HEADQUARTERS, US ARMY MEDICAL COMMAND
Fort Sam Houston, TX 78234-6007
251900Q September 2009

OPERATION ORDER 09-75 (NOVEL A(H1N1) INFLUENZA VACCINE IMMUNIZATION PROGRAM)

References:

a. Assistant Secretary of Defense for Health Affairs (ASD(HA)) memorandum, subject: DOD Vaccine Guidance for Novel Influenza A (H1N1), when available, will be published at www.ha.osd.mil/policies/default.cfm.

b. Use of Influenza A (H1N1) 2009 Monovalent Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009 / 58;1-8 (21 August 2009). Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm.

c. Department of Defense Joint Regulation (Army Regulation 40-562, BUMEDINST 6230.15A, AFJI 48-110, CG COMDTINST M6230.4F), Immunizations and Chemoprophylaxis, dated 29 September 2006.

d. Centers for Disease Control and Prevention (CDC), subject: Novel A(H1N1) Influenza Vaccine Information Statements (VIS). Available at: www.cdc.gov/vaccines/pubs/vis.

e. Medical Materiel Instruction (MMI), Subject: MMI-XX-XXXX: Clarification/ Information Novel A(H1N1) Influenza Virus Vaccine, dated XXXX 2009. Available at: http://www.usamma.army.mil/products.cfm.

f. OSHA 3327-02N 2007, Guidance on Preparing Workplaces for an Influenza Pandemic. Available at: http://www.osha.gov/Publications/influenza_pandemic.html.

Time zones used throughout the order: Quebec (Eastern Daylight Time).

Task Organization: No change.

1. SITUATION.

a. General. Novel A(H1N1) influenza is a new influenza virus of swine origin that first caused illness in Mexico and the United States in April 2009. It is thought that the H1N1 virus spreads in the same way that regular seasonal influenza viruses spread, through coughs and sneezes of people who are sick with the virus, and by touching infected objects and then touching one's nose or mouth. On 11 June 2009, the World Health Organization (WHO) signaled that a global pandemic of novel A(H1N1) influenza was underway by raising the worldwide pandemic alert level to Phase 6. Since the WHO declaration of a pandemic, the new H1N1 virus has continued to spread. In the

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United States, novel A(H1N1) influenza illness has continued into the summer, with localized, and in some cases, intense outbreaks occurring. The novel H1N1 virus, in conjunction with regular seasonal influenza viruses, poses the potential to cause significant illness with associated hospitalizations and deaths during the U.S. influenza season.

b. The Federal Government has contracted with vaccine manufacturers to acquire as many as 195 million doses of the novel A(H1N1) vaccine. The Department of Defense (DoD) purchased enough Influenza A (H1N1) 2009 Monovalent Vaccine from the Department of Health and Human Services (DHHS) to ensure a basic quantity of vaccine is available for its operational forces. DoD will receive additional vaccine through allocations from the DHHS to cover all categories of beneficiaries.

(1) Vaccine will be available beginning in October 2009.

(2) Monovalent intranasal and injectable vaccine formulations will be available. The Food and Drug Administration (FDA) licensed H1N1 vaccines do not contain adjuvants. The FDA and WHO have selected A/California/07/2009 (H1N1) as the strain for the H1N1 vaccines.

(3) The CDC's Advisory Committee on Immunization Practices (ACIP) has developed recommendations for novel A(H1N1) influenza vaccines (see reference b).

2. MISSION. US Army Medical Command (MEDCOM) implements the Novel A(H1N1) Influenza Vaccine Immunization Program (NIVIP) immediately upon receipt of vaccine to protect all Active Duty (AD) and Reserve Component (RC) personnel, healthcare personnel (HCP), DoD civilians, and military essential contractors from contracting the H1N1 influenza virus.

3. EXECUTION.

Intent. The goal of the Army NIVIP is to protect all personnel listed above from the novel A(H1N1) influenza virus and its complications. TRICARE beneficiaries are also offered immunization IAW national guidelines, which are denoted by age and medical condition as listed in reference b. The key task for this operation is to vaccinate personnel listed above, excluding those medically or administratively exempted, with novel A(H1N1) influenza vaccine. Vaccination is mandatory for uniformed personnel and highly encouraged for all others. Vaccine will be delivered in stages, necessitating prioritization of vaccine recipients. If severity of disease is similar to the spring/summer H1N1 influenza outbreak, vaccine will be targeted toward deployed and deploying forces, new accession sites (including Service Academies), and healthcare personnel. If the novel A(H1N1) influenza virus begins to cause more severe disease, vaccine will be prioritized towards protecting forces responsible for completing DoD operational missions as determined by the Joint Staff. No vaccine shortages are anticipated,

allowing all members of the DoD community who wish to be immunized to receive the vaccine.

a. Concept of operations. All USAMEDCOM regional medical commands (RMC) and major subordinate commands (MSC) will begin immunizing immediately upon receipt of vaccine.

(1) Vaccine for operational forces will come from the Defense Supply Center Philadelphia (DSCP). This process is similar to the seasonal influenza distribution model.

(2) CONUS (including Alaska and Hawaii) military treatment facility (MTF) commanders, in coordination with installation public health emergency officers (PHEOs), will register through their respective states as an immunizer to vaccinate dependents and retirees (http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm). The state, in turn, will incorporate this population and forward to the CDC. The CDC will supply vaccine to the state based on this population. The state will coordinate with the vaccine distributor and the installation to have the vaccine delivered to the MTF. Within the civilian community, there will be multiple sites offering vaccine. DoD civilians and contractors are encouraged to seek vaccine through non-DoD sources when available as this will likely result in quicker access to vaccine. For OCONUS beneficiaries, vaccine will be supplied according to the seasonal influenza vaccine distribution model.

b. Tasks to RMCs and MSCs.

(1) RMCs will manage DoD- and DHHS-purchased vaccine for all uniformed personnel and DoD beneficiaries.

(2) Direct CONUS (including Alaska and Hawaii) MTF commanders and PHEOs to engage state officials to receive allocations sufficient to protect their beneficiary population.

(3) Ensure subordinate MTFs are prepared to provide H1N1 immunizations to beneficiaries immediately upon receipt of the vaccine. Subtasks include:

(a) Require subordinate MTFs develop plans to immediately conduct immunization programs for all beneficiaries authorized to receive the H1N1 vaccine.

(b) Require subordinate MTFs to conduct exercises of their plans with supported garrisons and units.

(c) Receive back briefs from MTFs ensuring that the MTF is prepared to execute their H1N1 immunization plan immediately upon receipt of vaccine.

(d) No later than 1700Q on 5 October 2009, RMCs will submit a report to the point of contact in paragraph 5.b.(1) verifying that all subordinate MTFs have completed tasks (a) – (c) above and are prepared to provide H1N1 immunization immediately upon receipt of the vaccine.

(4) Provide novel A(H1N1) influenza vaccine to immunize Continuity of Operations Personnel (COOP).

(5) All individuals, regardless of their previous H1N1 exposure, will be vaccinated.

(6) Implement policies and procedures to prevent the unnecessary and avoidable loss of novel A(H1N1) influenza vaccine.

(7) To preclude the need for return visits, ensure both seasonal influenza and H1N1 influenza vaccinations are administered and recorded as required.

(8) All vaccinations for Soldiers and Department of the Army Civilians (DAC) will be immediately posted and tracked in MEDPROS. For the purpose of capturing workload, entry into AHLTA should also be considered. For all other beneficiary categories, documentation in AHLTA will be used. Electronic entry will occur at the time of or, at a maximum, within 72 hours of vaccination.

(a) Proper documentation includes patient identification, the date vaccine was given, vaccine name or code, manufacturer, lot number, volume of dose, administration route and anatomic site, name and rank of prescribing healthcare provider, vaccinator name, the date patient is given the Vaccine Information Statement (VIS), and the VIS version date. There are 4 CVX codes for this vaccine: 125 - live intranasal; 126 - injectable-preservative free; 127 – injectable; and CVX code 128 which should be used only when the actual H1N1 formulation cannot be determined.

(b) Soldiers who receive novel A(H1N1) influenza vaccinations from non-military facilities will provide immunization data (shot record) to their unit's MEDPROS point of contact at the earliest opportunity.

(9) MTF commanders will coordinate with supported organizations to distribute and administer vaccine.

(10) The CDC will publish separate Vaccine Information Statements (VIS) for the live attenuated and inactivated vaccines. These VISs cannot be completed until information concerning contraindications, adverse events, etc., is available for the FDA licensed vaccines. Once available, these statements must be displayed at immunization clinics and provided to each vaccinee or their parent/guardian. VISs can be downloaded at http://www.cdc.gov/vaccines/pubs/vis/ and reproduced locally

(reference d). In the absence of an available VIS, immunization clinics and healthcare personnel will screen personnel receiving novel A(H1N1) influenza vaccinations according to package insert information to identify contraindications to immunizations. Note: Federal law does not require that a vaccine be withheld if a VIS for it does not yet exist.

c. Tasks to OneStaff.

(1) Director, Strategic Communications. Provide accurate, relevant flow of information to educate media, military healthcare beneficiaries, and the general public on steps they can take to mitigate the spread of the novel A(H1N1) influenza virus.

(2) Assistant Chief of Staff, Operations.

(a) Task Public Health Emergency Officers to report vaccine registration IAW 8 September 2009 Health Affairs memorandum, subject: Public Health Emergency Officer Accountability.

(b) Implement operational reporting requirements associated with H1N1 vaccine.

(c) Provide a summary report to ASD (HA) of MTFs registered by state and anticipated H1N1 vaccine delivery.

(d) Ensure the Military Vaccine (MILVAX) Agency monitors MEDCOM influenza immunization compliance through MEDPROS beginning 1 December 2009.

(e) Ensure MILVAX reports MEDCOM novel A(H1N1) influenza immunization compliance in OTSG/MEDCOM Operations Updates as directed.

(f) Ensure MILVAX monitors and reports novel A(H1N1) influenza immunization compliance for Army Commands, Army Service Component Commands, and Direct Reporting Units as required.

(g) Ensure MILVAX works with the FDA and the CDC to facilitate prompt reporting of potential vaccine related adverse events (see safety annex).

d. Coordinating instructions.

(1) The injectable novel A(H1N1) influenza vaccine will be administered intramuscularly, over the deltoid muscle as a single dose for those ≥10 years of age. Those 6 months to 9 years of age, will receive a two dose regimen separated by approximately one month.

(2) Precluding shortages, no eligible beneficiary should be denied immunization.

(3) ACIP Recommendations. When vaccine is first available, ACIP recommends that programs and providers administer vaccine to persons in the following five target groups (order of target groups does not indicate priority):

(a) Pregnant women.

(1) ACIP recommends pregnant women be considered a target group for vaccination because they are at higher risk of complications and can potentially provide protection to infants who cannot be vaccinated.

(2) Immunization clinics and healthcare personnel will display a prominent sign directing women to alert the technician or provider if they think they might be pregnant.

(3) All females of childbearing age will be asked about the possibility of pregnancy prior to receiving the vaccine. If women have questions or concerns, they should consult with their healthcare provider before receiving the vaccine.

(4) Every effort should be made to vaccinate pregnant women with a preservative-free vaccine. Vaccination should not be withheld if a preservative-free vaccine is not available.

(b) Persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers).

(c) Healthcare and emergency medical services personnel.

(d) Persons aged 6 months–24 years.

(e) Persons aged 25–64 years who have medical conditions that put them at higher risk for influenza-related complications.

(4) The NIVIP should continue until supply is exhausted or the vaccine expiration date has been reached.

(5) Should an unexpected vaccine shortage occur, directions regarding prioritization will be provided by ASD (HA), and will be consistent with recommendations published in subsequent issues of the CDC Morbidity and Mortality Weekly Report.

(6) Screening.

(a) Immunization clinics and soldier readiness processing (SRP) sites will screen personnel receiving novel A(H1N1) influenza vaccinations according to package insert information to identify contraindications to immunizations. Package inserts are available at http://www.vaccines.mil/H1N1.

(b) According to the ACIP (ref b), simultaneous administration of inactivated vaccines against seasonal and novel influenza A (H1N1) viruses is permissible if different anatomic sites are used. However, simultaneous administration of live, attenuated vaccines against seasonal and novel influenza A (H1N1) virus is not recommended.

(c) The novel A(H1N1) influenza vaccine should not be administered to people who have hypersensitivity (e.g., allergic reactions including anaphylaxis) to eggs or other vaccine components without first consulting a physician. Allergy to the novel A(H1N1) influenza vaccine should not be confused with mild systemic reactions characterized by fever, malaise, myalgia, and headache.

(d) People with acute febrile illness should not be vaccinated until their symptoms have resolved. However, minor illnesses with or without fever are not contraindications to the vaccine, particularly among children with mild upper respiratory tract infection or allergic rhinitis.

(e) Individuals with asthma or recurrent wheezing, altered immuno-competence, or prior history of Guillain-Barrẽ Syndrome should be carefully evaluated for the potential risks versus benefits prior to being immunized with any influenza product. See package inserts located at http://www.vaccines.mil/H1N1.

(7) Adverse reactions. 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.

(a) Report known or suspected adverse events related to the administration of influenza vaccine to the Vaccine Adverse Event Reporting System (VAERS) www.vaers.hhs.gov.

(b) AR 40-562, Immunizations and Chemoprophylaxis establishes minimum requirements for submission of a VAERS form as vaccine reactions resulting in hospitalization or time lost from duty (more than 24 hours), or if contaminated lots are suspected (see reference c).

(8) An effective communication strategy for the Army Influenza Program is critical to success. Assistance in developing a local communication plan can be found at www.vaccines.mil/h1n1commplan.

(9) Soldiers may access their on-line immunization record in Army Knowledge Online (AKO). To view or print individual immunization records from the AKO

homepage, go to “my professional data” on the right hand side of the home page, then select “more”. Then click on “my medical readiness status” and select “view detailed information” under the immunization profile stoplight.

(10) Leaders at all levels can track individual service member and unit compliance using MEDPROS (accessed via www.mods.army.mil). Leaders may obtain information on how to obtain a logon ID directly from the website or by calling the MODS help desk at (703) 681-4976 or DSN: 761-4976/OCONUS DSN 312-761-4976 or e-mail mods-helps@asmr.com for assistance.

(11) Vaccine availability is expected to increase over time as subsequent allocations are received.

e. Reporting Requirements for Military Immunizations.

(1) Accurate records of vaccine usage must be kept. Detailed records will help facilitate evaluation of adverse events (AEs) following administration of the novel A(H1N1) influenza vaccine(s). Destruction documents for unused, expired vaccine must be submitted to U.S. Army Medical Material Agency (USAMMA) at vaccine expiration date. Further instructions are located at http://www.usamma.army.mil/assets/docs/Destruction%20SOP%20updated%2020%20NOV%2008.pdf.

(2) Universal implementation of procedures at installation in-and out-processing stations is required to ensure that personnel changing duty stations receive immunization before departure. MEDPROS and Defense Enrollment Eligibility Reporting System (DEERS) registry of new Soldiers (e.g., accessions) must be accomplished to capture immunization data. Immunization clinics and SRP sites will screen for novel A(H1N1) influenza immunization at mobilization, demobilization, and other similar opportunities until vaccine supplies are exhausted or expired.

(3) Commanders are charged with ensuring immunization data is entered into MEDPROS at the time of immunization, or at a maximum, within 72 hours of vaccination. Data entry may be accomplished using the MEDPROS web-based application (www.mods.army.mil), the MODS mainframe, the Remote Immunization Data Entry System (RIDES), compact disc (CD), or other systems or processes in coordination with the MODS support team. Data entry support may be obtained from the MODS help desk (see paragraph 3.b.(3).

(4) MEDPROS will continue to offer command drill-down reporting capability to allow all users to track compliance. The Army standard is for each ACOM, ASCC, DRU, and installation to achieve a green status NLT 1 April 2010. Compliance will be categorized as green (≥ 90% vaccinated), amber (80-89% vaccinated), and red (< 80% vaccinated).

(5) Issues Unique to RC.

(a) In accordance with AR 40-562 (ref c), Reserve Component members must be in a duty status to receive required immunizations.

(b) RC members who receive novel A(H1N1) influenza vaccinations from their personal physician or other non-military facilities will provide immunization date, vaccine manufacturer, and vaccine lot number to their unit's MEDPROS point of contact no later than their next drill following vaccination.

(c) RC members who incur or aggravate any injury, illness, or disease while performing active duty for less than 30 days, or on inactive duty training status are entitled to medical care appropriate for the treatment of the injury, illness, or disease. An adverse reaction from a DoD-directed immunization is a line of duty condition. Therefore, when a member of the RC presents for treatment at an MTF expressing a belief that the condition for which treatment is sought is related to receiving an immunization during a period of duty, the member must be examined and provided necessary medical care.

(d) When treatment has been rendered or the individual's emergent condition is stabilized, a line of duty and/or notice of eligibility will be determined as soon as possible. For injuries, illness or disease unrelated to duty, RC members should seek medical attention from their personal healthcare providers.

f. Non-Sentinel Site Surveillance and Case Reporting.

(1) MTFs will institute procedures to identify and monitor patients with influenza-like illness (ILI) and ensure that appropriate clinical specimens are collected and submitted for laboratory analysis. For this purpose, ILI may be defined as fever, respiratory symptoms, sore throat, myalgia, and headache with or without clinical or radiographic evidence of acute non-bacterial pneumonia. Nasopharyngeal washes, nasal, or throat swabs should be taken from patients with ILI or acute non-bacterial pneumonia who are at high risk for complications of influenza or ill enough to be hospitalized. MTFs are directed to send samples to the US Air Force as described in paragraph 3.g.(3).

(2) All laboratory-confirmed cases of novel A(H1N1) influenza infection will be reported through preventive medicine activities to the Reportable Medical Events System (RMES) at the Armed Forces Health Surveillance Center (AFHSC). POC at AFHSC is the Army Reportable Disease Project Officer at DSN 295-3240, commercial 301-319-3240.

(3) Aliquots of original samples and culture material, if available, from all confirmed 2009 HINI positive samples should be maintained and forwarded to the

Walter Reed Army Institute of Research, Division of Viral Diseases, (301-319-9612) for full genome sequencing in collaboration with the CDC.

(4) Report outbreaks and deaths from the novel A(H1N1) influenza to The Surgeon General's Proponency Office for Preventive Medicine, DSN 761-8134 (OCONUS 312-761-8134), commercial 703-681-8134; email: robert.l.mott@us.army.mil.

g. Sentinel Site Influenza Laboratory Surveillance.

(1) The United States Air Force School of Aerospace Medicine (USAFSAM) is the Executive Agent for laboratory-based influenza surveillance. Sentinel sites have been selected based on location, mission, and training status. Submission of clinical samples for virus isolation is encouraged.

(2) Information concerning the surveillance program can be obtained at https://gumbo.brooks.af.mil/pestilence/Influenza, DSN 240-5353, commercial 210-536-5353, or email: victor.macintosh@brooks.af.mil.

(3) MTFs will coordinate specimen collection strategies with the regional preventive medicine offices and with Brooke Army Medical Center Laboratory, William.Nauschuetz@us.army.mil. These individuals and organizations will coordinate with the army medical center labs, with the US Army Center for Health Promotion and Preventive Medicine and with the USAFSAM lab/DoD Global Influenza Surveillance Program. In addition, samples should be sent from patients admitted to MTFs with the diagnosis of viral pneumonia.

4. SERVICE SUPPORT. Refer to Annex I (SERVICE SUPPORT).

5. COMMAND AND SIGNAL.

a. Command. Normal command relationships remain in effect.

b. Signal.

(1) The primary OTSG/MEDCOM point of contact for this message is LTC Patrick Garman at (703) 681-5101 (DSN 761) or via email at vaccines@amedd.army.mil or vaccines@hqda-s.army.smil.mil (Attention: MILVAX).

(2) OTSG OPSCENTER 21 may be reached at (703) 681-8052 or via e-mail at eoc.opns@amedd.army.mil.

(3) The MODS help desk may be reached at (703) 681-4976 (DSN 761) or via e-mail at mods-helps@asmr.com. The help desk may also be reached at 1-888-849-4341.

(4) The USAMMA point of contact for vaccine destruction reports is the USAMMA Distribution Operations Center (DOC) at (301) 619-4318 or 7235 (DSN 343) or via e-mail at: usammadoc@amedd.army.mil.

ACKNOWLEDGE: OPS21 at eoc.opns@amedd.army.mil.

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ANNEXES:
Annexes A – H: Not used.
Annex I (Service Support)
Annexes J – R: Not used.
Annex S (Safety)

DISTRIBUTION:
AMEDDC&S
CHPPM
DENCOM
ERMC
GPRMC
HCAA
MRMC
NARMC
PRMC
SERMC
USAG Ft. Detrick
USAG Walter Reed
VETCOM
WRMC
WTC
DASG-DC
DIR, Health Policy and Services
DIR, Human Resources
DIR, Facilities
DIR, Information Management

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DIR, Logistics
DIR, Programs, Analysis, and Evaluations
DIR, Resource Management
DIR, Special Staff
DIR, AMEDD Transformation
DIR, Strategy and Innovation
DIR, Executive Agencies
DIR, Strategic Communications
POPM
DIR, Reserve Affairs

ANNEX I (SERVICE SUPPORT) TO OPERATION ORDER 09-75 (NOVEL A(H1N1)) INFLUENZA VACCINE IMMUNIZATION PROGRAM) – USAMEDCOM

1. GENERAL. This annex provides details on the novel A(H1N1) influenza vaccine and on the distribution of the vaccine. The NIVIP is a commander's force health protection responsibility. Commanders will follow guidance provided to properly identify and educate service members to be vaccinated, track immunizations, and ensure appropriate medical evaluation if they experience adverse reactions following any vaccination.

a. Education. Information is available to leaders on the MILVAX website, http://www.vaccines.mil/H1N1. Specific attention should be paid to the "education tool kit" and "questions and answers" posted on the influenza link. Unclassified references and educational tools will be available at the same location.

b. Key Messages.

(1) Your health and safety are our number one concern.

(2) The vaccine is safe and effective.

(3) Vaccination offers a layer of protection in addition to antivirals and other measures that are needed for the armed forces.

(4) The DoD NIVIP is part of our national defense strategy to safeguard DoD personnel against influenza disease**.**

(5) Vaccination acts as an internal body armor and offers a 24/7 layer of protection.

(6) Take everyday actions to stay healthy.

(a) Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash after you use it.

(b) Wash your hands often with soap and water, especially after you cough or sneeze. Alcohol-based hands cleaners are also effective.

(c) Avoid touching your eyes, nose or mouth. Germs spread that way.

(d) Stay home if you get sick. CDC recommends that you stay home from work or school and limit contact with others to keep from infecting them.

c. Medical Issues.

(1) Vaccine Healthcare Centers Network (VHCN). The VHCN is available to assist patients and healthcare personnel with treatment of health problems potentially related to vaccinations. Contact information can be found at http://www.vhcinfo.org/.

(2) DoD Information Call Centers. There are two available resources to answer vaccine related questions.

(a) The DoD GETVACC line is (1-877-438-8222), and is manned from 0800 to 1800 (Eastern), Monday through Friday.

(b) The DoD Vaccine Clinical Call Center 24-hour toll-free number is 1-866-210-6469.

2. Logistics.

a. The H1N1 influenza vaccine is a temperature sensitive product and activities must comply with cold chain management guidelines when transporting and storing this vaccine. Destruction documents for unused, expired vaccine must be submitted to USAMMA at vaccine expiration date. The USAMMA website provides additional guidance on handling, storage, transportation, and administration of influenza vaccine at http://www.usamma.army.mil/flu_h1n1.cfm.

b. The novel A(H1N1) influenza vaccine contracted for DoD and listed in MMI-XX-XXXX (Reference e), has the following characteristics; (All manufacturer presentations and NSNs are not represented below. Information from remaining vaccine manufacturers will be published in a fragmentary order once available.

(1) NSN: 6505-01-577-5940 - Novartis Vaccines Influenza A (H1N1) 2009 Monovalent Vaccine; USP, 0.5-mL Prefilled single dose syringe; Package of 10 syringes per carton, For immunizing persons 4 years of age and older; For IM Use. Storage: requires refrigeration. Do not freeze. Store product at 2º to 8ºC (36º and 46ºF). Cold chain must be maintained when transporting and storing this product.

(2) NSN 6505-01-577-5936 - Novartis Vaccines Influenza A (H1N1) 2009 Monovalent Vaccine; USP, 5-mL Multidose vial, contains preservative, individually packaged in a carton. For IM use in persons 4 years of age and older; Storage: requires refrigeration. Do not freeze. Store product at 2º to 8ºC (36º and 46ºF). Cold chain must be maintained when transporting and storing this product.

(3) NSN: XXX-XX-XXX-XXXX - Sanofi Pasteur Influenza A (H1N1) 2009 Monovalent Vaccine; USP, Prefilled 0.25-mL single dose pediatric syringe, package of 10 prefilled syringes per carton. For IM use in persons 6 months to 36 months of age. Storage: requires refrigeration. Do not freeze. Store product at 2º to 8ºC (36º and 46ºF). Cold chain must be maintained when transporting and storing this product.

(4) NSN: XXX-XX-XXX-XXXX - Sanofi Pasteur Influenza A (H1N1) 2009 Monovalent Vaccine; USP, Prefilled 0.5-mL single dose syringe in a package of 10; For IM use in persons 36 months of age and older. Storage: requires refrigeration. Do not freeze. Store product at 2º to 8ºC (36º and 46ºF). Cold chain must be maintained when transporting and storing this product.

(5) NSN 6505-01-577-6430 - Sanofi Pasteur Influenza A (H1N1) 2009 Monovalent Vaccine; USP, 5-mL Multidose vial, containing ten 0.5mL doses; contains preservative. For IM use in persons 6 months of age and older. Storage: requires refrigeration. Do not freeze. Store product at 2º to 8ºC (36º and 46ºF). Cold chain must be maintained when transporting and storing this product.

(6) NSN: XXX-XX-XXX-XXXX - CSL Biotherapies Influenza A (H1N1) 2009 Monovalent Vaccine; USP, 5-mL multidose vial, containing ten 0.5mL doses contains preservative. For IM use in persons 18 years of age and older. Storage: requires refrigeration. Do not freeze. Store product at 2º to 8ºC (36º and 46ºF). Once the stopper has been pierced, the vial must be discarded within 28 days. Cold chain must be maintained when transporting and storing this product.

(7) NSN: XXX-XX-XXX-XXXX - CSL Biotherapies Influenza A (H1N1) 2009 Monovalent Vaccine; USP, 0.5-ml prefilled single dose syringe in a package of 10. For IM use in persons 18 years of age and older. Storage: requires refrigeration. Do not freeze. Store product at 2º to 8ºC (36º and 46ºF). Once the stopper has been pierced, the vial must be discarded within 28 days. Cold chain must be maintained when transporting and storing this product.

(8) NSN: XXX-XX-XXX-XXXX – MedImmune Influenza A (H1N1) 2009 Monovalent Live, Intranasal Vaccine; USP, 0.2-mL prefilled, single-dose intranasal sprayer in a package of 10. For intranasal use in persons 2-49 years of age. Storage: requires refrigeration. Do not freeze. Store product at 2º to 8ºC (36º and 46ºF). Cold chain must be maintained when transporting and storing this product.

c. Distribution.

(1) The US Army Medical Materiel Agency is the inventory control point (ICP) for the Army for the novel A(H1N1) influenza vaccine which is an Acquisition Advice Code (AAC) service regulated item. The DSCP acquires the vaccine, and distributes it to activities based on the priorities established by ASD (HA). USAMMA follows all requisitions until they are fulfilled.

(2) Novel A(H1N1) influenza vaccine is distributed to MTFs and deployed units through pharmacy and/or medical logistics activities. Information and official messages regarding the distribution of novel A(H1N1) influenza vaccine may be obtained from the

USAMMA website: www.usamma.army.mil, DSN 343-3242, commercial 301-619-3242, or email usammafluvaccine@amedd.army.mil.

(3) Novel A(H1N1) influenza vaccine is heat and cold sensitive. The vaccine must be stored within the appropriate temperature range (35° to 46°F or 2° to 8°C). The USAMMA website provides additional guidance on handling, storage, transportation, and administration of influenza vaccine at http://www.usamma.army.mil/cold_chain_management.cfm.

ANNEX S (SAFETY) TO OPERATION ORDER 09-75 (NOVEL A(H1N1)) INFLUENZA VACCINE IMMUNIZATION PROGRAM) – USAMEDCOM

1. General. For a mass vaccination program utilizing the H1N1 vaccine(s) in a military population, it is important to be prepared to detect potential serious adverse events. Although clinical pre-licensure studies on any new H1N1 vaccine may identify potential vaccine-associated adverse events, rare adverse events associated with the vaccine will likely go unrecognized until there is widespread use of the vaccine in the population. Therefore, the timely identification of rare serious adverse events once the vaccine is in use is important to warrant the safe use of the vaccine in the military population.

2. Goal. The goal of the H1N1 vaccine safety surveillance project is to evaluate potential adverse events following administration of the new H1N1 vaccine(s) administered in US military active duty personnel using the Defense Medical Surveillance System (DMSS) and the military's electronic health record data.

3. Collaboration. The project is a collaboration between the DoD Military Vaccine (MILVAX) Agency, Armed Forces Health Surveillance Center, the Food and Drug Administration Center for Biologic Evaluation and Research, and the Centers for Disease Control and Prevention (CDC) Immunization Safety Office.

4. ICD-9 Codes. HCPs are encouraged to adhere to the following guidance when using ICD-9 codes to document their diagnosis. The following ICD-9 codes form a nationally recognized tier one list of pre-specified codes may signal a potential vaccine related adverse event. The codes will be actively monitored for DoD vaccine safety surveillance projects.

a. Guillain-Barrẽ Syndrome (GBS) - 357.0

b. Encephalomyelitis and transverse myelitis.

(1) Encephalitis, myelitis, and encephalomyelitis following immunization procedures – 323.5.

(2) Postinfectious encephalitis, myelitis, and encephalomyelitis – 323.6.

(3) Other causes of encephalitis, myelitis, and encephalomyelitis – 323.8.

(4) Unspecified cause of encephalitis, myelitis, and encephalomyelitis – 323.9.

(5) Acute transverse myelitis – 341.2.

c. Optic Neuritis.

(1) Optic neuritis – 377.3.

(2) Optic neuritis, unspecified – 377.30.

(3) Optic papillitis – 377.31.

(4) Retrobulbar neuritis – 377.32.

(5) Optic neuritis, other – 377.39.

d. Anaphylaxis.

(1) Other anaphylactic shock – 995.0.

(2) Anaphylactic reaction to serum -999.4.

e. Bell's Palsy.

(1) Bell's palsy – 351.0.

(2) Facial weakness/facial droop – 781.94.

f. Idiopathic thrombocytopenia (ITP).

(1) Immune (or idiopathic) thrombocytopenic purpura – 287.31.

(2) Primary thrombocytopenia (includes unspecified, Evans Syndrome, immune, other – 287.3.

(3) Thrombocytopenia, unspecified – 287.5.