

NHCP Vaccine Distribution Program Acknowledgement Agreement



Naval Hospital Camp Pendleton Vaccine Distribution Program

General Information

1. Your unit/facility is registering with the Naval Hospital Camp Pendleton (NHCP) Preventive Medicine Department (PMD) for the NHCP Vaccine Distribution Program. All submissions must include a log documenting two weeks of temperatures on ALL vaccine storage refrigerators and freezers. List your facility name as you would like it to appear on your folder and with all correspondence regarding immunizations.

Acknowledgement agreements must be renewed / updated when:

1. The senior medical personnel are no longer employed at the listed facility.
2. The majority of the trained vaccine personnel are no longer with the facility.
3. Significant changes with the facility have happened requiring change.

It is the responsibility of the unit to ensure that all acknowledgement agreements are current. The outgoing trained vaccine personnel should ensure that proper turnover is conducted.

2. There will be **no more than 50 doses each of any type of single vaccine kept on site longer than 48 hours**, with the exception of scheduled unit/facility stand downs.
- a. ALL vaccine requests for a stand down must be placed **two weeks prior to the date of the stand down**, and the date the unused vaccine will be returned to PMD, documented on the vaccine order form.
 - b. All forms must be typed or printed legibly. Illegibly or incorrectly filled forms will result in the order being denied.

Note: Any unit found to violate this standard will be subject to administrative penalties and notification of the units' specific major subordinate element Surgeon's Office including a Commanding General notification.

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The document contains six separate sections; a description of each section is provided below.

Section 1: Vaccine Pick-Up Information

- List the person(s) who will be picking up vaccines.
- List the unit physical address (building # / area).
- Include telephone and fax numbers, as well as an e-mail address for each point of contact.
- Ensure that ALL personnel designated to pick-up vaccines have been properly trained in accordance with the BUMEDINST 6230.15A.

Section 2: Training Information / Requirements

- All personnel designated to pick-up vaccines must meet the minimum requirements for training as outlined in the attached registration and acknowledgement agreement.

Section 3: Senior Medical Officer Registration

- The certifying physician, advanced nurse practitioner, physician's assistant, or IDC must read the Naval Hospital Camp Pendleton Vaccine Distribution Program acknowledgement agreement terms. He/she must provide his/her name and other pertinent information for purposes of accountability and tracking. Providers must date and sign the acknowledgement agreement in the designated area.

Section 4: Additional Personnel in the Facility Trained to Transport Vaccines

- List all Cold Chain trained personnel that will be picking up vaccines from the Naval Hospital Camp Pendleton Vaccine Distribution Program.
- Include each provider's rank, name, title and training completion date on the form provided. If a provider's training is pending, write "pending" in pencil and call the program as soon as the training is completed. Failure to do so will result in the listed provider being unable to pick up vaccine.

Section 5: Emergency Plan

- Fill in the emergency plan template provided and post the document on the outer door of your storage unit. It needs to be visible to anyone who would need to move the vaccines in case of an emergency.

Section 6: Fraud, Waste and Abuse Policy

Note: If you have any further questions, please call the Preventive Medicine Dept at 760-725-1270.

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NHCP Vaccine Distribution Program Registration & Acknowledgement Agreement

Unit / Facility Name: _____

Please select one:

- Initial registration Renewal of my existing registration

Section 1: Vaccine Pick-Up Information

Information for Primary Point of Contact

Unit / Facility Point of Contact and Title: _____

Unit / Facility Address (bldg #): _____

City: _____ State: _____ Zip Code: _____

Phone: _____ FAX: _____ E-mail: _____

Special Instructions or additional information:

Additional Information for Second Point of Contact

Unit / Facility Contact and Title: _____

Unit / Facility Address (bldg #): _____

City: _____ State: _____ Zip Code: _____

Phone: _____ FAX: _____ E-mail: _____

Personnel who pick up vaccines MUST be in the proper uniform of the day, with an approved transportation container, 8-Part folder with all documents, and with documented training.

Be aware that personnel who do not meet the above requirements will be not be issued vaccine

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Section 2: Training Information and Requirements

1. The following course segments will be taken by each member listed as a vaccinator on this acknowledgement agreement. The NHCP PMD will provide classes on the below topics in the form of an interactive classroom experience. All personnel providing immunizations will also complete the Project Immune Readiness (<https://vhcprojectimmunereadiness.com>) training modules for each vaccine that is administered.

- a. Vaccine storage and handling
- b. Vaccine characteristics
- c. Patient interviewing techniques
- d. Distinguishing valid and invalid contraindications
- e. Injection technique
- f. Documentation
- g. Managing and reporting of adverse events
- h. Anaphylaxis
- i. Administration and management of the immunization program

2. Certificates will be issued to the individuals for the training conducted by NHCP PMD personnel. The students must place a copy of the course completion certificate and/or class roster in their 8-Part Folder.

3. Copies of the certificates for completion of an Immune Readiness module should be placed in the unit's 8-Part Folder.

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Section 3: Senior Medical Officer Registration

1. I, (Last Name, First Name, Rank) _____ certify, that in while in the course of administering vaccines received from the NHCP PMD for use within my facility / unit; we will provide patients, parents and guardians a copy of the most current "Vaccine Information Statement" (VIS) as before administering each dose of vaccine. We will record the following information in the patient's 'hard' medical record and electronic medical records system (e.g., AHLTA, MRRS)

- a. Type of vaccine administered
- b. Date vaccine administered
- c. Manufacturer name and lot number of the vaccine
- d. Anatomical site of administration
- e. Method of administration: intranasal, ID, IM, SC
- f. Signature and professional title of person administering the vaccine
- g. Statement on the issuance of the VIS

2. We will submit the most current required forms and documents in the NHCP Vaccine Distribution Handbook when taking issuance of or returning vaccine to PMD. **I understand that vaccine orders will not be filled if the required documents are not in the 8-Part Folder.**

3. We will maintain an 8-Part folder with all required information that mirrors that of the NHCP Vaccine

Distribution Program to ensure correctness, completeness and accuracy of all orders. This will also enable the unit to maintain historical data on their vaccine program and keep track of all vaccine orders placed along with their status.

- a. Approved and current Vaccine Distribution Program Acknowledgement Agreement
- b. Record of Vaccine Storage and Handling training for unit personnel
- c. Vaccine Order Forms
- d. Vaccine Return Forms
- e. Vaccine Loss Statements and Incident Reports
- f. Inventory Sheets
- g. Emergency Plan
- h. Copies of temperature logs and / or thermometer graphs from the storage refrigerator(s) and freezer (s) used for vaccine storage.

4. I understand that **no more than 50 doses** each of any type of single vaccine will be kept on site in our vaccine storage refrigeration units. The only exception to this rule is in the event of a medical readiness stand down. The PMD must be notified in writing on the vaccine order form when the order is placed. I further acknowledge that any doses of vaccines above the maintenance dose amounts must be returned to the PMD.

5. We will return all compromised, damaged, or expired vaccines (including partial vials) to the PMD along with the completed Vaccine Return Form, and if applicable a Vaccine Loss Statement and Incident Report. I will ensure that all vaccines are maintained at the appropriate temperatures as published in the vaccine product insert and in accordance with NHCP instructions.

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6. We will ensure that the vaccine storage temperatures are monitored and recorded at a minimum of twice daily and that refrigerator/freezer temperature logs and thermometer graphs are maintained for a **minimum of three (3) years**.
7. We will have a plan in place to ensure that temperatures are also monitored and recorded at a **minimum of twice daily on weekends and holidays** through the use of unit or facility duty personnel without exception.
8. **For Varicella and Zoster vaccines only:** We will ensure that our facility has a freezer (with a separate, sealed freezer door) that will maintain an average temperature of +5° F (-15° C) or colder.
9. We will ensure that the facility staff members are instructed in the special handling requirements of varicella and zoster vaccines, and the vaccine will be stored and handled according to the product insert.
10. I will ensure that our unit/facility vaccine storage refrigerator is approved and of commercial or biomedical-grade. However, household refrigerator/freezer units with dual controls also may be used to store vaccines. Dormitory-style refrigerators are not authorized for vaccine storage.
11. I will ensure that my clinic/aid station complies with the Immunization Program Manager's request for monthly testing of our auto-dialer system, and will seek permission for weekend and holiday storage of our vaccines if we have the appropriate monitoring systems in place.
12. I will ensure that when our staff brings vaccine to the PMD for weekend and holiday storage, all vaccine is in a transparent plastic bag, with the vaccine inventory log and unit name clearly displayed.
13. I will ensure we comply with the appropriate immunization recommendations, schedules, dosages, and contraindications established by the MILVAX Agency, BUMEDINST 6230.15A, DHHS Advisory Committee of Immunizations Practices (ACIP), and NAVHOSPCAMPENINST 6230.2C.
14. We will comply with the NHCP Vaccine Distribution Program Fraud, Waste and Abuse policy.
15. We will, in accordance with these guidelines, allow the NHCP PMD access to our immunization office for the purpose of conducting Quality Assurance Reviews.

Physician / Advanced Nurse Practitioner / IDC Representing Facility
(Print)

Date

Physician / Advanced Nurse Practitioner / IDC Representing Facility
(Signature)

Received by Preventive Medicine:

Name/Signature _____

Date: _____

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Section 5: Temperature Out of Range/Emergency / Power Outage Plan

Clinic or Department Designated POC: _____
Phone # _____ Cell # _____ Pager # _____
Secondary POC: _____
Phone # _____ Cell # _____ Pager # _____

KEEP ALL REFRIGERATOR AND FREEZER DOORS CLOSED

(Unless moving vaccines)

Temperature out of Range $\geq 3^{\circ}$

- Document out of range temperature on log.
- Determine that refrigerator/freezer is still operational. If not, proceed to Mechanical Failure or Power Outage instructions.
- Adjust thermostat in refrigerator or freezer up or down as needed. Note adjustment on temperature log.
- Recheck in one hour. Document rechecked temperature on log. If temperature is in range, no further action is necessary.
- If temperature remains out of range, proceed to mechanical failure below.

Mechanical Failure:

- Transfer medication/vaccine to alternative storage unit designated below.
- Prior to transferring, record the temperature of the refrigerator(s) and freezer(s). If transporting off-site, follow instructions for Alternative Off-Site Storage procedures below.

Power Outage / Natural Disaster

- If the building has lost electrical power, check with your area building maintenance or facilities.
- If a generator is available, ensure that the generator is operational and has been activated.
- If power interruption is anticipated to be brief, and temperatures remain within range, keep refrigerator/freezer doors closed and closely monitor temperatures. If temperatures fall out of range, or power outage is prolonged, transfer medication/vaccine to alternative storage site. Prior to transferring, record the temperature of the refrigerator(s) and freezer(s). Follow instructions for Alternate Off-Site Storage below.

Alternate Off-Site Storage

- Contact your alternate facility listed below to notify them of your situation and the need to store vaccine at their location. If an alternate site is not feasible in your area, utilize the Preventive Medicine Department as your alternate site. Prior to transporting the vaccine, record the temperature of the refrigerator(s) and freezer(s). Transport the vaccine following the proper cold chain procedures for storage and handling.
- Use a thermometer or temperature monitoring device while in transit and record the temperature on arrival.

For all situations where medications or vaccines may have been compromised, isolate and maintain at appropriate temperatures. Do not administer or discard until you have contacted:

- NHCP Pharmacy (for medications) at 760-725-1147 or by pager (760) 293-2198;
- NHCP Preventive Medicine Department (for vaccines) at 760-725-1270 or by pager at 760-312-0047.

Emergency Contact List:

OOD: _____ FMD: _____ Building Maintenance: _____
Alternate Storage Facility: _____ Contact #: _____

- **If medications or vaccines are moved to the alternative storage facility fill out the information below:**

Contact Name (person who moved meds): _____ Contact #: _____
Other information: _____

Emergency Supplies and Location:

Location of other storage units in facility: _____
Location of packing materials for transport: _____

Post Event:

Store vaccine or medications within a working refrigerator/freezer marked "DO NOT USE"

Gather the following information:

- What happened i.e. power outage
- Which vaccines or medications were involved, including number of doses, lot number and expiration date.
- Minimum/Maximum temperature and how long the vaccine was exposed to these temperatures.
- Contact the Preventive Medicine Department for vaccine incident report

Contact Pharmacy for information regarding use of medications.

Immunization Program Manager: Jennifer Holden (for information & references only)

Phone# 760-763-9136 Pager# 760-293-2224

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Section 6



NHCP Vaccine Distribution Program Fraud, Waste and Abuse Policy

Purpose

The purpose of this policy is to provide programmatic direction for the prevention of fraud and abuse in the utilization of vaccine provided to Military Health Care Facilities by the NHCP Vaccine Distribution Program through our funding sources. The NHCP Vaccine Distribution Program is required by the Commanding Officer to implement a fraud, waste and abuse prevention policy.

Given vaccine usage constraints relative to vaccine funding, vaccines provided by the NHCP Vaccine Distribution Program must be used according to the guidelines outlined for each specific vaccine. Misuse of vaccine may result in military legal action if fraud or abuse is determined to have occurred.

Definitions

Fraud is defined as “an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person.” (42 CFR 455.2)

Abuse is defined as “provider practices that are inconsistent with sound, fiscal, business, or medical practices, and result in an unnecessary cost to the program or for services that are not medically necessary or that fail to meet professionally recognized standards for health care ...” (42 CFR 455.2)

Examples of Fraud, Waste and Abuse

Hoarding vaccines and keeping levels in excess of 50 doses of multiple vaccines.

Ordering vaccines above the required need or usage rate.

Excessive or repetitive vaccine spoilage or expiration due to negligence.

Assessment of Compliance

In order to receive vaccines, units / facilities enrolled in the program must submit patient profile and unit numbers. With each order providers must submit vaccine inventory data, usage data, return reports, and temperature logs and graphs for the bulk storage refrigerator/freezer. Every order submitted is compared to the unit's / facility's most recent patient profile and usage reports. NHCP Vaccine Distribution Program staff examines each order through analysis of inventory data and usage data.

Unjustified excessive and/or repeated discrepancies between provider profile data, vaccine orders and vaccine usage will be identified by the NHCP Vaccine Distribution Program staff. Suspected cases of fraud, waste and abuse will be determined and/or/ evaluated by the program and referred for further investigation as required by the guidelines of the program.

Referrals

The NHCP Vaccine Distribution Program is required to report suspected cases of fraud, waste or abuse to the Commanding Officer, Naval Hospital Camp Pendleton, who may in turn notify and or involve the following agencies: Commanding Generals for the 1st MEF, 1st MHG, 1st MARDIV, 1st MLG and 3rd MAW.

Resolution

Determination of fraud, waste and abuse is made by the NHCP Vaccine Distribution Program in conjunction with the parties above. Providers who are found to be engaged in these activities will have their certification and ability to receive vaccines inactivated. Reinstatement to the program will be contingent on the outcome of discussions or actions by the aforementioned entities. Final resolution may include the following interventions and are not all inclusive: remedial education, recoupment of funds, reinstatement without penalty, or referral for legal action and resolution.