenza A (H1N1) vaccine will be based upon the established seasonal influenza program model. Service preventive medicine and medical logistic leadership organizations will coordinate with MILVAX to plan the immunization program and distribute novel Influenza A (H1N1) vaccine, which will be provided by the Defense Supply Center Philadelphia. To decrease competition for logistic assets, direct shipments from the manufacturer to sites outside the continental United States (OCONUS) may occur if advantageous to DoD.

MILVAX will coordinate with the Services to centralize electronic tracking and reporting of vaccine coverage. Vaccine safety efforts are of national importance and should emphasize collaboration with state and federal agencies. MILVAX will work with the FDA and the Centers for Disease Control and Prevention (CDC) to facilitate

prompt reporting of potential vaccine related adverse events. The DoD Vaccine Healthcare Centers Network will be used for referral and case management of serious adverse events. The Armed Forces Health Surveillance Center (AFHSC), in conjunction with FDA and CDC, will be responsible for determining estimates of vaccine effectiveness. The Air Force, as the Executive Agent for influenza laboratory surveillance, will continue to coordinate and conduct the DoD-wide influenza laboratory surveillance program.

Vaccine storage will be maintained at the manufacturer and at Defense Logistics Agency (DLA) facilities in compliance with the manufacturer's guidelines. Appropriate cold chain management procedures will be used in the shipment and distribution of vaccines. Overseas Geographic Combatant Commands (COCOMs) will ensure expedited transportation of vaccines across borders in their areas of responsibility. Coordination with Department of State or primary agency should be conducted to ensure vaccine delivery access in the event that borders are closed. In accordance with authorities, geographic COCOMs and Services must plan for the availability of ancillary material to administer the vaccines at the points of administration and ensure confirmation of receipt is reported by the ultimate consignees to the Joint Staff and the DLA.

Vaccine allocation should target groups at high risk for transmission if disease severity is mild. The following groups should receive the vaccine first: deployed forces, training sites (large scale training sites including Service Academies and new accessions), ships afloat, and health care providers who are at very high or high exposure risk (defined by "Guidance on Preparing Workplaces for an Influenza Pandemic," Occupational Safety and Health Administration (OSHA) Publication 3327-02N 2007). After these groups have been immunized, the remaining vaccine will be allocated to ensure mission assurance. The Deputy Secretary of Defense will determine prioritization categories for DoD personnel. COCOMs, Services, and Agencies will determine who is critical and what priority they are given for the vaccine to ensure mission assurance.

Should the epidemic/pandemic have an increased disease severity characterized by a case fatality rate equal to or exceeding 0.5 percent in DoD populations, then prioritization for vaccine will shift from the transmission-based risk to a prioritization based on mission assurance. This determination will be made by the Assistant Secretary of Defense for Health Affairs using data provided by CDC and AFHSC.

The dose requirement for this vaccine is one dose that may be administered with seasonal influenza at the same time. This document will be amended should this guidance change. Additionally, those who recover from the novel Influenza A (H1N1) disease may be immune and may not require immunization. Guidance regarding immunization requirements will be posted on the DoD Pandemic Influenza Watchboard (http://www.dod.mil/pandemicflu), along with changes to this document as new information warrants.

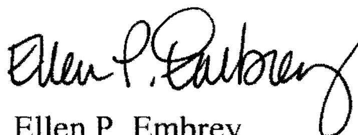
Beneficiaries not directly responsible for the overall DoD mission, such as family members and retirees, are included in the U.S. Department of Health and Human Services (HHS) vaccine allocation plan that identifies target groups, as described in the Advisory Committee on Immunization Practices (Use of Influenza A (H1N1) 2009 Monovalent Vaccine: Morbidity and Mortality Weekly Report (MMWR), August 21, 2009/58 (Early Release); 1-8). These target groups include pregnant women, household contacts of infants under 6 months of age, young people between the ages of 6 months and 24 years, first responders and health care workers, and non-elderly adults (under age 65) with underlying risk conditions such as diabetes and chronic lung disease. Subsets of the initial target groups are further defined in the MMWR. These groups are target groups and not prioritization groups. As a target group, every effort should be made to ensure that the vaccine is offered to these individuals. If vaccine allocated for nonoperational use is available, no DoD beneficiaries wishing to be immunized should be turned away.

Vaccine for family members and retirees will be provided through an HHS-managed system that allocates vaccine to each State based on its population (including DoD populations). Those family members and retirees not enrolled for care through a military medical treatment facility (MTF) will receive vaccine through this HHS-managed, state-based system. MTF commanders, in conjunction with Public Health Emergency Officers (PHEOs) or their designees, must engage with the appropriate state public health agency to ensure that their enrolled nonoperational DoD population (family members and retirees) are included in the state allocation. The first step in this process is registration of the MTF with the respective state public health department as an immunization provider. Registration Web sites for each state have been collated by the CDC and can be found at http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm. Registration requires completion of a web-based form for each state. All MTFs that provide seasonal influenza vaccinations shall register to provide novel Influenza A (H1N1) vaccine to their beneficiaries. After registration, the MTF commander, in conjunction with the PHEO or designee, will notify the state of the installation's nonoperational vaccine requirement based on the current MMWR population target groups. Place orders in increments of 100 doses each. Ancillary kits to include needles, syringes, alcohol wipes, and gauze pads may be ordered with the vaccine free of charge. The state will relay this information to the CDC. The CDC, in turn, will submit that vaccine order to a vaccine distributor (McKesson), who delivers the vaccine directly to the DoD address, as specified. The amount of vaccine delivered will depend on the overall vaccine allocation to each state and the relative proportion of the DoD population in that state.

Family members and retirees who are enrolled for care at OCONUS MTFs (excluding Hawaii and Alaska) will receive vaccine via a direct allocation to DoD from CDC. MTFs in Alaska and Hawaii are included in the continental United States distribution plans.

The U.S. Coast Guard, unless operating under the U.S. Navy, is not part of the DoD allocation. The Coast Guard will use DoD logistical and medical assets for shipment and administration of its vaccine allotment, where appropriate.

This guidance reflects both the Department's policy and current national immunization plans. Should the national plan or guidance change, this policy will be modified accordingly and posted at http://www.dod.mil/pandemicflu.



Ellen P. Embrey
Deputy Assistant Secretary of Defense
(Force Health Protection and Readiness)
Performing the Duties of the
Assistant Secretary of Defense
(Health Affairs)

cc:
USD (P&R)