



Priority 1: Novel H1N1 Mass Vaccination Operational Plan

I. Name and Contact information for the Lead Individual for State (*Please provide the following information: Name, Street Address, City, State, Zip, Phone, Email*):

John Talarico, D.O., M.P.H.
Chief
Immunization Branch
California Department of Health Services
850 Marina Bay Parkway
Richmond, California 94804
Phone: (510) 412-5838
E-mail: John.Talarico@cdph.ca.gov

II. Agencies involved in the planning for this Priority Area.

The California Department of Public Health's Immunization Branch (CDPH-IZB) in preparation for arrival of H1N1 vaccine by October 2009 established in May 2009 a very aggressive planning schedule with a multitude of statewide partners, which included State agencies, local health departments, private providers, pharmacies, hospitals, medical organizations, and emergency preparedness organizations. (See Appendix A for a complete list of planning partners and CDPH-IZB workgroup.)

III. Planning assumptions, vaccine information, vaccine distribution network, and disease risk as of September 8, 2009.

A. Planning Assumptions:

1. CDPH-IZB will control the vaccine and be responsible for working with local public health to prioritize allocation, amount of vaccine, distribution, and tracking of vaccine to vaccinators based on vaccine supply, disease severity and other factors.
2. All potential vaccinators will be registered using the CDPH website www.CalPanFlu.org.
3. In order to maximize the acceptance and effectiveness of the intervention, CDPH-IZB will adopt a consistent statewide pandemic influenza vaccination prioritization policy and practice for California. However, the importance of consistent application of statewide vaccine priority groups must be weighed against local conditions and local health officers may request a vaccine priority group variance from CDPH based upon emergent needs.
4. Vaccine production is in progress and availability is anticipated by October 2009 or later.



5. U.S. Department of Health and Human Services (DHHS) will purchase vaccine and make it available for vaccinators at no cost. (Some vaccinators may charge an administration fee and these exceptions are noted under the reimbursement section.)
6. DHHS will purchase and supply syringes, needles, sharps containers, and alcohol swabs.
7. Once vaccine is available, it will take several months to produce an adequate supply for the U. S. population. When first available, Centers for Disease Control and Prevention (CDC) will distribute limited supplies of vaccine to states on a pro-rated basis. California comprises approximately 12 percent of the U.S. population.
8. McKesson Specialty is the federally contracted vaccine distributor. After CDPH-IZB and local public health approve the vaccinator and vaccine amount, vaccine will be shipped directly to the vaccinators by McKesson.
9. Initial vaccine supply will be used to vaccinate priority groups established by CDC Advisory Committee on Immunization Practices (ACIP) as of July 29, 2009. (See target group prioritization section for list of ACIP priority groups.)
10. Vaccination of federal employees who work for Department of Defense will be a federal responsibility and will receive separate federal allocation.
11. Number of vaccine doses recommended per person will be probably two, perhaps one for persons over 60 years or for some formulations - pending results of 8/09 clinical trials.
 - a. Minimum interval between two doses will be 3 weeks.
12. H1N1 vaccine supply and availability is projected to increase quickly over time, and vaccine SHOULD NOT be kept in reserve for later administration of a 2nd dose.
13. CDPH-IZB will receive a small proportion of vaccine to distribute as needed depending on the epidemiology of the pandemic and particular geographic needs related to priority groups.
14. Two types of H1N1 vaccines will be available in the United States (U.S.), inactivated non-adjuvanted vaccine and a live vaccine. Both these products will be eligible for FDA licensure and will not require an Emergency Use Authorization (EUA).
15. Vaccine providers will use either the Immunization registry or the www.CalPanFlu.Org website to record aggregate number of doses administered by age category in compliance with CDC requirements.
16. Vaccine safety will be monitored by several surveillance systems, active and passive.



- 17. Any individual will be able to report potential vaccine reactions to the Vaccine Adverse Event Reporting System (VAERS), via the web or toll-free telephone call.
- 18. Seasonal and novel H1N1 vaccines may be administered together with the exception of Seasonal LAIV and H1N1 LAIV.

Vaccine	Seasonal Inactivated	Seasonal LAIV
H1N1 Inactivated	Allowed	Allowed
H1N1 LAIV	Allowed	Not Permitted

B. Vaccine Information:

Vaccine Manufacturers:

Five manufacturers are producing vaccine for the U.S.

- Inactivated injectable vaccine - Sanofi Pasteur, Novartis, GSK, and CSL
- Live, intranasal vaccine – Medimmune

Vaccine formulations:

1. Preservative:

- Majority of vaccine will be inactivated in multi-dose vials with preservative.
- Remainder will be single dose vials or nasal spray that doesn't contain preservative.
- If there is not enough vaccine in single dose formulations for young children and pregnant women then an exemption to the California mercury law will be required.

2. Adjuvant:

- Currently there are no adjuvanted vaccines being proposed for use in the U.S.
- CDC and FDA are considering use of adjuvanted vaccines that are being used outside of the U.S. If this is necessary, vaccine would be authorized under E.U.A

Clinical trials:

Clinical trials sponsored by manufacturers and U.S. National Institutes of Health were started mid-July 2009; results of first dose of vaccine are anticipated by mid-September.

- a. Results from second doses of vaccine expected by late September or later.
- b. A variety of ages, doses, and combinations with seasonal influenza vaccine, etc. are being evaluated.



Volume of vaccine to be produced as of August 19, 2009:

Pandemic influenza vaccine formulations	Multidose vials	Nasal Spray	PFS- 0.25 ml dose	PFS 0.5 ml dose	
Preservative-free (Complies with California law)?	No	Yes	Yes	Yes	
Dose per container	Multiple	Single	Single	Single	
Live or Killed?	Killed	Live	Killed	Killed	
Method of delivery	Injection	Intranasal	Injection	Injection	
FDA-licensed age groups	>6 months	2-49 years	6-23 months	>3 years	
FDA-licensed includes pregnancy?	Yes	No	(Double-dose)	Yes	
8/19/09 Estimates of pandemic influenza vaccine availability in California (subject to change)					Total
9/30/2009 vs. mid-mid October	125,000	708,750		1,125,000	1,958,750
10/15/2009	2,725,000	378,750		587,500	3,691,250
10/31/2009	856,250	625,000	243,750	600,000	2,325,000
Cumulative total through October 2009	3,706,250	1,712,500	243,750	2,312,500	7,975,000

C. Vaccine Distribution Network:

CDPH promotes the use of a mixed model of public and private providers to accomplish vaccine administration. The mixed model for vaccine administration includes but is not limited to the following venues:

- Local health department clinics;
- Pediatric, family practice, internal medicine practices;
- Obstetrical practices;
- Hospitals;
- Occupational Health Clinics;
- School-based Clinics; and
- Pharmacies.

This model has advantages over a purely public or private provider distribution network in that:

- It allows distribution to a broader array of providers;
- It allows for more venues than either model alone; and
- It allows healthcare providers to directly promote vaccine uptake to those who are at high risk for severe disease.



CDPH is promoting this mixed model by:

- Pre-registering providers on a statewide website
- Submitting order from private providers to CDC;
- Promoting private provider participation through provider associations including state chapters of ACOG, AAP, AAFP and CMA.
- Providing alternate vaccine distribution for providers that have smaller volumes than CDC allows.
- Providing support for local health department participation through technical assistance, registering of providers, training of providers, and providing streamlined reporting for their jurisdictions.
- Advocating for and providing information to providers on vaccine administration fees

D. Disease Risk

Current severity of novel H1N1 disease: Less than or equal to average seasonal influenza viruses.

Current ranking of probability of severity of novel H1N1 disease during the fall and winter of 2009-2010:

- 1) Less than or equal to average seasonal influenza viruses
- 2) Similar to severe seasonal influenza (e.g., 2003-04 Fujian strain)
- 3) Similar lethality to 1918 pandemic

Similar to seasonal influenza:

- Children younger than 5 years old. The risk for severe complications from seasonal influenza is highest among children younger than 2 years old.
- Persons with the following conditions:
 - Chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), neurologic, neuromuscular, or metabolic disorders (including diabetes mellitus);
 - Immunosuppression, including that caused by medications or by HIV;
 - Pregnancy
 - Persons younger than 19 years of age who are receiving long-term aspirin therapy;

IV) Summary of current State activities with respect to novel H1N1 Mass Vaccination including a description of recent accomplishments:

May 2009---September 2009:

CDPH-IZB started aggressive planning for novel H1N1 influenza vaccination in May 2009 and accelerated planning by July 1, 2009 as applications for the Public Health Emergency



Response (PHER) funds were solicited and submitted. In addition to responding to the application requests for multiple phases for PHER funds, the following activities have been initiated and are ongoing:

1. CDPH-IZB conducts the following teleconference meetings:
 - a. Weekly statewide vaccine operational planning with local public health, immunization coordinators, and agency partners to discuss H1N1 vaccine preparation, distribution, and administration;
 - b. Weekly statewide seasonal influenza immunization planning with immunization coordinators and local public health; and
 - c. Organization specific meetings to discuss planning and policy issues. E.g., Department of Education, Department of Managed Health Care, and health care organizations (AMA, CMA, etc.).
2. CDPH-IZB provides ongoing vaccine updates and technical support during the following weekly teleconferences:
 - a. Statewide Agency Call co-sponsored by the California Department of Public Health (CDPH) Emergency Preparedness Office and Center for Infectious Diseases.
 - b. Local Health Jurisdiction Technical call sponsored by Center for Infectious Diseases.
3. CDPH-IZB maintains current with CDC and HHS H1N1 vaccine activities by monitoring and participating in multiple weekly information calls from the agencies.
4. A website was created for all potential vaccinators to pre-register and order vaccine (www.CalPanFlu.org). The information obtained from the website will allow CDPH-IZB to verify provider commitment, capacity and authority to administer vaccine; confirm shipping addresses and site hours; and map provider lists to different delivery scenarios (ample, medium and scarce or staggered supply). The website went live on September 1, 2009.
5. A website vaccine tracking system was developed on the website so providers can either use the Immunization registry or CalFluPan.Org website to record aggregate number of doses administered by age category in compliance with CDC requirements. CDPH-IZB will upload and send this information to CDC using the Countermeasure Response Administration System (CRA).
6. A hotline for H1N1 vaccine questions and orders has been created. Staffing of the hotline began on September 1, 2009. This included training of staff for hotline.
7. CDPH has a trained spokesperson to interface with the media.



8. Information materials specific for H1N1 have been created and are available on the CDPH-IZB website <http://www.cdph.ca.gov/programs/immunize/Pages/default.aspx>

The eziz.org site also hosts a separate page of H1N1 resources, www.eziz.org/resources/materials_h1n1.html, to help providers prepare their practices for H1N1. The page provides links to information on vaccine storage and handling, standard immunization practices, documentation requirements, and promotional and educational materials. (See Appendix B for list of H1N1 Influenza Vaccine Communication Activities.)

Further activities are planned to provide additional immunization training materials through the interactive web especially for local vaccinators with special emphasis on non-Vaccine For Children (VFC) providers who may have limited experience. Training materials will assist providers to assess their vaccine storage capability and capacity of H1N1 vaccine inventory. Two new online lessons, *Storing Vaccines* and *Monitoring Vaccine Temperatures*, will be added to the curriculum in September and October 2009.

9. CDPH-IZB created a vaccine planning guidance document to be used by all vaccine providers titled "California Department of Public Health Mass Vaccination Planning Guidance 2009 H1N1 Influenza Vaccine." (See Appendix C)
10. CDPH-IZB created a guidance for Local Health Departments (LHDs) to use for ordering and distribution of vaccine titled "Rules for the Ordering and Distribution of Pandemic Influenza Vaccine." (See Appendix D)
11. Currently CDPH-IZB has the staff and equipment to process orders for routine childhood vaccines for over 4,000 VFC providers, based on the CDC VACMAN system. More staff and resources will be needed. PHER funding will be used to expand the VFC ordering system to accommodate many thousands of public and private sites that will repeatedly order shipments of vaccine.
12. CDPH-IZB convened meetings with Kaiser, California Emerging Infections Program (CEIP), and CDPH Viral and Rickettsial Disease Laboratory (VRDL) to discuss vaccine safety monitoring and tracking incidence of Guillain-Barre Syndrome (GBS). Kaiser will continue with its existing system through the Vaccine Safety Datalink. Planning is in progress for both the CEIP and VRDL surveillance projects.
13. CDPH-IZB has discussed planning for evaluation of the novel immunization campaign. One way of collecting evaluative information would be by adding questions to already existing statewide surveys, such as the Woman's Health Survey and the Behavioral Risk Survey. Another evaluation tool would be for CDPH to create a method to compare the web registration program and the existing vaccine registry. At this time, additional monies would be needed.

**January 2008---April 2009:**

(Brief summary of key planning and preparedness activities.)

In 2007, CDPH required each California Local Health Department (LHD) to develop a Pandemic Influenza operations plan as a condition of receiving state funds for pandemic influenza planning. In 2008, CDPH-IZB completed the reviews for 60 out of 61 plans providing feedback to the LHDs in September 2009. The mass vaccination sections of the plans were assessed for completeness and documentation of the following: protocols for vaccine receiving, storage, distribution, administration, and security; identifying vaccination sites and staffing requirements; procedure for tracking vaccine usage, recipients, and adverse events; and identifying target groups for vaccine prioritization.

For the 2008-09 seasonal influenza vaccination campaign CDPH-IZB and CDPH EPO encouraged immunization programs to collaborate with their public health emergency preparedness / bioterrorism planners on a mass vaccination clinic exercise that was required for emergency planners funding. Most of the programs complied with the request.

CDPH-IZB, in anticipation CDC Counter Measure Response Administration (CRA) software would be required to track pandemic vaccine administration, encouraged LHDs to pilot test the software. Forty-eight of California's 61 LHDs participated in the pilot test for the 2008-09 seasonal influenza campaign. These LHDs ran either a mass vaccination clinic or traditional seasonal influenza clinics, using CRA to input the data and transmit it. Data from each clinic was compiled and transmitted successfully. LHDs had the option of collecting aggregate and/or patient-level data. A total of 57,132 vaccinations were entered and transmitted.

V) Activities by Pandemic Phase

CDPH-IZB has completed all activities for the previous pandemic phases. Listed below are the ongoing activities for Phase 6. Some of the activities are a continuation from Phase 5.

Pandemic Period: Phase 6**Pre-Vaccine**

- Monitor reports and teleconferences from CDC and Federal Drug Administration to obtain information on plans for vaccine manufacture.
- Estimate weekly allocation of vaccine based on vaccine availability, project area population size, and target group prioritization
- Ensure vaccine providers are ready to implement plans for receiving, storing, security and delivering vaccines as vaccine becomes available.
- Ensure that human resources, equipment, data management systems and plans for mass immunization clinics are in place.
- Distribute guidance for vaccine providers for ordering and distribution of vaccine.
- Distribute guidance to assist vaccine providers with planning and implementation of mass vaccination activities.



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- Continue updating and adjusting plan based on latest information from federal agencies and epidemiological surveillance.
 - When the initial vaccine shipment date is publicized by CDC, work with vaccine providers to establish delivery date; review and update distribution plan; and make sure signed agreements are in place.

Vaccine available:

- Notify vaccine providers to implement plans and staffing for:
 - Receiving, storing, and distributing vaccine; vaccine transportation; vaccine security; vaccine chain of custody; and vaccine accountability.
- Estimate weekly allocation of vaccine based on vaccine availability, project area population size, and target group prioritization.
- Verify all vaccine ship-to site information.
- Verify that all signed agreements are current.
- Monitor inventory and vaccine using data management systems
- Monitor vaccine safety
 - Active surveillance and timely reporting to VAERS.

Postpandemic Period

- Return to inter-pandemic activities



VI) Operating procedures and/or protocols for the following activities:

- **Registration**
- **Vaccinators**
- **Reimbursement**
- **Vaccine and Ancillary Supply Distributer**
- **Estimate for weekly allocation of vaccine based on vaccine availability assumptions and project area population size**
- **Target Groups Prioritization**
- **Seasonal and pneumococcal vaccination**
- **Vaccine tracking and documentation**
- **Vaccine safety monitoring**
- **Roles for LHD for ordering and distribution of vaccine**
- **Shipment Sites and State Storage**
- **State: Transportation, chain of custody, security**
- **LHD: Transportation, Chain of Custody, Security**
- **Number, Staffing and Location of clinics based on planning assumptions**
- **Staffing Training Requirements**

Registration

All potential vaccinators will pre-register at (www.CalPanFlu.org). The information obtained from the system will allow CDPH-IZB to verify provider commitment, capacity and authority to administer vaccine; confirm shipping addresses and site hours; and map provider lists to different delivery scenarios (ample, medium and scarce or staggered supply).

The mechanism for placing vaccine orders with distributor:

- Providers are registered at state using CalPanFlu.org
- LHDs verify and prioritize providers (CDPH is anticipating that LHDs will control initial vaccine distribution to achieve vaccination of priority groups)
- Orders processed and entered into centralized order entry system by CDPH with verification of orders required

Vaccinators

Vaccinators will be selected to receive vaccine based on the following models developed by CDPH-IZB to rank vaccination probability based on the severity of novel H1N1 disease during the fall and winter of 2009-10:

- 1) **Modified seasonal model with prioritization of initial supply**: Thousands of private and public immunizers who are experienced with delivering seasonal vaccine in individual and mass settings. Additional providers will be needed to reach new target groups or to supplement seasonal vaccine providers. Prioritization of initial supply according to vaccine formulations, ACIP recommendations and other factors.
- 2) **Medical prioritization**: Seasonal model network of immunizers who are restricting or prioritizing administration based on medical need.



- 3) High-severity Pandemic Model: Smaller network of immunizers prioritizing vaccine based on medical need and preservation of critical infrastructure.

Reimbursement

The vaccine will be procured and purchased by the federal government and made available to vaccinators at no cost. The following are the exceptions:

- Private providers may charge a fee for the administration of the vaccine to the patient, their health insurance plan, or other third party payer.
- The administration fee cannot exceed the regional Medicare vaccine administration fee
- If the administration fee is billed to Medicaid, the amount reimbursed cannot exceed the state Medicaid administration fee of \$9.00.
- Billing of 3rd party payers or charging of patients will not be allowed in large-scale public health-organized vaccination clinics.
- Routine (non-mass) public health clinics are expected to be able to bill for administration fees cannot charge for pandemic vaccine.
- Medicare regional administration fee

<http://www.cms.hhs.gov/AdultImmunizations/Downloads/AdminRates09.pdf>

- Anaheim/Santa Anna \$24.94
- Los Angeles \$24.35
- Marin/Napa/Solano \$24.75
- Oakland/Berkeley \$25.16
- San Francisco \$27.43
- San Mateo \$27.39
- Santa Clara \$25.44
- Ventura \$24.82
- Rest of California \$21.64

Vaccine and Ancillary Supply Distributer

Vaccine will be distributed by CDC's contractor for centralized distribution, McKesson Specialty. The distribution process for vaccine builds on the existing mechanism for shipping vaccine to VFC providers. Vaccine orders will be submitted by CDPH-IZB on behalf of vaccine providers. These orders will be transmitted to CDC and will be processed and forwarded to McKesson. McKesson, in turn will ship vaccine directly to the end user. The centralized distribution contract for the VFC program has been supplemented to provide for both vaccine distribution and distribution of ancillary supply kits (syringes and needles, alcohol swabs and sharps containers).

- Minimum order size of 100 doses per vaccine product, which may effectively exclude smaller providers
- ~ 9300 sites of distribution in CA allowed under the federal contract with McKesson



- Supplementation by state contract with McKesson and/or GIV using federal funds is being explored to fill gaps.

Estimate for weekly allocation of vaccine based on vaccine availability assumptions and project area population size

California has approximately 38 million residents, plus millions of visitors from all over the world. Once vaccine is available, it will take several months to produce an adequate supply for the U.S. population. Below is the projected supply of Novel H1N1 vaccine for California for three different planning scenarios.

Projected Supply of Novel H1N1 Influenza Vaccine Supply for California, 2009-10, millions (M) of doses			
	CDC Scenario 1: MINIMUM (40 M initial US doses)	CDC Scenario 2: MEDIUM (80 M initial US doses)	CDC Scenario 3: HIGH (160 M initial US doses)
Initial shipment	3.4 M California doses	6.9 M	13.9 M
Weekly Supply	0.8 M	1.7 M	2.6 M
Supply by 13 weeks (1 quarter)	13 M	27 M	45 M

After the initial shipment, vaccine distribution to shipment sites will be determined by State and local public health departments using a population-based formula depending on vaccine prioritization, vaccine supply, disease severity and other factors.

CDPH created a spreadsheet to calculate vaccine quantities for each jurisdiction by population size. Calculations include estimated product strength, packaging considerations, and estimated quantity of vaccine available per shipment for several distribution scenarios. The spreadsheet can be accessed at the www.CalPanFlu.Org website at anytime and local jurisdictions can generate new calculations as the information changes.

Target Groups Prioritization

Identifying target groups is the first step toward planning and implementing an effective pandemic vaccination program. Public health pandemic planners should use the prioritization lists recommended by ACIP as a framework for developing prioritization



recommendations for their local jurisdictions. CDPH recommends that pandemic planners develop tables for inclusion in local pandemic plans with the following information:

- List of target groups
- List of local population estimates for each target group
- List of organizations that provide critical services and comprise the defined target groups

The following groups should be included in local health planning estimates. They will primarily be the responsibility of local public health to vaccinate according to their ACIP prioritization status:

1. Indian Health Service (IHS)-served populations
2. Local correctional facilities
3. CDPH and State employees

CDPH and State employees will be notified to utilize private and public networks within their counties of residence. Separate allocations will go to California Department of Corrections and Rehabilitation (CDCR) and other State Departments that purchase and provide seasonal influenza vaccine.

ACIP recommendations 7/29/09:

(ACIP meets again in October 2009 and these recommendations will be revisited and revised if necessary.)

Initial efforts should focus on vaccination of as many people as possible in the initial target groups

- Pregnant women
- Household and caregiver contacts of children <6 months of age
- Healthcare workers and EMS personnel
- Persons 6 months through 24 years of age.
- Persons 25-64 years of age with high risk conditions (as for seasonal influenza)

When vaccine demand exceeds availability

- Subgroups within the target groups should be prioritized where feasible are (changes from above underlined):
 - Pregnant women
 - Household and caregiver contacts of children <6 months of age
 - Healthcare workers and EMS personnel
 - Children 6 months through 4 years of age
 - Children 5 -- 18 years of age with chronic medical conditions (as for seasonal influenza)

H1N1 vaccine supply and availability is projected to increase quickly over time, and vaccine SHOULD NOT be kept in reserve for later administration of a 2nd dose.



When vaccine availability is sufficient at the local level to vaccinate initial target populations and after consultation with state and local public health authorities, vaccination against novel influenza A (H1N1) is recommended for healthy adults 25-64 years of age. When supply allows vaccination of all above priority groups, and after consultation with state and local public health authorities, vaccination can be extended to adults 65 years and older.

Seasonal and pneumococcal vaccination

CDPH-IZB as part of ongoing planning currently:

1. Recommends that seasonal influenza vaccination should begin as soon as it is available for all groups currently recommended to receive it.
2. Promotes seasonal influenza vaccination in traditional high-risk groups, school-age children and particularly subgroups in which coverage levels are low (e.g., minorities and persons under age 65 years with chronic medical conditions). Increasing routine, annual vaccination coverage in these groups will facilitate access to these populations when a pandemic occurs;
3. Promotes pneumococcal vaccination coverage to reduce the incidence and severity of secondary bacterial pneumonia in traditionally high-risk groups;
4. Promotes seasonal influenza vaccination coverage rates among healthcare workers;

Roles for LHD for ordering and distribution of vaccine

California LHDs are expected to participate in the pandemic influenza vaccine by providing vaccine and support its administration by a broad network of public and private partners in their LHDs. CDPH-IZB has developed a guidance document to help LHDs with ordering and distribution of vaccine. (See Appendix D.)

Vaccine tracking and documentation

Each LHD will be responsible for weekly reporting to the CDC of aggregate doses of H1N1 vaccine administered, categorized by age group and by doses in series. It is anticipated that this reporting requirement will only last for the first month or two after vaccine becomes available at which time information will then be gathered by national population-based surveys.

Providers will be asked to report weekly doses of H1N1 vaccine administered using one of the following two options:

Option #1: Users of the California Immunization Registry (CAIR) can enter patient H1N1 vaccine usage data directly into CAIR.



Option #2: Non-users of CAIR will be asked to login to the H1N1 website at www.CALPANFLU.org, choose the Report H1N1 Vaccine Usage page, and enter total doses administered during the previous week.

Vaccine usage data reported from these two sources will be combined and aggregated by the California Department of Public Health (CDPH) in order to report data to the CDC. Vaccine usage data should be reported by noon on Tuesdays for all doses administered during the previous week (MMWR week Sunday through Saturday).

In previous years, LHDs may have participated in exercises using the Countermeasure Response Administration (CRA) system to report seasonal flu vaccine doses administered. LHDs will not be expected to track seasonal flu vaccine administration via CRA. CDPH will be the only party responsible for accessing the CRA system to report doses administered in California.

Vaccine safety monitoring

Vaccine Safety Coordinator Position:

CDPH has designated a nurse consultant specialist/epidemiologist from the Immunization Branch as its vaccine safety coordinator. The coordinator is assisted by the staff in the Surveillance Section of the Immunization Branch, who currently use the Vaccine Adverse Event Reporting System (VAERS) for reporting vaccine adverse events. The coordinator makes every attempt to forward reports received within 5 days to CDC. As noted in the procedures, if the coordinator receives an incomplete form, ten attempts are made to get the complete information. If, after ten attempts, the information is still incomplete, the report is sent to CDC. This statewide system has been in place for at least ten years. (See Appendix E for CDPH VAERS procedure.)

Passive surveillance--VAERS:

CDPH will utilize VAERS system to report adverse events from pandemic influenza vaccine, unless another system is identified by CDC. Similar to seasonal influenza and other enhanced surveillance activities, CDPH will notify providers and any groups administering pandemic vaccine to notify LHDs or to directly report adverse events through VAERS, and to advise vaccine recipients to do the same. CDPH will assist any provider or LHD to report and will follow up on any unusual adverse events or clusters of events reported.

Active surveillance:

Kaiser Permanente Northern California and Southern California have well established systems for vaccine safety monitoring; they are the two largest members of the national Vaccine Safety Datalink.

- Any vaccine administered by Kaiser Permanente will be included in rigorous safety monitoring programs that can detect early signals of possible adverse events.



- Kaiser Permanente Northern California delivers over 1 million doses of seasonal influenza, more than delivered statewide by public health departments.

Two additional active surveillance systems are planned and are as follows:

- The California Emerging Infections Program will track the incidence of Guillain-Barre Syndrome (GBS), which occurred infrequently after receipt the 1976 Swine Flu vaccine, in at least Alameda, Contra Costa and San Francisco Counties.
- CDPH IZB and the VRDL California Encephalitis Project: Plans expansion for reporting and testing of pediatric GBS and for statewide surveillance of GBS hospitalizations.

Shipment Sites and State Storage

Although McKesson will ship vaccine directly to the end user, a small proportion of vaccine will also be received by the State at the Richmond Warehouse which has refrigeration. If for any reason, the State needs activate the State Receiving, Staging and Storing (RSS) for vaccine or any other medical supplies, the procedures for this are addressed throughout the next sections of this document. The State RSSS does not have refrigeration but has a resource list of vendors who would be able to supply refrigeration.

CDPH has identified a primary State RSS warehouse where CDPH will:

1. Formally accept custody of vaccines and other pharmaceutical and medical supplies;
2. Store pandemic vaccine along with other pharmaceutical and medical supplies;
3. Stage materiel according to pre-established allocations or in response to delivery orders generated by the inventory control function for delivery to Operational Area (OA) RSS distribution sites;
4. Initiate distribution of the released materiel by transportation to the selected and approved OA RSS distribution sites; and
5. Ensure the proper storage, handling, and transfer of materials.

Other potential State RSS warehouse sites are listed within the CDPH *Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile* and are considered back-up facilities for immediate use if the primary RSS warehouse identified for pandemic response becomes unusable for any reason or if additional space is required to support California's RSS warehouse needs. CDPH maintains a list of pre-identified vendors that can supply additional portable cold storage and provide temperature controlled transportation that can be used from any RSS location.

CDPH no longer receives and ships state-purchased vaccines to LHDs because of centralized distribution for VFC. However, the three large state depots across the State that had been used for vaccine storage and distribution will be activated, if necessary, and



maintained for a pandemic response as a supplemental facility for SNS operations. The CDPH-IZB has the ability to quickly activate the storage and refrigeration facilities using the "CDPH Vaccine Shipping and Handling Procedures Manual (updated June 2008)" for just-in time training of staff.

Inventory control is the responsibility of CDPH at the State RSS Warehouse. Inventory control functions at the State RSS Warehouse include:

1. Tracking all receipts;
2. Apportioning supplies as directed by CDPH's Joint Emergency Operations Center (JEOC);
3. Recording the locations to which vaccines are sent; and
4. Monitoring stock levels.

CDPH currently uses an electronic inventory management system and maintains a paper backup system. LHDs are required to continue inventory control from local receipt to administration site.

State: Transportation, chain of custody, security

Transportation

If for any reason CDPH needs to transport vaccines and other medical and pharmaceutical supplies for distribution to the LHDs, CDPH will act as the State distribution manager. CDPH will be responsible for providing transportation from the State RSS Warehouse to the local receiving sites. CDPH will follow the procedure for "Moving the Components of the State RSS to Local Sites (Appendix F)". The LHDs will then be responsible to transport the vaccines and other supplies to the mass vaccination sites for administration.

Chain of Custody

To staff the State RSS warehouse, CDPH has identified and trained personnel and backup personnel to receive custody of vaccines. A list of the job titles, job descriptions and number of staffing required is in the *State Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS)*, June 1, 2009, pgs 119-122 and 127-130. Specific information about who is assigned is not included in this plan or the SNS plan due to the sensitive nature of the information and provisions of California's Public Records Act. Chain of custody records will be maintained with signature documentation at all levels of vaccine receipt and distribution points. These lists are reviewed and updated on a quarterly basis per CDC policy.

Chain of Custody policies and procedures are outlined within CDPH's *Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS)*, Chapter 7, pg. 33 and Appendix F, pgs. 72-73 and the *Pandemic influenza Antiviral Allocation and Distribution Plan*, pgs 7-8 have been incorporated and are included as Appendices H, I, and J in this plan. This includes having a DEA registrant, or designated representative, signing the necessary State/Federal Medical Supply Transfer Form, DEA Form 222, if



required, and any other manifests or required documentation. Specific information and existing process and procedures have been reviewed and approved by CDC-SNS Program Evaluators. *NOTE: California's Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS)* and appropriate Appendices and Annexes have been provided to CDC – DSNS and can be reviewed through the State's CDC – SNS Representative.

Security

Using the procedures and protocols from the CDPH's *Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS)* and is included as Appendix G in this plan, security will be provided at all levels of deployment. This will include all locations that support the operation, vehicles that transport the vaccines, and controlling crowds that might interfere with effective operations or transport of the vaccines.

Over 600 State and local law enforcement entities fall under the certification requirements of the California Peace Officers Standards and Training (POST) division of the California Department of Justice. Each entity has standard operating procedures and use of force policies related to riots and securing facilities during emergencies. Detailed planning for these types of events is required under POST Certification and reviewed annually by POST reviewers. Those procedures and policies are confidential and are not included in this document. Existing process and procedures for State and local jurisdictions are available for on-site review only by appropriate law enforcement personnel.

The CHP is the lead agency providing security for state operations plans and procedures, assets, facilities, and personnel. The CHP SNS Security Plan is a confidential document protected under the provisions of California's Public Records Act and is not included in this Plan. CHP has participated in exercises and conducted vulnerability assessments of all State RSS warehouse sites where vaccines would be received.

Security personnel will maintain access control into, within, and out of the RSS Warehouse as well as monitor transportation personnel. This includes sign-in logs after proper identification, and identification badges for authorized personnel.

California will follow the Badging/Credentialing System outlined in CDPH's *Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS)* and is included as Appendix G in this plan. All personnel will be properly identified and receive their badges and credentials prior to arriving at any State location utilized during a pandemic influenza response. As per the Operational Plan, the security forces will NOT allow any individual within the facilities without proper badges and credentials, and will detain and/or turn away all non-badged individuals. This badge and credential system has been tested and exercised on several occasions and led to the arrest of one person who had an outstanding warrant. Processes and procedures for badging and credentialing personnel are confidential and will not be included in this document due to possible release to the media or public. Existing process and procedures have been reviewed by CDC-SNS



Program Evaluators and are available for on-site review only. *NOTE: California's Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS) and appropriate Appendices and Annexes have been provided to CDC – DSNS and can be reviewed through the State's CDC – SNS Representative.*

Further Operating Procedures and Protocols for State

CDPH has received and distributed vaccine to LHDs and providers for over 13 years. If, for any reason, CDPH needs to either maintain storage or transport vaccine, CDPH operating procedures comply with CDC recommendations and policies for maintaining a vaccine depot and storage and distribution practices that preserve the integrity of the cold chain and inventory controls. These procedures can be found in the "CDPH Richmond Warehouse Activation--Vaccine Shipping and Handling Procedures Manual" (Appendix L)." Detailed operating procedures for receiving, storing, staging, distributing vaccines, and inventory control of pharmaceutical and medical supplies can be found in California's *Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS)* and are included as Appendices F-K in this plan.

CDPH has developed protocols for vaccine delivery including:

1. Preparing delivery and distribution with LHDs.
2. Arranging secure delivery of vaccine to and from CDPH storage facilities to LHDs.
3. Providing LHDs with updated protocols for receiving, storing, securing, and administering vaccine, including reviewing or updating of memoranda of understandings for identified vaccination sites; and ensuring adequate security of vaccination clinic sites and storage facilities.
4. Coordinating vaccine delivery and receipt by CDPH's Emergency Pharmaceutical Services Unit at a pre-identified warehouse location.

CDPH-IZB will continue to review and refine its plans for delivering and storing vaccine as additional federal protocols and policy become available concerning additional mechanisms of H1N1 vaccine delivery.

LHD: Transportation, Chain of Custody, Security

California LHDs have a long history of providing vaccine to the public. The principles of maintaining cold chain, inventory control, distribution and administration of vaccines are well-known at the local level. California's 61 LHDs will be responsible for receipt, storage, distribution and administration of vaccination, either directly or through local providers. CDPH requires LHDs to identify a local RSS site within their jurisdiction or work with other jurisdictions within their region to receive vaccines, pharmaceuticals, and medical supplies. LHDs are responsible to transport the vaccines from the receiving shipment site to the



vaccination clinics. LHDs are also responsible for including Tribal entities within their local jurisdictions in their mass vaccination plans and procedures. As part of the planning process, LHDs should obtain written agreements from any organizations and/or facilities that are part of the dispensing campaign before the event or emergency occurs.

CDPH recommends that LHDs use protocols and procedures from their SNS Operations Plans developed to receive, store, stage, and transport pharmaceutical and medical supplies from their local SNS Plans to accomplish this task. Inventory control, chain of custody, transportation and security are all components of their existing SNS plans. CDPH regularly reviews and provides technical assistance on all the components of their SNS plans.

The 61 LHDs will follow the badging/credentialing systems described in their respective SNS and Mass Vaccination plans. All personnel will be properly identified and receive their badges and credentials prior to arriving at any local site utilized during a pandemic influenza response. As per the local operational plan, the security forces will not allow any individual within the facilities without proper badges and credentials, and will detain and/or turn away all non-badged individuals. Processes and procedures for badging and credentialing personnel are confidential and are not included in this document. Several local process and procedures have been reviewed by CDC-SNS Program Evaluators and are available for on-site review at CDPH.

Local law enforcement is responsible for site security. This includes providing security at local receiving and distribution sites, dispensing sites such as mass vaccination clinics, and treatment centers as well as coordinating with and complementing, if necessary, state security escorts vaccines and other medical and pharmaceutical supplies to these locations.

CDPH has reviewed all aspects of the LHD Pandemic Influenza Operations Plans including the mass vaccination plans. CDPH provided technical assistance and feedback to LHDs in September 2009 to strengthen their plans. The mass vaccination sections of the plans were assessed for completeness and documentation of the following: protocols for vaccine receiving, storage, distribution, administration, and security; identifying vaccination sites and staffing requirements; procedure for tracking vaccine usage, recipients, and adverse events; and identifying target groups for vaccine prioritization.

Appendix M contains examples of Job Action Sheets (JAS) to function at either the CDPH or LHD RSS site. Included are JAS for Logistics Section Chief, Security Officer, Ground Distribution Unit Leader, Receipt and Storage Manager, Inventory Control Supervisor, and Prep and Pack Manager. Appendix N contains the points of contact with LHD immunization programs.



Number, Staffing and Location of clinics based on planning assumptions

As part of their Pandemic Influenza Response Plans, California's LHDs are required by CDPH to develop a detailed section on mass vaccination and report location and staffing capabilities for vaccination sites in the pandemic influenza operations plans. CDPH provides tools, where needed, to document: (1) locations for vaccination clinics; (2) requirements for staffing vaccination clinics (e.g., medical, non-medical, security, transportation, logistics); and (3) personnel, including pre-identified volunteers and rosters, for each clinic.

Currently, lists of pre-established vaccination clinic sites are maintained by LHDs. These often correspond to their mass prophylaxis sites, also known as Points of Dispensing (POD), and/or clinics within their existing SNS plans. Depending on population and geographic size of the jurisdiction, the number of sites varies and ranges from several (three-five) to hundreds. LHDs can use the spreadsheet created by CDPH to calculate estimated pandemic vaccines quantities that would be allotted for each POD by population size. The spreadsheet can be updated at anytime on www.CalPanFlu.org as the information changes and new calculations can be generated immediately.

California has 61 LHDs and over 2,000 potential clinics, treatment centers, points of dispensing, and vaccination sites (Los Angeles County has approximately 240 alone). Each of these locations and points of contact have been included within each LHD's SNS and Mass Vaccination plans. For security reasons, the locations and points of contact of vaccination clinics are not included in this document. Information on these locations and points of contact is available for on-site review at CDPH.

CDPH required each LHD immunization program to conduct at least one mass vaccination exercise using state-purchased influenza vaccine during the 2007-08 influenza season. This requirement was repeated for the 2008-09 influenza season and LHDs were instructed to conduct mass vaccination clinic exercises in collaboration with the immunization programs and public health emergency preparedness planners. CDC has made available nationally created standardized templates and best practices to assist LHDs in developing point of dispensing (POD) models for mass vaccination clinics that use as few staff as possible while processing as many people as possible. These templates can be found at the CDC website for Pandemic Influenza. (See Appendix O for Clinic Personnel)

LHDs utilize staff for the majority of activities and have sufficient personnel for initial and back-up deployment. Under the State of California Emergency Act, additional personnel are designated as "Disaster Service Workers" and can be utilized during an emergency. All LHDs have incorporated the Disaster Service Worker designation into their emergency plans. In addition, California has implemented its Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) to register licensed medical professionals who volunteer to assist in emergency response. LHDs that have agreements with other sources of staff for receiving, storing, staging, and distributing vaccines maintain



those agreements under their authority. These documents are not be included in this document in order to maintain confidentiality but are available for review on-site.

Staffing Training Requirements

LHDs oversee planning and implementation of mass vaccination clinics. CDPH issued the *Receiving, Distributing, and Dispensing Medical Supplies and Strategic National Stockpile Assets – A Guide for Local Preparedness, August 2007* which includes general definitions and guidelines that apply to all mass vaccination clinics. The guide includes lists and forms to assist LHDs in operating clinics. The California public is familiar with seasonal influenza vaccine and it would require a minimum amount of time to educate the public about the few side effects and contraindications of pandemic vaccine.

In 2003, CDPH conducted a satellite broadcast on mass vaccination. A recent distance learning conference focused on rapid modalities for just-in-time training through web-based or other technology. Concepts from state and local plans can be adapted through use of these distance learning modalities for clinic training.

CDPH offers on-going training opportunities for LHDs on SNS and pandemic influenza planning. These trainings include guidance on mass prophylaxis/vaccination clinics and receiving, storing, staging, and distributing medical and pharmaceutical resources. Just-in-time training for volunteers and public health staff has been developed and practiced by many of the LHDs during mass prophylaxis and vaccination clinic exercises. CDPH makes training materials and job action sheets available throughout the state to be used and adopted for local communities.

EZ-IZ Immunization Skills Training for Providers and Staff

CDPH hosts a one-stop shop at www.eziz.org for immunization training and resources for LHDs, providers and their staff. The EZ-IZ training is free, available 24/7, and offers immunization skills training, including the online lessons *Preparing Vaccines* and *Administering Vaccines*. The self-paced interactive lessons include video demonstrations and practice exercises that can be combined with hands-on practice activities. Various counties in California and other states have already integrated the EZ-IZ training into their curricula for mass vaccination, new employee training, and refresher training. Many providers require completion of the online courses, including the pre-test and posttest, as a pre-requisite to their on-site hands-on training and exercises. Over 1500 people have completed the lessons. Two new online lessons, *Storing Vaccines* and *Monitoring Vaccine Temperatures*, will be added to the curriculum in September and October 2009.

CDPH promotes this training to VFC providers, partners, local health departments, coalitions, and medical assistant training programs and nursing schools. CDPH is in the process of making the training available via www.train.org. CDPH also sends frequent updates via email blasts to a list of over 3000 current eziz.org users. The eziz.org site also hosts a separate page of H1N1 resources, www.eziz.org/resources/materials_h1n1.html, to



help providers prepare their practices for H1N1. The page provides links to information on vaccine storage and handling, standard immunization practices, documentation requirements, and promotional and educational materials.



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Appendix A: Planning Partners and CDPH-IZB Planning Workgroup

Planning Partners

	Planning Partners	Input	Notification
Planning Team Coordinator	X	X	X
Chief, Center for Infectious Diseases	X	X	X
Chief, Division of Communicable Disease Control	X	X	X
Immunization Branch	X	X	X
Deputy Director, Public Health Emergency Preparedness	X	X	X
Chief, Planning and Response Branch	X	X	X
Chief, Emergency Pharmaceutical Services Unit	X	X	X
Deputy Director, Office of Public Affairs	X	X	X
Chief, Center for Health Quality		X	X
Chief, Center for Family Health		X	X
Chief, Office of Multicultural Health		X	X
Chief, Viral and Rickettsial Disease Laboratory Branch		X	X
Children's Medical Services		X	X
Medi-Cal		X	X
Healthy Families		X	X
CHDP		X	X
Stakeholders			
Local Health Departments	X	X	X
CCLHO	X	X	X
CHEAC	X	X	X
Immunization Program Coordinators	X	X	X
PHEP Coordinator	X	X	X
CD Controller		X	X
CHPHL		X	X
Kaiser Permanente	X	X	X
California Academy of Family Physicians	X	X	X
American Academy of Pediatrics	X	X	X
California Medical Association	X	X	X
Medical Board of California	Use MD lists		X
California Hospital Association		X	X
California Primary Clinic Association		X	X
California Association of Health Facilities		X	X
Emergency Medical Services Authority		X	X
Department of Health Care Services		X	X
Department of Managed Health Care		X	X



Department of Education		X	X
Department of Developmental Services			X
Department of Mental Health			X
Department of Social Services			X
Department of Rehabilitation			X
Department of Aging			X
Department of Corrections			X

Novel H1N1 Vaccine Planning Workgroups - CDPH Immunization Branch and Partners

Name of Group	Group Lead/ Co-Lead	Sub-Group Lead	Group Members	Tasks
Distribution and Tracking	1.Steve Nickell 2.Nisha Gandhi 3.Eileen Yamada (Backup)	1.Claudia Aguiluz (Laurie Hauer)	1.Mey Phu 2.Melissa Dahlke 3.AnneCordon/San Diego 4.Melissa Dahlke 5.Laurie Hauer 6.Steve Vantine	- Oversees all Distribution Planning subgroups - Manufacturer/VFC lists - Identify and contact partners - CRA - Registry and operationalization issues - (?)VACMan
SNS supplies		Lou Lallo	EPO SNS staff	
Warehouse			R. Lamar Collins	
Education and communication	1.Tammy Pilisuk 2.AI Lundeen		1.Jenny Bailey 2.Edgfar Ednacot 3.Erin Parker	- Promote seasonal information - Compiling FAQs - Identify additional resources, incl. \$
Local Health Department Guidance Documents	Gwen Hammer	Harvey Kayman	1.Dave Hubbard 2.Laurie Hauer 3.Julie Hamilton 4.Ann Roslosnik	- H1N1 Vaccination Clinic Guidance - Vaccine prioritization - Vaccine implementation
Training and Exercises	Sandra Jo Hammer	Dave Hubbard	Julie Hamilton	- Identify training needs at LHD level
Reimbursement	Eileen Yamada			- Contact payers
Safety monitoring/GBS & AE surveillance	Rob Schechter			- VAERS - Kaiser - Virology Lab/Neurologists for GBS - Botulism cases - CEIP - Monitoring
Policy and Legal	Vacant	Harvey Kayman	1.OLS attorney TBD 2.Legislative liaison 3.CCLHO	- Emergency regulations - No registry for vaccinators

Note: All group leads are to identify co leads, in case of illness or inability of team lead to direct activities



Appendix B: H1N1 Influenza Vaccine Communication Activities

Activities Completed to Date	Month
Updated flu promotional materials	June-July 2009
Assisted RCCC with risk communication text for CDPH site	July 2009
Updated 2009-10 flu suite of materials flyer for LHDs	August 2009
Announced updated flu materials in August IZ Update	August 2009
Produced new flyer "Stop Flu in the Workplace"	August 2009
Produced Flu Contest video PSA for OPA	August 2009
Created flyer to announce CalPanFlu.org to all CA providers	August 2009
Designed CalPanFlu.org logo	August 2009
Designed SurveyMonkey template for Epi survey to CA hospitals	August 2009
Attended CDC focus groups with pediatricians and nurses in San Francisco	August 2009
Created/maintain Q&A script for H1N1 Customer Call Center	August 2009 (ongoing, as needed)
Created/maintain FAQ posted on CalPanFlu.org website	August 2009 (ongoing, as needed)
Posted new and revised promotional materials online, updated relevant web pages	August 2009 (ongoing, as needed)
Contributed staff to assist in H1N1 Customer Call Center	September 2009 (ongoing, as needed)
Updated pregnant women brochure/web content	September 2009
Flu PSA video contest website launched www.cdphfilmfest.org at event in Burbank CA	September 2009
Projected Future Communication Activities 2009-10 Flu Season	Month
Distribute flu and respiratory prevention materials to local health departments (as supplies permit)	Ongoing
Launch two new online training modules on vaccine storage and handling and refrigerator temperature monitoring	September 2009
Distribute DVDs of updated "Immunization Techniques" video to California providers (contingent on resources)	October 2009
Collaboration with the California Immunization Coalition to promote influenza vaccine and prevention messages	Ongoing, as materials become available
Provider translation assistance for 2009-10 season and H1N1 influenza VIS	TBD, when VIS becomes available
Create new H1N1 influenza informing materials (contingent	TBD



on information needs and available resources)	
Create a listserv of California vaccinators (contingent on resources)	TBD
Other Influenza prevention promotion	TBD



Appendix C: California Department of Public Health Mass Vaccination Planning Guidance 2009 H1N1 Influenza Vaccine

Introduction

This guidance is intended to

- Assist local health departments (LHDs), emergency planners, healthcare providers and their partners in the delivery of pandemic influenza vaccine in mass vaccination clinics.
- Help build partnerships between the LHD, schools, hospitals, clinical providers and/or private vaccination companies for the purposes of H1N1 vaccine administration.
- Outline responsibilities and collaboration between
 - state (e.g., Preparedness, Immunization) and
 - local partners (e.g., emergency responders, hospitals, private providers, military, tribal entities, Veteran's Administration (VA), Indian Health Service (IHS) and tribal facilities, primary care associations or any other additional vaccinators)
- Be updated with new information as it becomes available.

Additional resources from the California Department of Public Health (CDPH) and the federal Centers for Disease Control and Prevention (CDC) are available at

www.flu.gov

<http://cdc.gov/h1n1flu/>

www.cdph.ca.gov/HealthInfo/discond/Pages/SwineInfluenzaLHD.aspx

www.CalPanFlu.org

H1N1 Mass Vaccination Clinic Planning

1. Determine populations to reach with H1N1 mass vaccination clinic

The following information is based on recommendations of the federal Advisory Committee on Immunization Practices (ACIP) (August 20, 2009 version at

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm>).

A. When vaccine supply is ample, pandemic influenza vaccine should be offered to anybody without medical contraindication to the vaccine who is interested in protection from pandemic influenza.

B. When vaccine demand exceeds supply, pandemic vaccine should be targeted to:

- Pregnant women
- Persons who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers)
- Health-care and emergency medical services personnel
- persons aged 6 months--24 years
- persons aged 25--64 years who have medical conditions that put them at higher risk for influenza-related complications

C. When vaccine supply is very scarce, it may be prioritized if feasible to (changes from above emphasized in underline):

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



- Health-care and emergency medical services personnel with direct patient contact or with infectious material
- Children aged 6 months -- 4 years of age
- Children and adolescents aged 5--18 years who have medical conditions that put them at higher risk for influenza-related complications)

LHDs will need public and private sector vaccinators to reach each group.

2. Determine settings of mass vaccination clinics

This could include large scale/public health sponsored clinics, smaller clinics or private provider's offices:

- Walk-through clinic
- Drive-through clinic
- School-based clinic
- Other type of clinic to serve target population

http://www.cdc.gov/flu/professionals/vaccination/pdf/Vax_Clinic_guidelines.pdf

A. School-based/School located clinics

Schools are potential sites for immunization clinics while in session or during evenings, weekends or vacation periods.

- Partner with their local departments of education, and/or school superintendents, and/or any other school-based entities to take advantage of existing resources for school-based mass vaccination clinics. If clinics are not being conducted at schools within their jurisdiction, LHDs should consider how this priority group will get vaccinated.
- Develop a plan to inform and obtain support of principals, teachers, and parent organizations
- Contact education partners, including school districts, community colleges, universities, private schools and adult education centers and create a list of entities willing to participate in school-located clinics
- Develop plan for informing and obtaining support from physicians in the community about school-located vaccination
- Develop plans for staffing school-located clinics, including identification of sources of volunteers and development of MOAs with relevant organizations
- Provide H1N1-specific informational materials for parents
- Ensure a Vaccine Information Sheet (VIS) is provided to parents for each vaccination dose
- Provide culturally sensitive information about the vaccine in the languages of the populations served by the clinic
- Ensure schools have consent forms that have been reviewed by legal counsel
- Develop plans to distribute and maximize return of consent forms where applicable (i.e., if school clinics during school hours and without parents present are planned)
- Plan for consent related issues at time of clinic (verifying identity of consented child when parent is not present)
- Address issues specific to vaccination of children (flow from classroom to vaccination)

<http://www.readycaschools.org>

http://www.naccho.org/topics/HPDP/infectious/immunization/resources/schoolkit.cfm#Macro_Planning

B. Tribal and IHS clinics

- Include IHS and tribal planners in vaccination plans
- Ensure tribal populations are included in the allocation of vaccine



C. Other possible venues include

- Businesses
- Armories
- Sports facilities
- Fairgrounds
- Convention centers
- Health care facilities
- Colleges and universities
- Faith-based organizations
- Other venues

D. Special populations

- Identify hard to reach populations and develop plans for communication and transportation to clinic sites
- Develop MOAs with public agencies, volunteer organizations, and others to help reach these populations
- Identify all audiences that need to receive specific information and instructions about the vaccine, vaccination, and clinic site.

3. Determine the clinic location and facility

Location considerations

- Size and type (target and priority groups) of population to be served per site:
- Easily accessible to target populations
- Adequate parking (for vaccine recipients and staff) and traffic flow
- Exterior lighting
- Safety and security
- Accessible to mass transit (e.g., bus routes, train)
- Well delineated covered gathering areas outside of the clinic (weather protected) and inside the clinic

Facility considerations:

- Separate entry and exit doorways
- Patient flow
- Adequate space for the clinic population serviced and logistical set up
- Handicapped accessible
- Restrooms
- Refrigeration for vaccine cold chain
- Social distancing for target population, as applicable
- Ability to secure the facility, control ingress and egress to the clinic
- Waste disposal
- Areas/side rooms for screening and staff rest areas
- Utilities-
 - Heating and air conditioning (HVAC)
 - Water and sewer
 - Power and outlets
 - Alternate power sources, if needed (e.g., generators)
 - Phones
 - Internet connectivity

4. Determine the clinic staffing, including training and support

- Determine the number and licensure/skill sets of staff required to operate the mass vaccination clinic to achieve the hours and/or numbers of people to be vaccinated.



- Review with public health counsel which allied health professionals are legally permitted to administer vaccine, to what types of patients, and under what conditions.
- Develop or use existing job action sheets and just in time training.
- Determine size of staff (total and staff with direct patient contact) and provide for vaccination of staff.
- Develop identification badges for clinic staff.
- Develop a document containing pertinent contact information for staff.
- Develop contingency plans in the event of absenteeism.
- Plan for volunteer credentialing, training, and supervision during the clinic
- Provide of easily-locatable information on health department website for vaccinators, indicating what role they might play in given state/jurisdiction and how they can obtain information.

Suggested staffing includes:

- Greeters/educators
- Priority client screeners
- Registration personnel
- Medical screeners
- Forms collectors
- Clinic flow controllers
- Vaccination assistants
- Vaccination administrators
- Security
- Emergency medical personnel
- Runners to maintain stations stocked with supplies and equipment

Staffing augmentation strategies:

- Existing local health department staff—licensed and non-licensed/clerical staff
- Staff from other local government agencies
- Nursing Registry Staff/Temporary contracted vaccinators

Consider community staffing resources as needed:

- California Medical Reserve Corps (MRC) <http://www.medicalreservecorps.gov>
- Disaster Healthcare Volunteers (DHV)
- California Medical Assistance Teams (<http://www.cdmsa.org/>)
- Community Emergency Response Teams (CERT)
- American Red Cross
- Community-based organizations
- EMS providers
- Healthcare providers and organizations (e.g., hospitals, clinics)
- Home health nurses
- Schools and colleges
- Military
- EMT-Paramedics (<http://www.emsa.ca.gov/paramedic/default.asp>) if approved for jurisdiction
- Other non-traditional extenders: dentists, veterinarians, etc

Support staff:

- Mental health services
- Janitorial services
- Security and Safety
- Data Entry
- Greeters
- Educators
- EMS personnel
- Translation services



- Medical Reserve Corps (MRC) personnel
- Disaster Healthcare Volunteers (DHV)

A. Develop and implement a staff training plan

- Determine the level and type of training that will need to be conducted prior to the mass vaccination clinic:
 - H1N1 influenza information
 - General vaccine information
 - Vaccination techniques and follow up
 - How to answer recipient questions
 - Medical screening expectations
 - Personal protection and infection control information

Free online training on *Preparing Vaccines* and *Administering Vaccines* is available on eziz.org. The online lessons are appropriate for initial or refresher training.

B. Staff and volunteer support

- Contact community resources to provide food and beverages for staff and volunteers:
 - American Red Cross
 - California Medical Volunteers
 - Service (e.g., Lions, Rotary, and Kiwanis) clubs
 - Local businesses and healthcare providers
- Schedule rest and relaxation breaks for staff and volunteers during duties
- Designate a specific location out of the clinic mainstream for staff and volunteers to break

5. Determine and obtain supplies and equipment

Major equipment:

- Ensure adequate refrigerated storage for vaccine to include preloaded syringes and multi-dose vials of vaccine and possibly to include vaccine with adjuvant
 - Do not freeze vaccine
- Walkie-talkies for internal clinic communications
- Cell phones and pagers
- Land lines
- Fax
- Computers
- Internet access
- Printer and copy machine
- Power cords, batteries, chargers, surge protectors
- Megaphone
- Public address (PA) system
- Lighting and back up power/lighting
- Partitions/screens for privacy and ropes and stands to delineate routes for recipients to follow from station to station
- Seating for recipients at each appropriate station (e.g., registration/paperwork, vaccination station, medical screening area)

Vaccines and medications:

- Adequate vaccine to vaccinate target population
- Consider antipyretics (e.g., acetaminophen)
- Supplies for protocols: anaphylaxis, syncope etc.

Ancillary supplies:



- Band-aids
- Blood pressure cuff and stethoscope.
- Supplies for adverse event protocols: anaphylaxis, syncope, etc.
- Personal protective equipment (e.g., gloves, masks)
- Respiratory hygiene supplies (for target population use)
- Masks
- Tissues
- Waste receptacles
- Hand sanitizer
- Cots for screening/assessment area
- Wheelchair(s)

Other equipment:

- Identification/badges
- ICS vests
- Phone directories
 - Internal to the mass vaccination clinic
 - Key outside contacts

If wait times may be long, consider

- Reading, TV or other entertainment materials, TV
- refreshments

A. Documentation/Paperwork

- Vaccine Information Statements and related educational information
 - Languages of clients
 - Appropriate quantities
 - Audience-specific
- Immunization consent forms (if applicable to the clinic population or LHD elects to use consent forms)
- Documentation of doses given
- Sign-in sheets for staff and volunteers
- Staffing rosters and assignment sheets
- Job action sheets for each position
- Signage to direct vaccine recipients, indicate locations within the clinic, display instructions or important information

B. Vaccination data collection

- Define local data collection needs
- Develop staffing plan and training for data collection, entering and forwarding at public clinics and at local and state health departments
- Determine equipment needs at all data collection and forwarding sites
- Report doses of vaccine administered weekly using either
 - California Immunization Registry (CAIR)
 - www.CALPANFLU.org, choose the "Report H1N1 Vaccine Usage" link.

6. Arrange for security, especially at large clinics

- Security at receiving sites, in transport to administration sites, and at administration site
- Contingency plan in place for unexpected disruption at administration site
- Assign security staff; recommended for large clinics even if low risk of disruption.
- Ensure an orderly flow of traffic at the parking site
- Assist in maintaining orderly movement of vaccine recipients through the clinic processes



- Provide necessary control of persons if they become unruly
- Assist in securing vaccines and other supplies
- Protect the staff and volunteers

7. Develop marketing and communications for clinics

A. Marketing

- Publicize the mass vaccination clinic in multi-media and multi-lingual formats to widely post clinic purpose, dates, locations, times, and which populations will be served:
 - Radio and TV public service announcements
 - Newspaper
 - Press conferences
 - Press releases
 - Websites
 - Media web postings
 - Community bulletin boards
 - Newsletters
 - Enlistment of community-based organizations and businesses to recruit vaccine recipients
 - Reverse 911 calls to targeted areas
- Provide instructions on how to set up appointments via telephone, in person, or web-based if pre-scheduling will be used
- Be prepared to direct clients to other facilities or vaccination clinics if the clinic is overwhelmed with people presenting for vaccination or supply of vaccine is not adequate for the numbers.

B. Communications

- Identify Public Information Officers (PIO) and backups
- Identify a systematic way to communicate with all vaccinators; options include mass mailing, e-mailing or blast-fax lists from licensing boards or medical societies
- Identify capacity to prepare press releases
- Consider setting up a web-based information system
- Consider setting up an H1N1 hotline
- Ensure clear communication about implementation of target and priority group recommendations and need for second dose
- Local partners for messages can include
 - medical societies,
 - hospital associations,
 - healthcare provider professional organizations,
 - California Health Alert Network (CAHAN)
- Involve local stakeholders and/or key audience liaisons in shaping outreach strategies
- Identify language and cultural barriers and develop a plan to address these barriers
- Plan testing of messages for receipt and understanding by the general public
- Create MOAs with channels for communication (e.g., print media/local papers, community and social or religious networks, commerce or local business partners)
- Determine best means for targeting communication broadly to different ethnic and socioeconomic populations (Media, clinician outreach, websites or new media)
- Reach out to widely diverse local partners, volunteer groups and other NGOs with specific instructions and technical support on how to help disseminate messages and aid the general public in accessing vaccination sites.
- Plan information communication network throughout agencies at state and local levels to ensure coordination of messages
- Conduct ongoing assessment of strategies, and adjust messages as needed.



Brief Overview of Clinic Operations

Command and Control for the Mass Vaccination Clinic

Use of Incident Command System (ICS)/Hospital Incident Command System (HICS):

<http://www.emsa.ca.gov/hics/>

- Activate appropriate roles:
 - Command (e.g., Incident Commander, Safety Officer, Public Information Officer, and Liaison Officer)
 - General Staff (e.g., Operations Section, Planning Section, Logistics Section, Finance/Administration Chiefs)
 - Roles to cover clinic operations, staffing, census, flow and structure
- Consider activating the Department Operations Center (DOC) to assist with communication, decision-making, and logistical support of the mass vaccination clinic
- Orient as needed LHD staff and partners to both ICS and partners' command systems

Operation of H1N1 Mass Vaccination Clinic Stations

Receiving and accounting of vaccine

- Develop and implement procedures
- Ensure adequate cold storage for the volume of vaccine that will be stored.

Intake:

- Clinic patrons are directed to a location where a greeter-educator briefs the group(s) on
 - Influenza vaccine information (VIS) or consent process
 - Clinic processes
 - Required information and paperwork
- Paperwork and registration forms are checked for completeness
- Screen for target group inclusion when vaccine supply is limited.
- Screening for deferral or contraindication
 - Inactivated vaccine <http://www.immunize.org/catg.d/p4066.pdf>
 - Live vaccine <http://www.immunize.org/catg.d/p4067.pdf>
- Determine if any medical contraindications for vaccination
- Vaccine recipients who have symptoms of illness should be triaged to a medical screening area

Medical screening area:

- Provide a private/screened area for large-scale mass vaccination operations.
- Medical professional (e.g., MD, RN, or paraprofessional with good interviewing skills)
 - Assesses recipients for symptoms of acute illness that might defer vaccination, redirecting ill persons to appropriate section of clinic as indicated
 - Applies infection control measures for ill patients, directing them to sick bay
- http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm
- Confirms medical contraindications for vaccination and advise the recipient they may not receive a vaccine

Vaccination:

- Prepare recipient for vaccination
- Vaccinate according to protocol
- Apply bandage
- Develop plan for responding to medical emergencies or acute adverse events (e.g. fainting, allergic reaction)
 - Determine level of emergency care will be available at the clinic (e.g., crash cart, bag valve mask, oxygen)?
 - Determine emergency medical response (i.e. 911) and transport for emergencies



- Designate an area for individuals requiring medical assessment and monitoring (short term, e.g., feeling faint after vaccination)
- Confirm protocols for syncope, anaphylaxis

Paperwork Collection and Release:

- Provide client with standard card or similar record of completed immunization
 - Include date of vaccination, whether 1st vs. 2nd dose, lot number, return date for 2nd dose, VAERS contact information
- Ensure information on return date for second dose is provided
- Vaccine recipient paperwork is collected
- Any remaining questions are answered
- Staff should observe vaccine recipients for potential adverse events or medical issues and report them to the medical assessment area staff immediately
- Vaccine recipient exits clinic

Reporting

- Report doses of vaccine administered weekly using either
 - California Immunization Registry (CAIR)
 - www.CALPANFLU.org, choose the "Report H1N1 Vaccine Usage" link.

References: <http://www.cdc.gov/h1n1flu/vaccination/statelocal/ga.htm>
http://www.cdc.gov/H1N1flu/vaccination/statelocal/pdf/H1N1_DosesAdministered.pdf
http://www.cdc.gov/H1N1flu/vaccination/statelocal/planning_checklist.htm



Appendix D: Roles for California Local Health Departments (LHDs) for the ordering and distribution of pandemic influenza vaccine

Participate in the campaign to deliver pandemic influenza vaccine

California LHDs are expected to

- Participate in the pandemic influenza vaccine campaign beginning in 2009 by
 - Providing vaccine
 - Supporting its administration by a broad network of public and private partners in your jurisdiction.
- Participate for the duration of the campaign, the length of which is currently unknown
- Utilize additional funding under federal Public Health Emergency Response (PHER) Act grants to support the planning and implementation of the campaign
- Utilize the collaborative efforts of LHD staff based in
 - Immunization Programs
 - Emergency Preparedness Programs
 - Other programs as indicated or needed

Register on www.calpanflu.org

- LHDs need to register their Department's sites that might receive vaccine on www.calpanflu.org
 - County vaccine clinics
 - County hospitals
 - County and municipal jails, including juvenile detention facilities
 - County Employee Health
 - Other?
- Register each site expected to receive vaccine directly from the vaccine distributor (instead of the LHD's central supply)
 - LHD A will receive vaccine centrally and then provide vaccine to 20 other sites – should only register the single central site
 - LHD B prefers vaccine to be shipped directly by the distributor to 20 public clinics and hospitals – each of the 20 sites should register separately
 -

Promote vaccinator registration in your jurisdiction

- Invite other vaccinators in your jurisdiction to register at www.calpanflu.org using
 - Provider lists maintained by the LHD
 - Local medical societies
 - CAHAN
 - Hospitals
 - Other recruiting mechanisms

Place an initial order

- Either at the time of registration or later LHDs may place an initial order that anticipates
 - Usage at its regular clinics



- Additional clinics (using federal PHER Phase III grant funding)
- The option of a small reserve stock to address local urgencies;
 - LHDs will also have priority for additional orders as needed
- It is expected that LHDs will revise their orders as needed to reflect changing information about
 - Other vaccinators in the jurisdiction
 - Funding
 - Staffing.

Review vaccinators registered in your jurisdiction

- CDPH will send each LHD at least weekly an Excel spreadsheet with updated information from www.calpanflu.org about registrants that want to provide pandemic vaccine and the populations that they serve
 - Currently scheduled for end of each week starting September 10
 - Will be sent to LHD Immunization Coordinator – to add additional names, contact Nisha.Gandhi@cdph.ca.gov
- LHDs need to review the weekly updated lists to check
 - Who's missing? Recruit additional parties that haven't yet registered
 - What seems wrong? Is there information on registrants that is
 - Erroneous
 - Incomplete or needing validation
 - Possibly inappropriate name, order size, etc
 - Duplicate entries
- For multijurisdictional vaccinators based in your jurisdiction, contact the vaccinator, other jurisdictions, or CDPH as needed to clarify vaccinator's activities and how vaccinator's inventory might be used in each jurisdiction

Prioritize vaccinators for pre-approval of initial orders

- A method for prioritization is being defined that can accommodate the current incomplete or changing information (e.g., timing, volume, which formulations are first available, etc.) about the pandemic vaccine. Additional information will be provided shortly.
- The goal of this process is to be able, once vaccine is available, to promptly fulfill initial orders to vaccinators, especially those serving target populations. The prioritization process will assist LHDs to tell CDPH, before vaccine is available, which vaccinators are to receive initial orders.
- Prioritization will eventually not be needed as vaccine supply becomes ample. Therefore, a threshold number of statewide vaccine doses that approximates an ample initial supply, or a date which corresponds to the availability of this amount, will be designated.

LHDs will

- Calculate the allocation for your jurisdiction by using your proportional allocation of vaccine and the threshold number of doses.



- Compare the number of doses allocated in the jurisdiction to those registered vaccinators are initially requesting
- As the prioritization method is defined, rank vaccinator list
 - Revise as weekly updates received
- Adjust LHD's own order (LHD clinic, public hospital, etc.) estimates as needed according to
 - Updated information on registrants
 - LHD resources to administer vaccine, including PHER funding
 - Submit new order on www.calpanflu.org
- LHDs are expected to submit before vaccine is first available (by dates to be determined) a ranked version of the Excel spreadsheet indicating pre-approval of initial provider orders, thus allowing time for orders to be processed
 - Lists may be still be modified after vaccine is available to reflect later registrants, but later orders may be further delayed or adjusted

Settings and populations expected to be served by separate vaccine allocations, not from LHD allocations

- Federal Government:
 - DOD - active duty (but not dependents)
 - VA medical facilities
 - Federal employees, including staff at federal correctional facilities
- State Government:
 - Correctional facilities and hospitals.
 - Possibly other State clinical settings that routinely order seasonal influenza vaccine from State contracts
- Kaiser Permanente Northern California and Southern California will receive supplies based on their geographical proportion of population

Settings and populations currently expected to be considered by LHDs in their planning and allocations

- The settings for immunization that LHDs should consider for their allocations include but are not limited to
 - Routine LHD clinics, central and satellite
 - Public hospitals
 - Tribal and IHS facilities
 - Large scale clinics in a variety of settings
 - Local schools, public and private, serving persons 6 months–24 years
 - Pre-school and Head Start
 - K-12
 - Post-secondary, including community colleges
 - WIC Agency staff and clients
 - Local correctional facilities, including those serving juveniles



- State institutions located within county boundary including developmental centers and mental health facilities
- Some of these sites are already VFC program sites and may have registered separately on www.calpanflu.org.

● **Role of schools as pandemic influenza immunization clinics**

- LHDs are expected to contact local schools as possible vaccine clinic sites
- Toolkit for school clinics currently available at www.immunizeca.org/ under “School Flu Clinics” → “Flu Clinic Resources”
- Options for immunization at local schools include
 - Staffing
 - Temporary Clinics staffed by
 - LHD
 - Contracted private vaccinators
 - Volunteers
 - Existing School-based health centers
 - Hours
 - During school
 - More efficient for reaching students
 - Afternoon, evenings, weekends, vacation
 - Easier to immunize community as well
 - Populations served
 - Students
 - Staff
 - Families
 - Community
 -

Potential roles of private community or mass vaccinators

- Options for private vaccinators include serving
 - As contracted staff for LHD-affiliated clinics at schools, community centers or other venues that reach target populations
 - In this role could receive vaccine from LHD’s supply
 - Efforts are in progress to provide LHDs with standard language for contracting with private vaccinators
 - In their traditional roles as independent fee-for-service vaccinators
 - In this role they register separately and are receive supply from jurisdiction’s total allocation according to prioritization process
 -

Vaccine shipment information

- General information about the federal contract for vaccine distribution by McKesson Specialty Inc. is available at http://www.cdc.gov/H1N1flu/vaccination/statelocal/centralized_distribution_ga.htm



- CDPH will forward to each LHD jurisdiction updates about shipments sent in its jurisdiction.
- LHDs and other vaccinators will be able to call www.calpanflu.org customer support to check on status of orders; additional capacity for customer order notification and tracking is being explored.

LHDs that plan to redistribute vaccine from their own supply should review their:

- Vaccine storage and handling capacity (applies also to LHDs who are not re-distributing)
- Staffing needed for receipt, storage, breakdown and repackaging of vaccine
- Systems to track inventory as it is redistributed
 - Replenish supply in timely manner
 - Ship vaccine to peripheral sites, including back-up systems
- Procedures for staff signing for receipt of delivery, chain of custody, etc.

Report adverse events related to LHD-sponsored clinics

- Report adverse events associated with immunization at LHD clinics to VAERS:
 - <http://www.vaers.hhs.gov/> or
 - 1-800-822-7967
- LHDs will be given additional instructions on reporting possible cases of Guillain-Barre Syndrome in immunized and unimmunized persons in their jurisdictions

Report administered doses weekly

- LHDs will be expected to report each week the aggregate doses of H1N1 vaccine that have been administered weekly out of the supply received by the LHD (but not by all vaccinators in the jurisdiction) using either:
 - California Immunization Registry (CAIR), from which data will be extracted automatically, or
 - www.calpanflu.org, choose the "Report H1N1 Vaccine Usage" link, and enter the total doses administered during the previous week.
- CDPH will enter this data from all vaccinators including LHDs into CDC's Countermeasure Response Administration (CRA) system.
- LHDs will not need to use CRA this season to report either pandemic or seasonal influenza vaccine administration.

Handling of unused or expired vaccine

- Awaiting federal guidance



MISCELLANEOUS INFORMATION:

Reimbursement

CDC will shortly provide written clarification on reimbursement for public health and private vaccinators.

Clinics sponsored by public health

- o Cannot turn patients away based on ability to pay
- o Large-scale clinics
 - Billing of 3rd party payers or charging of patients not allowed
- o Routine (non-mass) clinics
 - Able to bill insurers (see below) but not charge patients
- Private vaccinators can charge or bill for administration
 - o Reimbursement may vary by health plan; contact each plan for details
 - o MediCal patients: \$9.00
 - o All others: Upper limit is Medicare regional administration fee

Anaheim/Santa Anna	\$24.94
Los Angeles	\$24.35
Marin/Napa/Solano	\$24.75
Oakland/Berkeley	\$25.16
San Francisco	\$27.43
San Mateo	\$27.39
Santa Clara	\$25.44
Ventura	\$24.82
Rest of California	\$21.64
- The Medicare vaccine reimbursement guidance posted at:
<http://www.cms.hhs.gov/MLN Matters Articles/downloads/SE0920.pdf>

Supply footprints

The supply footprints for H1N1 flu vaccine packages have not been released yet. Until then, here are approximate measurements for seasonal flu vaccine packaging.

Sanofi Multidose vials, 10 vials	6 cm x 15 cm x 6cm
Sanofi single dose syringes, 10 syringes	11.5 cm x 13.5 cm x 4 cm
Medlimmune LAIV nasal sprayers, package of 10	4 cm x 11.5 cm x 14.5 cm
GSK single dose vial, 10 vials	7 cm x 17.5 cm x 8cm



Liability coverage under the PREP Act

<http://www.flu.gov/vaccine/vacresearch.html>

Will HHS be providing liability protection for vaccine manufacturers? And will HHS compensate eligible individuals who might be injured by a vaccine?

On June 15, 2009, HHS Secretary Sebelius signed a declaration under the Public Readiness and Emergency Preparedness (PREP) Act to extend liability immunity against tort claims (except for willful misconduct) to individuals and entities involved in all stages of 2009 H1N1 influenza vaccine development, testing, manufacture, distribution, prescribing, administration, and use. Liability immunity means that there is no legal tort claim that can be pursued in state or federal court. Individuals and entities that receive liability immunity under the declaration include manufacturers, distributors, States, locals, Tribes, and other entities that supervise or administer a vaccination program, and healthcare professionals or others authorized under State law to prescribe, administer, and dispense vaccines, when they are carrying out activities in accordance with the conditions stated in the declaration. One condition of the declaration is that the vaccination activities must relate to a present or future federal contract, grant, cooperative agreement, interagency agreement, or memorandum of understanding. Vaccines procured by the federal government for distribution are included. PREP Act declarations are intended to encourage manufactures to produce vaccine, and other entities to participate in distribution, dispensing, administration, and use of the vaccine.

The PREP Act also authorizes the Department to establish a compensation program when a declaration is issued under the Act. Funds for a compensation program were provided under the June 24 Supplemental Appropriations Act. The Department is currently working on developing a compensation program for eligible individuals who sustain covered injuries following vaccination.



Estimated proportion for each jurisdiction of each 1 million doses of pandemic million vaccine designated for California based on population, including and excluding health plan members of Kaiser Permanente

Preliminary estimates to assist in planning – NONBINDING -Date: 8/24/09

Jurisdiction	All	non-Kaiser	Jurisdiction	All	non-Kaiser
Alameda (not Berkeley)	37,850	25,410	Orange	81,970	72,440
Alpine	30	30	Pasadena	3,920	3,340
Amador	990	870	Placer	8,870	6,150
Berkeley	2,800	1,880	Plumas	540	540
Butte	5,760	5,740	Riverside	55,040	46,400
Calaveras	1,200	1,130	Sacramento	37,430	25,520
Colusa	570	560	San Benito	1,520	1,400
Contra Costa	27,690	17,870	San Bernardino	53,820	44,000
Del Norte	770	770	San Diego	82,870	70,100
El Dorado	4,710	3,730	San Francisco	22,080	17,590
Fresno	24,610	22,320	San Joaquin	18,010	13,860
Glenn	760	760	San Luis Obispo	7,060	7,060
Humboldt	3,470	3,460	San Mateo	19,480	14,670
Imperial	4,680	4,670	Santa Barbara	11,260	11,250
Inyo	470	470	Santa Clara	48,510	36,010
Kern	21,600	19,070	Santa Cruz	7,020	6,850
Kings	4,040	3,960	Shasta	4,780	4,770
Lake	1,670	1,610	Sierra	90	90
Lassen	930	930	Siskiyou	1,200	1,200
Long Beach	12,870	10,960	Solano	11,140	6,310
Los Angeles (not LB, P)	254,650	216,890	Sonoma	12,710	8,300
Madera	3,980	3,600	Stanislaus	13,750	11,550
Marin	6,750	4,830	Sutter	2,520	2,430
Mariposa	480	460	Tehama	1,640	1,640
Mendocino	2,360	2,330	Trinity	360	360
Merced	6,700	6,540	Tulare	11,530	11,520
Modoc	250	250	Tuolumne	1,470	1,450
Mono	350	350	Ventura	21,830	19,700
Monterey	11,280	11,220	Yolo	5,240	4,290
Napa	3,590	2,250	Yuba	1,900	1,750
Nevada	2,580	2,520			



Appendix E: Procedure for VAERS Documentation

A. Private or federally funded vaccines:

1. Healthcare providers, parents, patients, or others can report directly to VAERS by:
 - 1) Internet: Report on-line at <https://secure.vaers.org>
 - 2) Fax: Fax the completed report form to 1-877-721-0366 (toll-free)
 - 3) Mail: Mail completed form to:
VAERS
P.O. Box 1100
Rockville, MD 20849-1100
2. CDC requests form within 5 days of reporting the event.

B. State funded vaccines:

1. Healthcare providers, parents, patients, or others report to State Immunization Branch by:

- 1) Mail: Mail completed forms to:
CDPH Immunization Branch
ATTN: SIRE Vaccine Adverse Events Coordinator
850 Marina Bay Parkway
Bldg. P, 2nd floor
Richmond, CA 94804-6403

- 2) Phone: Call (510) 620-3737 and ask for SIRE Vaccine Adverse Events Coordinator.

- a. Ask caller to fill out form and send it to Richmond campus.

- 3) Fax: Fax completed form to (510) 620-3774

2. SIRE Vaccine Adverse Coordinator will make sure form is completely filled out.

If not:

- 1) Call health care provider and fill in missing information.
- 2) If unable to reach the medical provider, leave message and ask the provider to call back.
- 3) If provider does not return message, call again. Keep calling until the provider is reached and able to provide answers to the questions that were left blank on the form.
- 4) If unable to reach the provider after 10 calls, fax incomplete form to CDC and let them know.

3. All forms received by SIRE Vaccine Adverse Coordinator after review:

- 1) Fax form to the VAERS staff at CDC 1-877-721-0366 (toll-free)

4. CDC requests receiving report within 5 days after receipt of form.

C. Pre- and Pandemic Vaccine:

According to decision by CDC at time of vaccine release, will follow one of the above procedures for reporting vaccine adverse events.



Appendix F: Moving the Components of the State RSS to Local Sites

Distributing Resources or SNS Materiel

CDPH may transport materiel by ground (road or rail), air, water, or a combination of transport mechanisms, depending on the location of the LHD and available transport systems. CDPH will arrange for transportation through its State RSS Warehouse Transportation Unit. CDPH may request assistance through the California Emergency Management Agency (CalEMA) [former Governor's Office of Emergency Services(OES)] for the allocation of transportation resources for State cache or SNS shipments from the State RSS Warehouse. CalEMA will also assist with the allocation of needed escort and traffic control resources for the State Cache and SNS shipments from the State RSS Warehouse.

Interagency Coordination

CalEMA will carry out interagency coordination and mission tasking. CalEMA will mission task appropriate agencies, as needed, in support of the SNS operations at all levels. Mission tasking may include, but is not limited to:

1. transportation for air, ground, rail, waterways;
2. law enforcement to ensure public safety and traffic control;
3. public works for vehicles, drivers, fuel, and repair; and,
4. general services for procurement and contract assistance, personnel, and facilities.
5. Communication capabilities and processes identified within the State's *Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS)*, Chapter 11 will be utilized for deployment and distribution of antiviral medications. Existing telecommunication systems available within existing caches will be provided to RSS communication staff, drivers, and recipient locations agency representatives. Radio, telephone, push-to-talk, direct connect, satellite and web interface connects will be utilized for primary and back-up communications with all necessary parties. Specific information regarding telephone identification, radio frequencies, and capabilities are confidential and will not be included in this document due to possible release to the media or public. Specific information and existing process and procedures have been reviewed by CDC-SNS Program Evaluators and are available for on-site review only. *NOTE: State's Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS) and appropriate Appendices and Annexes have been provided to CDC – DSNS and can be reviewed through the State's CDC – SNS Representative.*



Alternative Sources of Transportation

In addition to the State, LHDs are responsible for obtaining transportation of the State Cache or SNS materiel from local RSS sites to dispensing sites, and treatment centers. Local transportation assets may also be utilized to augment state transportation needs in order to decrease delivery time. These transportation arrangements are consistent with CDPH's requirement that LHDs plan for redundant transportation. CDPH requires temperature controlled vehicles to be used during weather conditions that will expose antiviral medications to temperatures outside of 59 to 86 degrees Fahrenheit.

Distribution Planning and Operational Information

CDC will arrange transport of SNS materiel to the designated State and Los Angeles County RSS Warehouse sites.

In coordination with CalEMA, CDPH will be responsible for transporting the State Cache or SNS materiel from State to the local level.

Delivery locations identified by the 61 local public health jurisdictions will receive materiel based on pre-established allocations of existing caches and those entities requests for additional resources. Specific routes for distribution will be established utilizing the California Highway Patrol (CHP) and California Department of Transportation (CalTrans) Road Condition Network. These two State Department's have been assigned to the RSS and Distribution Warehouse functions of Vehicle Dispatch, Routing Control, and Escort and Facility Security. As the CHP has vehicle and asset security responsibilities they will determine the best primary and secondary routes to the potential 61+ locations throughout the state at the time of deployment. Pre-planned routes are maintained as confidential information and will not be included in this document due to possible release to the media or public. Pre-planned routes are available for on-site review only.

The initial push of state pre-allocated medications and supplies that are currently cached in State RSS Warehouses (antiviral medications, N-95 masks, and Alternate Care Supply Cache's) will be delivered to the appropriate jurisdictions within 8-10 hours of a decision to deploy. Upon receipt of federal pre-allocated medications and supplies, they will be processed and delivered to each recipient within 6-8 hours of receipt. Frequency of distribution of any additional resources will be determined based on the availability of those resources to the state RSS Warehouse and the local jurisdictions requests for additional materiel. All requests received through the SEMS Ordering System will be processed by the State RSS Warehouse and ready for shipment within 2 hours of the request's receipt. Based on the availability of supplies, distribution will be accomplished on 6 to 12 hour intervals for each of the 61 public health jurisdictions.

Vehicle Dispatch

CDPH maintains Vehicle Dispatch as a specific function in the State RSS. This function assigns deliveries to specific drivers, monitors each driver's progress and location, and



reassigns deliveries based on the problems that drivers encounter, such as breakdowns. Dispatchers will keep track of:

1. all vehicles used in transporting State Cache or SNS materiel;
2. all vehicles containing State Cache or SNS materiel while in transit;
3. preferred routes;
4. coordination for security escort;
5. location of problems such as congestion, closed roads, and downed bridges that require rerouting vehicles; and,
6. drivers who need repair, security, or other support.

Vehicle and Driver Identification

Vehicles and drivers support facilities that restrict access during an event. At the time of setting up the specific distribution network, Vehicle Dispatch will:

1. Work with all receiving facilities to determine how to mark vehicles (e.g., bumper sticker) and drivers (e.g., ID badge) so they do not encounter problems entering these areas.
2. Work with transportation authorities and law enforcement to ensure they recognize vehicles and drivers as part of the emergency response team.



Appendix G: Security

Security Support

The California Highway Patrol (CHP) is the lead state agency for arranging and providing security for state assets, facilities, and personnel. CHP has developed an SNS Security Plan in order to provide direction to the CHP's eight regional divisions. A State wide Security Coordinator and alternate Security Coordinators for each of the CHP's Divisions have been identified and are included within the CHP's *SNS Security Plan*. Processes and procedures for overall security coordination are confidential and will not be included in this document due to possible release to the media or public. Existing process and procedures have been reviewed by CDC-SNS Program Evaluators and are available for on-site review only. *NOTE: State's Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS) and appropriate Appendices and Annexes have been provided to CDC – DSNS and can be reviewed through the State's CDC – SNS Representative.*

LHDs are responsible for providing security at local RSS distribution sites and treatment centers, as well as coordinating with and complementing, if necessary, state security escorts of the State cache or other SNS materiel to these locations.

Security and Communications Support

Security of distribution vehicles from the State RSS warehouse to the local RSS distribution sites (traffic control and protection) and the ability to communicate with drivers will be critical for the smooth operation of the distribution network. During an event, crowd and traffic control may rapidly become major problems.

Drivers will communicate with dispatchers via locally established protocols for any problems or needs. These may include: cellular phones, two-way radio, etc. (See State's *Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS)*, Chapter 10, Security and Communication Support, pg. 41)

CalEMA will assist with the allocation of needed escorts and security for drivers and vehicles supporting SNS activities.

Security before CDC Transfer of the SNS Materiel to CDPH

If SNS materiel is deployed to California, CDC is responsible for securing these resources. However, CHP will coordinate with federal security entities when SNS materiel is being transported on California roads and highways to ensure safe delivery to the State RSS warehouse.

SNS Security Following Transfer from CDC to the State

The State RSS Warehouse Security Officer will determine the need and level of armed law enforcement security services for the following:



1. State RSS Warehouse (internal/external);
2. Distribution vehicles loading, offloading, and in transit from State RSS to local RSS sites; and,
3. Distribution routes used by vehicles transporting the State antiviral cache or SNS materiel.

Additional security needs will be tasked by CalEMA, as needed.

State RSS Warehouse Security

CDPH and CHP have developed security procedures for State RSS warehouse. These procedures will prevent all unauthorized entry through the perimeter of the State RSS site and security personnel will be responsible for determining and securing the perimeter. State and local law enforcement will coordinate to provide security at the State RSS warehouse, which involve planning for the following:

1. Access control into, within, and out of the RSS warehouse. This measure involves actions such as sign-in logs after proper identification, and identification badges for authorized personnel. Volunteers to staff RSS facilities will be credentialed upon reporting to the facility. The RSS Warehouse Logistics Section will provide the credentialing process. The public, including members of the media, will not be allowed access to the State RSS Warehouse site. The location of the State RSS Warehouse site will not be intentionally disclosed to the public or the media. The State will follow the Badging/Credentialing System outlines in the State's *Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS)*, Chapter 5, pg 22 and Appendix CC. ALL personnel will be properly identified and receive their badges and credentials prior to arriving at any State location utilized during a Pandemic Influenza Response. As per the Operational Plan, the security forces will NOT allow any individual within the facilities without proper badges and credentials, and will detain and/or turn away all non-badged individuals. This badge and credential system has been tested and exercised on several occasions and even lead to the arrest of one person who had an outstanding warrant. Processes and procedures for badging and credentialing personnel are confidential and will not be included in this document due to possible release to the media or public. Existing process and procedures have been reviewed by CDC-SNS Program Evaluators and are available for on-site review only. *NOTE: State's Operational Plan and Procedures for Receiving and Distributing the Strategic National Stockpile (SNS) and appropriate Appendices and Annexes have been provided to CDC – DSNS and can be reviewed through the State's CDC – SNS Representative.*
2. Alternate routes for entry and exit to the facility based on traffic flow and security concerns to ensure uninterrupted transportation operations.



-
3. Perimeter protection using physical barriers such as perimeter fences, barriers of various types, vehicle gates, personnel gates and turnstiles, closed circuit television, and perimeter lighting.

Distribution System Security

CHP will provide escort, including traffic control and security in transit, while materiel is moved from the State RRS warehouse to the local RSS distribution sites. These movements will occur largely under the jurisdiction of the CHP. Areas of needed security will include, but not be limited to the following:

1. Escort of vehicles to and from local distribution sites;
2. Securing key transportation arteries so that only vehicles involved in transporting the State antiviral cache or SNS materiel and other emergency vehicles can use them; and,

Use of alternatives to ground transportation, including helicopters, railway, or watercraft.



Appendix H: Storing, Staging and Distribution of State and Federal Caches of Materiel/Vaccine

CDPH has identified a single warehouse for long term storage of the State cache and caches of materiel provided by federal agencies (see **Pandemic Influenza Antiviral Allocation and Distribution Plan: Long Term State RSS Warehouse Appendix**). When notified by CDC of the federal decision to commence the Pandemic Influenza Stage Two – Countermeasure Distribution, CDPH will initiate distribution to LHDs of the pre-established allocation of the State Cache materiel. The State RSS warehouse will begin to ship materiel to each local RSS site according to the pre-identified allocations for each county. The inventory control function will enter the orders into its inventory management system and create an issue document. The document will prompt storage personnel to pull materiel and staging personnel to organize it by delivery location in the shipping area of the State RSS Warehouse.

1. As the State cache of materiel and other items are moved out of the State RSS warehouse, they will be debited from the State inventory and credited to the LHD inventory. This will be done electronically if CDC has an electronic inventory control system in operation. Otherwise, CDPH will use paper records.
2. Rack spaces emptied of State cached materiel will remain empty in preparation for the receipt of additional State or Federal deployed assets.
3. As CDPH receives the SNS materiel, it will allocate them to each LHD and their corresponding local RSS location(s) according to the pre-identified allocations based on population.
4. As other SNS materiel is received it will be allocated to LHDs based on their requests and operational need. LHDs that require additional resources or SNS materiel will make their requests through the SEMS/NIMS process. Recipient Locations will process requests for additional supplies or materiel through their local public health department, emergency medical services agency and their respective Operational Area Emergency Operations Center following the Standardized Emergency Management System (SEMS) process. Requests not filled locally will be forwarded to the State Regional Emergency Operations Center for allocation of existing resources within the region or forwarded to the State Operations Center for allocation of State and federal resources directly to the local jurisdictions. Existing request and dispatching communications channels and documentation processes will be followed for required request and resource allocation tracking.



Temperature Control of SNS Items and Vaccine in Staging, Storage and Transit

All pharmaceuticals must remain at appropriate temperatures (59°F to 86°F) to ensure potency. Unless advised to keep frozen, most vaccines are stored at temperatures between 36-46 °F (2 to 8 °C). The refrigerators are monitored electronically and temperature readings would be recorded at as minimum every 12 hours. These environmental conditions will be maintained at the State RSS warehouse and within transport vehicles to the extent possible.

Chain of Custody for Transferring Pharmaceutical, Medical Supplies, and Vaccine

In order to ensure chain of custody for pharmaceutical, medical supplies, and vaccine shipped from the State RSS Warehouse to OA receiving sites and PODs the Preparation and Packaging Manager shall ensure that outbound shipments are accompanied by the SNS Medical Supplies Transfer Form (See Appendix I). The Preparation and Packaging Manager or his/her designated representative will sign the form and ensure the inventory list is completed. In lieu of the inventory list, a copy of the RSS Inventory Management System (RITS) packing list may be attached to the transfer form. Drivers shall be instructed to have the transfer form signed by the appropriate authority at the receiving site or POD and return the signed originals to the Preparation and Packaging Manager. If the local receiving site or POD manager desires a copy of the transfer paperwork they may make copies of the original documents.



Appendix I: Medical Supplies and Vaccine Transfer Form



CDPH Strategic National Stockpile Program

Medical Supplies and Vaccine Transfer Form

The California Department of Public Health (CDPH) Strategic National Stockpile Program hereby transfers medical materiel from the CDC provided Strategic National Stockpile assets into the custody and control of the receiving authority listed below. By signing this transfer form, the receiving authority acknowledges receipt of the medical materiel listed.

The receiving authority accepts full responsibility for the materiel entrusted into its possession and agrees to abide by the terms, conditions, and responsibilities, of all applicable agreements between the state and local authorities, as well as all applicable federal and state laws and regulations. See attached sheet(s) for listing of items received.

**Provisionary CDPH Strategic National
Stockpile Authority
(PRINT NAME & TITLE)**

SIGNATURE & DATE

**Authorized Receiving Authority
(PRINT NAME & TITLE)**

SIGNATURE & DATE



**If control Schedule II Substances are Transferred
Authorized Receiving DEA Registrant**

SIGNATURE & DATE

(PRINT NAME, TITLE, DEA REGISTRATION No.)



Appendix K: Control and Apportionment

Controlling Inventory

CDPH is responsible for inventory control of the State Cache Pandemic Influenza Countermeasure, and SNS materiel while at the State RSS warehouse. CDPH shall conduct the following inventory management activities at the State RSS warehouse:

1. tracking all receipts;
2. apportioning supplies as directed by the pre-established allocation distribution lists or alternate policy decisions made by CDPH;
3. processing requests from OA RSS distribution sites, as directed by the JEOC;
4. recording the locations to which it sends all pharmaceutical and medical supplies and equipment;
5. monitoring stock levels in coordination with the JEOC and CDC to replenish materiel; and,
6. recovering unused resources and SNS materiel.

It is the responsibility of LHDs that receive State caches or SNS materiel to maintain SNS inventory control of all materiel transferred to their local RSS sites.

Recovering SNS Assets

CDPH will return to CDC all usable Pandemic Influenza Countermeasure or SNS materiel, including:

1. specialized cargo containers;
2. refrigeration systems;
3. unused medications that can be verified were kept within proper temperature ranges;
4. ventilators;
5. portable suction units; and
6. generators.

Recovery efforts will be facilitated through the inventory control system record of the party (e.g., local RSS distribution sites) to which it issues medical materiel. The manifest and computer data that CDC provides for each SNS shipment will facilitate the recovery of CDC owned assets.



Appendix L: California Department of Public Health--Immunization Branch Richmond Warehouse Activation--Vaccine Shipping Procedures

A. GENERAL OVERVIEW:

Recommend rotating staff through different stations periodically, e.g., every 2-3 hours.

Vaccine mantra: Always check vaccine lot number with order sheets.

1. Facility setup:

- a. Prepare a map in advance with work stations identified.
- b. Do not setup stations in walkways or exit areas.
- c. Put stations in a logical order to keep the process moving. E.g., vaccine counters near refrigerators; the quality assurance station next to vaccine counter station.
- d. Clear the warehouse area to be able to set up stations so processing moves smoothly and efficiently.
- e. Supply tables and chairs for staff to work ergonomically soundly.

2. Supplies needed (specifics are identified below for each station):

- a. Adequate amount of water for staff.
- b. Tables: Minimum of 15.
- c. Chairs: Enough for all staff.
- d. "Toolbelts" containing: box cutters, scissors, pens, magic markers, calculators.

Supply each person with an apron or fanny pack to hold these supplies for their section.

- e. Rubber bands (correct size for holding 10 vials of vaccine together)
- f. Tape and tape machines.
- g. Boxes, styrofoam, insulation (paper, bubble wrap)
- h. Ice packs
- i. Multiple hand carts—several for each section

3. Staff Positions (minimum needed):

- a. Person in charge: one
- b. Vaccine order preparer: one
- c. Vaccine counters: six
- d. Vaccine retriever: one
- e. Quality assurers: two
- f. Vaccine box packers: four
- g. Shipper preparer: one
- h. Warehouse rover: one
- i. Box preparer: one



**CDPH Immunization Branch
Richmond Warehouse Activation and Vaccine Shipping Procedures (Cont.)**

B. SECTION DUTIES:

Person in Charge

Minimum number of people needed: One

Supplies needed: Clipboard, pens

Duties:

- Oversees all operations to make sure moving in timely manner.
- All staff report to this person for assignment.
- All problems reported to this person.
- Assigns someone to make sure food and water available for staff.

Vaccine Order Prepare (VOP)

Minimum number of people needed: One

Supplies needed: Computer, vaccine order forms.

Duties:

1. Vaccine order sheets are prepared in advance for each county.
 - Two copies of each, paper clipped together.
 - At the end of each day, VOP collects the vaccine order sheets that have been processed.

Vaccine Counter and Pre-Packing Section

Minimum number of people needed: Seven. (Prefer more for this section.)

Supplies needed: Tables, chairs, rubber bands, calculator, ice packs, boxes (see box preparer section), insulation, box cutters, scissors, magic markers, pens, handcart for each vaccine counter team and person removing vaccine from refrigerator.

Duties:

1. One person is in charge of removing vaccine from walk-in refrigerator and bringing it to vaccine counter tables.
 - Remove only as much vaccine as can be prepared for shipping in two hours.
 - Have separate tables for each type of vaccine and lot number. Put a sign on the table identifying product and lot number.
 - Person removing vaccine from refrigerator will batch loose vaccines with rubber bands in bundles of 10 vials, when possible.
 - This person will keep replenishing supply of cold packs for vaccine counters.
 - If ice packs have melted, if re-freezable, make sure ice packs are re-frozen before use.
2. Vaccine counters should, when possible, work in teams of two.
 - Each vaccine counter team should have their own table.
 - Each vaccine counter team receives a vaccine order sheet.



CDPH Immunization Branch Richmond Warehouse Activation and Vaccine Shipping Procedures (Cont.)

- The counter goes to the tables that have vaccine and brings to their own table the amount of vaccine needed for each order.
- **CHECK THE VACCINE ORDER SHEET AND PACK THE VACCINE THAT MATCHES THE LOT NUMBERS LISTED ON THE ORDER SHEET.**
- A second person should double-check the order quantity and verify that everything is correct.
- Choose the appropriate size box with white styrofoam inserts for the vaccine order. Helpful hints for box size:
 - Approx. 2,000 doses of the multi-dose vials fit into a medium box.
 - Approx. 5,000-6,000 doses of the multi-dose vials fit into a large box.
 - Fluvirin syringes take up significantly more space.
- Place ice packs in the bottom of the insulated container.
- Place a layer of insulator (bubble wrap, foam wrap, or several sheets of crumpled paper) on top of the ice packs so the vaccines do not directly touch them. Flu vaccine is destroyed if it gets too cold, so you need to be sure to put enough insulation between the vaccine and the cold packs.
- Place vaccine on top of insulator.
- **DO NOT spend time carefully packing vaccine at this section.** Put the vaccine in a box that seems the right size with the ice in the bottom. It will need to go through the quality assurance check station. At that station they will be removing product and re-counting. Then it will go to the packers.
- **LABEL EACH BOX ON THE OUTSIDE:**
 - County's name and the number of vials or packs of each type of vaccine.
 - If using one box, label box 1 of 1.
 - If more boxes, label box 1 of how many. **ONLY** put the number of product for the entire order on the first box to avoid confusion.
- Vaccine order sheet put inside box one.
- Vaccine counter brings completed order to Quality Assurance Section.

Quality Assurance (QA) Section

Minimum number of people needed: Two. (Would need more if more vaccine counters.)

Supplies needed: Tables, chairs, rubber bands, pens, calculator, hand cart.

Duties:

- Vaccine is re-counted.
- If error, go to vaccine counters to retrieve or return vaccine as needed.
- If boxes are mislabeled with number of vaccine, correct this information on the outside of the box.



**CDPH Immunization Branch
Richmond Warehouse Activation and Vaccine Shipping Procedures (Cont.)**

- **DO NOT spend time packing vaccine at this section.** Put vaccine back in a the box(es). It will be going to the packers.
- Vaccine order sheet put inside box one.
- QA person brings completed order to Packing Section.
- Check for safety layer of insulation between ice packs and vaccine.

Packing Section

Minimum number of people needed: Four.

Supplies needed: Tables, chairs, ice paks, boxes, insulation, box cutters, scissors, magic markers, pens, handcart for each team.

Duties:

- Work in teams of two. It's easier and quicker to seal boxes with one person holding and one taping.
- Check the order sheet corresponds with the labeled box.
- If more than one box for the order, make sure have all boxes together.
- Re-pack boxes after receiving from QA section. When packing:
- Place ice packs in the bottom of the insulated container.
- Place a layer of insulator (bubble wrap, foam wrap, or several sheets of crumpled paper) on top of the ice packs so the vaccines do not directly touch them. Flu vaccine is destroyed if it gets too cold, so you need to be sure to put enough insulation between the vaccine and the cold packs.
- Place vaccine on top of insulator.
- Add another layer of insulator over the vaccines.
- Insert another layer of ice packs on top of the insulator and add more insulator until the container is full, to keep the vaccine securely in place.
- **DO NOT seal vaccine order sheet in the box.**
- Seal the box with tape.
- Place "Refrigerate" stickers on the boxes.
- Vaccine order sheet taped lightly to top of sealed box one.
- Packers bring completed order to shipping.

Warehouse Rover

Minimum number of people needed: One.

Supplies needed: Fork lift, hand cart.

Duties:

- Person needs to be certified to use fork lift.
- Moves completed vaccine order boxes on palettes to shipping dock.
- Proactively checks with stations to help move boxes from one station to another.



CDPH Immunization Branch Richmond Warehouse Activation and Vaccine Shipping Procedures (Cont.)

Shipping Section

Minimum number of people needed: Two; one to process the orders and the other to move completed orders to shipping dock.

Supplies needed: Pens, shipping labels, invoice sleeves.

Duties:

1. Shipper takes order form off the box.
2. On the order form, write down the number of doses shipped, number of boxes, and initial.
3. Weigh the box and ship the package using Golden State Overnight.
 - a. Enter the name of the health department and search for the address matching the order slip; **ensure all of the information is correct** (use the order slip), including contact person. Some health departments have more than one address. Make sure correct address, room number, etc.
 - b. Add insurance for the order—\$500.00 per order (one order can contain 1 box or numerous boxes).
 - c. Make sure you know how many boxes you are shipping to a health department—you will be asked this question.
4. Attach the shipping label on the box and stick the bottom portion with the tracking number on your original order sheet.

5. A copy of the order sheet should be placed in a sleeve and attached to the box.

6. Original order sheets will be put in a folder and given to vaccine order preparer at the end of each day.

7. Completed boxes are placed on palettes and prepared to go to the shipping dock by one person in charge of this.

Box Preparer Section

Minimum number of people needed: One or two.

Supplies needed: Tables, chairs, boxes, styrofoam, tape and tape machine, large bins to store the different size Styrofoam.

Duties:

- Once Styrofoam packages are open, they need to be put in a bin and labeled what size box they fit into. Need a minimum of 3 bins.
- If possible, review order forms to get an idea of the size boxes that may be needed.
- Periodically check with vaccine counters to make sure addressing boxing needs.
- Prepare boxes by taping and putting the correct Styrofoam inserts in each.
- Put prepared boxes in an area where vaccine counters can retrieve.



Appendix M: Job Action Sheets

The job action sheets that follow are for key management positions responsible for storage, transportation, chain of custody and security in RSS sites and clinics.

Logistics Section Chief

Section: Logistics Section

Report to: RSS Director

Supervises: Communications Unit Leader; Procurement and Purchasing Unit Leader, Supply Unit Leader; Food Unit Leader; Facilities Unit Leader; Transportation Unit Leader

Minimum Qualifications: Completed ICS 100 and Logistics Section Chief Training for the JEOC and RSS or experience work in the RSS Logistics Section as a Manager or Unit Leader.

Job Description:

The Logistics Section Chief is a member of the General Staff and responsible for providing facilities, services, and materiel to the RSS Warehouse. The Section Chief participates in development and implementation of the Action Plan and activates and supervises the Units within the Logistics Section.

Beginning of Shift Duties:

1. Sign in with the Check-In Recorder and obtain an RSS Badge.
2. Check in with RSS Director.
3. Locate the outgoing Logistics Section Chief and obtain a briefing on status of assignments and operations.
4. Read the Action Plan (AP) for your shift; obtain a copy from the Plan & Intel Section.
5. Check out an RSS Radio from the Telecommunications Manager in Logistics Section.
 - Know your assigned frequency(ies) for your area of responsibility and ensure that communication equipment is operating properly.
 - Use clear text in all radio communications.
6. Review the check list for your position; a copy of which will be in your section's box.
7. Assemble and brief Unit Leaders.

Job Duties:

- Plan organization of Logistics Section and brief subordinates.
- Assign work locations and preliminary work tasks to Managers and Unit Leaders.



- Develop, implement and maintain accountability, safety and security measures for personnel and resources.
- Advise General Staff on current service and support capabilities.
- Review Action Plan and estimate Section needs for next operational period.
- Participate in preparation of Action Plan by providing service and support elements to the Action Plan.
- Identify service and support requirements for planned and expected RSS operations.
- Provide input to and review Communications Plan, Medical Plan and RSS Site Traffic Plan.
- Be current on status of Section's activities.
- Maintain Unit/Activity Log (ICS Form 214).

Forms:

ICS 206 / EPO 206 – Medical Plan
ICS 214 - Unit Log
ICS 214b - Unit Log Extension
ICS 221 - Demobilization Checkout
ICS 226 - Individual Performance Rating

End of Shift Duties:

1. ***Brief next shift's Logistics Section Chief on status of assignments and operations.***
2. Verify starting time of your next shift.
3. Check in your RSS Radio to the Telecommunications Manager in Logistics Section.
4. Check out of the RSS.

Demobilization Duties:

1. ***Receive Demobilization Plan from Planning Section***
2. Supervise demobilization of Logistics Section and coordinate with other sections on the packing up or RSS supplies.
3. Recommend release of unit resources in conformity with Demobilization Plan.
4. Conduct Logistics Section debriefing.
5. Complete forms and reports required of your position and give to Documentation Unit Documentation Unit Leader in the Plan & Intel Section.

Reference Materiel

- ***Current shift's Action Plan (AP); obtain a copy from the Plan & Intel Section.***
- ***SNS Plan; each section has a copy of the plan.***
- ***Check list for your position. Located in the Logistics Section box.***
- State Pharmaceutical and Medical Supply Processing Chart & Checklist. Located in the Logistics Section box.
- Inventory Control Documents Overview. Located in the Logistics Section box.



- RSS Organization Chart. Located in the Logistics Section box.
- Floor Plan of RSS Warehouse. Obtain from Facilities Unit Leader in Logistics Section.

Security Manager

Section: Logistics Section

Report to: Facilities Unit Leader

Supervises: *Security Teams*

Minimum Qualifications: CHP or Law Enforcement Officer

Job Description:

The Security Manager in most situations will be a CPH Officer. The Security Manager is responsible for providing safeguards at the State RSS Warehouse as needed to protect personnel and property from damage and theft.

Beginning of Shift Duties:

1. Sign in with the Check-In Recorder and obtain an RSS Badge.
2. Check in with Management Staff – Security Officer, if established.
3. Check in with the Facilities Unit Leader.
4. Locate the out going Security Manager and obtain a briefing on the status of assignments and operations.
5. Read the Action Plan (AP) for your shift; obtain a copy from the Logistics Section Chief.
6. Check out an RSS Radio from the Telecommunications Manager in Logistics Section.
 - Know your assigned frequency(ies) for your area of responsibility and ensure that communication equipment is operating properly.
 - Use clear text in all radio communications.
7. Assemble and brief those you supervise.
8. Review the check list for your position; a copy of which will be in your section's box.

Job Duties:

- Participate in Logistics Section planning activities.
- Coordinate site security, through the Security Officer, if established, to maintain required military and/or site security protocols.
- Establish contacts with local law enforcement agencies as required.
- Contact Agency Representatives to discuss any special requirements that may affect warehouse activities.
- Request required personnel support to accomplish work assignments.



- Ensure that support personnel are qualified to manage security problems.
- Coordinate with Escort Unit Leader for special security needs.
- Develop Security Plan for State RSS Warehouse facilities.
- Adjust Security Plan for personnel and equipment changes and releases.
- Coordinate security activities with appropriate warehouse personnel.
- Prevent theft of all government and personal property.
- Document all actions and suspicious occurrences.
- Remove unauthorized persons from restricted areas.
- Secure the State RSS Warehouse and other areas from unauthorized access in coordination with security staff.
- Post non-entry signs around secured areas.
- Advise the State RSS Director, Safety Officer, and Security Officer of any unsafe, hazardous or security condition.
- Maintain Unit/Activity Log (ICS Form 214).

Forms:

ICS 211 Activity Check In List

ICS 214 - Unit Log

ICS 214b - Unit Log Extension

ICS 221 - Demobilization Checkout

ICS 226 - Individual Performance Rating

ICS 259-15 - Resource Order Supplies

End of Shift Duties:

1. ***Brief the next Security Manager on status of assignments and operations.***
2. Verify starting time of your next shift.
3. Check in your RSS Radio to the Telecommunications Manager in Logistics Section.
4. Check out of the RSS.

Demobilization Duties:

1. Demobilize in accordance with the Demobilization Plan and direction from the Logistics Section Chief.
2. Complete forms and reports required of your position and submit them to the Documentation Unit Leader in the Plan & Intel Section.

Reference Materiel

- ***SNS Plan; each section has a copy of the plan.***
- ***Check list for your position. Located in Logistics Section box.***
- ***Emergency Resource Directory (ERD). Located in the Logistics Section.***

Floor Plan of RSS Warehouse. Obtain from Facilities Unit Leader in Logistics Section.



Ground Distribution Unit Leader

Section: Operations Section

Report to: Operations Section Chief

Supervises: *Vehicle Dispatch Manager, Routing Control Manager*

Minimum Qualifications: [Insert]

Job Description:

The Ground Distribution Unit Leader is responsible for supporting and managing the trucking and ground transportation activities used to distribute resources and SNS materiel from the RSS Warehouse to local health department's RSS site, dispensing locations and or treatment centers.

Beginning of Shift Duties:

1. Sign in with the Check-In Recorder and obtain an RSS Badge.
2. Check in with the Operations Section Chief.
3. Locate the out going Ground Distribution Unit Leader and obtain a briefing by on status of assignments and operations.
4. Read the Action Plan (AP) for your shift; obtain a copy from the Plan & Intel Section.
5. Check out an RSS Radio from the Telecommunications Manager in Logistics Section.
 - Know your assigned frequency(ies) for your area of responsibility and ensure that communication equipment is operating properly.
 - Use clear text in all radio communications.
6. Review the check list for your position; a copy of which will be in your section's box.
7. Assemble and brief assigned managers.

Job Duties:

- Organize preliminary ground operations.
- Coordinate with the Security Officer, if established, Facilities Unit Leader, Security Manager, and the State RSS Warehouse site property owner for truck access to, from and on the property.
- Participate in preparation of the Action Plan through the Operations Section Chief. Insure that the Ground Distribution portion of the Action Plan takes into consideration trucking and ground transportation requirements.
- Assist Supply Unit Leader, as needed for the movement of resources and SNS materiel to the State RSS Warehouse Site.
- Perform operational planning for materiel loading and distributing.
- Establish procedures for assignment of trucks and transports.



- Coordinate with the Escort Unit Leader for assignment of escort units and to incorporate security issues for routing determination.
- Provide information to the Transportation Unit Leader on ground operations activities and vehicle support.
- Arrange for an accident investigation team through the Safety officer, when warranted.
- Develop, implement and maintain accountability, safety and security measures for personnel and resources.
- Maintain Unit/Activity Log (ICS Form 214).

Forms:

Truck Manifest

RIMS County Order

Bill of Lading

ICS 214 - Unit Log

ICS 214b - Unit Log Extension

ICS 221 - Demobilization Checkout

ICS 226 - Individual Performance Rating

End of Shift Duties:

2. ***Brief next shift's Ground Distribution Unit Leader on status of assignments and operations.***
3. Verify starting time of your next shift.
4. Check in the RSS Radio from Communications Unit Leader (Logistics Section).
5. Check out of the RSS.

Demobilization Duties:

1. Demobilize in accordance with Demobilization Plan and direction from the Operations Section Chief.
2. Complete forms and reports required of your position and submit them through the Operations Section Chief to the Documentation Unit Leader in the Plan & Intel Section.

Reference Materiel

- ***Current shift's Action Plan (AP); obtain a copy from the Plan & Intel Section.***
 - ***SNS Plan; review copy in the Operations Section.***
 - ***Check list for your position. Located in the Operations Section box.***
 - State Pharmaceutical and Medical Supply Processing Chart & Checklist. Located in the Operations Section box.
 - Inventory Control Documents Overview. Located in the Operations Section box.
 - RSS Organization Chart. Located in the Operations Section box.
- Floor Plan of RSS Warehouse. Obtain from Facilities Unit Leader in Logistics Section.



Receipt and Storage Manager SNS Materiel

Section: Logistics Section

Report to: Supply Unit Leader

Supervises: *SNS Inventory Control Supervisor, SNS Receipt and Storage Team, and Unload Teams*

Minimum Qualifications: [Insert]

Job Description:

The Receipt and Store Manager SNS Materiel is responsible for teams of warehouse workers that unload trucks delivering SNS materiel to the RSS Warehouse and storing those resources in the warehouse. The Receipt and Storage Manager is responsible for supervising the SNS Inventory Control Supervisor.

Beginning of Shift Duties:

1. Sign in with the Check-In Recorder and obtain an RSS Badge.
2. Check in with the Supply Unit Leader.
3. Locate the out going Receipt and Storage Manager SNS Materiel and obtain a briefing on the status of assignments and operations.
4. Read the Action Plan (AP) for your shift; obtain a copy from the Logistics Section Chief.
5. Check out an RSS Radio from the Telecommunications Manager in Logistics Section.
 - Know your assigned frequency(ies) for your area of responsibility and ensure that communication equipment is operating properly.
 - Use clear text in all radio communications.
6. Check out appropriate personal protective equipment (PPE), gloves, box cutter, etc., from Supply Clerk.
7. Review the check list for your position; a copy of which will be in your section's box.
8. Assemble and brief those you supervise.

Job Duties:

- Verify the Truck Manifest of delivered SNS materiel.
- Write the location on the manifest of where the delivered items have been placed in the Warehouse.
- Provide a copy of the Completed Manifest to the Ordering Manager and the SNS Inventory Control Supervisor.
- Supervise the SNS Receipt and Storage Team(s), and Unload Teams in receiving and storing of SNS materiel (12 Hour Push Package, Managed Inventory and State supplies).
- Oversee the work of the SNS Inventory Control Supervisor.



- In coordination with the Pharmacist Technical Specialist of the Plan & Intel Section ensure the proper documentation and storage of controlled drugs.
- Develop, implement and maintain accountability, safety and security measures for personnel and resources.
- Familiar with the equipment used (e.g., fork lifts and pallet jacks) and the protective gear that staff should have (e.g., steel-toed shoes).
- Ensure the orderly return and accounting of unused SNS materiel.
- Maintain Unit/Activity Log (ICS Form 214).

Forms:

Truck Manifest

ICS 214 - Unit Log

ICS 214b - Unit Log Extension

ICS 221 - Demobilization Checkout

ICS 226 - Individual Performance Rating

End of Shift Duties:

1. ***Brief next Receipt and Store Manager SNS Materiel on status of assignments and operations.***
2. Verify starting time of your next shift.
3. Check in your RSS Radio to the Telecommunications Manager in Logistics Section.
4. Check out of the RSS.

Demobilization Duties:

1. Demobilize in accordance with Demobilization Plan and direction from the Logistics Section Chief and Supply Unit Leader.
2. Complete forms and reports required of your position and give to your supervisor to give to the Documentation Unit Leader in the Plan & Intel Section.

Reference Materiel

- ***SNS Plan; each section has a copy of the plan.***
- ***Check list for your position.***
- State Pharmaceutical and Medical Supply Processing Chart & Checklist. Located in Logistics Section box.
- Inventory Control Documents Overview. Located in Logistics Section box.
- RSS Organization Chart. Located in Logistics Section box.

Floor Plan of RSS Warehouse. Obtain from Facilities Unit Leader in Logistics Section.

SNS Inventory Control Supervisor

Section: Logistics Section

Report to: Receipt and Storage Manager SNS Materiel



Supervises: RITS Clerk(s)

Minimum Qualifications:

Operational knowledge of both the RITS and RITS Backup Inventory Management Systems. Ability to teach RITS Clerks how to use both systems. Knowledge of RSS Warehouse operations.

Job Description:

The SNS Inventory Control Supervisor is responsible for accounting for all SNS materiel from the RSS Warehouse. This position supervises RITS Clerk(s) who process incoming SNS supplies and outgoing RIMS County orders for SNS supplies.

Beginning of Shift Duties:

1. Sign in with the Check-In Recorder and obtain an RSS Badge.
2. Check in with the Receipt and Storage Manager SNS Materiel.
3. Locate the out going SNS Inventory Control Supervisor and obtain a briefing on the status of assignments and operations.
4. Read the Action Plan (AP) for your shift; obtain a copy from the Logistics Section Chief.
5. Check out an RSS Radio from the Telecommunications Manager in Logistics Section.
 - Know your assigned frequency(ies) for your area of responsibility and ensure that communication equipment is operating properly.
 - Use clear text in all radio communications.
6. Review the check list for your position; a copy of which will be in your section's box.
7. Assemble and brief the RITS Clerk(s).

Job Duties:

- Operates or oversees RITS Clerk(s) operating either RITS or RITS Backup inventory control program. This includes entering new inventory into the program and processing outgoing orders; print pick and pack lists and Bill of Lading.
- In coordination with the Ordering Manager for SNS Materiel establish resupply thresholds for SNS supplies.
- Follow established data entry and tracking system protocols.
- Develop, implement and maintain accountability, safety and security measures for personnel and resources.
- Maintain Unit/Activity Log (ICS Form 214).

Forms:

- Truck Manifest
- RIMS County Order
- Pick List



- Pack List
- Bill of Lading
- ICS 214 - Unit Log
- ICS 214b - Unit Log Extension
- ICS 221 - Demobilization Checkout
- **ICS 226 - Individual Performance Rating**

End of Shift Duties:

1. Brief next SNS Inventory Control Supervisor on status of assignments and operations.
2. Verify starting time of your next shift.
3. Check in your RSS Radio to the Telecommunications Manager in Logistics Section.
4. Check out of the RSS.

Demobilization Duties:

1. Demobilize in accordance with Demobilization Plan and direction from the Logistics Section Chief and Supply Unit Leader.
2. Complete forms and reports required of your position and give to your supervisor to give to the Documentation Unit Leader in the Plan & Intel Section.

Reference Materiel

- **SNS Plan; each section has a copy of the plan.**
- **Check list for your position.**
- RITS and RITS Backup Instruction Binder. Located in Logistics Section Box.
- State Pharmaceutical and Medical Supply Processing Chart & Checklist. Located in Logistics Section box.
- Inventory Control Documents Overview. Located in Logistics Section box.
- RSS Organization Chart. Located in Logistics Section box.

Floor Plan of RSS Warehouse. Obtain from Facilities Unit Leader in Logistics Section.

Preparation and Packaging Manager

Section: Logistics Section

Report to: Supply Unit Leader

Supervises: Preparation and Packaging Supervisor

Minimum Qualifications: [Insert]

Job Description:

The Preparation and Packaging Manager is responsible for supervising the packaging of outgoing SNS orders.



Beginning of Shift Duties:

1. Sign in with the Check-In Recorder and obtain an RSS Badge.
2. Check in with the Supply Unit Leader.
3. Locate the out going Preparation and Packaging Manager and obtain a briefing on the status of assignments and operations.
4. Check out an RSS Radio from the Telecommunications Manager in Logistics Section.
 - Know your assigned frequency(ies) for your area of responsibility and ensure that communication equipment is operating properly.
 - Use clear text in all radio communications.
5. Check out appropriate personal protective equipment (PPE), gloves, box cutter, etc., from Supply Clerk.
6. Review the check list for your position; a copy of which will be in your section's box.
7. Assemble and brief those you supervise.

Job Duties:

- Receive the Pick List and Pack List from the SNS Inventory Control Supervisor and records receipt of the lists. Give the lists to the Prep and Pack Supervisor.
- Oversee the process of dividing up, in proper proportions, SNS materiel that will be distributed to local health department distribution sites, treatment centers and dispensing sites.
- Quality check outgoing orders; verify that the information on the Pack List matches what was picked.
- Coordinate with the Ground Distribution Leader in Operations Section on loading order for each truck (back to front). Give this information to the Preparation and Packaging Supervisor.

Forms:

- Pick List
- Pack List
- ICS 214 - Unit Log
- ICS 214b - Unit Log Extension
- ICS 221 - Demobilization Checkout
- **ICS 226 - Individual Performance Rating**

End of Shift Duties:

1. **Brief next Preparation and Packaging Manager on status of assignments and operations.**
2. Verify starting time of your next shift.
3. Check in your RSS Radio to the Telecommunications Manager in Logistics Section.
4. Check out of the RSS.

Demobilization Duties:



-
1. Demobilize in accordance with Demobilization Plan and direction from the Logistics Section Chief and Supply Unit Leader.
 2. Complete forms and reports required of your position and give to your supervisor to give to the Documentation Unit Leader in the Plan & Intel Section.

Reference Materiel

- ***SNS Plan; each section has a copy of the plan.***
- Check list for your position.
- State Pharmaceutical and Medical Supply Processing Chart & Checklist. Located in Logistics Section box.
- Inventory Control Documents Overview. Located in Logistics Section box.
- RSS Organization Chart. Located in Logistics Section box.

Floor Plan of RSS Warehouse. Obtain from Facilities Unit Leader in Logistics Section.



Appendix N: Local Health Department Immunization Coordinators

<u>County</u>	<u>Coordinator</u>
Alameda	Leslie Greenwood, PHN
Alpine	Lynette Bennett
Amador	Lori Jagoda, PHN Debbie Staniford
Berkeley City	Janet Cusick
Butte	Evelyn Jones
Calaveras	Jill Sullivan
Calaveras	Linda Winn
Colusa	Jo Corbin
Contra Costa	Erika Jenssen, MPH
Del Norte	Linda Nichols, RN
El Dorado	Valerie Rudd
El Dorado	Cathy Dunbar
El Dorado	Lenette Mapes
Fresno	Peggy Richardson
Glenn	Bill Price
Humboldt	Susan Wardrip
Imperial	Angela Ramirez
Inyo	Tamara Pound
Inyo	Melissa Best-Baker
Kern	Ann McIntosh-Walker, PHN
Kings	Pat Harder



Lake	Val Kuhn
Lassen	Laura Ng
Long Beach City	Mary Wright
Los Angeles	Michelle T. Parra, PhD.
Madera	Kari Moore
Marin	Christine Stipp
Mariposa	Marna Klinkhammer
Mendocino	Jennifer Dutton, PHN
Merced	Annie Carlson
Modoc	Linda Nelson
Mono	Margee Neer
Monterey	Molly C. Hubbard, MS
Napa	Diane Buchanen
Nevada	Karen Smith-Sayer
Orange	Linda Scott
Pasadena City	Rachel Estuar
Placer	Eileen Johnson
Plumas	Debi Bradfield
Riverside	Karen Jones, RN
Sacramento	Lynnan Svennson
San Benito	Claudia Arnold, RN
San Bernardino	Abigail Ryan
San Diego	<u>Karen Waters-Montijo</u>
San Francisco	Amy Pine



San Joaquin	Kathleen Tully
San Luis Obispo	Debbie Jo Trinidad, RN, MPH
San Mateo	Robyn Ziegler
Santa Barbara	Carol Cullen, PHN, BSN
Santa Clara	Noel Panlilio
Santa Cruz	Laurie Lang
Shasta	Kate Thomas Pasley
Shasta	Sue Holderman
Sierra	Janis Hardeman
Siskiyou	Lillian Lokey
Solano	Paula Holm,SPHN
Sonoma	Michele Davis
Stanislaus	Nancy Bancroft
Sutter	Vicki Coleman
Tehama	Virginia Sandberg
Tehama	Linda Wimer
Trinity	Carol Huang
Tulare	Pam Sola, RN
Tuolumne	Jill Castle
Ventura	Lin Glusac
Yolo	Lynne Foster
Yuba	Theresa McClain



Appendix O: Suggested Personnel for a Mass Vaccination Clinic

This is a summary of the types of positions needed to accommodate the suggested layout and patient flow for a mass vaccination clinic.

Breakdown of Clinic Personnel

Position (include backup)	Number per 12-hour Shift	Number per 24-hour Day	Experience
Clinic Supervisor	1	2	Familiarity with ICS and SEMS
Public Information Assistant	1 – optional depending on need from Incident PIO	2 - optional depending on need from Incident PIO	Public Relations
Safety Officer	1	2	Safety/Risk Management
Medical Director	1 – optional depending on number of clinics and operational need	2 - optional depending on number of clinics and operational need	MD
Intake Unit Leader	1	2	Nonmedical
Service and Support Unit Leader	1	2	Nonmedical
Dispensing Unit Leader	1	2	Medical training required
Exit Unit Leader	1	2	Nonmedical
Triage Manager	1	2	Nurse or EMT
Triage Team	4	8	EMT's
Emergency Medical Personnel	2	4	Paramedic/EMT
Greeting/Entry Manager	1	2	Nonmedical
Greeters/Orientation	5	10	Nonmedical (five rooms running; one staff per room)
Briefing Manager	1	2	Nonmedical supervisor
Translators (not counted in total clinic staffing estimates)	X At least one per major language per shift; determined by community demographics	X At least one per major language per shift; determined by community demographics	Language fluency with training
Registration/Education	5	10	Nonmedical volunteers to assist with registration, information sheets, and clinic flow
Forms Distribution Manager	1	2	Nonmedical
Form Distribution Team	5	10	Nonmedical (five rooms running; one staff per room)
Form Assistance & Checking (check screening forms)	10	20	Nonmedical volunteers to assist with forms completion, collection, and clinic flow
Medical Evaluation Manager	1	2	Medical training required nurse or MD
Examiners	6	12	Medical training required nurse or MD
Vaccination Triage Manager	2	4	Physicians to evaluate ill or more difficult medical history screening
Vaccinators	20 (20 stations, 1.0	40	Cross-trained to alternate



	vaccinators per station)		vaccination, fill out vaccine card
Pharmacy/Medical Supply Managers	1	2	Pharmacist, pharmacy tech, or nurse experienced with vaccine or medication reconstitution
Pharmacy/Medical Supply Staff	2	4	Pharmacist, pharmacy tech, or nurse experienced with vaccine preparation
Medical Data Review Manager	1	2	Medical or public health personnel for final questions/instructions
Medical Data Follow-up Team	3	6	Medical or public health personnel for final questions/instructions
Medical Records/Data Collection Manager	1	2	Nonmedical, data entry supervisor
Data Entry Staff	8	16	Nonmedical, data entry for information collected on vaccinees
Mental Health Manager	1	2	Mental Health (social workers, counselors, etc.)
Mental Health Evaluators/ Counselors	2	4	Mental Health (social workers, counselors, etc.)
Security Manager	1	2	Non-public health resource
Security Team	18	36	Non-public health resource
Supply Staff	5	10	Nonmedical volunteers
Facility Manager	1	2	Environmental services supervisor, e.g. hospital housekeeping.
Communications Specialist	1	2	Communications experience
IT Support	1	2	Nonmedical
Facility Workers	4	8	Environmental services experience, e.g. hospital housekeeping.
Subsistence Coordinator (provide food and water for staff and patients)	1	2	Nonmedical volunteers
Subsistence Service Workers	4	8	Nonmedical volunteers
Float Staff	3	6	Medical; RN or EMT to assist where needed
Disability Assistants	3	6	Nonmedical volunteers
Total Personnel	132	264	

Staffing estimates are based upon a “best case” scenario. Availability of resources may necessitate use of decreased staffing levels or different levels of expertise.

This is a brief summary of job descriptions and training that are necessary to support the suggested layout and patient flow for a mass vaccination clinic.



Clinic Supervisor: The Clinic Supervisor is responsible for the overall clinic operations and is the primary decision-maker for the site. The Clinic Supervisor should be very familiar with and able to implement the Incident Command System (ICS) and the clinic's placement within the overall response. Localities should designate appropriate personnel, including public health officials, trained in ICS and SEMS to serve as Clinic Supervisors during vaccination efforts. ICS and SEMS training can be provided by local EMS agencies, local Emergency Management, and local Public Health departments.

Translators: Local populations will determine the need for translators. If unable to locate a sufficient number of translators to staff the clinic, planners may consider using telephone interpretation services (e.g. AT&T). As part of the planning process, planners should make arrangements for such services in the event of a pandemic.

Staff Orientations: Clinic staff should be walked through the process as if they are a vaccine recipient. They should sit through any patient briefing and orientation presentations as well. Initial vaccination of clinic staff presents an opportunity for such an orientation. Clinic staff could walk through the process as they receive their vaccinations. This provides for orientation as well as hands-on training for the many vaccinators who will be administering the vaccine for the first time.

Public Perception: Staff should be educated on and prepared to deal with emotional and/or violent reactions from the public. This would occur as a result of long waiting times, public frustration, as well as fear and anxiety.

Supply Specialists: Assist in the delivery of supplies to locations within the clinic; respond to requests for re-supply; maintain inventory of supplies, anticipate future needs and report such needs to the Service and Support Unit Leader as needed.

Security: Ensure an orderly flow of traffic and parking at the clinic site; assist in maintaining orderly movement of vaccine recipients through the clinic process; provide necessary control of persons become unruly; assist supply specialists in maintaining security of vaccine and other clinic supplies.

Facility Workers: Ensure a clean environment for all stations within the vaccination clinic; respond to requests for waste removal and clean-up, safely and effectively managing all biohazard materials; maintain adequate supplies in restrooms and vaccination stations as needed.

Subsistence Service Workers: Assist in the delivery of food to staff and patients as needed; prepare and package food for delivery; ensure availability of fluids for staff and patients.

Mental Health Evaluators/Counselors: Respond to requests for mental health interventions; provide counseling and referrals as needed.



Triage Team: Interview all patients presenting to the clinic to assess for presence of symptoms. Refer any ill patients to the Ill Evaluation Area, direct all non-ill patients to the waiting area or directly to an orientation area. If necessary, refer patients to the proper clinic or area if vaccinating a specific population (Healthcare workers or contacts).

Vaccination Triage Manager: Evaluate ill patients to determine if they should be admitted to the vaccination clinic. If further evaluation is needed, arrange for referral and/or transportation to the appropriate facility. Refer patients for medical care as appropriate.

Form Checkers: Review completed medical screening forms, looking for self-indicated contraindications (boxes checked "yes" or "maybe"). Refer all patients with boxes checked "yes" or "maybe" to the Medical Evaluator Station. If all boxes are checked "no" patients may be referred directly to the vaccination station.

Medical Evaluators: Assess patients for contraindications to vaccination and answer any medical questions. If patient will be vaccinated, ensure that the consent form is read and understood, if necessary.

Forms Distribution Team: Conduct orientations using the provided video and any supporting materials. Distribute screening and consent forms; instruct patients to read and complete the forms; assist with completion when necessary.

Vaccinators/Vaccinator Assistants: Administer the vaccine and observe patients for immediate reactions or complications. Assistants and Vaccinators will be cross-trained and may alternate positions.

Registration/Education: Direct patients through the clinic flow process and monitor overall clinic flow. Request assistance for areas that experience a backlog of patients. Monitor clinic occupants for situations that may require security assistance.

Exit Unit Leader/Data Review Manager: Ensure that patient exits with all necessary paperwork and documentation; answer any questions upon exit.

Float Staff/Disability Assistants: Respond to requests for assistance from all stations in the clinic. Retrieve supplies and deliver messages as needed.

Data Entry Staff: Input data from patient vaccination documentation forms. Maintain database of all vaccine recipients.

Translators: Assist staff with interpretation as needed. Identify patients who may need assistance; assist in completing forms as needed.

Emergency Medical Personnel: Respond to medical emergencies and transport patients to definitive care as needed.