U.S. Department of Homeland Security

**United States** 

**Coast Guard** 

COMMANDANT United States Coast Guard US Coast Guard Stop 7907 2703 Martin Luther King Jr Ave SE Washington DC 20593-7907 Staff Symbol: CG-112 Phone: (202) 475-5165

COMDTINST 6230.10B 19 FEB 2019

# COMMANDANT INSTRUCTION 6230.10B

# Subj: COAST GUARD SMALLPOX VACCINE PROGRAM (SVP)

- Ref: (a) Privacy Act of 1974; Department of Homeland Security, United States Coast Guard Notice of Privacy Act System of Records (011 Military Personnel Health Records System of Records), 73 Fed. Reg. 245 (19 Dec 2008)
  - (b) Information and Life Cycle Management Manual, COMDTINST M5212.1 (series)
  - (c) Department of Defense (DOD) Immunization Program for Biological Warfare Defense, DOD Directive 6205.3
  - (d) United States Coast Guard Countering Weapons of Mass Destruction Capabilities Manual (CWMD Manual), COMDTINST M3400.51 (series)
  - (e) Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases Manual, COMDTINST M6230.4 (series)
- 1. <u>PURPOSE</u>. This Instruction establishes policy, assigns responsibilities, and provides guidelines regarding the Coast Guard (CG) Smallpox Vaccine Program (SVP), unit prioritization, automated tracking system and reporting requirements, communications/education, military personnel guidance, and civilian personnel guidance.
- 2. <u>ACTION</u>. All CG Commanders, Commanding Officers, Officers-In-Charge, Deputy/Assistant Commandants, and Chiefs of Headquarters staff elements must comply with the provisions of this Instruction. Internet release is authorized.
- 3. <u>DIRECTIVES AFFECTED</u>. Coast Guard Smallpox Vaccine Program (SVP) Manual, COMDTINST M6230.10A, is hereby cancelled.
- 4. <u>DISCLAIMER</u>. This guidance is not a substitute for applicable legal requirements, nor is it itself a rule. It is intended to provide operational guidance for CG personnel and is not intended to nor does it impose legally-binding requirements on any party outside the CG.
- 5. <u>MAJOR CHANGES</u>. This Instruction clarifies and revises which personnel are mandated to receive the smallpox vaccine. It also no longer contains technical guidance more appropriate for a depot level publication IAW the Mission Support Business Model.

DISTRIBUTION – SDL No. 169																										
	а	b	с	d	e	f	g	h	i	j	k	1	m	n	0	р	q	r	S	t	u	V	W	Х	у	Ζ
А	Х	Х		Х	Х	Х	Х		Х	Х	Х	Х	Х	Х	Х	Х	Х		Х		Х	Х				
В	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
С	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х
D	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х		Х	Х
Е	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х		Х	Х	Х	Х	Х	Х	Х	Х	Х		
F																	Х	Х	Х							
G		Х	Х	Х	Х																					
Н	Х	Х	Х	Х	Х	Х	Х	Х		Х	Х															

DISTRIBUTION - SDL No. 169

NON-STANDARD DISTRIBUTION

### COMDTINST 6230.10B

### 6. ENVIRONMENTAL ASPECTS AND IMPACT CONSIDERATIONS.

- a. The development of this Instruction and the general policies contained within it have been thoroughly reviewed by the originating office in conjunction with the Office of Environmental Management, Commandant (CG-47). This Instruction is categorically excluded under current Department of Homeland Security (DHS) categorical exclusion (CATEX) A3 from further environmental analysis in accordance with "Implementation of the National Environmental Policy Act (NEPA), DHS Instruction Manual 023-01-001-01 (series).
- b. This Instruction will not have any of the following: significant cumulative impacts on the human environment; substantial controversy or substantial change to existing environmental conditions; or inconsistencies with any Federal, State, or local laws or administrative determinations relating to the environment. All future specific actions resulting from the general policy in this Instruction must be individually evaluated for compliance with the National Environmental Policy Act (NEPA), Department of Homeland Security (DHS) and Coast Guard NEPA policy, and compliance with all other applicable environmental mandates.
- <u>DISTRIBUTION</u>. No paper distribution will be made of this Instruction. An electronic version will be located on the following Commandant (CG-612) web sites. Internet: <u>http://www.dcms.uscg.mil/directives/</u>, and CG Portal: <u>https://cgportal2.uscg.mil/library/directives/SitePages/Home.aspx</u>.
- 8. <u>RECORDS MANAGEMENT CONSIDERATIONS</u>. This Instruction has been thoroughly reviewed during the directives clearance process, and it has been determined there are further records scheduling requirements, in accordance with Federal Records Act, 44 U.S.C. 3101 et seq., National Archives and Records Administration (NARA) requirements, and Reference (a). This Instruction does not have any significant or substantial change to existing records management requirements. See Reference (b) for specific records management and privacy requirements in regards to storage of medical records.

## 9. <u>OVERVIEW</u>.

- a. <u>Department of Defense (DOD) Immunization Program for Biological Warfare</u>. Reference (c) prescribes DOD policy for the use of vaccines for biological defense. The smallpox vaccine meets each of the requirements outlined in this directive. The Secretary of Defense has designated the Secretary of the Army as the Executive Agent for the program.
- b. Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD). Unlike vaccines used for preventive medicine, vaccines used specifically for biological defense are controlled by the JPEO-CBD. Under JPEO-CBD, the Joint Project Manager Medical Countermeasure Systems (JPM MCS) administers the Joint Vaccine Acquisition Program (JVAP), which procures and maintains

adequate stockpiles of smallpox vaccine to vaccinate and protect required DOD and CG personnel in the event of exposure to smallpox. In the event of a largescale exposure to smallpox within the United States, the DOD and CG's smallpox vaccine requirement is being met through an Interagency Agreement with the Department of Health and Human Services (HHS), under which the DOD and CG draw upon supplies held within the Strategic National Stockpile (SNS).

- c. <u>CG Countering Weapons of Mass Destruction (CWMD) Program</u>. The CG CWMD Program is managed by Commandant (CG-721). Reference (d) describes the capabilities provided to enhance the CG's ability to provide force protection in support of response operations in or near a Chemical, Biological, Radiological, and Nuclear (CBRN) contaminated environment. The CG SVP, along with other medical pre-treatment and medical countermeasure programs, is a subset of the overall force protection capabilities provided to CG forces in support of CBRN response operations.
- d. <u>Smallpox Vaccine</u>. The smallpox vaccine currently provided through JVAP, ACAM2000<sup>™</sup>, is licensed and approved by the U.S. Food and Drug Administration (FDA). ACAM2000<sup>™</sup> is indicated for active (i.e. pre-exposure) immunization against smallpox disease for persons determined to be at elevated risk for smallpox infection. It can also be used for post-exposure prophylaxis. ACAM2000<sup>™</sup> is a live vaccinia virus derived from plague purification cloning from Dryvax and grown in African Green Monkey kidney (Vero) cells. The smallpox vaccine does not contain smallpox virus (variola) and cannot spread or cause smallpox. The smallpox vaccine will be administered in the standard full-strength concentration (in accordance with the original labeled reconstitution instructions), unless the Centers for Disease Control and Prevention (CDC), FDA, or other responsible health authority issues explicit instructions to the contrary.

#### 10. <u>POLICY</u>.

- a. Mandatory Vaccination with Smallpox Vaccine.
  - (1) The SVP applies to CG military personnel. CG dependents who require smallpox vaccination by virtue of accompanying a CG service member on a remote assignment will be handled by a CG clinic or DOD MTF on a case-bycase basis.
  - (2) The SVP is a mandatory program for the following CG personnel (unless medically or administratively exempted): Deployable specialized forces (DSF) personnel (e.g., Maritime Security Response Team (MSRT), Maritime Safety and Security Team (MSST), Tactical Law Enforcement Team (TACLET), Port Security Unit (PSU), and National Strike Force (NSF)), International Port Security personnel, and any personnel deploying to DOD Combatant Commands (COCOM) requiring smallpox vaccination for theater entry. Medical personnel who directly support (i.e.: physically deploy with) DSF

personnel during DSF operations must also be immunized against smallpox.

- (3) When indicated, this vaccine is a required immunization unless medically exempted (e.g., for pregnancy) by competent medical authority or administratively exempted by command authority. The Clinical Consultation Services (CCS) section of the Immunization Healthcare Branch, Defense Health Agency (DHA-IHB) (<u>https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Clinical-Consultation-Services</u>) is available to assist healthcare personnel with medical consultation when members refuse or have serious concerns about vaccination.
- (4) Members refusing vaccination will show as Partially Medically Ready from an Individual Medical Readiness standpoint, but can still be ordered to deploy on the order of their Commanding Officer.
- (5) Absent an exemption, military personnel who refuse to be vaccinated may be in violation of Article 92 of the Uniform Code of Military Justice (UCMJ) for failure to obey a lawful order or for being derelict in the performance of their duties. United States Coast Guard Regulations 1992, COMDTINST M5000.3 (series), Chapter 8, section 8-2-1 (21) requires persons in the Coast Guard to permit action to be taken to immunize them against disease, as prescribed by competent authority. Any military service member who refuses to be vaccinated or fails to comply with a lawful order to be vaccinated may be subject to disciplinary proceedings under the UCMJ or other appropriate administrative proceedings.
- (6) Smallpox vaccine is not available through the Reserve Health Readiness Program. Selected Reserve (SELRES) members who require the vaccine must obtain it from a CG or DOD MTF during drill or a period of active duty.
  - a. <u>Availability</u>. Vaccines will only be available at clinics and sickbays that have been authorized by Commandant (CG-112) to administer the smallpox vaccine.
  - b. <u>Supplies</u>. United States Army Medical Material Agency (USAMMA) will coordinate with the JPEO-CBD to ensure adequacy of vaccine supplies and the distribution to CG clinics. Commandant (CG-112) will provide total CG vaccine requirements to USAMMA upon request.
  - c. <u>Distribution</u>. USAMMA will coordinate the distribution of the vaccine to the supporting medical supply activities for all services. Commandant (CG-112) will serve as the CG liaison with USAMMA. Units will furnish vaccine requirements to the supporting clinic. Clinics will order through the Health, Safety and Work-Life Service Center (HSWL SC) via Commandant (CG-112) to USAMMA.

- d. <u>Record keeping</u>. Service Treatment Record (STR) keeping (including reporting adverse reactions) will be maintained to document immunizations IAW Paragraph 13.b of this Instruction.
- 11. <u>ADMINISTRATIVE EXEMPTIONS</u>. Administrative exemptions from smallpox vaccination are authorized for personnel by the individual's Commanding Officer or Officer-In-Charge for the reasons found in Reference (e). Although religious exemptions are considered a type of administrative exemption, they must be coded as "Medically Declined" (MD) in the Medical Readiness Reporting System (MRRS).

#### 12. MEDICAL EXEMPTIONS.

- a. <u>General Information</u>. Some individuals will have either acute or chronic preexisting conditions that may warrant medical exemption from smallpox vaccination. In some cases, vaccination should be withheld if the individual cannot avoid household contact with another person who has contraindicating conditions. Furthermore, a small proportion of individuals will develop a more serious reaction after vaccination that may warrant medical exemptions, temporary or permanent, from further smallpox vaccination.
  - (1) In a smallpox emergency, there are no absolute contraindications to vaccinating people with a high-risk exposure to an infectious case of smallpox (e.g., face-to-face contact). Prior contraindications to vaccination could be overshadowed by personal risk of smallpox disease. Smallpox vaccine would be made available for people exempted during pre-outbreak vaccination programs. People at greatest risk for experiencing serious vaccination complications are often those at greatest risk for death from smallpox. If a relative contraindication to vaccination exists, the risk for experiencing serious vaccination complications must be weighed against the risks for experiencing a potentially fatal smallpox infection.
  - (2) Granting medical exemptions is a medical function performed by a privileged healthcare provider. The provider will grant individual exemptions when medically warranted, with the overall health and welfare of the patient clearly in mind, balancing potential benefits with the risks while taking into consideration the threat situation. Medical exemptions are not based on preferences of the patient.
- b. <u>Temporary and Permanent Medical Exemptions</u>. A list of types of medical exemptions can be found in Reference (e). The two most common annotated medical exemption categories are "Medical Temporary" (MT) and "Medical Permanent" (MP). Annotate the patient's STR and the Immunization Tracking System (ITS) with these codes, and update them as appropriate. In the event of a confirmed smallpox outbreak, permanent exemptions could be rescinded, based on individual risk.

#### (1) Temporary.

- (a) Temporary medical exemptions are warranted when a provider has a concern about the safety of immunizations in people with certain clinical conditions. The vaccine's package insert contains examples of situations that warrant a temporary medical exemption (e.g., immune-suppressed people and pregnant women). The CDC's Advisory Committee on Immunization Practices (ACIP) notes that people with acute, chronic, or exfoliative skin conditions (e.g., burns, impetigo, varicella zoster, herpes, psoriasis, severe or uncontrolled acne) may also be at higher risk for inadvertent auto-inoculation and should not be vaccinated until the condition resolves or a provider affirms it is under maximal control.
- (b) People who have household contact with a person who has a contraindication to smallpox vaccination (e.g., immune-suppressed people, people with atopic dermatitis or eczema, pregnant women, children under the age of 1 year) must either have alternative housing arrangements during the vaccination period or be exempted from smallpox vaccination until the household-contact situation is no longer applicable. Avoidance of contact should continue for 30 days after vaccination and until the vaccine site is healed.
- (c) Military- unique berthing settings require similar precautions. Exempt individuals should be physically separated and exempt from duties that pose the likelihood of physical contact with potentially infectious materials (e.g., clothing, towels, linen) from recently vaccinated people. This separation will include not having the vaccine recipient share or alternate the use of a common sleeping space (e.g., cot, bunk, berth) with people with contraindications to vaccination.
- (d) In situations where a medical condition is being evaluated or treated, a temporary deferral of smallpox vaccination may be warranted, up to a maximum of 12 months. This would include significant vaccineassociated adverse events that are being evaluated or while awaiting specialist consultation. The attending provider will determine the deferral interval, based on individual clinical circumstances.
- (2) Permanent.
  - (a) Medical Permanent exemptions are generally warranted if the medical condition or adverse reaction is so severe or unremitting that the risk of subsequent immunization is not justified. In the case of smallpox vaccine, these permanent exemptions could be lifted if the individual had face-toface contact with someone contagious with smallpox. Examples of situations warranting a permanent medical exemption appear in the vaccine's package insert (e.g., life-threatening allergy to vaccine component, immune-suppressed people, people infected with human

immunodeficiency virus, people with atopic dermatitis or eczema or a past history of those disorders). People with contraindicating skin conditions who received smallpox vaccine earlier in life may be revaccinated after medical consultation for individual risk-benefit decision making.

- (b) The ACIP recommends exempting individuals with known cardiac condition(s) and persons with three or more known major cardiac risk factors. Personnel with the following cardiac conditions will be exempted: myocardial infarction, angina pectoris, cardiomyopathy, congestive heart failure, stroke, transient ischemic attacks, chest pain or shortness of breath with activity associated with a heart condition, other coronary artery disease, and other heart conditions under the care of a physician.
- (c) The following cardiac risk factors should be identified during preimmunization processing: current tobacco use, hypertension, hypercholesterolemia, diabetes mellitus, and family history of heart disease in a 1<sup>st</sup> degree relative with onset before age 50. Persons with three or more of the above referenced risk factors should be exempted from receiving smallpox vaccine.
- (d) If a permanent medical exemption is indicated, follow Reference (e) for granting such exemptions. If the situation changes, an appropriate medical specialist can remove a medical exemption.
- (e) A permanent medical exemption renders a CG service member ineligible for assignment to DSF units.
- (f) A permanent medical exemption may prevent a CG service member from deploying under the Operational Control of a DOD COCOM. The gaining COCOM Command Surgeon will determine if such a CG service member meets theater entry requirements.
- (3) I<u>mmune</u>. Use this code to indicate that a patient has either had smallpox disease or has been successfully immunized. Do not set an end date greater than 10 years from the date of infection or the date of the last vaccination.
- (4) If an individual's clinical case is complex or not readily definable, healthcare providers should consult an appropriate medical specialist with vaccine safety-assessment expertise before granting a permanent medical exemption. In addition, providers may consult with allergy/immunology specialists at the CCS, DHA-IHB, at <u>https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Clinical-Consultation-Services</u> or by calling 877-438-8222. In such cases, providers will document specialty consultation in the individual's STR, including the considerations and reasons why a temporary or permanent medical exemption is or is not granted.
  - (a) Exemption Referral. An individual who disagrees with a provider's

recommendation regarding an exemption may request a referral for a second opinion. In such cases, the individual will be referred to a provider experienced in vaccine adverse event management who has not been involved in the decision-making to this point. This provider may be at the same facility or, when applicable, at a referral facility. If the patient disagrees with the second opinion, he or she may be referred directly to the CCS. Commandant (CG-112) retains the authority to review all appealed exemption determinations and may delegate this authority to individuals with appropriate expertise within their organization.

(b) Specialty Consultation. Each clinic administrator will assist patients in obtaining appropriate specialty consultations expeditiously and in resolving patient difficulties. Specialists may grant permanent medical exemptions. Return of a patient to his or her primary care provider is not required if the referring specialist deems a permanent medical exemption is warranted. A Vaccine Adverse Event Reporting System (VAERS) report must be completed for any permanent medical exemption granted due to a vaccine related adverse event. If providers have questions about contraindications, the need for an exemption, adverse events after vaccination or possible contact transfer, they can contact the CCS.

## 13. <u>MEDICAL REPORTING</u>.

- <u>PURPOSE</u>. The purpose is to ensure the success of the SVP by tracking CG personnel immunized with smallpox vaccine. An automated ITS is mandated by the Office of the Assistant Secretary of Defense, Health Affairs (OASD (HA)). Additionally, OASD (HA) has directed that all immunization data of military members be entered into the Defense Enrollment and Eligibility Reporting System (DEERS) database.
- b. <u>IMMUNIZATION TRACKING SYSTEM (ITS)</u>. Currently, MRRS is mandated as the ITS for smallpox vaccination for CG personnel receiving immunizations within the CG system. All CG medical facilities/personnel providing immunization services are required to be familiar with MRRS and its use.
  - <u>Coast Guard members</u>. CG units having members requiring initial or subsequent doses (e.g., revaccination every 10 years) of smallpox vaccine will ensure those members receive their vaccination from CG clinics/sickbays or DOD Military Treatment Facilities (MTFs). Medical unit personnel will ensure the immunization data is entered into the appropriate ITS.
  - (2) <u>DOD members</u>. DOD members may receive initial or subsequent doses of smallpox vaccine from a CG clinic/sickbay. For these non-CG service members, an entry will be made in the appropriate ITS. The ITS will transmit

the immunization data to DEERS. An entry will also be made on a Chronological Record of Medical Care (Smallpox Vaccination Initial Note), SF-600 SVP Overprint for entry into the DOD service member's STR. The member must notify his or her medical readiness point of contact to ensure the immunization data in DEERS is uploaded into their service specific ITS.

(3) <u>Coast Guard members at DOD MTFs</u>. The servicing CG clinic or assigned IDHS will enter the vaccine data for CG personnel vaccinated at DOD MTFs into local service component ITS. This data will automatically download to DEERS.

#### c. <u>REPORTING REQUIREMENTS</u>.

- <u>Service Treatment Record</u>. Documentation of all smallpox vaccinations must be made in the following locations in the STR: Chronological Record of Medical Care (Smallpox Vaccination Initial Note), SF-600 SVP Overprint and the Adult Preventive and Chronic Care Flow Sheet, DD Form 2766 (MRRS version is acceptable).
- (2) <u>Exemptions</u>. The servicing CG clinic or assigned IDHS will record all exemptions (exceptions), both medical and administrative, in the ITS. The proper codes to use may be found in Reference (e). Several exemptions are considered indefinite and no end date is entered in the ITS. Any exemption that is not indefinite (e.g., MT) must have an exemption end date recorded in the ITS.

#### d. ADVERSE EVENTS REPORTING.

- (1) <u>Where to enter data</u>. The servicing CG clinic or assigned IDHS will enter all adverse events or reactions to immunizations into MRRS under comments section, as well as in the STR.
- (2) When to report a problem. The servicing CG clinic or assigned IDHS must report all adverse vaccine reactions resulting in hospitalization or duty time lost (in excess of 24 hours), as well as due to suspected lot contamination, must be reported in the Vaccine Adverse Event Report System (VAERS). VAERS forms and information can be obtained by calling 1-800-822-7967 or from the Web at <u>https://vaers.hhs.gov/reportevent.html</u>; reports can filed online. Additionally, the servicing CG clinic or assigned IDHS will file a VAERS report for any permanent medical exemption due to a vaccine related adverse event. Other reactions may be reported to VAERS, either by a healthcare provider or the vaccinated individual.
- (3) <u>Distribution of forms</u>. If a paper or Portable Document Format (PDF) VAERS form is completed at a CG unit/facility, the original is forwarded to the FDA. A copy of the completed VAERS form will be retained on file at the local command or unit. If a report is completed online, document that the report was made in the patient's STR.
- (4) <u>Report originators</u>. Anyone may report a vaccine-associated event through

VAERS to the FDA. Healthcare providers should assist in the completion and forwarding of a VAERS report for any vaccine recipient desiring to complete one. Healthcare providers assisting in the VAERS process are not expected to determine the causality by the smallpox vaccine, but only establish that a temporal relationship exists between the immunization and the possible adverse reaction.

### 14. <u>RESPONSIBILITIES</u>.

- a. <u>Commandant (CG-11)</u>. Provides technical expertise to the Commandant for the prevention of the smallpox disease threat.
- b. <u>Commandant (CG-112)</u>.
  - (1) Develops and disseminates medical education, information, policy, and doctrine to the field as required in accordance with the CG SVP.
  - (2) Functions as liaison between HSWL SC and USAMMA to order vaccine supplies for the CG.
  - (3) Provides approval for smallpox vaccine orders from HSWL SC.
  - (4) Provides timely notification to the field regarding any changes to designated units or individual mobilizations to high threat areas. Such notifications may be classified.
  - (5) Maintains a liaison with SVP program managers in other services, keeping current with the latest educational and communications information available.
  - (6) Forwards new information/briefings to HSWL SC for distribution to the appropriate audiences.
  - (7) Refers media queries from outside the CG to Commandant (CG-0922).
  - (8) Refers congressional queries and briefings to Commandant (CG-0921).
- c. Commandant (CG-0922).
  - (1) Provides coverage of immunization program in internal CG media.
  - (2) Provides communication tools about the immunization program to CG Public Affairs Officers (PAOs) for their internal and external information needs.
  - (3) Responds to media inquiries and assist CG District PAOs in responding to media queries.
  - (4) Provides Commandant (CG-112) any relevant information received from other sources.
  - (5) Functions as the CG liaison to DOD public affairs offices and workgroups with regard to the CG SVP.
- d. <u>Commandant (CG-0921)</u>. Coordinates response to congressional queries, as appropriate.

- e. Health, Safety, and Work-Life Service Center.
  - (1) Coordinates with USAMMA through Commandant (CG-112) to ensure sufficient vaccines and ancillary supplies are available to units.
  - (2) Executes logistics management for the CG SVP.
  - (3) Maintains the Interagency Support Agreement between the CG and USAMMA for the CG SVP.
  - (4) Executes funding for the CG SVP.
  - (5) Ensures executive summaries (EXSUMs) for vaccine destruction are routed to USAMMA through Commandant (CG-112).
- f. Unit Commanding Officers and Officers-In-Charge.
  - (1) Have the ultimate responsibility to ensure their personnel meet the standards of this Instruction.
  - (2) Determine smallpox vaccine needs on a monthly basis, at least 30 days in advance, and coordinate with the cognizant medical clinic or sickbay to ensure that personnel are immunized on schedule (e.g., revaccination every 10 years).
  - (3) Ensure all required personnel are available for smallpox vaccination in accordance with this Instruction.
  - (4) Ensure all assigned personnel reported as overdue for vaccination (as reported from the Coast Guard Business Intelligence (CGBI) System) receive or have received the smallpox vaccination. If there is an ongoing issue regarding non-compliance, the command should discuss with the cognizant clinic or sickbay.
- g. <u>Coast Guard clinics and sickbays</u>. CG clinics and sickbays that have been authorized by Commandant (CG-112) to administer the smallpox vaccine must:
  - (1) Have full responsibility for implementing the SVP.
  - (2) Complete a registry agreement with USAMMA in order to participate in the SVP to order and administer smallpox vaccine. To complete a registry agreement, contact USAMMA's Distribution Operations Center (DOC) at (301) 619-9539, or send an email inquiry to <u>usarmy.detrick.medcom-</u> <u>usamma.mbx.doc@mail.mil.</u>
  - (3) Provide vaccination for CG personnel at CG clinics and sickbays and ensure data entry is completed. Clinics and sickbays should use the designated electronic ITS (e.g., MRRS) for tracking purposes.
  - (4) Provide the smallpox vaccination to personnel from other services who are enrolled in the DOD SVP in accordance with OASD (HA) guidance.
  - (5) Ensure personnel receiving the smallpox vaccine have been educated about the SVP. Prior to administering the smallpox vaccine, ensure that personnel are

provided the "What You Need to Know About Smallpox Vaccine" Brochure and the FDA's ACAM2000<sup>TM</sup> Medication Guide (these brochures can be downloaded from the following web site: https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Smallpox/. The brochure and guide provide specific information regarding the vaccine, its safety, benefits, and the need for adherence to the immunization schedule (i.e. revaccination every 10 years). The provision of this information must be documented by health services personnel on the Chronological Record of Medical Care (Smallpox Vaccine Screening Form), SF-600 SVP Overprint. A continuation sheet is also available, as are a Smallpox Vaccine Take Check Medical Note and a Smallpox Vaccine Sick Call Medical Note. These forms are prescribed and are available at the same website as the brochure and medication guide above. An optional Smallpox Vaccine 30-day Diary Card is also available for patients. Clinics must also provide members with "Questions and Answers for Household Members and Community Members" to bring home to household contacts, available from the same website.

- (6) Ensure that personnel receiving the vaccination are given the opportunity to ask questions about the vaccine and its administration.
- (7) Ensure that reservists, both those who are assigned permanently and those assigned temporarily, understand they may seek CG medical care if they have an adverse reaction to any immunization required by the CG.
- h. Privileged Healthcare Providers.
  - (1) Must provide counseling (one on one or in a group setting) to personnel receiving the smallpox vaccination.
  - (2) Must review and sign the SF-600 SVP overprints.
  - (3) Must grant medical exemptions in accordance with Paragraph 12 of this Instruction. Only physicians can evaluate patients for religious exemptions; see Reference (e). Record all exemptions in the appropriate ITS and in the STR on SF-600 SVP overprints.
- <u>Health Services Technicians and Nurses who administer smallpox vaccine</u>. Complete the "DOD Smallpox Vaccination Training", available at <u>https://jkodirect.jten.mil/Atlas2/page/coi/externalCourseAccess.jsf?v=1549487046398</u> <u>&course\_prefix=DHA&course\_number=-US081</u>, prior to administering any smallpox vaccine. This will be verified by the Health Services Administrator.

- j. <u>Coast Guard Personnel</u>.
  - (1) Read and take all steps necessary to understand the "What You Need to Know about Smallpox Vaccine" Brochure.
  - (2) Read the FDA-mandated ACAM2000<sup>TM</sup> Medication Guide.
  - (3) Report to appropriate CG clinic, sickbay, DOD MTF, or other designated facility for the smallpox vaccination and any follow up evaluation.
  - (4) Report adverse reactions to the appropriate CG clinic, sickbay, or DOD MTF.
- 15. <u>ADDITIONAL GUIDANCE</u>. Additional information for commanders and medical personnel. There is a significant amount of misleading and inflammatory misinformation circulating in the media and on the internet regarding the SVP and the vaccine. Accurate information can be found on the web at: <u>https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Smallpox/Smallpox-Resource-Center</u>.
- 16. <u>FORMS/REPORTS</u>. Forms related to the SVP can also be found on the following site: <u>https://health.mil/Military-Health-Topics/Health-Readiness/Immunization-Healthcare/Vaccine-Preventable-Diseases/Smallpox/Smallpox-Resource-Center</u>. Clinics and sickbays will receive a Smallpox Trifold for each dose of Smallpox that they order. All enclosures may be reproduced locally. The <u>Adult Prevention and Chronic Care Flow</u> <u>Sheet, DD Form 2766</u>, is a restricted form; contact the DOD forms manager for additional forms.
- 17. <u>REQUEST FOR CHANGES</u>. Units and individuals may recommend changes via the chain of command to: hqs-dg-lst-cg-112@uscg.mil.

ERICA G. SCHWARTZ /s / Rear Admiral, U.S. Public Health Service Director of Health, Safety, and Work-Life

Enclosure: (1) SMALLPOX VACCINE COMMUNICATIONS AND EDUCATION PLAN

## SMALLPOX VACCINE COMMUNICATIONS AND EDUCATION PLAN

- 1. <u>PURPOSE</u>. To disseminate standardized education and communications material for the CG SVP.
- 2. <u>BACKGROUND</u>. The CG is a full participant in the SVP. Internal and external education programs and public affairs support are required.
  - a. <u>Gulf War-related illnesses</u>. Biological and chemical warfare countermeasures, including vaccines, have been perceived as possible causes for health concerns of Gulf War veterans. Although no scientific evidence links the smallpox vaccination to Gulf War-related illnesses, these perceptions may cause some patients to ask to sign informed consent waivers before they receive the vaccine. Others may want the right to refuse vaccination without risk of reprisal.
  - b. <u>Refusal</u>. As with other vaccinations required by the military, service members may not refuse the smallpox vaccine. Informed consent for military personnel is not required for FDA-licensed immunizations when used for an FDA-approved indication. CG members who refuse vaccination may be subject to administrative or disciplinary action, or both, at the discretion of the commander, for disobeying a lawful order.
  - c. <u>Other Medical Conditions</u>. CG personnel may also be concerned about how the smallpox vaccination affects their existing medical conditions; see Paragraph 12.b of this Instruction for contraindications and precautions.
- 3. <u>OBJECTIVES</u>. Ensure full understanding and support of the CG SVP by CG personnel, their families, and the media by providing education and planning guidance to all CG commanders, unit senior leadership, public affairs officers, and health services personnel. Objectives include:
  - a. <u>Information</u>. Inform all personnel that immunization is a necessary part of the plan to eliminate smallpox as a threat to U.S. Forces.
  - b. <u>Support</u>. Gain the support of CG personnel and their families for the vaccination of U.S. Forces against smallpox.
  - c. <u>Threat reality</u>. Use this opportunity to inform the American public that biological warfare is a very real threat to our forces and mission readiness.
- 4. <u>TALKING POINTS</u>. The following talking points will be emphasized:
  - a. <u>Threats</u>. Smallpox is deadly and would disrupt military missions.
    - (1) Contagious. Smallpox is a disease that spreads quickly from one person to another by air.
    - (2) Dangerous. Smallpox is one of the most dangerous diseases in human history, having killed over 300 million people in the 20<sup>th</sup> century alone.

- (3) Disruptive. A smallpox outbreak would significantly affect military readiness.
- b. <u>Precautions</u>. Smallpox vaccine prevents smallpox, but requires very careful use.
  - (1) The World Health Organization used smallpox vaccine to eradicate natural smallpox from the Earth.
  - (2) The smallpox vaccine does not contain smallpox virus. Instead, it uses a similar virus (cowpox virus) that also can give immunity to smallpox.
  - (3) All vaccines cause side effects, but smallpox vaccine has unique features that require special handling.
  - (4) People vaccinated with the smallpox vaccine should not touch the smallpox vaccination site. This is to reduce the risk of spreading virus somewhere else, either on one's own body or someone else's.
  - (5) Very rarely, smallpox vaccine can cause serious side effects.
  - (6) Some people should not get smallpox vaccine except in an emergency.
  - (7) DOD and the CG will use smallpox vaccine licensed by FDA, unless there is a smallpox outbreak. In an outbreak, DOD and the CG may use investigational supplies of vaccine that FDA permits to be used.
- c. <u>Our people</u>. Preserving the health and safety of our people is our top concern.
  - (1) Healthy service members complete their missions. Vaccines will help keep each member of the CG team healthy.
  - (2) Vaccines have kept troops healthy since the days of General Washington.
  - (3) Vaccination offers a layer of protection, in addition to other measures, needed for certain members of the Armed Forces.
- (4) <u>National strategy</u>. The CG smallpox vaccination program is part of our national strategy to safeguard Americans against smallpox attack.
  - (1) DOD and CG are working with other federal departments to strengthen America's defenses against smallpox.
  - (2) The U.S. Government has been preparing for some time for the remote possibility of smallpox being used as a biowarfare agent or as a weapon of terrorism.
- 5. <u>AUDIENCES</u>. Education and public affairs information will be targeted to the following audiences:

- a. <u>Coast Guard personnel</u>. All CG personnel who will be vaccinated and their families (Active Duty, SELRES, and others).
- b. <u>Coast Guard civilian personnel</u>. Coast Guard civilian personnel who will be vaccinated and their families, if any.
- c. Coast Guard leadership.
- d. Coast Guard healthcare personnel.