

2014

California Department of Public Health Interim Guidance:

# Implementing A Pandemic Influenza Vaccine Immunization Program in California



## **IMPORTANT INFORMATION REGARDING CALIFORNIA DEPARTMENT OF PUBLIC HEALTH VACCINE IMPLEMENTATION GUIDANCE DOCUMENTS**

The California Department of Public Health Implementation Guidance includes planning assumptions and recommendations based on an influenza pandemic of high to moderately high severity. The majority of recommendations presented in the guidance are based on limited vaccine supply scenarios. These implementation recommendations will be updated during a pandemic to reflect new information about vaccine production and effectiveness, the characteristics of pandemic illness, and the health risks that prioritized target groups will face.

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# 1: PURPOSE

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The purpose of the California Department of Public Health (CDPH) guidance is to provide a consistent and effective statewide pandemic influenza vaccine implementation policy and practice for California. This document presents recommendations to local health departments (LHDs) and tribal entities that are consistent with the United States (US) federal government's vaccine implementation recommendations, while accounting for the pandemic response needs and resources at the state and local levels.

## 2: INTRODUCTION

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### 2.1: BACKGROUND

Pandemic influenza threatens to cause widespread illness and death in California as well as significant economic and social disruption. Because influenza can be spread among people before they show signs or symptoms of illness, vaccination will be the most effective response measure for decreasing the health impacts of a pandemic. Once vaccine first becomes available, it is likely that the US federal government will allocate vaccine to states and territories. State and LHDs will then distribute and dispense the vaccine to their residents as quickly as possible.

Implementing a statewide pandemic influenza vaccination program will take place over many months and will involve vaccinating a very large number of people. Moreover, this vaccination program will need to be conducted in several phases to allow for targeting vaccine to designated priority populations (target groups). CDPH will be the state agency responsible for executing a large-scale pandemic influenza vaccination program in California and has taken a lead role in pandemic influenza vaccine planning. CDPH has developed a comprehensive vaccine implementation strategy to determine how best to distribute, allocate, administer, and monitor this resource as it becomes available.

### 2.2: GUIDANCE OVERVIEW

The goal of this guidance is to present a realistic approach to developing a large-scale vaccination program with recommendations can be implemented by local public health pandemic planners under a variety of conditions and over an extended period of time. This guidance is intended to be flexible as the epidemiology and health impacts will not be known until the next pandemic occurs. The implementation recommendations in this document will be updated during a pandemic to reflect developments in vaccine production and effectiveness, the characteristics of pandemic illness, and the health risks that prioritized target groups will face.

## 2.3: STRUCTURE OF THE GUIDANCE DOCUMENT

The CDPH Pandemic Influenza Vaccine Implementation Guidance: Core Document provides an overview of the CDPH implementation process and presents the framework CDPH used for developing the vaccine implementation recommendations.

The Core Document also presents information on and recommendations for the following implementation issues:

- Vaccine Distribution: Distributing vaccine from manufacturers to state and local jurisdictions.
- Vaccine Allocation: Dividing vaccine among equally prioritized target groups.
- Vaccine Administration: Designating responsibility for vaccination, verifying target group membership, and planning for a two dose vaccine regimen.
- Vaccine Monitoring and Tracking: Developing systems to track vaccine utilization and to monitor adverse events.

## 2.4: ADDITIONAL GUIDANCE FOR LOCAL PLANNERS

- Appendix A presents action steps to assist state and local public health pandemic planners in implementing the vaccination recommendations issued in the CDPH Vaccine Implementation Guidance: Core Document.
- Appendixes B and C provide examples, detailed descriptions, and rationales of the vaccine allocation and target group membership verification recommendations.

## 3: VACCINE PLANNING ASSUMPTIONS AND PRINCIPLES

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This section presents the key planning assumptions and principles regarding procurement, distribution, and prioritization of pandemic vaccine and additional planning assumptions for pneumococcal and seasonal influenza vaccine.

### 3.1: PANDEMIC INFLUENZA VACCINE

- Vaccine production for a novel virus may require four to six months or more from the time the pandemic influenza virus strain is identified.
- Once vaccine is available, vaccine production may not be sufficient for the State's entire population. As a result, state and LHDs will need to prioritize vaccine administration within their jurisdictions.

- If vaccine supplies are in limited quantity during initial production, the Center for Disease Control and Prevention's (CDC) distribution of available vaccine to states will be proportional to population or related criteria.
- The pandemic vaccine distribution and administration system will incorporate elements of existing systems for seasonal influenza vaccine administration.
- CDPH developed the "CDPH Interim Guidance: Prioritizing Populations for Pandemic Influenza Vaccine in California" to provide recommendations for LHDs on prioritizing target groups to reduce health consequences (severe illness, death) and to maintain health care, public security, and essential community services [1].
- In a pandemic, CDPH will activate its emergency response structure. This structure would coordinate response activity. The response will draw on expertise in vaccine immunization and distribution currently housed in the CDPH Immunization Branch (IZB) and other programs.
- Epidemiologic investigations during the pandemic will guide decisions by determining ages and groups at highest risk for adverse health outcomes, including death.
- CDPH staff will be available to advise LHDs on local allocation, distribution and tracking strategies based on vaccine supply, disease severity, and other factors.
- Two doses of vaccine administered at an interval of at least 21 days apart might be required to develop maximal immunity to the novel virus. Further data on the relative safety and immunogenicity of one or two doses of a novel virus vaccine will result from federally-sponsored or international human clinical trials.
- Pandemic vaccine will either be licensed or will be approved for use under the Emergency Use Authorization (EUA) issued by the US Food and Drug Administration.<sup>1</sup>
- Vaccine safety will be monitored by reports sent to the Vaccine Adverse Event Reporting System (VAERS).
- During the 2009 H1N1 influenza pandemic, the US federal government was able to provide vaccine ancillary supplies (syringes, needles, sharps containers, and alcohol swabs) along with pandemic vaccine. It is unclear whether the US federal government will maintain this capability, so local public health pandemic planners

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<sup>1</sup> The Project Bioshield Act of 2004 permits the FDA Commissioner, upon a determination of an emergency to authorize the use of unapproved products or unapproved uses of approved products for the diagnosis, treatment or prevention of serious or life-threatening diseases or conditions caused by chemical, biological, radiological, or nuclear agents and for which there are no adequate, approved, or available alternatives.  
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>

are encouraged, prior to a pandemic, to identify options for acquiring vaccine ancillary supplies if needed.

- The CDPH vaccine implementation guidance is in accordance, but not identical to the US federal government vaccination program recommendations.
- CDPH Division of Communicable Disease Control (DCDC) will review and update the implementation guidance based on revisions or adjustments made to the US federal vaccine implementation guidance.
- CDPH DCDC will periodically reassess the guidance to consider potential impacts of scientific advances in vaccine development, improvements in vaccine production capacity, and advances in other medical and public health pandemic influenza countermeasures.

### **3.2: PNEUMOCOCCAL AND SEASONAL VACCINE**

- Pneumococcal pneumonia is one of the most common secondary infections or complications of influenza. Increasing pneumococcal vaccination before a pandemic will decrease demand for this vaccine during a pandemic and the risk of a pneumococcal vaccine shortage.
- Seasonal influenza vaccination will continue to be strongly recommended given the potential for mutation of a novel virus if a person becomes simultaneously infected with both the novel and seasonal influenza strains.

## **4: CDPH GUIDANCE DEVELOPMENT PROCESS**

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This section outlines the CDPH process that was developed within the context of the US federal government recommendations.

### **4.1: US FEDERAL GOVERNMENT RECOMMENDATIONS**

In 2008, the US Department of Health and Human Services (HHS) and CDC convened an interagency work group to develop pandemic influenza vaccine implementation recommendations. These agencies drafted pandemic influenza operational plans that included recommendations to state, local, territorial, and tribal governments on allocating, distributing, and administering vaccine to prioritized target populations within their jurisdictions [2, 3]. The CDC operational plan acknowledges that state and local jurisdictions will bear most of the responsibility for executing mass vaccination programs during an influenza pandemic [3].

### **4.2: CDPH GUIDANCE DEVELOPMENT PROCESS-COLLABORATORS**

CDPH in collaboration with the University of California Berkeley Center for Infectious Disease and Emergency Readiness (CIDER) engaged in a systematic process to

develop vaccine implementation recommendations. The CDPH IZB and CIDER coordinated and convened the Pandemic Influenza Vaccine and Antiviral (PIVA) Advisory Group to advise and recommend to CDPH implementation strategies for the allocation, distribution, and administration of vaccine.<sup>2</sup> (See Supplemental Document 2 for a list of the participants and staff.)

### **4.3: DECISION MAKING SCORING TOOL**

CDPH IZB and CIDER researchers developed the Pandemic Vaccine Implementation Decision Making Scoring Tool (DMST) to assist the PIVA Advisory Group in selecting implementation options for likely vaccination scenarios.

Refer to Supplemental Document 1 for a description of the CDPH pandemic influenza vaccine implementation process and DMST methodology.

## **5: PLANNING GUIDANCE FRAMEWORK FOR A VACCINATION PROGRAM**

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This section discusses the factors affecting planning a vaccination program that were considered in developing the guidance recommendations.

### **5.1: FACTORS AFFECTING DEVELOPING A VACCINATION PROGRAM**

There is no “one-size-fits-all” approach to developing a vaccination program. The guidance contains different recommendations based on a variety of factors or conditions that will affect the implementation of a mass vaccination program including: the timing in the pandemic (vaccination period), the availability of vaccine (vaccine supply), the effectiveness of the vaccine, and the characteristics of the populations receiving the vaccine (target groups).

### **5.2: PLANNING A PHASED VACCINATION PROGRAM**

The US Federal Draft Vaccine Implementation Guidance identifies three vaccine implementation periods: Pre-pandemic Vaccination Period, Early Pandemic Vaccination Period, and Later Pandemic Vaccination Period. The vaccination periods are unrelated to the epidemiologic concepts of the World Health Organization’s global phases or the US government pandemic phases. These vaccination periods are based on the type of vaccine being distributed and the timing of the distribution process. Table 1 presents a comparison of the vaccination periods and describes how these periods differ based on the timing of the pandemic, the vaccine supply, the control of vaccine, and the use of dose tracking and security systems. The timing of the transition between these

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<sup>2</sup> The PIVA Advisory Group was comprised of a core group of key statewide pandemic preparedness and emergency response experts from public health, medical, and select critical infrastructure sectors. Six Advisory Group meetings were convened over nine months for PIVA members to discuss key implementation issues and to develop recommendations.

vaccination periods will be affected by the supply of, and demand for, vaccine and the ability of the public health infrastructure to sustain a large-scale vaccination program [5].

### **5.3: VACCINE SUPPLY**

The supply of pre-pandemic and pandemic vaccine will be dependent on scientific advances in vaccine development and effectiveness and improvements in vaccine production capacity. Refer to the US federal government's pandemic influenza website (<http://www.flu.gov/#>) for updates on vaccine production and development.

**Table 1 – Description of Pandemic Vaccination Periods**

Characteristics	Pandemic Vaccination Periods		
	Pre-pandemic Vaccination Period	Early Pandemic Vaccination Period	Later Pandemic Vaccination Period
Type of Vaccine	<ul style="list-style-type: none"> <li>• Pre-pandemic vaccine</li> </ul>	<ul style="list-style-type: none"> <li>• Pandemic vaccine</li> </ul>	<ul style="list-style-type: none"> <li>• Pandemic vaccine</li> </ul>
Timing	<ul style="list-style-type: none"> <li>• Before pandemic begins.</li> <li>• Vaccine dispensed once sustained person-to-person transmission of a novel influenza virus has been documented.</li> </ul>	<ul style="list-style-type: none"> <li>• 4-6 months into the pandemic.</li> <li>• Vaccine dispensed late in the first wave or early in the second wave of influenza activity.<sup>1</sup></li> </ul>	<ul style="list-style-type: none"> <li>• At least several months after the early pandemic period.</li> <li>• Vaccine will continue to be dispensed if pandemic on-going or if there is a second wave of influenza activity.<sup>1</sup></li> </ul>
Vaccine Supply	<ul style="list-style-type: none"> <li>• Very limited vaccine supply.</li> <li>• Demand for vaccine far exceeds vaccine supply.</li> </ul>	<ul style="list-style-type: none"> <li>• Limited initial vaccine supplies.</li> <li>• Demand for vaccine exceeds supply.</li> </ul>	<ul style="list-style-type: none"> <li>• Widely available vaccine supply.</li> <li>• Demand for vaccine does not exceed supply.</li> </ul>
Control of Vaccine	<ul style="list-style-type: none"> <li>• Tight control of vaccine by government.</li> <li>• Vaccine distributed to limited number of state designated receiving sites.</li> <li>• Vaccine administered in a limited number of settings including local VPODS and workplace dispensing sites.<sup>2</sup></li> </ul>		<ul style="list-style-type: none"> <li>• Direct distribution and dispensing with health care providers receiving vaccine from manufacturers and administering it in private offices, outpatient clinics, and pharmacies.</li> <li>• Similar to seasonal influenza vaccination.</li> </ul>
Dose Tracking and Security Systems	<ul style="list-style-type: none"> <li>• Dose Tracking and Security Systems are similar for pre-pandemic and early pandemic vaccination periods.</li> <li>• Systems will be in place to track doses of vaccine administered and monitor adverse events.</li> <li>• More rigorous methods will be used to verify that individuals belong to a given target group before receiving vaccine.</li> <li>• High level of physical security may be needed to protect vaccine and staff at dispensing sites.</li> </ul>		<ul style="list-style-type: none"> <li>• Systems will be in place to track doses of vaccine administered and monitor adverse events.</li> <li>• It will not be necessary to verify individuals belong to a given target group</li> <li>• Less physical security will be needed; similar to security coverage for routine seasonal influenza vaccination.</li> </ul>
<p><sup>1</sup> A pandemic may last up to two years and come in waves of influenza activity. Waves may last 6-8 weeks. Age groups and geographical areas not affected by the first wave are often vulnerable during the second pandemic wave months after the first wave. The second wave can be more severe than the first.</p> <p><sup>2</sup> Vaccine Point of Dispensing Sites (VPODS) are dispensing sites established by local health departments to vaccinate large numbers of persons and can include stationary clinics, drive-thru clinics, mobile clinics, school-located clinics, and targeted clinics serving special populations (prisons, homeless, critical workers).</p>			

## 6: VACCINE DISTRIBUTION

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**NOTE: Refer to Appendix A for detailed vaccine distribution action steps for local public health pandemic planners.**

### 6.1: US FEDERAL DISTRIBUTION PROCESS

The US federal government is responsible for coordinating pre-pandemic and pandemic influenza vaccine distribution from vaccine manufacturers directly to designated sites. CDC is the lead agency in the federal government responsible for managing this effort. Ten percent to twelve percent of the total federal allocation of pre-pandemic and pandemic vaccine is likely to be designated for California on the basis of population.

CDPH will be the liaison with CDC for California and will authorize the allocation of pre-pandemic and pandemic vaccine to LHDs proportional to population or related factors. The plan at this time is the vaccine (pre-pandemic and pandemic) will be shipped from manufacturers directly to LHDs and LHD designated providers.

LHDs will identify and approve vaccine receiving sites within their jurisdiction to receive vaccine directly from the manufacturer. As part of the approval process, vaccine receiving sites will complete an electronic form found on the CDPH website verifying that the vaccine receiving site meets receipt, storage, cold chain, documentation, and security requirements as determined by CDPH and federal agencies. The US federal government is responsible for distribution costs. Once delivered to vaccine receiving sites, a transfer of responsibility will occur where physical control, security of, and accountability for vaccine will become local responsibility or the responsibility of the agency or facility receiving vaccine [5].

## 7: VACCINE PRIORITIZATION AND ALLOCATION

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This section provides an overview of the CDPH vaccine prioritization guidance and presents the CDPH recommendations for allocating or dividing incoming shipments of vaccine among equally prioritized target groups. Understanding the vaccine allocation recommendations presented in this guidance document requires familiarity with the CDPH vaccine prioritization guidance.

It is suggested that local public health pandemic planners read the “2013 CDPH Interim Guidance: Prioritization Populations for Pandemic influenza Vaccine in California” prior to reading this section of the implementation guidance [1]. After reviewing the document, it is recommended LHDs identify providers and agencies within their jurisdictions that represent specific target groups so if prioritization is needed, LHDs can rapidly designate distribution of vaccine directly to those groups.

## 7.1: OVERVIEW OF VACCINE PRIORITIZATION

The CDPH Vaccine Prioritization Guidance was developed in a structure that organizes persons targeted for vaccine (e.g., target groups) into the four federal categories: Homeland and National Security, Health Care and Community Support Services, Critical Infrastructure, and Health-vulnerable Groups and General Population.

Each category is comprised of target groups that fall into vaccination tiers ranging from Tier 1 (highest priority) to Tier 5 (lowest priority). All target groups within a tier have equal priority for vaccine, unless sub-prioritization is recommended. Target groups in vaccination tiers differ depending on pandemic severity to reflect the differences that more or less severe pandemics pose to society and to individuals.

## 7.2: RE-CLASSIFICATION OF PRIORITIZATION CATEGORIES INTO TARGET GROUP TYPES

In order to simplify the implementation strategy, CDPH has re-classified the four federal categories found in the “2013 California Department of Public Health Interim Guidance: Prioritizing Populations for Pandemic Influenza Vaccine in California” into four target group types. See Table 2 for the re-classification of the federal categories into CDPH target group types. The four CDPH target group types that will be referred to throughout the rest of the guidance are: federal-based, role-based, health-vulnerable general population, and healthy general population. For example, CDPH combined the two federally created categories “Health Care and Community Support Services and Critical Infrastructure” into one target group type labeled “role-based.” All the target groups represented under the CDPH role-based target group type category would be considered equally critical to maintaining health care, public security, and essential community services during a pandemic. Federal vaccine planning documents<sup>3,4</sup> indicate that the federal government may take responsibility for the federal-based groups located in the States. At some point there may be more direction from the federal government as to who will vaccinate these groups, so LHDs may want to include some federal-based groups in allocation planning estimates.

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<sup>3</sup> US Department Health and Human Services and US Office of Homeland Security. “Guidance on Allocating and Targeting pandemic Influenza Vaccine. (2008).”

[http://www.flu.gov/images/reports/pi\\_vaccine\\_allocation\\_guidance.pdf](http://www.flu.gov/images/reports/pi_vaccine_allocation_guidance.pdf)

<sup>4</sup> US Department of Health and Human Services and US Office of Homeland Security. “The Prioritization of Critical Infrastructure for a Pandemic Outbreak in the United States Working Group (2007).”

[http://www.dhs.gov/xlibrary/assets/niac/niac-pandemic-wg\\_v8-011707.pdf](http://www.dhs.gov/xlibrary/assets/niac/niac-pandemic-wg_v8-011707.pdf)

**Table 2 – Re-classification of Federal Prioritization Categories and CDPH Target Groups by CDPH Target Group Type Categories**

<b>Federal Category</b>	<b>CDPH Target Group</b>	<b>CDPH Target Group Type Category</b>
<b>Homeland and National Security</b>	Deployed and Mission Critical Personnel	Federal based <sup>1</sup>
	Essential Support and Sustainment Personnel	Federal-based <sup>1</sup>
	Intelligence Services	Federal-based <sup>1</sup>
	Border Protection Personnel	Federal-based <sup>1</sup>
	National Guard Personnel	Federal-based <sup>1</sup>
	Other Domestic National Security Personnel	Federal-based <sup>1</sup>
	Other Active Duty and Essential Support Personnel	Federal-based <sup>1</sup>
<b>Health Care and Community Support Services</b>	Public Health Personnel	Role-based
	Hospital-based Inpatient Health Care Providers	Role-based
	Outpatient and Home Care Providers	Role-based
	Health Care Providers in Other Inpatient and Long-Term Care Facilities (LTFC)	Role-based
	Community Support Service and Emergency Management Personnel	Role-based
	Pharmacists	Role-based
	Mortuary Service Personnel	Role-based
	Laboratory Technicians and Other Licensed Health Care Personnel	Role-based
<b>Critical Infrastructure</b>	Emergency Services Sector Personnel (EMS, law enforcement, fire, corrections)	Role-based
	Manufacturers of Pandemic Vaccine, Antiviral Drugs, and Other Key Pandemic Response Materials	Role-based
	Key Government Leaders and Critical Government Personnel	Role-based
	Energy Sector Personnel (electricity, nuclear, oil and gas)	Role-based
	Communications Sector Personnel (telephone and IT)	Role-based
	Water Sector Personnel (potable and waste water)	Role-based
	Financial Clearing and Settlement Personnel	Role-based
	Other Important Government Personnel	Role-based
	Transportation Sector Personnel	Role-based
	Other Banking and Finance Sector Personnel	Role-based

<b>Federal Category</b>	<b>CDPH Target Group</b>	<b>CDPH Target Group Type Category</b>
	Pharmaceutical Sector Personnel	Role-based
	Food and Agriculture Sector Personnel	Role-based
	Chemical Sector Personnel	Role-based
	Postal, Shipping, and Warehousing Sector Personnel	Role-based
	Educational Services Personnel	Role-based
	Broadcasting and Publishing Personnel	Role-based
	Solid Waste Management Personnel	Role-based
<b>Health-vulnerable Groups and General Population</b>	Pregnant Women, all ages	Health-vulnerable General Population
	Infants and Toddlers, 6-35 months	Health-vulnerable General Population
	Household Contacts of Infants Less than 6 Months, all ages	Health-vulnerable General Population
	Children 3-18 years with High-risk Medical Conditions	Health-vulnerable General Population
	Children 3-18 years without High-risk Medical Conditions	Health-vulnerable General Population
	High-risk Persons, 19-64 years	Health-vulnerable General Population
	High-risk Persons, 65 years and older (includes all persons 65+)	Health-vulnerable General Population
	Healthy Adults, 19-64 years not included in other categories	Healthy General Population
<sup>1</sup> The federal government may take responsibility for the federal-based groups in California. At some point there may be more direction from the federal government as to who will vaccinate these groups.		

### 7.3: CDPH TARGET GROUP TYPE BY PRIORITIZATION TIERS

Table 3 presents descriptions of the CDPH target group types as well as the CDPH target groups organized by target group type along with their corresponding vaccination tiers for pandemics of different severities.

**Table 3 – Description of CDPH Target Group Type Categories and List of CDPH Designated Target Groups with Vaccination Tiers by Pandemic Severity**

CDPH Target Group Type Category	Description	CDPH Target Groups	Severe Pandemic Vaccination Tiers	Moderate Pandemic Vaccination Tiers	Less Severe Pandemic Vaccination Tiers
<b>Federal-based<sup>1</sup></b>	<ul style="list-style-type: none"> <li>Provide critical services that are essential to maintain during a pandemic</li> <li>Include only <b>critical workers</b>, not the entire workforce</li> </ul>	Deployed and Mission Critical Personnel	Tier 1	Tier 1	Tier 1
		Essential Support and Sustainment Personnel	Tier 2	Tier 2	Tier 2
		Intelligence Services	Tier 2	Tier 2	Tier 2
		Border Protection Personnel	Tier 2	Tier 2	Tier 2
		National Guard Personnel	Tier 2	Tier 2	Tier 2
		Other Domestic National Security Personnel	Tier 2	Tier 2	Tier 2
		Other Active Duty and Essential Support Personnel	Tier 3	Tier 3	Not Targeted <sup>2</sup>
<b>Role-based</b>	<ul style="list-style-type: none"> <li>Provide critical services that are essential to maintain during a pandemic</li> <li>Include only <b>critical workers</b>, not the entire workforce</li> </ul>	Public Health Personnel	Tier 1	Tier 1	Tier 1
		Medical Care Providers	Tier 1	Tier 1	Tier 1
		Public Safety Personnel (EMS, police, fire, etc.)	Tier 1	Tier 1	Tier 1
		Manufacturers of Pandemic Countermeasures	Tier 1	Tier 1	Not Targeted <sup>2</sup>
		Critical Government Personnel	Tiers 2 & 3	Tier 2	Not Targeted <sup>2</sup>
		Community Support and Emergency Management Personnel	Tier 2	Tier 2	Not Targeted <sup>2</sup>
		Basic Utilities (energy, water, communications)	Tier 2	Tier 2	Not Targeted <sup>2</sup>
		Other Critical Infrastructure Personnel <sup>1</sup>	Tier 3	Not Targeted <sup>2</sup>	Not Targeted <sup>2</sup>
<b>Health-vulnerable General Population</b>	<ul style="list-style-type: none"> <li>At highest risk of developing influenza complications (severe illness and/or death)</li> </ul>	Pregnant Women, all ages	Tier 1	Tier 1	Tier 1
		Infants and Toddlers, 6-35 months <sup>3</sup>	Tier 1	Tier 1	Tier 1
	<ul style="list-style-type: none"> <li>At moderate risk of developing influenza complications (severe illness and/or death)</li> <li>Persons who are at risk of transmitting the virus to infants less than 6 months living in the household<sup>3</sup></li> </ul>	Children 3-18 years with High-risk Medical Conditions	Tier 2	Tier 2	Tier 2
		Household Contacts of Infants Less than 6 months, all ages	Tier 2	Tier 2	Tier 2

CDPH Target Group Type Category	Description	CDPH Target Groups	Severe Pandemic Vaccination Tiers	Moderate Pandemic Vaccination Tiers	Less Severe Pandemic Vaccination Tiers
<b>Health-vulnerable General Population</b>	<ul style="list-style-type: none"> <li>At somewhat risk of developing influenza complications (severe illness and/or death)</li> </ul>	Children 3-18 years without High-risk Medical Conditions <sup>4</sup>	Tier 3	Tier 2	Tier 2
		High-risk Persons, 19-64 years <sup>4</sup>	Tier 4	Tier 3	Tier 2
		High-risk Persons, 65 years and older <sup>4</sup>	Tier 4	Tier 3	Tier 2
		All persons, 65 years and older <sup>4</sup>	Tier 4	Tier 3	Tier 2
<b>Healthy General Population</b>	<ul style="list-style-type: none"> <li>Adults who do not have a medical condition that increases their risk of developing influenza complications and who are not included within the role-based target groups</li> </ul>	Healthy Adults, 19-64 years not included in other categories	Tier 5	Tier 4	Tier 3

<sup>1</sup> The federal government may take responsibility for the federal-based groups in California. At some point there may be more direction from the federal government as to who will vaccinate these groups. Local health departments may want to include some federal-based groups in allocation planning estimates.

<sup>2</sup> Persons in federal and role-based target groups not targeted for vaccine in moderate and less severe pandemics will be vaccinated according to their age and health status in the general population.

<sup>3</sup> Includes all children who turn age 6-35 months during the pandemic.

<sup>4</sup> The level of risk complications for these age groups may vary and will be determined by epidemiological investigations during the pandemic.

## 7.4: VACCINE ALLOCATION

**NOTE: Refer to Appendix B for examples, detailed description, and rationales of the vaccine allocation recommendations presented in this section.**

CDPH recommends different allocation approaches based on the pandemic vaccination period and vaccine supply. Table 4 presents the CDPH recommended vaccine allocation approaches by vaccine implementation period and vaccine supply.

**Table 4 – CDPH Recommended Vaccine Allocation Approaches by Vaccination Period**

Vaccination Period	Vaccine Supply	Recommendation
<b>Pre-pandemic Vaccination Period</b>	≥3 million CA doses (total) <sup>1,2</sup>	• No Allocation Approach
	<3 million CA doses (total)	• Hybrid Allocation Approach
<b>Early Pandemic Vaccination Period</b>	≥3 million CA doses per week <sup>3</sup>	• No Allocation Approach
	<3 million CA doses per week	• Hybrid Allocation Approach: (1) Sub-prioritization by Target Group Type (2) Proportionate Allocation
<b>Later Pandemic Vaccination Period</b>	≥3 million CA doses per week	• No Allocation Approach
<p><sup>1</sup> Pre-pandemic vaccine is recommended for all critical role-based workers in CDPH Prioritization Tier 1. The total pre-pandemic vaccine supply required to vaccinate these workers is 1.5 million 2-dose courses or 3 million total doses.</p> <p><sup>2</sup> For planning purposes, “total” implies there may be in the pre-pandemic period a stockpile with a fixed amount and this may be different than the weekly allocation after the stockpile is distributed.</p> <p><sup>3</sup> California weekly vaccine supply estimate is based on CDC vaccine supply scenario of expanded vaccine supply (e.g., 25 million US doses per week) [6]. For planning purposes, weekly allotments of vaccine may increase overtime. Reference: US Department of Health and Human Services. “Update: Status of pandemic influenza vaccine manufacturing capacity, pre-pandemic stockpile, and planning for vaccine distribution.” February 2009, unpublished.</p>		

## 7.5: ALLOCATION APPROACH RECOMMENDATIONS: PRE-PANDEMIC VACCINATION PERIOD

### 7.5.1: NO ALLOCATION APPROACH

If there is sufficient vaccine supply to cover all role-based target group members in CDPH Prioritization Tier 1, then no allocation approach is necessary. Instead, incoming shipments of vaccine will be allocated and dispensed on a first-come, first-serve basis to designated role-based target group members in Tier 1.

### 7.5.2: HYBRID ALLOCATION APPROACH

If the pre-pandemic vaccine supply is not sufficient to cover all role-based target group members in CDPH Prioritization Tier 1, then the hybrid allocation approach is recommended. Under this approach, the role-based target groups within Tier 1 will be sub-prioritized by role and risk level (e.g., contact with infected persons) with several target

groups included in one sub-prioritization level. Including several role-based defined target groups within a sub-prioritization level ensures that target groups who rely on one another to provide critical services receive vaccine at the same time. It is assumed that CDPH will develop the sub-prioritization levels within each vaccination tier to ensure uniformity across all local health jurisdictions. See Appendix B for detailed description with step by step instructions of how to allocate vaccine using the hybrid approach.

### **7.5.3: PROPORTIONATE ALLOCATION APPROACH**

If CDPH does not develop sub-prioritization levels prior to vaccine availability, then local health jurisdictions should implement the proportionate allocation approach rather than the hybrid allocation approach. Under this approach, incoming shipments of vaccine supply will be divided proportionately amongst the target groups within a tier and administered until all the target groups in the tier are vaccinated. Proportionate coverage is equal to the size of the population group relative to the size of the tier. Those groups that represent a larger proportion of the tier (e.g., have a greater number of target group members) will receive more vaccine from each shipment.

## **7.6: ALLOCATION APPROACH RECOMMENDATION: EARLY PANDEMIC VACCINATION PERIOD**

### **7.6.1: NO ALLOCATION APPROACH**

If there is sufficient vaccine supply to cover all target group members in a particular tier, then no further allocation approach is necessary. Vaccine will be allocated and dispensed on a first-come, first-serve basis.

### **7.6.2: HYBRID APPROACH**

The initial quantities of pandemic vaccine will likely not be sufficient to cover all of the target groups within a single vaccination tier. CDPH recommends the hybrid allocation approach in which several target groups within a tier are sub-prioritized by target group type. All role-based target groups will be included in one sub-prioritization level and health-vulnerable general population target groups will be included in a separate sub-prioritization level. Next, vaccine will be divided proportionately to all target groups within a sub-prioritization level. See Appendix B for detailed description with step by step instructions of how to allocate vaccine using the hybrid approach.

## **7.7: ALLOCATION APPROACH RECOMMENDATION: LATER PANDEMIC VACCINATION PERIOD**

### **7.7.1: NO ALLOCATION APPROACH**

In the later vaccination period, vaccine supply will be expanded and there will be a transition to a seasonal influenza vaccination model with health care providers directly receiving vaccine from manufacturers and administering it in private offices and clinics. During this vaccination period, incoming shipments of vaccine will be allocated and dispensed on a first-come, first-serve basis similar to seasonal influenza vaccination.

## **7.8: ADDITIONAL ALLOCATION APPROACH RECOMMENDATIONS FOR LHDS**

CDPH recommends LHDs review the settings where role-based and health-vulnerable general population target groups will be immunized. For example, vaccine designated to role-based target group members will likely be distributed and dispensed at their workplaces or other large occupational settings (headquarters) whereas health-vulnerable general population target groups will likely be vaccinated in local vaccine point of dispensing sites (VPODS)<sup>5</sup> or in traditional health care settings.

## **8: VACCINE ADMINISTRATION**

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This section presents recommendations for determining the persons and settings responsible for administering vaccine to different target groups, for verifying target group membership, and for planning a two dose regimen for target group members. It should be noted these are NOT requirements but general recommendations to help guide local planners. Also, the recommendations were developed assuming a severe pandemic with limited vaccine supply.

### **8.1: DESIGNATING RESPONSIBILITY FOR VACCINATION**

“Designating Responsibility for Vaccination” refers to the agencies and organizations that will be responsible for administering vaccine to different target groups and the settings where vaccine will be dispensed. Certain agencies and organizations will be responsible for establishing dispensing sites and vaccinating designated target groups regardless of pandemic severity, vaccination period, or vaccine supply. Table 5 presents the vaccine administration strategies for different CDPH target groups.

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<sup>5</sup> Local Vaccine Point of Dispensing Sites (VPODS) are dispensing sites established by local health departments to vaccinate large numbers of persons and can include stationary clinics, drive-thru clinics, mobile clinics, school-located clinics, and targeted clinics serving special populations (prisons, homeless, critical workers).

**Table 5 – CDPH Vaccine Administration Recommendations for a Severe Pandemic by CDPH Target Group Types, CDPH Target Groups, and Vaccine Dispensing Settings**

CDPH Target Group Types	CDPH Target Groups	Responsible for Vaccination	Vaccine Dispensing Settings, in addition to seasonal influenza immunization sites
<b>Federal-based<sup>1</sup></b>	Critical Federal Security Personnel.	<ul style="list-style-type: none"> <li>Federal Government <b>OR</b></li> <li>California Department of Public Health (CDPH)/ Local Health Jurisdictions</li> </ul>	<ul style="list-style-type: none"> <li>Vaccine dispensing sites at federal agencies and Veterans Administration (VA) facilities</li> <li>To Be Determined</li> </ul>
	National Guard. <sup>2</sup>	<ul style="list-style-type: none"> <li>California Department of Public Health (CDPH)/Local Health Jurisdictions</li> </ul>	<ul style="list-style-type: none"> <li>To Be Determined</li> </ul>
<b>Role-based<sup>3</sup></b>	Health Care Providers in Inpatient Care Settings.	<ul style="list-style-type: none"> <li>Employers</li> </ul>	<ul style="list-style-type: none"> <li>Workplace dispensing sites at inpatient care facilities</li> </ul>
	Health Care Providers in Outpatient and Home Health Care Settings.	<ul style="list-style-type: none"> <li>Employers <b>OR</b></li> <li>Local Health Jurisdictions</li> </ul>	<ul style="list-style-type: none"> <li>Local vaccine point of dispensing sites (VPODS)</li> <li>Workplace</li> </ul>
	Community Support Service and Emergency Management Personnel.	<ul style="list-style-type: none"> <li>Local Health Jurisdictions</li> </ul>	<ul style="list-style-type: none"> <li>Local VPODS</li> <li>Workplace</li> </ul>
	Public Safety Personnel and Other Frontline Responders.	<ul style="list-style-type: none"> <li>Employers</li> </ul>	<ul style="list-style-type: none"> <li>Workplace dispensing sites at public safety agencies</li> </ul>
	Non-frontline Critical Infrastructure Personnel.	<ul style="list-style-type: none"> <li>Employers <b>OR</b></li> <li>Local Health Jurisdictions</li> </ul>	<ul style="list-style-type: none"> <li>Workplace dispensing sites at critical infrastructure organizations</li> <li>Local VPODS</li> </ul>
<b>Health-vulnerable General Population</b>	<p>Tiers 1-3: Pregnant Women; Infants and Toddlers, 6-35 months; Household Contacts of Infants less than 6 months (all ages); Children 3-18 years with High-risk Medical Conditions; Children 3-18 years without High-risk Medical Conditions</p> <p>Tier 4: High-risk Persons, 19-64 years; High-risk Persons, 65 years and older (includes all persons 65+).</p>	<ul style="list-style-type: none"> <li>Local Health Jurisdictions <b>AND/OR</b></li> <li>Traditional Health Care Providers</li> </ul>	<ul style="list-style-type: none"> <li>Local VPODS</li> <li>Seasonal influenza vaccination sites</li> </ul>

CDPH Target Group Types	CDPH Target Groups	Responsible for Vaccination	Vaccine Dispensing Settings, in addition to seasonal influenza immunization sites
<b>Healthy General Population</b>	Tier 5: All Healthy Adults, 19-64 years not included in other categories.	<ul style="list-style-type: none"> <li>• Traditional Health Care Providers</li> </ul>	<ul style="list-style-type: none"> <li>• Seasonal influenza vaccination sites</li> </ul>
<p><sup>1</sup> The federal government may take responsibility for the federal-based groups in California. At some point there may be more direction from the federal government as to who will vaccinate these groups. Local health departments may want to include some federal-based groups in allocation planning estimates.</p> <p><sup>2</sup> National Guard includes National Guard personnel activated in California. Guard personnel currently serving overseas will receive vaccine through federal distribution and administration channels.</p> <p><sup>3</sup> Refer to “CDPH Prioritizing Populations for Pandemic Influenza Vaccine in California (2013)” for complete list of CDPH target groups.</p>			

## **8.1.1: VACCINE ADMINISTRATION RECOMMENDATIONS: FEDERAL-BASED TARGET GROUP TYPES**

### **8.1.1.1: Critical Federal Homeland and National Security Personnel: Dispensing Sites at Federal Agencies and Veterans Administration Facilities**

Until federal guidance is updated, Critical Federal Security Personnel working and residing in California will receive vaccine at Veterans Administration (VA) Facilities or from their responsible federal department or agency [7].

### **8.1.1.2: National Guard Personnel: To Be Determined**

National Guard personnel activated in California are under the jurisdiction of the governor and may receive vaccine through either state and/or LHD distribution and administration channels along with all other critical state government workers in prioritization Tier 2.

## **8.1.2: VACCINE ADMINISTRATION RECOMMENDATIONS: ROLE-BASED TARGET GROUP TYPES**

### **8.1.2.1: Health Care Providers in Inpatient Care Settings: Workplace Dispensing Sites**

Hospitals and other inpatient care facilities have the capacity (e.g., facilities, equipment, and skilled staff) to vaccinate their own workforce. For this reason, LHDs should designate vaccine to be directly distributed to hospitals whose staff will be responsible for vaccinating their employees onsite.

### **8.1.2.2: Health Care Providers in Outpatient and Home Health Care Settings: Workplace or Targeted Dispensing Sites**

Most outpatient health care providers have the ability to vaccinate their own personnel. However, depending on the number of small dosages providers may need, it may be impractical for LHDs to designate vaccine to be directly delivered to all doctors' offices and clinics within their jurisdiction. For this reason, LHDs should identify secondary sites where medical office staff can receive vaccine such as LHDs, targeted dispensing clinics, or local VPODS.

### **8.1.2.3: Community Support Service and Emergency Management Personnel: Local VPODS**

Vaccinating community support workers is similar to vaccinating outpatient health care workers in that it may be impractical for local public health pandemic planners to designate small dosages of vaccine to be directly delivered to every community response organization in their jurisdiction. Also, it is unlikely that these organizations will have the capacity to vaccinate their employees. Therefore, LHDs should vaccinate community support workers at local VPODS.

#### **8.1.2.4: Public Safety Personnel and Other Frontline Emergency Responders: Workplace Dispensing Sites**

As with hospital workers, vaccinating police, firefighters, EMS, and other persons who provide public safety should be delegated to these agencies. LHDs should designate vaccine to be directly distributed to occupational health clinics at these agencies. The occupational health staff will be responsible for vaccinating public safety personnel associated with municipal police and fire departments onsite.

#### **8.1.2.5: Non-frontline Critical Infrastructure Personnel: Workplace Dispensing Sites and VPODS**

LHDs should identify those organizations in their jurisdictions with the capacity to establish workplace dispensing clinics to vaccinate their employees and develop plans to designate vaccine to be directly distributed to occupational health staff at these organizations. In addition, LHDs should identify organizations in their jurisdictions that do not have the capacity to establish workplace dispensing clinics and develop dispensing plans to assist these organizations in administering vaccine to eligible workers either at their worksites or at local VPODS.

### **8.1.3: VACCINE ADMINISTRATION RECOMMENDATIONS: HEALTH-VULNERABLE GENERAL POPULATION TARGET GROUP TYPES**

The health-vulnerable general population target group type category includes Californians that are not included in the role-based defined priority target groups. This category comprises approximately 50% of the total California population and represents a variety of target groups in which different vaccine administration strategies are recommended.

#### **8.1.3.1: Health-vulnerable General Population Target Groups in Tiers 1-3: Local VPODS and Outpatient Clinics**

Health-vulnerable general population target groups in prioritization tiers 1-3 for a severe pandemic include: pregnant women, infants and toddlers, household contacts of infants <6 months, and children 3-18 years (healthy and those with high-risk conditions). These target groups will receive vaccine in the early pandemic vaccination period when demand exceeds supply. In this period, vaccine may be tightly controlled by the LHD and dispensed at a limited number of sites.

##### ***8.1.3.1.a: Health-vulnerable General Population Target Groups Tier 1-3 Receiving Vaccine at Outpatient Clinics***

The health-vulnerable general population target group members who are currently receiving medical care at outpatient clinics should receive pandemic influenza vaccine directly from their health care providers, if their clinic is a designated site. If their clinic is not a designated site when vaccine is tightly controlled, target group members should be directed to available clinics either by their clinic or the LHD. LHDs should identify outpatient clinics (pre-natal clinics, birthing clinics, pediatric clinics, etc.) that vaccinate persons for seasonal influenza in their jurisdictions and designate vaccine to be directly

distributed to these clinics. During a pandemic, health care providers will be responsible for notifying their patients to report to the clinic to receive the vaccine.

#### ***8.1.3.1.b: Health-vulnerable General Population Target Groups Tier 1-3 Receiving Vaccine at Local VPODS***

The health-vulnerable general population target group members who either do not have a current clinic or those who have a clinic but the clinic does not have vaccine should be vaccinated at local VPODS. Some provider groups, like a health maintenance organization, may have a single site to cover multiple clinics for their organization.

#### **8.1.3.2: Health-vulnerable General Population Target Groups in Tiers 4: Traditional Health Care Settings (doctor's offices, clinics, retail pharmacies)**

Health-vulnerable general population target groups in vaccination Tier 4 include adults 19-64 years with high-risk medical conditions, and all adults 65 years and older (both healthy and high-risk) for a severe pandemic. Target group members in Tier 4 should receive vaccine in traditional health care settings where they receive their seasonal influenza vaccine such as doctors' offices, outpatient clinics, and retail pharmacies.

#### **8.1.4: VACCINE ADMINISTRATION RECOMMENDATIONS: HEALTHY GENERAL POPULATION TARGET GROUP TYPES**

Healthy adults, 19-64 years of age and not included in other target groups are represented in Tier 5 for a severe pandemic. They represent approximately 35 to 40% of the California population and will receive vaccine in the later vaccination period when vaccine supply is expanded and vaccine distribution and administration follows a seasonal influenza model. Vaccine should be available at doctors' offices, outpatient clinics, and retail pharmacies.

## **8.2: VERIFYING TARGET GROUP MEMBERSHIP**

**NOTE: Refer to Appendix C for detailed descriptions and rationales of the target group membership verification recommendations.**

If vaccine is very limited with strict prioritization, LHDs may need to recommend implementation verification protocols/strategies for providers to ensure that designated target groups are being vaccinated according to prioritization guidelines [5]. "Target Group Membership Verification" refers to the methods that can be used by vaccine screeners to verify that individuals belong to a given target group at the time of vaccination. Different target group membership verification methods are recommended for each type of target group as well as for different vaccination periods and vaccine supply scenarios.

## 8.2.1: VERIFYING FEDERAL-BASED TARGET GROUPS

### **8.2.1.1: Federal Worker Recommendation: Employee Lists (at federal or state/local dispensing sites)**

Critical federal government personnel working and residing in California will either receive vaccine at VA facilities or at local VPODS. Federal agencies will be responsible for developing and maintaining their lists of critical employees. Federal agency staff will notify their employees when and where to report for vaccine and will verify their identity and employment status at the time of vaccination.

## 8.2.2: VERIFYING ROLE-BASED TARGET GROUPS

Role-based target groups comprise less than 8% of the total California population because these groups include only those individuals who provide critical services and not the entire workforce. Vaccine screeners will need to verify the identity of role-based target group members before they receive vaccine. The majority of these workers are highly prioritized (Tiers 1-3) and will likely receive vaccine in the pre-pandemic and early pandemic periods when the demand for vaccine is greater than the supply. CDPH recommends different verification methods for different types of role-based target groups. Table 6 presents the target group membership verification recommendations for frontline responders and non-frontline responders.

**Table 6 – Role-based Target Group Membership Verification Recommendations**

Role-based Target Group	Sample Target Groups <sup>1</sup>	Recommendation Examples
<b>Frontline Responders</b> (Responders providing public health, health care and public safety services).	<ul style="list-style-type: none"><li>Hospital Based Inpatient Care Providers, Public Health Personnel, Emergency Services Sector Personnel.</li></ul>	<ul style="list-style-type: none"><li>Prepare critical personnel lists in advance and use one the following documents to verify:<ul style="list-style-type: none"><li>Employee identification numbers,</li><li>Employee badges,</li><li>Tickets/vouchers issued by organization, or</li><li>Most recent paycheck stub.</li></ul></li></ul>
<b>Non-Frontline Responders</b> (Personnel providing essential security, community support and critical infrastructure services).	<ul style="list-style-type: none"><li>Community Support Service Personnel, Energy Sector Personnel, Educational Services Personnel.</li></ul>	

<sup>1</sup> Sample target groups include examples of CDPH designated role-based target groups. Refer to “CDPH Interim Guidance: Prioritization Populations for Pandemic influenza Vaccine in California (2013)” for a complete discussion of the CDPH vaccine prioritization [1].

### **8.2.2.1: Frontline Responder Recommendation: Employee Lists (at workplace dispensing sites)**

Frontline responder agencies have the capacity (e.g., facilities, equipment, and skilled staff) to vaccinate their own workforce. These organizations will be responsible for setting up and staffing vaccination clinics at their workplaces. These agencies will also be responsible for developing and maintaining their lists of critical employees. When vaccine is available, LHDs will notify staff at these organizations. Staff will notify their employees when to report for vaccination and to bring proper documentation to verify target group membership. Staff at these organizations will verify the identity and target group membership status of these workers at the time of vaccination.

### **8.2.2.2: Non-Frontline Responder Recommendation: Employee Lists (at workplace dispensing sites or targeted dispensing sites)**

Larger employers will likely have the resources to establish vaccine dispensing clinics at their workplaces. Medium to smaller employers lacking the resources to independently establish workplace vaccination clinics can notify their LHD. LHDs with additional resources could work with medium and smaller sized employers to establish vaccination clinics at their workplaces or at local VPODS. (For example, LHDs could provide the vaccinators and employers could provide the screening staff.) Again, these employers will be responsible for developing and maintaining their lists of critical employees. These employers will also be responsible for notifying their employees when and where to report for vaccination and to bring proper documentation to verify target group membership.

### **8.2.3: VERIFYING HEALTH-VULNERABLE GENERAL POPULATION TARGET GROUPS**

The health-vulnerable general population target groups are prioritized in different vaccination tiers and will receive vaccine in different vaccination periods. For example, pregnant women are prioritized in Tier 1 and children with high-risk medical conditions are prioritized in Tier 2 for a severe pandemic. Individuals in these target groups will likely receive vaccine in the early pandemic periods at local dispensing clinics and/or outpatient clinics. When vaccine supply is limited, more rigorous methods to verify the identity of persons in these target groups may be useful. Adults with high-risk medical conditions are prioritized in Tier 4 for a severe pandemic and will likely receive vaccine in the later pandemic period in more traditional health care settings. When vaccine supply is less limited, less rigorous target group membership verification methods are sufficient. Table 7 presents the target group membership verification recommendations for the health-vulnerable general population target groups.

**Table 7 – Health-vulnerable General Population Target Group Membership Verification Recommendations by Vaccination Period**

Health-vulnerable General Population Target Group	Vaccination Period	Recommendation
<b>Pregnant Women, all ages</b>	• Early Vaccination Period	<ul style="list-style-type: none"> <li>• Patient Lists (at prenatal clinics)</li> <li>• Signed Physician Referral Forms (at local VPODS)</li> </ul>
<b>Infants and Toddlers, ages 6-35 months</b>	• Early Vaccination Period	<ul style="list-style-type: none"> <li>• Patient Lists (at pediatric clinics)</li> <li>• Written Documentation of Age (at local VPODS)</li> <li>• Oral Self-report (at local VPODS)</li> </ul>
<b>Household Contacts of Infants &lt;6 Months, all ages</b>	• Early Vaccination Period	<ul style="list-style-type: none"> <li>• Signed Physician Referral Forms (at local VPODS)</li> <li>• Self-reported Health Information Forms (at local VPODS)</li> </ul>
<b>Children 3-18 years with High-risk Medical Conditions</b>	• Early Vaccination Period	<ul style="list-style-type: none"> <li>• Patient Lists (at pediatric clinics)</li> <li>• Signed Physician Referral Forms (at local VPODS)</li> <li>• Self-reported Health Information Forms (at local VPODS)</li> <li>• Oral Self-report (at local VPODS)</li> </ul>
<b>Children 3-18 years without High-risk Medical Conditions</b>	• Early Vaccination Period	<ul style="list-style-type: none"> <li>• Patient Lists (at pediatric clinics)</li> <li>• Oral Self-report (at local VPODS)</li> </ul>
	• Later Vaccination Period	• No Verification Required (at local VPODS or traditional health care sites)
<b>High-risk Persons, 19-64 years</b>	• Early Vaccination Period	<ul style="list-style-type: none"> <li>• Self-reported Health Information Forms (at local VPODS)</li> <li>• Oral Self-report (at local VPODS)</li> </ul>
	• Later Vaccination Period	• No Verification Required (at local VPOS or traditional health care sites)
<b>High-risk Persons, 65 years and older (includes all persons 65+)</b>	• Later Vaccination Period	• No Verification Required (at traditional health care sites)

**8.2.3.1: Pregnant Women Verification Recommendations:**

***8.2.3.1.a: Patient Lists (at prenatal clinics)<sup>6</sup>***

Pregnant women may receive vaccine from the outpatient clinics where they are currently receiving prenatal care. LHDs should identify prenatal clinics that vaccinate pregnant women for seasonal influenza in their jurisdictions and designate vaccine to be directly distributed to staff at these clinics. Prenatal clinic staff will be responsible for setting up and staffing vaccination clinics at their facilities and for developing and maintaining their lists of eligible patients. These staff will also be responsible for notifying their patients when to report for vaccine and for training staff to review proper identification documents to verify target group membership at the time of vaccination.

<sup>6</sup> Health care providers should prioritize pregnant women in their second and third trimesters because these women are at higher risk of developing influenza complications.

### ***8.2.3.1.b: Signed Physician Referral Forms (at local VPODS)***

Pregnant women not receiving prenatal care at outpatient clinics or if their clinic doesn't have pandemic vaccine need to be vaccinated at local VPODS. If vaccine supply is limited in the early vaccination period, CDPH recommends requiring pregnant women to present signed physician referral forms to verify target group membership. Health care providers should mail/email reminder cards to their patients indicating they qualify for vaccine and that they should report to local VPODS to receive it.<sup>7</sup> Patients will present the signed physician referral form at the dispensing site to verify medical condition (e.g., pregnancy status) at the time of vaccination. Vaccine screeners will also verify the identity of the pregnant women requesting vaccine by reviewing appropriate documents (e.g., drivers' licenses, passports, etc.).

### **8.2.3.2: Infants and Toddlers Verification Recommendations**

#### ***8.2.3.2.a: Patient Lists (at Pediatric Clinics)***

The majority of infants and toddlers should receive vaccine from the pediatric clinics where they receive their seasonal influenza vaccine. LHDs should identify pediatric clinics that vaccinate children and designate vaccine to be distributed to staff at these clinics. The list should include both Vaccine for Children (VFC) and non-VFC pediatric providers. Clinic staff will be responsible for setting up and staffing vaccination clinics at their facilities and for developing and maintaining their lists of eligible patients.

#### ***8.2.3.2.b: Written Documentation of Age (at VPODS)***

Under a limited vaccine supply scenario, CDPH recommends requiring parents/guardians to present written documentation of the age of the infant/toddler.<sup>8</sup> If parents/guardians do not have written documentation, VPODS should include triage stations to allow children who have the documentation be first in line to receive vaccination.

#### ***8.2.3.2.c: Oral Self-report (at local VPODS)***

If parent/guardians do not have written documentation, vaccine screeners will verify target group membership by asking the age of the child. The parent/guardian will self-report (e.g., answer the question). If age of child is in question, it is up to the LHD to create a protocol for the vaccine screeners.

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<sup>7</sup> This reminder card should include in the following information: patient's name, date of birth (DOB), medical condition (due date or trimester number), and physician's contact information.

<sup>8</sup> Appropriate documentation of age can include: birth certificates, immunization records, or other medical documents.

### **8.2.3.3: Household Contacts of Infants <6 Months Membership Verification Recommendations**

#### ***8.2.3.3.a: Vaccinate Household Contacts of Infants <6 months (at traditional health care sites)***

Verifying household contacts of infants <6 months should be done before delivery. CDPH recommends that during a pandemic, family members of pregnant women in their second and third trimesters be vaccinated by their health care providers at least two months prior to the woman's expected date of delivery. This recommendation represents the most efficient vaccination method because household contacts of infants <6 months can be accurately identified and vaccinated prior to the birth of the child thereby reducing the risk of transmission to newborns. If household contacts are not able to be immunized prior to the delivery, household contacts should be immunized as soon as possible after the delivery of the infant. Household contacts should bring a copy of the birth certificate to their health care provider.

#### ***8.2.3.3.b: Signed Physician Referral Forms (at local VPODS)***

If household contacts of infants <6 months are unable to receive vaccine from the birthing provider or their own health care provider, these individuals should provide a signed referral form from a physician or nurse midwife to verify the birth of the infant in order to receive vaccine at local VPODS.

#### ***8.2.3.3.c: Self-reported Health Information Forms (at local VPODS)***

CDPH also recommends using self-reported health information forms at local VPODS for household contacts of infants who did not receive vaccine from a traditional health care provider. The form should collect the same information as the written referral form from the birthing provider.

### **8.2.3.4: Children 3-18 Years with High-risk Medical Conditions Verification Recommendations**

#### ***8.2.3.4.a: Patient Lists (at pediatric clinics)***

Children with high-risk medical conditions may receive vaccine from outpatient clinics where they are currently receiving medical care. LHDs should identify pediatric clinics that vaccinate children for seasonal influenza in their jurisdictions and designate vaccine to be directly delivered to these clinics. Pediatric clinic staff will be responsible for setting up and staffing vaccination clinics at their facilities and for developing and maintaining their lists of eligible patients.

#### ***8.2.3.4.b: Signed Physician Referral Forms (at local VPODS)***

Children with high-risk medical conditions not receiving medical care at pediatric clinics that receive vaccine need to be vaccinated at local VPODS. If vaccine supply is limited in the early vaccination period, CDPH recommends requiring signed physician referral forms to verify target group membership. Parents/guardians of children will present a signed physician referral form to vaccine screeners to verify the child's medical

condition. Vaccine screeners will review the form and will also verify the identity of the child by reviewing appropriate documents (e.g., birth certificate, passport, immunization record). CDPH recommends that dispensing sites include triage stations to allow children with physician referral forms to be the first in line to receive vaccine.

#### ***8.2.3.4.c: Self-reported Health Information Forms and Oral Self-report (at local VPODS)***

During a pandemic, if health care providers are overwhelmed and do not have the resources to issue signed physician referral forms for their patients, CDPH recommends parents/guardians of children with high-risk conditions complete self-reported health information forms or answer a series of screening questions to verify their child's health status. LHDs should develop self-reported health information forms or a list of screening questions. Vaccine screeners will either review the forms or ask the screening questions to verify the child's health status. Vaccine screeners will also need to verify the identity of the child by reviewing appropriate documents.

#### **8.2.3.5: Children 3-18 Years without High-risk Medical Conditions Verification Recommendations**

##### ***8.2.3.5.a: Patient Lists (at Pediatric Clinics)***

As with infants and toddlers, the majority of healthy children (3-18 years) should receive vaccine from the pediatric clinics where they receive their seasonal influenza vaccine. Clinic staff will be responsible for setting up and staffing vaccination clinics at their facilities and for developing and maintaining their lists of eligible patients.

##### ***8.2.3.5.b: Oral Self-report (at local VPODS)***

If vaccine supply is still limited in the early vaccination period healthy children may receive vaccine at local VPODS. CDPH recommends using oral-self report as the primary method to verify the age of children. Vaccine screeners will verify target group membership by asking the age of the child. The child and/or parent will self-report (answer the question). No additional documentation (written or oral) will be required for verification.

##### ***8.2.3.5.c: No Verification Method (at local VPODS or traditional health care sites)***

If vaccine supply has expanded in the later vaccination period, the primary goal will be to distribute and dispense vaccine as quickly and efficiently as possible. To achieve this, no target group membership verification method will be required to obtain vaccine; however, LHDs and health care providers will need to verify the identity of individuals receiving vaccine to track vaccine utilization and monitor adverse events.

### **8.2.3.6: High-risk Persons 19-64 Years Verification Recommendations**

#### ***8.2.3.6.a: Self-reported Health Information Forms and Oral Self-report (at local VPODS)***

If vaccine is not available at traditional settings, adults with high-risk medical conditions may receive vaccine at local VPODS. When target group membership verification methods are indicated, CDPH recommends requiring adults to either complete a self-reported health information form or answer a series of screening questions to verify their health status. The screening questions should collect the same information as the health information form.

#### ***8.2.3.6.b: No Verification Required (at local VPODS and/or traditional health care settings)***

If vaccine supply has expanded in the later vaccination period, vaccine will be administered in traditional health care settings similar to seasonal influenza vaccine. The primary goal will be to distribute and dispense vaccine as quickly and efficiently as possible. To achieve this, no target group membership verification method will be required to obtain vaccine; however, LHDs and health care providers will need to verify the identity of individuals receiving vaccine to track vaccine utilization and monitor adverse events.

### **8.2.3.7: High-risk Persons 65 Years and Older (includes all persons 65+) Verification Recommendation**

#### ***8.2.3.7.a: No Verification Method (at traditional health care sites)***

Individuals in this target group will likely receive vaccine in the later pandemic period when vaccine is dispensed in more traditional health care settings. No verification method will be required to allow for quick and efficient vaccine dispensing; however, LHDs and health care providers will need to verify the identity of individuals receiving vaccine to track vaccine utilization and monitor adverse events.

## **8.2.4: VERIFYING HEALTHY GENERAL POPULATION TARGET GROUPS**

### **8.2.4.1: Healthy Adults 19-64 Years not Included in Other Categories Verification Recommendation**

Healthy Adults (19-64 years) will likely receive vaccine in the later pandemic period when vaccine is dispensed in more traditional health care settings. Because supply will be expanded, CDPH recommends less rigorous target group membership verification methods for adults. However, LHDs and health care providers will need to verify the identity of individuals receiving vaccine to track vaccine utilization and monitor adverse events.

## **8.3: DOSING REGIMEN**

### **8.3.1: TWO DOSE SCHEDULE**

The US federal government will make recommendations when a pandemic vaccine becomes available as to whether one or two doses would be required. For the H1N1 pandemic, adults only required 1 dose of vaccine whereas children age nine years and under required 2 doses to confer adequate protection to the influenza virus. Although only one dose for adults for the H1N1 vaccine was required, pandemic plans should be developed for two doses of vaccine administered at a minimum of 21 days apart for both adults and children [8].

### **8.3.2: SEVERE PANDEMIC DOSING REGIMEN RECOMMENDATIONS**

For a severe pandemic with limited vaccine, CDPH recommends, depending on the epidemiological data and vaccine effectiveness, that prioritized role-based and health-vulnerable general population target group members receive second doses of vaccine prior to distributing any first doses to additional members within their target groups.

#### **8.3.2.1: Frontline and Non-frontline Critical Workers Target Groups**

The majority of role-based target groups are highly prioritized (Tiers 1-3) and will likely receive vaccine in the pre-pandemic and early pandemic periods when the demand for vaccine exceeds the supply. Recommending fully vaccinating as many critical workers as possible before proceeding to more target group members protects the vaccinated workers from occupational exposures and reduces transmission in the workplace.

#### **8.3.2.2: Health-vulnerable General Population Target Groups**

Health-vulnerable general population target groups are prioritized in Tiers 1-4 with some groups receiving vaccine in the early vaccination periods and other groups receiving vaccine in the later vaccination period. When the first dose of vaccine provides a low level of protection, in order to ensure protection, the recommendation is to vaccinate Tier 1 target groups who received first doses with the second dose of vaccine before proceeding to additional target groups. Recommending fully vaccinating target group members within the same target group before proceeding to more target members reduces their risks of infection (and influenza complications) and reduces the rate of transmission in the community.

### **8.3.3: RECOMMENDATION IF VACCINE IS WIDELY AVAILABLE**

If vaccine is widely available, then CDPH recommends all target group members be eligible to receive their first or second dose on a first-come, first-serve basis (e.g. those who are first in line or by some other individual dispensing method). This represents the most equitable approach in order to reduce transmission at workplaces and in the community.

### **8.3.4: INITIAL BOLUS OF VACCINE**

The initial release of pandemic influenza vaccine for distribution and administration may consist of an approximately 8-10 week supply. Following the initial supply bolus, vaccine

will be allocated to states at a constant weekly rate [6]. The primary objective for CDPH and LHDs will be to administer this bolus of vaccine as quickly and efficiently as possible. CDPH assumes that local vaccine receiving sites will receive vaccine weekly and therefore, CDPH does not recommend withholding any of the vaccine from the bolus unless there is a reason to reserve doses to protect critical workers and/or health-vulnerable general populations. CDPH acknowledges that some local jurisdictions will dispense their bolus more quickly than others depending on their level of resources.

### **8.3.5: IMPLEMENTING REMINDER-RECALL TRACKING SYSTEMS**

Vaccination sites should implement a system for reminder-recall for the second dose. Reminder-recall interventions can range from passive measures like reminder cards or written follow-up instructions at the time of first vaccination to active measures like follow-up letters, phone call reminders, and home visits. At a minimum, those receiving a first dose of vaccine should receive clear, written instructions on procedures for receiving their second dose [5].

### **8.3.6: PRIORITIZING FIRST AND SECOND DOSES AT VACCINE SITES**

Plans should be developed to prioritize target group members who need either their first or second dose of vaccine when they arrive at the vaccine site. If target group members who have received first doses do not report back in a timely manner for the second dose, they will be able to receive their second dose on a first come, first serve basis when they do come back. Vaccine sites may want to designate certain hours for first doses versus second doses.

## **9: MONITORING VACCINE UTILIZATION AND ADVERSE EVENTS**

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This section presents recommendations for developing systems to track pre-pandemic and pandemic vaccine utilization (e.g., that appropriate target groups are being targeted for and receiving vaccine) and for monitoring adverse events.

### **9.1: MONITORING VACCINE UTILIZATION**

During an influenza pandemic there will be a need to collect, manage and analyze information about vaccine utilization to ensure that the appropriate priority groups are being targeted for and are receiving vaccine according to established guidelines. This will be accomplished by tracking vaccine doses administered through the CDC's Countermeasure and Response Administration system (CRA).<sup>9</sup> [5].

Although the CRA is operated and maintained at the federal level, it depends on state and local participation and reports from vaccine administration sites to successfully perform its monitoring functions. CDPH will establish a statewide CRA database and

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<sup>9</sup> CRA is an electronic system designed to accept and process aggregate counts of pre-pandemic and pandemic influenza vaccine doses administered by tracking a set of minimum data elements.

LHDs will have the primary responsibility for data entry. CDPH recommends that LHDs develop electronic tracking systems if possible to facilitate reporting to CDPH. However, if an electronic system for vaccine tracking is not feasible then a back-up paper system can be used. This paper system should include the same required CRA data elements as the electronic system. The CRA minimum aggregated data elements that must be transmitted to CDC include: project area identification, date of vaccination, priority group designation, and dose number (e.g., first or second dose).<sup>10</sup>

As pandemic influenza vaccine supplies increase, vaccine administration will shift to a broader range of locations to include more traditional health care settings (e.g., doctors' offices, pharmacies, outpatient clinics). Once the number of persons vaccinated is large enough to be detected on a national survey CRA will be stopped and a population-based survey system will be utilized to monitor coverage [5].

## 9.2: TRACKING ADVERSE EVENTS

CDPH will use the Vaccine Adverse Events Reporting System (VAERS) to track adverse vaccine reactions. Health providers, patients, and vaccine manufacturers will report serious adverse events on paper forms, by telephone, or electronically. CDPH, in conjunction with LHDs, will analyze the VAERS and other reports of serious adverse events to determine whether such events are reported more frequently than expected. CDPH will analyze signals of potential vaccine-associated events for biologic plausibility and may conduct epidemiologic studies to assess possible causation. CDPH may supplement the VAERS with additional surveillance and studies (e.g., active surveillance for adverse events in a sample of vaccine recipients.)

## 10: CONCLUSION

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The goal of this guidance is to present a realistic approach to a large-scale vaccination program with recommendations that are flexible and can be implemented by local pandemic planners under a variety of conditions and over an extended period of time. Implementing a vaccination program of this magnitude and duration requires close collaboration with all pandemic response planners including: public health, public safety, medical care, emergency management, government, business and volunteers at the federal, state and local levels.

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<sup>10</sup> Source: CDC Novel H1N1 Vaccination Planning Q&A. Available at: [www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm](http://www.cdc.gov/h1n1flu/vaccination/statelocal/qa.htm)

## 11: REFERENCES

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<sup>11</sup> Document no longer available on federal websites

<sup>12</sup> CDPH was part of a federal vaccine task force in which these documents were created for the workgroup only and are not available for distribution.

# APPENDIX A: PLANNING ACTIONS FOR LOCAL PANDEMIC PLANNERS

## A.1: INTRODUCTION

Appendix A presents a summary and action steps to assist local pandemic planners in implementing the vaccination recommendations issued in the CDPH Vaccine Implementation Guidance: Core Document. Table A.1 presents a summary of the implementation issues. Starting with Table A.2 are a series of tables, with action steps that can help local pandemic planners develop an implementation plan for their LHD.

**Table A.1 – Summary of CDPH Vaccine Implementation Issues, Recommendations, and Pandemic Planning Partners**

Implementation Issue	Recommendations	Pandemic Planning Partners
Vaccine Distribution (Table A.2)	<ul style="list-style-type: none"> <li>All Recommendations</li> </ul>	<ul style="list-style-type: none"> <li>Federal Government</li> <li>CDPH</li> <li>Local Health Departments</li> </ul>
Allocation Approach (Table A.3)	<ul style="list-style-type: none"> <li>Pre-planning</li> <li>No Allocation Approach</li> <li>Hybrid Allocation</li> </ul>	<ul style="list-style-type: none"> <li>CDPH</li> <li>Local Health Departments</li> <li>Critical Infrastructure Organizations</li> </ul>
Vaccine Administration Strategies (Table A.4)	<ul style="list-style-type: none"> <li>All Recommendations</li> </ul>	<ul style="list-style-type: none"> <li>CDPH</li> <li>Local Health Departments</li> <li>Critical Infrastructure/Key Resource Organizations</li> </ul>
Role-based Target Group Membership Verification Methods (Table A.5)	<ul style="list-style-type: none"> <li>Lists of Employees</li> </ul>	<ul style="list-style-type: none"> <li>Local Health Departments</li> <li>Critical Infrastructure/Key Resource Organizations</li> <li>Target Group Members</li> </ul>
Health-vulnerable General Populations and Healthy General Populations Target Group Membership Verification Methods (Table A.6)	<ul style="list-style-type: none"> <li>Patient Lists</li> <li>Signed Physician Referral Forms</li> <li>Self-reported Health Information Forms</li> <li>Written Documentation of Age</li> <li>Vaccinating Household Contacts of Infants &lt;6 Month Prior to Expected Date of Delivery</li> <li>Oral Self-report</li> <li>No Verification Required</li> </ul>	<ul style="list-style-type: none"> <li>CDPH</li> <li>Local Health Departments</li> <li>Health Care Providers</li> <li>Target Group Members</li> </ul>
Dosing Regimen (Table A.7)	<ul style="list-style-type: none"> <li>Plan for Two Doses</li> </ul>	<ul style="list-style-type: none"> <li>CDPH</li> <li>Local Health Departments</li> <li>Target Group Members</li> </ul>

<b>Implementation Issue</b>	<b>Recommendations</b>	<b>Pandemic Planning Partners</b>
Monitoring Vaccine Utilization (Table A.8)	<ul style="list-style-type: none"> <li>• Designate vaccine tracking coordinator</li> <li>• Ensure staff are trained on data collection and reporting, including non-LHD vaccine providers</li> <li>• Develop capability to transmit weekly to CDPH vaccine doses administered in LHD jurisdiction</li> </ul>	<ul style="list-style-type: none"> <li>• CDPH</li> <li>• Local Health Departments</li> <li>• Critical Infrastructure/Key Resource Organizations</li> </ul>
Tracking Adverse Events (Table A.9)	<ul style="list-style-type: none"> <li>• Designate vaccine coordinator to implement adverse events reporting</li> <li>• Provide outreach to providers administering vaccine on reporting adverse events</li> </ul>	<ul style="list-style-type: none"> <li>• CDPH</li> <li>• Local Health Departments</li> <li>• Health Care Providers</li> <li>• Critical Infrastructure/Key Resource Organizations</li> </ul>

The following steps should be done to facilitate distribution of vaccine from manufacturers to local health jurisdictions.

**Table A.2 – Vaccine Distribution**

Federal Government Planning Actions	California Department of Public Health (CDPH) Planning Actions	Local Health Department (LHD) Planning Actions
<ul style="list-style-type: none"> <li>• Coordinate vaccine distribution from vaccine manufacturers directly to designated sites according to information received from CDPH.</li> <li>• May distribute needles, syringes, and vaccine ancillary supplies to state and local health jurisdictions.</li> </ul>	<ul style="list-style-type: none"> <li>• Estimate California’s weekly allocation of vaccine based on vaccine availability assumptions and the state’s proportion of the US population.</li> <li>• Determine the proportion of vaccine that will be apportioned to each LHD.</li> <li>• Maintain list of California vaccine receiving sites and provide necessary distribution information to CDC.</li> <li>• Develop and disseminate to LHDs plans and procedures for state-level tracking of vaccine receipt and dosages administered.</li> <li>• Develop procedures for LHDs to distribute to local receiving sites for receiving, storing, maintaining cold chain for vaccine, and tracking dosages administered.</li> </ul>	<ul style="list-style-type: none"> <li>• Determine the proportion of the overall local allocation of vaccine that will be apportioned to each vaccine receiving site.</li> <li>• Distribute CDPH procedures to vaccine receiving sites for documentation of vaccine receipt, storage, cold chain, reporting adverse reaction, and tracking dosages administered.</li> <li>• Ensure the availability of sufficient storage capacity at all vaccine receiving sites to maintain the cold chain before authorizing a site to receive vaccine.</li> <li>• Develop plans for distributing needles and syringes and other ancillary supplies to local vaccine dispensing sites, if not available federally.</li> <li>• Develop security plans for vaccine receiving sites and dispensing sites.</li> <li>• If vaccine re-distributed from LHD to another vaccine receiving site, develop chain of custody and other procedures to maintain accountability for vaccine during the distribution process.</li> </ul>

The following pre-planning actions should be done **prior to implementing either allocation approach.**

**Table A.3 – Vaccine Allocation**

CDPH Planning Actions	LHD Planning Actions	Critical Infrastructure/Key Resource (CI/KR) Organizations Planning Actions <sup>a</sup>
<ul style="list-style-type: none"> <li>Estimate allocation of weekly vaccine shipments to local health jurisdictions based on vaccine supply and local population proportions within the state.</li> </ul>	<ul style="list-style-type: none"> <li>Obtain CDPH allocation estimate of weekly vaccine shipments for local health jurisdiction.</li> <li>Develop population estimates for role-based target groups.</li> <li>Identify organizations that include members of priority groups and obtain estimates of members from these organizations.</li> <li>Compile regional or local demographics data to develop population estimates for health-vulnerable and healthy general population target groups.</li> <li>Determine overall relative allocations for vaccine receiving sites and administration sites (public health run clinics, workplace clinics, health care providers, etc.) in your jurisdiction.</li> </ul>	<ul style="list-style-type: none"> <li>Contact the LHD in your jurisdiction to identify your organization as a critical infrastructure/key resource (CI/KR) organization.</li> <li>Estimate the number of critical workers within your organization.</li> </ul>

No Allocation Approach		
CDPH Planning Actions	LHD Planning Actions	CI/KR Organizations Planning Actions
<ul style="list-style-type: none"> <li>No additional planning actions required.</li> </ul>	<ul style="list-style-type: none"> <li>No additional planning actions required.</li> </ul>	<ul style="list-style-type: none"> <li>No additional planning actions required.</li> </ul>

<sup>a</sup> Critical Infrastructure/Key Resource Organizations include large health care organizations (inpatient care facilities, outpatient clinics, long term care facilities), frontline responder agencies, community organizations, and large businesses that provide essential community services during a pandemic.

Hybrid Allocation Approach		
CDPH Planning Actions	LHD Planning Actions	CI/KR Organizations Planning Actions
<ul style="list-style-type: none"> <li>Develop sub-prioritization recommendations for CDPH target groups in prioritization Tiers 1-3.</li> </ul>	<ul style="list-style-type: none"> <li>Obtain CDPH sub-prioritization recommendations for target groups in prioritization Tiers 1-3.</li> <li>Develop proportionate allocation estimates for each target group within a sub-prioritization level.</li> <li>Develop allocation plans that allow for splitting vaccine supply (incoming shipments of vaccine) to target groups within a tier or sub-prioritization level based on their population proportions.</li> </ul>	<ul style="list-style-type: none"> <li>No additional planning actions required.</li> </ul>

The following planning actions should be done **prior to implementing any of the vaccine administration strategies.**

**Table A.4 – Vaccine Administration**

CDPH Planning Actions	LHD Planning Actions	CI/KR Organizations Planning Actions
<ul style="list-style-type: none"> <li>• Update vaccination plans and identify local vaccine dispensing sites for the following target groups, when state and federal guidance becomes available.               <ul style="list-style-type: none"> <li>○ California National Guard Personnel stationed in California.</li> <li>○ Critical State Government Workers.</li> <li>○ Federal Government Workers employed in California</li> </ul> </li> <li>• May develop and maintain web domain registration site for all providers, agencies, and pharmacies that want to establish pandemic influenza vaccination clinics for their populations or responsibility may be at the local level.</li> </ul>	<ul style="list-style-type: none"> <li>• As part of advance planning:               <ul style="list-style-type: none"> <li>○ Develop a registration process for health care providers to indicate interest in independently establishing vaccination clinics.</li> <li>○ Identify and verify all potential health care vaccine providers (e.g., medical licensure, target populations served, and estimated number for target population.)</li> <li>○ If vaccine prioritized, establish how to target specific groups. (E.g., setting up triage stations to identify target population or designating days of the week/hours of operation for specific target groups to report to vaccine sites.)</li> </ul> </li> <li>• Identify sites and develop plans and procedures for establishing public health run vaccine point of dispensing sites (VPODS) in your jurisdiction. (E.g., schools to vaccinate children, secondary sites to vaccinate eligible outpatient and home health care staff.)               <ul style="list-style-type: none"> <li>○ Determine specific populations that will be targeted for vaccination and estimate sizes of target groups to be served at each VPODS.</li> <li>○ Develop operational plans for staffing, security, and additional resources for each VPODS.</li> <li>○ VPODS operational plans should include strategies for vaccinating role-based target group members as well as health-vulnerable and general population target group members in the same locations.</li> </ul> </li> <li>• Identify CI/KR organizations in your jurisdiction with the capacity to independently establish workplace vaccination clinics.</li> <li>• Identify CI/KR organizations in your jurisdiction that do not have the capacity to independently establish vaccination clinics and work with these organizations to develop plans</li> </ul>	<p><b>Organizations with capacity to vaccinate employees onsite</b></p> <ul style="list-style-type: none"> <li>• Work with LHD to develop plans and procedures for establishing vaccination clinics at your worksite including identifying clinic space, hiring vaccinators, and training vaccine screeners.</li> <li>• Estimate for LHD number of critical employees that will be vaccinated.</li> <li>• Pre-identify a point-of-contact at your organization that will be responsible for ensuring all eligible staff are vaccinated and reporting vaccine utilization information to LHD.</li> </ul> <p><b>Organizations that lack capacity to vaccinate employees onsite</b></p> <ul style="list-style-type: none"> <li>• Work with LHD to develop plans and procedures for either establishing workplace vaccination sites or administering vaccine to your employees at VPODS with the assistance of local public health resources.</li> <li>• Estimate for LHD total number of critical employees that will be vaccinated.</li> <li>• Pre-identify a point-of-contact at your organization that will be responsible for ensuring all eligible staff are vaccinated.</li> </ul> <p><b>Outpatient clinics that vaccinate patients for seasonal influenza</b></p> <ul style="list-style-type: none"> <li>• Work with LHD to develop plans and procedures for establishing vaccination clinics at your facility including identifying clinic space, hiring vaccinators, and training vaccine screeners.</li> </ul>

CDPH Planning Actions	LHD Planning Actions	CI/KR Organizations Planning Actions
	<p>for administering vaccine to their employees either at their worksites or at local VPODS with the assistance of local public health resources.</p> <ul style="list-style-type: none"> <li>• Identify clinical providers and health systems in your jurisdiction that vaccinate patients for seasonal influenza (e.g. pediatricians, family physicians, OBGYNs, internists, HMOs, hospitals and outpatient care facilities).</li> <li>• Identify institutions/organizations in your community with the capacity to vaccinate general population target groups (e.g. college and university health centers, military bases, VA clinics, Indian Health Service and tribal clinics.)</li> </ul>	<ul style="list-style-type: none"> <li>• Provide LHD with total number of eligible patients that will be vaccinated.</li> <li>• Pre-identify a point-of-contact at your facility that will be responsible for ensuring all eligible patients are vaccinated and reporting vaccine utilization information to LHD.</li> </ul>

**Table A.5 – Role-based Target Group Membership Verification**

Employee Lists (at workplace and targeted dispensing clinics)		
LHD Planning Actions	CI/KR Organizations Planning Actions	Target Group Members Planning Actions
<ul style="list-style-type: none"> <li>• Inform CI/KR organizations in your jurisdiction that they will be responsible for developing and maintaining their lists of employees and for ensuring that all eligible staff receive vaccine.</li> <li>• Inform CI/KR organizations that they will be responsible for informing their employees when and where to report for vaccination and to bring proper documentation to verify identity.</li> <li>• Inform CI/KR organizations that they will be responsible for providing vaccine screeners at dispensing sites to verify their employees are eligible to receive vaccine.</li> <li>• Notify CI/KR organizations when vaccine becomes available for their eligible employees.</li> </ul>	<ul style="list-style-type: none"> <li>• Pre-identify a staff member that will be responsible for developing and maintaining your list of critical employees and ensuring that all eligible staff receive vaccine.</li> <li>• Develop a system to pre-identify critical workers in your organization.</li> <li>• Determine the type of documentation that will be required for employees to provide at vaccination clinics to verify their employment status and target group membership. (Appropriate documentation could include employee identification cards, vouchers, pay stubs, etc.)</li> <li>• Develop communication messages for your employees notifying them when and where to report for vaccination and informing them to bring proper documentation to verify identity and target group membership.</li> <li>• Identify vaccine screening staff and develop materials to train staff in the appropriate verification methods.</li> <li>• Provide lists and screening instructions to vaccine screening staff at vaccine dispensing sites.</li> </ul>	<ul style="list-style-type: none"> <li>• Bring proper identification documents to vaccine dispensing sites to verify identity and tracking number of doses.</li> </ul>

**Table A.6 – Health-vulnerable General Population Membership Verification**

Patient Lists (at outpatient clinics) <sup>b</sup>			
CDPH Planning Actions	LHD Planning Actions	Health Care Providers/Outpatient Clinic Staff Planning Actions	Target Group Members Planning Actions
<ul style="list-style-type: none"> <li>Develop and maintain statewide list of health care providers that will establish pandemic influenza vaccination clinics.</li> </ul>	<ul style="list-style-type: none"> <li>Identify outpatient clinics in your jurisdiction that vaccinate patients for seasonal influenza and develop plans to designate vaccine to be delivered to staff at these clinics.</li> <li>Inform outpatient clinics in your jurisdiction that they will be responsible for developing and maintaining their lists of patients eligible to receive vaccine.</li> <li>Inform outpatient clinics that they will be responsible for informing their patients when and where to report for vaccination and to bring proper identification to verify identity and target group membership.</li> <li>Inform outpatient clinics that they will be responsible for providing vaccine screeners at dispensing sites to verify their patients are eligible to receive vaccine.</li> </ul>	<ul style="list-style-type: none"> <li>Pre-identify a staff member that will be responsible for developing and maintaining your list of eligible patients.</li> <li>Develop a system to pre-identify eligible patients in your practice.</li> <li>Develop communication messages for your patients notifying them when and where to report for vaccination and informing them to bring proper documentation to verify identity and target group membership.</li> <li>Identify vaccine screening staff and vaccinators.</li> <li>Develop materials to train staff in the appropriate verification methods.</li> <li>Provide lists and screening instructions to vaccine screening staff at vaccine dispensing sites.</li> </ul>	<ul style="list-style-type: none"> <li>Bring proper identification documents to vaccine dispensing sites to verify identity and health status.</li> </ul>

<sup>b</sup> Outpatient clinics can include: prenatal clinics, birthing clinics, specialty clinics, pediatric clinics (both VFC and non-VFC) providers, and outpatient facilities.

Signed Physician Referral Form			
CDPH Planning Actions	LHD Planning Actions	Health Care Providers Planning Actions	Target Group Members Planning Actions
<ul style="list-style-type: none"> <li>• Develop a template/sample physician referral (written form) for health care providers to complete. <sup>c</sup></li> <li>• Post on site(s) accessible to physicians.</li> </ul>	<ul style="list-style-type: none"> <li>• Use State template or develop a physician referral form (written referral form) for health care providers to complete.</li> <li>• Distribute written physician referral form to all health care providers in your jurisdiction and provide form online prior to pandemic vaccine availability.</li> <li>• Develop risk communication messages for health care providers in your jurisdiction informing them to provide signed physician referral forms for health-vulnerable populations to receive vaccine during a pandemic.</li> <li>• Develop risk communication messages informing persons with health-vulnerable <sup>d</sup> conditions to bring a signed physician referral form to the vaccine dispensing site to receive vaccine.</li> <li>• Develop training protocols and train vaccine screening staff in reviewing referrals to verify identity and target group membership for pregnant women and household contacts of infants &lt;6 months.</li> <li>• Develop training protocols and train vaccine screening staff in reviewing signed physician referral forms to verify an individual's health status.</li> </ul>	<ul style="list-style-type: none"> <li>• Complete signed physician referral forms for eligible patients.</li> <li>• Provide referral to family of pregnant women.</li> <li>• When vaccine becomes available for target group members, mail/email physician referral forms to your patients indicating that they qualify for vaccine and that they should report to a vaccine dispensing site to receive it.</li> </ul>	<ul style="list-style-type: none"> <li>• Obtain a signed physician referral forms from your health care provider prior to pandemic vaccine availability.</li> <li>• Bring signed physician referral forms and proper identification documents to vaccine dispensing sites to verify identity and health status.</li> </ul>

<sup>c</sup> Written physicians referral form should include standard patient information such as name of patient, medical condition, name of attending physician, year of diagnosis (or date of delivery), and list of medications.

<sup>d</sup> Health-vulnerable persons includes the following: pregnant women, infants and toddlers, household contacts of infants and toddlers, all children 3-18 years, high risk persons 19-64 years, and all persons 65 years and older.

Self-reported Health Information Forms			
CDPH Planning Actions	LHD Planning Actions	Health Care Providers Planning Actions	Target Group Members Planning Actions
<ul style="list-style-type: none"> <li>• Develop a template/sample health information form for individuals to complete at vaccine dispensing sites.<sup>e</sup></li> <li>• Post template on website.</li> </ul>	<ul style="list-style-type: none"> <li>• Use State template or develop a health information form for individuals to complete at vaccine dispensing sites.</li> <li>• Disseminate forms online prior to pandemic vaccine availability and make them available at vaccine dispensing sites.</li> <li>• Develop risk communication messages to inform health-vulnerable persons to complete self-reported health information forms and provide them to vaccine screeners at the vaccine dispensing site to receive vaccine.</li> <li>• Develop training protocols and train vaccine screening staff in reviewing health information forms to verify an individual's health status.</li> </ul>	<ul style="list-style-type: none"> <li>• No planning actions required.</li> </ul>	<ul style="list-style-type: none"> <li>• Complete self-reported health information form either online or at vaccine dispensing sites.</li> <li>• Bring proper identification documents to vaccine dispensing sites to verify identity and health status.</li> </ul>

<sup>e</sup> Forms should include standard patient information such as name of patient, medical condition, name of attending physician, year of diagnosis, and list of medications.

<b>Written Documentation of Age</b>			
<b>CDPH Planning Actions</b>	<b>LHD Planning Actions</b>	<b>Health Care Providers Planning Actions</b>	<b>Target Group Members Planning Actions</b>
<ul style="list-style-type: none"> <li>No planning actions required</li> </ul>	<ul style="list-style-type: none"> <li>Develop training protocols and train vaccine screening staff in reviewing appropriate documents to verify the age of infants and toddlers. <ul style="list-style-type: none"> <li>Documents could include: birth certificates, passports, immunization records, etc.</li> </ul> </li> <li>Develop risk communication messages for parents of children informing them to bring proper identification documents to verify the age of their child.</li> </ul>	<ul style="list-style-type: none"> <li>No planning actions required.</li> </ul>	<ul style="list-style-type: none"> <li>Bring proper identification documents to vaccine dispensing sites to verify identity and age of child.</li> </ul>
<b>Vaccine Household Contacts of Pregnant Women and Infants &lt;6 Months prior to Expected Date of Delivery</b>			
<b>CDPH Planning Actions</b>	<b>LHD Planning Actions</b>	<b>Health Care Providers Planning Actions</b>	<b>Target Group Members Planning Actions</b>
<ul style="list-style-type: none"> <li>Recommend vaccinating household contacts of pregnant women prior to expected date of delivery.</li> </ul>	<ul style="list-style-type: none"> <li>Identify health care providers in your jurisdiction that provide pre-natal and birthing services to pregnant women.</li> <li>Develop and disseminate risk communication messages to household contacts of pregnant women informing them to receive vaccine from their health care providers prior to the birth of the child.</li> <li>Develop and disseminate risk communications messages for health care providers at outpatient care facilities to inform them that household contacts of pregnant women should receive vaccine prior to the birth of the child.</li> </ul>	<ul style="list-style-type: none"> <li>Pre-identify a staff member that will be responsible for managing the vaccination program at the health care facility.</li> <li>Establish vaccine dispensing sites to vaccinate household contacts of pregnant women before the expected date of delivery.</li> <li>Develop communication messages for your patients and their families notifying them when and where to report for vaccination and informing them to bring proper documentation to verify identity.</li> <li>Identify vaccine screening staff and develop materials to train staff in the appropriate verification methods.</li> <li>Provide screening instructions to vaccine screening staff at vaccine dispensing</li> </ul>	<ul style="list-style-type: none"> <li>Bring proper identification documents to vaccine dispensing sites to verify identity.</li> </ul>

		sites.	
<b>Oral Self report</b>			
<b>CDPH Planning Actions</b>	<b>LHD Planning Actions</b>	<b>Health Care Providers Planning Actions</b>	<b>Target Group Members Planning Actions</b>
<ul style="list-style-type: none"> <li>• Develop a template/sample list of screening questions for individuals to answer at the VPODS.<sup>f</sup></li> <li>• Post template on website.</li> </ul>	<ul style="list-style-type: none"> <li>• Use State template or develop a list of screening questions for individuals to answer at the vaccine dispensing sites.</li> <li>• Make a list of screening questions available prior to pandemic vaccine availability and at vaccine dispensing clinics.</li> <li>• Develop risk communication messages to inform health-vulnerable persons that they need to answer a series of screening questions at the vaccine dispensing site to receive vaccine.</li> <li>• Develop training protocols and train vaccine screening staff in asking screening questions to verify an individual's health status.</li> </ul>	<ul style="list-style-type: none"> <li>• No planning actions required.</li> </ul>	<ul style="list-style-type: none"> <li>• Answer screening questions at vaccine dispensing sites.</li> <li>• Bring proper identification documents to vaccine dispensing sites to verify identity.</li> </ul>
<b>No Verification Required</b>			
<b>CDPH Planning Actions</b>	<b>Local Health Department (LHD) Planning Actions</b>	<b>Health Care Providers Planning Actions</b>	<b>Target Group Members Planning Actions</b>
<ul style="list-style-type: none"> <li>• No planning actions required.</li> </ul>	<ul style="list-style-type: none"> <li>• No planning actions required.</li> </ul>	<ul style="list-style-type: none"> <li>• No planning actions required.</li> </ul>	<ul style="list-style-type: none"> <li>• Bring proper identification documents to vaccine dispensing sites to verify identity.</li> </ul>

<sup>f</sup> Screening questions should include same information as self-reported health information forms such as name of patient, medical condition, name of attending physician, year of diagnosis, and list of medications.

**Table A.7 – Dosing Regimen**

Two Dose Regimen		
CDPH Planning Actions	LHD Planning Actions	Target Group Members Planning Actions
<ul style="list-style-type: none"> <li>• Develop recommendations for target groups based on the effectiveness of the vaccine and preliminary epidemiological data for specific target groups.</li> </ul>	<ul style="list-style-type: none"> <li>• Develop plans and procedures assuming two doses of vaccine will be required to confer protection.</li> <li>• Example for severe pandemic with limited vaccine:               <ul style="list-style-type: none"> <li>○ Develop plans and procedures for target group members who received first dose of vaccine to receive second dose of vaccine before vaccinating additional target group members.</li> <li>○ Develop risk communication messages for vaccine providers, frontline responders, non-frontline responders, and the general public informing them that it will take two doses of vaccine to be effective.</li> </ul> </li> <li>• Develop reminder-recall systems to remind individuals to report to the vaccination site to receive their second doses.</li> </ul>	<ul style="list-style-type: none"> <li>• Return to the vaccine dispensing sites at the appropriate time to receive your second dose of vaccine.</li> </ul>

The following planning actions should be done to ensure that designated target groups are receiving vaccine.

**Table A.8 – Monitoring Vaccine Utilization**

Federal Government Planning Actions	CDPH Planning Actions	LHD and/or CI/KR Organizations Planning Actions
<ul style="list-style-type: none"> <li>• Develop and maintain the Countermeasure and Response Administration System (CRA) to track vaccine utilization.</li> <li>• Collect and analyze national vaccine utilization data.</li> <li>• When vaccine supplies increase, develop a population-based survey to monitor vaccine uptake.</li> <li>• Inform states of the transition from CRA to population-based studies.</li> </ul>	<ul style="list-style-type: none"> <li>• Establish statewide pre-pandemic and pandemic vaccine database.</li> <li>• Collect and analyze statewide vaccine utilization data.</li> <li>• Produce weekly reports of vaccine doses administered and send information to federal government.</li> <li>• Provide technical assistance as needed to local health departments on vaccine reporting requirements.</li> </ul>	<ul style="list-style-type: none"> <li>• Designate a vaccine tracking coordinator to be the local-level planning and operational lead and subject matter expert on reporting doses administered.</li> <li>• Ensure vaccine dispensing site staff are trained on the data collection and CDPH reporting requirements.</li> <li>• Develop plans and procedures for data collection, storage, security, and maintenance.</li> <li>• Develop capability to produce and transmit at least weekly reports of pre-pandemic and pandemic influenza vaccine doses administered to CDPH.<sup>9</sup></li> <li>• Ensure vaccine administration staff have the training and resources to report on doses administered.</li> </ul>

<sup>9</sup> LHDs should collect the following information: vaccine lot number, date of vaccination, target group designation, and dose number (first or second dose).

The following planning actions should be done to ensure timely reporting of vaccine adverse events.

**Table A.9 – Tracking Adverse Events**

Federal Government Planning Actions	CDPH Planning Actions	LHD Planning Actions
<ul style="list-style-type: none"> <li>• Maintain the Vaccine Adverse Events Reporting System (VAERS) to track adverse vaccine reactions.</li> </ul>	<ul style="list-style-type: none"> <li>• Analyze VAERS data.</li> <li>• Produce supplementary studies of adverse events reports of adverse events and share with stakeholders.</li> <li>• Provide direct and website technical assistance as needed to local health departments on VAERS reporting requirements.</li> <li>• Provide outreach via website to CI/KR organizations administering vaccine on reporting adverse events.</li> </ul>	<ul style="list-style-type: none"> <li>• Designate a local coordinator to plan for and implement adverse events reporting and outreach to and education of providers and who will serve as the local point of contact with CDPH staff overseeing the VAERS.</li> <li>• Provide outreach to health care providers and CI/KR organizations administering pandemic vaccine on reporting vaccine adverse events.</li> <li>• Reviewing procedures for and familiarizing program staff with the strengths, limitations, and objectives of VAERS.</li> </ul>

## APPENDIX B: DISCUSSION OF ALLOCATION APPROACH RECOMMENDATIONS

### B.1: INTRODUCTION

“Allocation approach” refers to the method that could be used to divide incoming shipments of vaccine to equally prioritized target groups within prioritization tiers. Appendix B provides detailed descriptions, examples and rationales for the CDPH allocation recommendations. Table B.1 presents the CDPH recommended vaccine allocation approaches by vaccination period and vaccine supply using less than or equal to or greater than 3 million doses as an example.

**Table B.1 – CDPH Recommended Vaccine Allocation Approaches by Vaccination Period**

Vaccination Period	Vaccine Supply	Recommendation
<b>Pre-pandemic Vaccination Period</b>	≥ 3 million CA doses (total) <sup>1,2</sup>	• No Allocation Approach
	<3 million CA doses (total)	• Hybrid Allocation Approach
<b>Early Pandemic Vaccination Period</b>	≥ 3 million CA doses per week <sup>3</sup>	• No Allocation Approach
	<3 million CA doses per week	• Hybrid Allocation Approach: (1) Sub-prioritization by Target Group Type (2) Proportionate Allocation
<b>Later Pandemic Vaccination Period</b>	≥ 3 million CA doses per week	• No Allocation Approach

<sup>1</sup> Pre-pandemic vaccine is recommended for all critical role-based workers in CDPH Prioritization Tier 1. The total pre-pandemic vaccine supply required to vaccinate these workers is 1.5 million 2-dose courses or 3 million total doses.

<sup>2</sup> For planning purposes, “total” implies there may be in the pre-pandemic period a stockpile with a fixed amount and this may be different than the weekly allocation after the stockpile is distributed.

<sup>3</sup> California weekly vaccine supply estimate is based on CDC vaccine supply scenario of expanded vaccine supply (e.g., 25 million US doses per week). For planning purposes, weekly allotments of vaccine may increase overtime. Reference: US Department of Health and Human Services. “Update: Status of pandemic influenza vaccine manufacturing capacity, pre-pandemic stockpile, and planning for vaccine distribution.” February 2009, unpublished.

### B.2: DESCRIPTION: NO ALLOCATION APPROACH

- This approach is recommended for the following vaccination periods:
  - Pre-pandemic vaccination period: when vaccine supply is sufficient to cover Tier 1 role-based target groups (e.g., ≥3 million CA doses in total).
  - Early and Later pandemic vaccination period: when supply is widely available (≥3 million doses per week).
- If there is sufficient vaccine supply to cover all target group members in a single prioritization tier then no allocation approach is necessary. Local health

departments (LHDs) will not need to designate dividing incoming shipments of vaccine to equally prioritized target groups within a tier.

- Vaccine will be distributed and dispensed to designated target group members on a first-come, first-serve basis.

### **B.3: DESCRIPTION: HYBRID ALLOCATION APPROACH**

- This approach is recommended for the following vaccination periods:
  - Pre-pandemic vaccination period: when vaccine supply is not sufficient to cover tier 1 role-based target groups (e.g., <3 million CA doses in total).
  - Early pandemic vaccination period: when demand is greater than supply for a prioritization tier (<3 million doses per week).

#### **B.3.1: STEP 1. SUB-PRIORITIZATION**

- Target groups within Tier 1 are sub-prioritized with several target groups included in one sub-prioritization level.
  - Including several role-based target groups within a sub-prioritization level will ensure that target groups who rely on one another to provide critical services will receive vaccine at the same time.
  - Including several health-vulnerable target groups within a sub-prioritization level will ensure that target groups with comparable risks of severe illness and death will have equal access to the vaccine.

#### **B.3.2: STEP 2. PROPORTIONATE ALLOCATION**

- Incoming shipments of vaccine should be divided proportionately amongst the target groups within a sub-prioritization level and administered until all of the target groups in the sub-prioritization level are vaccinated.
  - Proportionate coverage is equal to the size of the target group relative to the size of the sub-prioritization level.
  - Those groups that represent a larger proportion of the sub-prioritization level (e.g., have a greater number of target group members) should receive more vaccine from each shipment.

## B.4: EXAMPLE: HYBRID ALLOCATION APPROACH

This section presents a theoretical example of the hybrid allocation approach for the early pandemic vaccination period assuming vaccine supply is “somewhat limited” (1 million CA doses per week). **Note: sup-prioritization groups and allocations are likely to differ from this example.**

Tables B.2 and B.3 present examples of how vaccine could be allocated under the hybrid option with somewhat limited vaccine supply. **Note: These examples include a subset of target groups from CDPH prioritization Tier 1. Target group population estimates are simulated.**

- Target groups in Tier 1 will be sub-prioritized into two levels.
- In this example, sub-prioritization levels are based on target group types (e.g., role-based versus health-vulnerable general population target groups).
- Sub-prioritization Level A is comprised of the role-based target groups in Tier 1 who rely on one another to provide critical services to carry out a pandemic emergency response.
  - Sub-prioritization Level A includes: critical public health personnel, critical medical care personnel, and critical public safety personnel.
- Sub-prioritization Level B is comprised of several health-vulnerable general population groups in Tier 1 who face high-risks of severe illness and death if infected with influenza.
  - Sub-prioritization Level B includes: pregnant women and infants and toddlers.
- Assume vaccine supply equals 1 million doses per week.
- Week 1 supply (1 million doses) should be divided amongst the three groups based on their population proportion within Sublevel A. (Table B.2)
  - Critical public health personnel comprise 2.5% of Sublevel A and should receive 2.5% of the weekly vaccine supply (25,000 doses).
  - Critical medical care personnel comprise 78% of Sublevel A and should receive 78% of the weekly vaccine supply (780,000 doses).
  - Critical public safety workers should receive 19.5% of the weekly vaccine supply (195,000 doses).
- After week 1 approximately 70% of each target group in sub-prioritization level A should have received one dose of vaccine.

- This allocation process can be repeated with each incoming shipment until all three target groups in sub-prioritization level A are vaccinated. Once this occurs, allocation can begin for sub-prioritization Level B in Tier 1. (Table B.3)
- Week 2 supply (1 million doses) should be provided first to the remainder of the target groups in sublevel A.
  - Critical public health personnel should receive an additional 11,000 doses.
  - Critical medical care personnel should receive an additional 320,000 doses.
  - Critical public safety workers should receive an additional 80,000 doses.
- By the end of Week 2 100% of all three groups in Sublevel A should have received one dose of vaccine
- The remainder of the Week 2 vaccine supply (589,000 doses) should be divided amongst the two groups in Sublevel B based on their population proportions
  - Pregnant women should receive 29% of the remaining weekly vaccine supply (170,810 doses).
  - Infants and toddlers should receive 71% of the remaining weekly vaccine supply (418,190 doses).
- By the end of Week 2, 31% of each target group, respectively, in Sub-prioritization Level B should have received one dose of vaccine.
- In Week 3, all 1,000,000 doses will be allocated to the remaining Level B population ( $1,930,000 - 589,000 = 1,341,000$ ), at a rate of 74.5% ( $1,000,000/1,341,000$ ) to each of the subpopulations ( $.745 \times 951,810 \approx 709,000$  and  $.745 \times 389,190 \approx 289,000$ ) leaving 343,000 to be vaccinated in week 4.
- Under this scenario (assuming a constant weekly vaccine supply) it will take approximately 4 weeks for all target groups within Tier 1 to receive one dose of the vaccine.

**Table B.2 – Week 1 Example of Hybrid Option allocating proportional coverage for somewhat limited vaccine supply scenario (1 million doses per week). Week 1 vaccine supply will be allocated to sub-prioritization level A target groups.**

Sub-prioritization Level Target Group	Target Group Type	Population Estimates <sup>1</sup>	Target Group Percent of Sublevel	Doses Allocated to Group by end of Week 1	Percent of Target Group Covered by end of Week 1
<b>Sub-prioritization Level A</b>					
Critical Public Health	Role-based	36,000	*2.5%	**25 ,000	***69%
Critical Medical Care	Role-based	1,100,000	78%	780,000	71%
Critical Public Safety (police, fire, corrections)	Role-based	275,000	19.5%	195,000	71%
<b>Total Sub-prioritization Level A</b>		<b>1,411,000</b>		<b>1,000,000</b>	
<b>Sub-prioritization Level B</b>					
Pregnant Women	Health-vulnerable	560,000	29%	0	0%
Infants and Toddlers, 6-35 months	Health-vulnerable	1,370,000	71%	0	0%
<b>Total Sub-prioritization Level B</b>		<b>1,930,000</b>	<b>0</b>		
<b>TOTAL TIER 1</b>		<b>3,341,000</b>		<b>1,000,000</b>	
<sup>1</sup> California Department of Public Health Interim Guidance: Prioritizing Populations for Pandemic Influenza Vaccine in California (2013). * $36,000/1,411,000=.025 \times 100=2.5\%$ ** $0.025 \times 1,000,000=25,000$ *** $25,000/36,000=0.69\%$					

**Table B.3 – Week 2 Example of Hybrid Option allocating proportional coverage for somewhat limited vaccine supply scenario (1 million doses per week).** Week 2 vaccine supply will be allocated to sub-prioritization Levels A and B target groups.

Sub-prioritization Level Target Group	Target Group Type	Population Estimates <sup>1</sup>	Target Group Percent of Sublevel	Doses Allocated to Group by end of Week 2	Percent of Target Group Covered by end of Week 2
<b>Sub-prioritization Level A</b>					
Critical Public Health	Role-based	36,000	2.5%	*11 ,000	100%
Critical Medical Care	Role-based	1,100,000	78%	320 ,000	100%
Critical Public Safety (police, fire, corrections)	Role-based	275,000	19.5%	80 ,000	100%
<b>Total Sub-prioritization Level A</b>		<b>1,411,000</b>	<b>100%</b>	<b>411,000</b>	
<b>Sub-prioritization Level B</b>					
Pregnant Women	Health-vulnerable	560,000	**29%	***170,810	****31%
Infants and Toddlers, 6-35 months	Health-vulnerable	1,370,000	71%	418,190	31%
<b>Total Sub-prioritization Level B</b>		<b>1,930,000</b>	<b>100%</b>	<b>589,000</b>	
<b>TOTAL TIER 1</b>		<b>3,341,000</b>		<b>2,000,000</b>	
<sup>1</sup> California Department of Public Health Interim Guidance: Prioritizing Populations for Pandemic Influenza Vaccine in California (2013). * 36,000-25,000 (doses given Week 1)=11,000 ** 560,000/1,930,000=0.29 x 100=29% *** 0.29 x 589,000=170,810 **** 170,810/560,000=31%					

Table B.4 presents examples of how vaccine could be allocated under the hybrid option with somewhat limited vaccine supply and vaccine being allocated simultaneously to both sub-prioritization levels A and B target groups. **Note: These examples include a subset of target groups from CDPH prioritization Tier 1. Target group population estimates are simulated.**

- Target groups in Tier 1 will be sub-prioritized into two levels.
- In this example, sub-prioritization levels are based on target group types (e.g., role-based versus health-vulnerable general population target groups).
- Sub-prioritization Level A is comprised of the role-based target groups in Tier 1 who rely on one another to provide critical services to carry out a pandemic emergency response.
  - Sub-prioritization Level A includes: critical public health personnel, critical medical care personnel, and critical public safety personnel.
- Sub-prioritization Level B is comprised of some of the health-vulnerable general population groups in Tier 1 who face high-risk of severe illness and death if infected with influenza.
  - Sub-prioritization Level B includes: pregnant women and infants and toddlers.
- Assume vaccine supply equals 1 million doses per week.
- Week 1 supply (1 million doses) should be divided amongst the two sub-prioritization groups (Table B.4).
- Vaccine will be distributed so equal coverage (30%) across all the groups in Sub-prioritization Levels A and B.

**NOTE: The vaccine dose numbers calculated are not exactly 30% but rounded in order to cover each target member group at the same rate at 1,000,000 million doses per week.**

- Critical public health personnel population: 36,000. 30%=10,800, rounded to 10,000 weekly doses.
- Critical medical care personnel population: 1,100,000. 30%=330,000. No rounding needed. Weekly doses 330,000.
- Critical public safety workers population 275,000: 30%=82,500, rounded to 80,000 weekly doses.

- Pregnant women population 560,000: 30%=168,000, rounded to 170,000 weekly doses.
- Infants and toddlers population 1,370,000: 30%=411,000, rounded to 355,000.
- After Week 1 approximately 30% of each target group will have received one dose of the vaccine.
- This allocation process can be repeated with each weekly incoming shipment until the two sub-prioritization levels are vaccinated.
- Week 2 supply (1 million doses) should be provided to the remainder of the target groups in the sublevels.
  - Critical public health personnel should receive an additional 10,000 doses.
  - Critical medical care personnel should receive an additional 330,000 doses.
  - Critical public safety workers should receive an additional 80,000 doses.
  - Pregnant women should receive an additional 170,000 doses.
  - Infants and toddlers should receive an additional 355,000 doses.
- Week 3 supply (1 million doses) should be provided to the remainder of the target groups in the sublevels.
  - Critical public health personnel should receive an additional 10,000 doses.
  - Critical medical care personnel should receive an additional 330,000 doses.
  - Critical public safety workers should receive an additional 80,000 doses.
  - Pregnant women should receive an additional 170,000 doses.
  - Infants and toddlers should receive an additional 355,000 doses
- Week 4 supply (1 million doses) should be provided to the remainder of the target groups in both sublevels. At this point all of the target groups do not need the full allocation to complete 100% vaccination for all the groups. 439,000 doses will be left over to allocate and start vaccinating prioritized target groups in Tier 2.
  - Critical public health personnel should receive an additional 6,000 doses.
  - Critical medical care personnel should receive an additional 110,000 doses.

- Critical public safety workers should receive an additional 35,000 doses.
- Pregnant women should receive an additional 50,000 doses.
- Infants and toddlers should receive an additional 305,000 doses
- Under this scenario (assuming a constant weekly vaccine supply) it will take approximately 4 weeks for all target groups within Tier 1 to receive one dose of vaccine.

**Table B.4 – Week 1 Example of Hybrid Option allocating equal coverage for somewhat limited vaccine supply scenario (1 million doses per week).** Week 1 vaccine supply will be allocated simultaneously to Sub-prioritization Levels A and B target groups with equal coverage (30%) across all groups in each level.

Sub-prioritization Level Target Group	Target Group Type	Population Estimates <sup>1</sup>	Target Group Percent of Sublevel	Doses Allocated to Group by end of Week 1 <sup>2</sup>	Percent of Target Group Covered by end of Week 1 <sup>7</sup>
<b>Sub-prioritization Level A</b>					
Critical Public Health	Role-based	36,000	2.5%	10,000 <sup>3</sup>	30%
Critical Medical Care	Role-based	1,100,000	78.0%	330,000	30%
Critical Public Safety (police, fire, corrections)	Role-based	275,000	19.5%	80,000 <sup>4</sup>	30%
<b>Total Sub-prioritization Level A</b>		<b>1,411,000</b>	<b>100%</b>	<b>420,000</b>	
<b>Sub-prioritization Level B</b>					
Pregnant Women	Health-vulnerable	560,000	29.0%	170,000 <sup>5</sup>	30%
Infants and Toddlers, 6-35 months	Health-vulnerable	1,370,000	71.0%	355,000 <sup>6</sup>	30%
<b>Total Sub-prioritization Level B</b>		<b>1,930,000</b>	<b>100%</b>	<b>580,000</b>	
<b>TOTAL TIER 1</b>		<b>3,341,000</b>		<b>1,000,000</b>	

<sup>1</sup> California Department of Public Health Interim Guidance: Prioritizing Populations for Pandemic Influenza Vaccine in California (2013).

<sup>2</sup> The vaccine dose numbers calculated are not exactly 30% but rounded in order to cover each target member group at the same rate at 1,000,000 million doses per week.

<sup>3</sup> Critical Public Health Personnel population 36,000. 30%=10,800, rounded to 10,000 weekly doses.

<sup>4</sup> Critical Public Safety Workers population 275,000. 30%=82,500, rounded to 80,000 weekly doses.

<sup>5</sup> Pregnant Women population 560,000. 30%=168,000, rounded to 170,000 weekly doses.

<sup>6</sup> Infants and Toddlers population 1,370,000. 30%=411,000, rounded to 355,000.

<sup>7</sup> Percentages may be approximates based on rounding vaccine doses for target groups.

## **B.5: RATIONALE FOR SELECTING HYBRID MODEL**

The hybrid model represents the best allocation strategy for dividing incoming shipments of vaccine to target group members within a tier when vaccine supply is limited.

### **B.5.1: STRENGTHS**

- Realistic allocation approach
  - The hybrid option represents a realistic allocation approach when the weekly vaccine supply is not sufficient to cover all target groups within a prioritization tier.
- Meets vaccination program goals
  - The hybrid approach meets the vaccination program goals of reducing health, economic, and social consequences by simultaneously allocating vaccine to multiple target groups who rely on one another to provide critical services in order to carry out a pandemic response.
  - The option also ensures that target groups with comparable risks of severe illness and death will receive vaccine at the same time.
  - Because vaccine prioritization recommendations (prioritization tiers and sub-prioritization levels) can be changed depending on the epidemiological conditions at the time vaccine is available, this option can be adapted based on the characteristics of the virus; the effectiveness of the vaccine; and local response needs.
- Ethical (equal access)
  - Dividing the vaccine supply proportionately across target groups based on population size promotes equal access among target group members within a sub-prioritization level.
  - Each designated target group member in a sub-prioritization level has an equal chance of receiving the vaccine.
- Applicable in multiple jurisdictions
  - The option can likely be applied in resource-rich jurisdictions.
- Sustainable

- There would likely be adequate resources to implement this option at the local level for at least three months. (Assuming all partners have a role in the pandemic response including public health, medical care, public safety, business, and government.)
- Compliant with federal recommendations
  - It is likely that this option will be in compliance with federal vaccine implementation recommendations.
  - The CDC Pandemic Influenza Operational Plan recommends that state and local health departments use a proportionate allocation approach to divide incoming shipments of vaccine supply amongst equally prioritized target groups according to each group's estimated population size.<sup>a</sup>
  - The plan indicates that additional considerations in allocating vaccine need to be made based on the available vaccine supply at the time of vaccination.
  - It can be inferred from the plan that if vaccine supply is very limited, vaccine may need to be allocated to target groups within a tier using a sub-prioritization scheme.
  - Additional federal guidance is needed to assist state and local jurisdictions in developing sub-prioritization levels for vaccine implementation.
- Clearly communicated (transparent)
  - The hybrid approach can be clearly communicated to local public health pandemic planners and the general public (including the health-vulnerable general population and role-based defined target group members) assuming local health departments develop allocation plans and procedures prior to the availability of pandemic vaccine.

### **B.5.2: LIMITATIONS**

- Requires substantial additional pre-planning at the local level
  - The hybrid model will require additional pre-planning at the local level to estimate the sizes of the target groups, to calculate the proportionate allocations, and to develop plans and protocols for designating distribution of vaccine based on these allocations.

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<sup>a</sup> Centers for Disease Control and Prevention. CDC Influenza Pandemic Plan: Annex F Community Interventions, January 11, 2008.

- If all of the planning is done prior to vaccine availability, then this approach will be feasible and represents an efficient and equitable vaccine allocation approach.
- Likely not applicable in resource-limited jurisdictions
  - Resource-limited local jurisdictions may not be able to implement this option because of the substantial resources involved in determining the appropriate allocations and developing plans to distribute and dispense vaccine based on the formulae developed.

## APPENDIX C: DETAILED DESCRIPTIONS OF TARGET GROUP MEMBERSHIP VERIFICATION RECOMMENDATIONS

### C.1: INTRODUCTION

Local health departments (LHDs) must strike a balance between administering vaccine to prioritized target groups as rapidly as possible and implementing verification protocols at clinic sites when appropriate to ensure that designated target groups are being vaccinated according to prioritization tiers.

“Target Group Membership Verification” refers to the methods that will be used by vaccine screeners to verify that individuals belong to a given target group at the time of vaccination. Appendix C provides detailed descriptions of the various CDPH target group membership verification recommendations. Table C.1 lists the CDPH target group membership verification recommendations by target group type and vaccination period.

**Table C.1 – Membership Verification Recommendations by Target Group Type, Target Group, and Vaccination Period**

Target Group Type	Target Group	Vaccination Period	Recommendation
Role-based Target Groups	Frontline Responders	<ul style="list-style-type: none"> <li>• Early Vaccination Period</li> </ul>	<ul style="list-style-type: none"> <li>• Employee Lists (at workplace dispensing sites)</li> </ul>
	Non-Frontline Responders	<ul style="list-style-type: none"> <li>• Early Vaccination Period</li> </ul>	<ul style="list-style-type: none"> <li>• Employee Lists (at workplace dispensing sites)</li> <li>• Employee Lists (at workplace or targeted dispensing sites)</li> </ul>
Health-vulnerable General Populations	Pregnant Women	<ul style="list-style-type: none"> <li>• Early Vaccination Period</li> </ul>	<ul style="list-style-type: none"> <li>• Patient Lists (at prenatal clinics)</li> <li>• Signed Physician Referral Forms (at local VPODS)<sup>1</sup></li> </ul>
	Infants and Toddlers, ages 6-35 months	<ul style="list-style-type: none"> <li>• Early Vaccination Period</li> </ul>	<ul style="list-style-type: none"> <li>• Patient Lists (at pediatric clinics)</li> <li>• Written Documentation of Age (at local VPODS)<sup>1</sup></li> <li>• Oral Self-report (at local VPODS)<sup>1</sup></li> </ul>
	Household Contacts of Infants <6 months, all ages	<ul style="list-style-type: none"> <li>• Early Vaccination Period</li> </ul>	<ul style="list-style-type: none"> <li>• Vaccinate Household Contacts prior to expected date of delivery (at traditional health care sites)</li> <li>• Signed Physician Referral Forms (at local VPODS)<sup>1</sup></li> <li>• Self-reported Health Information Forms (at local VPODS)<sup>1</sup></li> </ul>
	Children 3-18 years with High-risk Medical Conditions	<ul style="list-style-type: none"> <li>• Early Vaccination Period</li> </ul>	<ul style="list-style-type: none"> <li>• Patient Lists (at pediatric clinics)</li> <li>• Signed Physician Referral Forms (at local VPODS)<sup>1</sup></li> <li>• Self-reported Health Information Forms (at local VPODS)<sup>1</sup></li> <li>• Oral Self-report (at local VPODS)<sup>1</sup></li> </ul>

Target Group Type	Target Group	Vaccination Period	Recommendation
	<b>Children 3-18 years without Medical Conditions</b>	• Early Vaccination Period	• Patient Lists (at pediatric clinics) • Oral self-report (at local VPODS) <sup>1</sup>
		• Later Vaccination Period	• No Verification Required (at local VPODS or traditional health care sites) <sup>2</sup>
	<b>High Risk Persons, 19-64 years</b>	• Early Vaccination Period	• Self-reported Health Information Forms (at local VPODS) <sup>1</sup> • Oral Self-report (at local VPODS) <sup>1</sup>
		• Later Vaccination Period	• No Verification Required (at local VPODS or traditional health care sites) <sup>2</sup>
	<b>High Risk Persons, 65 years and older (includes all persons 65+)</b>	• Later Vaccination Period	• No Verification Required (at traditional health care sites) <sup>2</sup>
	<b>Healthy General Population</b>	<b>Adults, 19-64 years not included in other categories</b>	• Later Vaccination Period
<sup>1</sup> Local Vaccine Point of Dispensing Sites (VPODS) are dispensing sites established by local health departments (LHDs) to vaccinate persons and can include stationary clinics, drive-thru clinics, mobile clinics, school-located clinics, and targeted clinics serving special populations (prisons, homeless, critical workers). <sup>2</sup> Traditional Health Care Sites are settings where persons receive seasonal flu vaccine including doctors' offices, outpatient clinics, and retail pharmacies.			

## C.2: ROLE-BASED TARGET GROUP MEMBERSHIP VERIFICATION RECOMMENDATIONS

Role-based target groups comprise 7% of the total California population because these groups include only those individuals who provide critical services. For this reason, vaccine screeners may need to verify the identity of role-based target group members before they receive vaccine. The majority of these workers are highly prioritized (included in Tiers 1-3) and will likely receive vaccine in the pre-pandemic and early pandemic vaccination periods when the demand for vaccine is greater than the supply.

### C.2.1: EMPLOYEE LISTS AT WORKPLACE DISPENSING SITES

- **This method is recommended for the following target groups:**
  - Frontline Responders.
  - Non-frontline Critical Responders working in large organizations or agencies with the resources to establish workplace dispensing clinics.

- **Step 1. Developing Employee Lists**

- Critical Infrastructure/Key Resource (CI/KR) organizations will develop their own systems to pre-identify critical workers in their organizations. <sup>a,b</sup>
- The organization's continuity of operations manager will develop, maintain, and update their list of employees designated to receive vaccine.
- The organization's continuity of operations manager will provide their LHD with the total number of eligible staff members in their organization. <sup>c</sup>
- LHDs will not receive, store, or maintain the lists and will only serve in an assisting capacity at the workplace vaccination sites.

- **Step 2. Establishing Workplace Vaccine Dispensing Clinics**

- CI/KR organizations that have been designated to receive vaccine within a local jurisdiction will establish vaccine dispensing clinics at their workplaces.
- CI/KR organizations will be responsible for staffing their vaccination clinic either with their occupational health staff or through contracts with other qualified health care providers.
- When vaccine becomes available for the organization's critical workers, LHDs will designate distribution of vaccine to the organization's occupational health staff.
- The continuity of operations manager will provide the list to vaccine screeners at the workplace dispensing site.
- Organizations will notify critical employees who are included on the list when to report to the workplace clinic to receive vaccine.
- Organizations will notify employees to bring appropriate documentation to the workplace dispensing site to verify identity, proof of current employment status, and target group membership.<sup>d</sup>

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<sup>a</sup> Organizations determining which workers will be designated for vaccination will need to stratify their workforce by target group type and determine which functions are most critical based on National Infrastructure Advisory Council (NIAC) definitions of critical workforce sectors. (Source: [http://www.dhs.gov/xlibrary/assets/niac/niac-pandemic-wg\\_v8-011707.pdf](http://www.dhs.gov/xlibrary/assets/niac/niac-pandemic-wg_v8-011707.pdf))

<sup>b</sup> Organizations should use position titles or employee identification numbers rather than names as unique identifiers to protect against worker turnover.

<sup>c</sup> Refer to the US Department of Homeland Security National Infrastructure Advisory Council (DHS-NIAC) report "The Prioritization of Critical Infrastructure for a Pandemic Outbreak in the United States" for definitions and estimates of critical workers for target groups in the health care services and critical infrastructure sectors.

<sup>d</sup> Documents that can be used by organizations to verify target group membership status can include: employee identification numbers/badges/cards, tickets/vouchers issued by organization, or most recent paycheck.

- Vaccine screeners will verify target group membership and employment status at the time of vaccination.

### **C.2.2: EMPLOYEE LISTS AT TARGETED DISPENSING SITES**

- **This method is recommended for the following target groups:**
  - Non-frontline Critical Responders in medium sized to smaller organizations or agencies that lack the resources to independently establish workplace dispensing clinics.
- **Step 1. Developing Employee Lists**
  - Refer to the recommendation “Employee Lists at Workplace Dispensing Sites” for a description of Step 1.
- **Step 2. Establishing Targeted Vaccine Dispensing Sites**
  - LHDs will establish targeted dispensing sites at designated vaccine point of dispensing sites (VPODS).
  - When vaccine becomes available for the organization’s critical workers, continuity of operations managers and occupational health care staff will assist public health staff in dispensing vaccine.
  - CI/KR organizations will provide the vaccine screening staff as well as their lists of eligible employees and LHDs will provide the facility and the vaccine administration staff.
  - CI/KR organizations will notify critical employees who are included on the list when and where to report to receive vaccine.
  - CI/KR organizations will notify employees to bring appropriate documentation to the workplace dispensing site to verify identity, proof of current employment status, and target group membership.
  - Vaccine screeners will verify target group membership and employment status at the time of vaccination.

### **C.3: HEALTH-VULNERABLE GENERAL POPULATIONS MEMBERSHIP VERIFICATION RECOMMENDATIONS**

The general population target groups with health-vulnerable conditions are prioritized in different vaccination tiers and will receive vaccine in different vaccination periods. Pregnant women and infants and toddlers (6-35 months) are prioritized in Tier 1. Children with high-risk medical conditions and household contacts of infants <6 months (all ages) are prioritized in Tier 2, and healthy children (3-18 years) are prioritized in Tier

3 for a severe pandemic. Individuals in these target groups will likely receive vaccine in the early pandemic period at outpatient clinics or at local VPODS.

Because vaccine supply will be limited at this time, CDPH recommends more rigorous methods to verify the identity of persons in these target groups. Adults with high-risk medical conditions are prioritized in Tier 4 for a severe pandemic and will likely receive vaccine in the later pandemic period in more traditional health care settings. Because vaccine supply will be less limited at this time, CDPH recommends less rigorous target group membership verification methods for adults.

### **C.3.1: PATIENT LISTS AT OUTPATIENT CLINICS**

- **This method is recommended for the following target groups:**
  - Pregnant women receiving medical care at prenatal clinics.
  - Infants and toddlers, ages 6-35 months.
  - All children (ages 3-18 years), with and without high-risk conditions, receiving medical care at pediatric clinics.
- **Step 1. Pre-identifying Outpatient Clinics in Local Health Jurisdictions and Developing Patient Lists<sup>e</sup>**
  - LHDs will be responsible for identifying outpatient clinics that vaccinate patients for seasonal influenza.
  - Outpatient clinics will be responsible for developing, maintaining, and updating their list of patients eligible to receive vaccine.
- **Step 2. Establishing Vaccine Dispensing Sites at Outpatient Clinics**
  - Public Health-designated outpatient clinics will dispense pandemic influenza vaccine at their facilities.
  - When vaccine becomes available LHDs will designate distribution of vaccine directly to a point of contact at these clinics.
  - Health care staff at these facilities will provide patient lists to their vaccine screeners to verify patients' identities.
  - Health care staff will notify their patients that are included on the list of when to report to receive vaccine and to bring written documentation to verify identity at the time of vaccination.

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<sup>e</sup> Outpatient clinics can include: prenatal clinics, birthing clinics, specialty clinics, pediatric clinics [both Vaccine for Children (VFC) and non-VFC providers], and outpatient facilities.

- Health care staff will serve as vaccine screeners and will verify patient identity and target group membership at the time of vaccination.

### **C.3.2: SIGNED PHYSICIAN REFERRAL FORMS AT LOCAL VPODS**

- **This method is recommended for the following target groups:**

- Pregnant Women not receiving medical care at prenatal/OBGYN clinics.
- Children 3-18 years with high-risk medical conditions not receiving medical care at pediatric clinics.
- Household contacts of infants <6 months, all ages.

- **Step 1. Developing Signed Physician Referral Forms**

- CDPH or LHDs will develop a physician referral form for health care providers to complete.
  - Written physician referral form will include standard patient information such as name, age, medical condition, name of physician, year of diagnosis (or date of delivery), list of medications, and household contact of an infant <6 months of age.
- LHDs will distribute the physician referral form to all health care providers in their jurisdictions prior to pandemic vaccine availability.
- LHDs will develop risk communication messages for health care providers informing them to sign referral forms for their eligible patients to receive vaccine at local VPODS during a pandemic.
- LHDs will develop risk communication messages informing persons with high-risk medical conditions to bring a signed physician referral form to a local VPODS to receive vaccine.
- Physicians will sign referral forms for eligible patients.
- When vaccine becomes available for target group members, health care providers will mail/email reminder cards to their patients indicating they qualify for vaccine and they should report to a local VPODS to receive it.

- **Step 2. Verifying Signed Physician Referral Forms**

- Pregnant Women, household contacts of infants, and parents of children with high-risk medical conditions will be advised to present signed physician referral forms for verification of their medical conditions at local VPODS.

- Vaccine screeners will verify health status and the identity of the persons requesting vaccine by reviewing appropriate documents (e.g., drivers' licenses, passports, immunization records, birth certificates, etc.).

### **C.3.3: VACCINATING HOUSEHOLD CONTACTS OF INFANTS <6 MONTHS PRIOR TO EXPECTED DATE OF DELIVERY AT TRADITIONAL HEALTH CARE SITES**

- **This method is recommended for the following target group:**
  - Household contacts of infants <6 months (e.g., family members of pregnant women) currently receiving medical care at outpatient clinics.
- **Step 1. Pre-identifying Prenatal Clinics in Local Jurisdictions**
  - CDPH will develop and disseminate recommendations for vaccinating household contacts of pregnant women at least two months prior to expected date of delivery.
  - LHDs will be responsible for identifying birthing clinics that provide birthing services to pregnant women.
- **Step 2. Establishing Vaccine Dispensing Sites**
  - Prenatal and other outpatient care facilities will establish pandemic influenza vaccine dispensing clinics at their facilities.
  - When vaccine becomes available LHDs will distribute vaccine directly to a point of contact at these clinics.
  - Health care staff at these facilities will vaccinate household contacts of pregnant women prior to the expected date of delivery.
  - Health care staff will notify their patients that are included on the list of when and where they will report to receive vaccine.
  - Health care staff will notify designated patients to bring written documentation to verify identity at time of vaccination.
  - Health care staff will serve as vaccine screeners and will verify patient identity at the vaccine dispensing site.

### **C.3.4: SELF-REPORTED HEALTH INFORMATION FORMS AT LOCAL VPODS**

- This method is recommended for the following target groups:
  - Children 3-18 years with high risk medical conditions.

- High-risk persons, 19-64 years.
- **Step 1. Developing Self-reported Health Information Forms**
  - CDPH or LHDs will develop a health information form for individuals to complete at VPODS.
    - This form will be brief with limited questions asking for standard patient information such as name, age, medical condition, name of physician, year of diagnosis, and list of medications.
    - The form will contain a written perjury statement that individuals must sign certifying that their health information is correct.
    - The form will be translated into multiple languages and dictated for those with literacy issues.
  - LHDs will make these forms available online prior to a pandemic and at the VPODS.
- **Step 2. Verifying Self-reported Health Information Forms**
  - Persons with high-risk medical conditions will be advised to complete self-reported health information forms and present them to vaccine screeners for verification of their medical conditions.
  - Vaccine screeners will review the health information forms to verify an individual's health status.
  - Vaccine screeners will also verify the identity of the individuals presenting their health information forms by reviewing appropriate documents.

### **C.3.5: WRITTEN DOCUMENTATION OF AGE AT LOCAL VPODS**

- **This method is recommended for the following target group:**
  - Infants and Toddlers, ages 6-35 months
- **Step 1. LHDs Develop Protocols for Written Documents**
  - LHDs will distribute a list of appropriate written documents to verify age (e.g., birth certificates, passports, or immunization records) to VPODS in their jurisdictions.
- **Step 2. Implementing Written Document Review Protocols at local VPODS**

- CDPH recommends LHDs use written documents, if available, as the primary choice for verification.
- Parents of infants and toddlers will be informed to bring documents to VPODS to verify the age of their child.
- If a parent does not have written documents to verify age of their child, vaccine screeners will vaccinate those with documentation first. It is up to the discretion of the vaccine screener or LHD official at the VPODS, if vaccine is limited, to make the decision if the child is cleared or not cleared for vaccination.

### **C.3.6: ORAL SELF-REPORT AT LOCAL VPODS**

- **This method is recommended for the following target groups:**
  - Children with High-risk Medical Conditions (3-18 years).
  - Children without Medical Conditions (3-18 years).
  - Adults with High-risk Medical Conditions (19-64 years).
- **Step 1. Developing Standard Screening Questions**
  - CDPH or LHDs will develop a list of screening questions for individuals to complete at VPODS.
    - The screening questions should collect the same information as a self-reported health information form.
      - For example, these questions should ask individuals for standard patient information such as name, age, medical condition, name of physician, year of diagnosis, and list of medications.
    - The screening questions should be printed on index cards and translated into multiple languages and dictated for those with literacy issues.
  - LHDs will make this list of screening questions available online prior to a pandemic and at the VPODS.
- **Step 2. Verifying oral-self report**
  - Persons with high-risk medical conditions will be advised to answer screening questions at the VPODS for verification of their medical conditions.
  - Vaccine screeners will verify target group membership by asking the screening questions and individuals will self-report (e.g. answer the

questions) to verify their health status. E.g., Healthy children need only report their age.

- Vaccine screeners will also verify the identity of the individuals by reviewing appropriate documents, if available.

### **C.3.7: NO VERIFICATION REQUIRED (AT LOCAL VPODS AND/OR AT TRADITIONAL HEALTH CARE SITES)**

- **This method is recommended for the following target group:**
  - Adults with High-risk Medical Conditions (19-64 years).
- **Step 1. Developing Protocols for No Verification**
  - No documentation (written, oral) will be required for verification of target group membership.
  - Vaccine screeners will vaccinate all individuals (at local VPODS and/or at traditional health care sites) regardless of their target group membership.
- **Step 2. Verifying Identity of Individuals**
  - LHD and health care providers will need to verify the identity of individuals receiving vaccine to track vaccine utilization and monitor adverse events.

## **C.4: HEALTHY GENERAL POPULATION TARGET GROUP MEMBERSHIP VERIFICATION RECOMMENDATION**

The target group members in the healthy general population (adults, 19-64 years) were prioritized in Tier 5 for a severe pandemic and will likely receive vaccine in the later pandemic period when vaccine is dispensed in more traditional health care settings.

### **C.4.1: NO VERIFICATION REQUIRED (AT LOCAL VPODS AND/OR AT TRADITIONAL HEALTH CARE SITES)**

- **This method is recommended for the following general population target groups:**
  - Adults (65+ years)
  - Adults (19-64 years) with no underlying high-risk medical conditions.
- **Step 1. Developing Protocols for No Verification**
  - No documentation (written, oral) will be required for verification of target group membership.

- Vaccine screeners will vaccinate all individuals (at local VPODS and/or at traditional health care sites) regardless of their target group membership.
- **Step 2. Verifying Identity of Individuals**
  - LHD and health care providers will need to verify the identity of individuals receiving vaccine to track vaccine utilization and monitor adverse events.

# SUPPLEMENTAL DOCUMENT 1: DISCUSSION OF PANDEMIC INFLUENZA VACCINE IMPLEMENTATION DECISION MAKING PROCESS

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## SD1.1: INTRODUCTION

Supplemental Document 1 presents an overview of the California Department of Public Health's (CDPH) formal decision analysis process that informed the development of the CDPH vaccine implementation recommendations.

In December of 2008, The CDPH Immunization Branch (CDPH IZB) sought assistance from the University of California, Berkeley Center for Infectious Diseases and Emergency Readiness (CIDER) to develop a formal decision making process to assist in making vaccine implementation recommendations. In addition, CDPH IZB and CIDER coordinated and convened the Pandemic Influenza Vaccine and Antiviral (PIVA) Advisory Group to advise and recommend to CDPH pandemic influenza vaccine implementation strategies. The PIVA Advisory Group was comprised of 25-30 key statewide local health officers, pandemic preparedness and emergency response experts from public health, medical, and select critical infrastructure sectors. Six Advisory Group meetings were convened over a nine month period for PIVA members to discuss key implementation issues and to develop recommendations.

## SD1.2: DECISION MAKING SCORING TOOL (DMST)

CDPH IZB and CIDER researchers developed the Pandemic Vaccine Implementation Decision Making Scoring Tool (DMST) to assist the PIVA Advisory Group in selecting the best implementation options for likely vaccination scenarios. The scoring tool is based on an analytic hierarchy process, a “choice-based” modeling technique that evaluates implementation options along criteria and assigns a numerical score based on how well each option matches a given criterion.<sup>a</sup> The implementation options that fulfilled the most criteria and obtained the highest numerical scores were recommended by the PIVA Advisory Group for inclusion in the CDPH Pandemic Influenza Vaccine Implementation Guidance.

### SD1.2.1: DMST METHODOLOGY

Figure S1.1 presents the three stages of the DMST methodology. The Decision Making Scoring Tool methodology consists of three stages:

1. The Scoring Tool inputs (implementation issues, options, and evaluation criteria) were identified and defined in successive steps.

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<sup>a</sup> Ryan, M., et al., Eliciting public preferences for healthcare: a systematic review of techniques. *Health Technology Assess*, 2001. 5(5): p. 1-186.

2. The Scoring Tool was administered to the PIVA Advisory Group. The Group engaged in facilitated small group discussions to assess the degree to which implementation options met the criteria (e.g., strength of match) and to determine the number of criteria met in order to select the best implementation options for each scenario.
3. The Scoring Tool results from small group discussions were presented to the full PIVA advisory group for consensus and informed the development of recommended implementation strategies for each scenario.

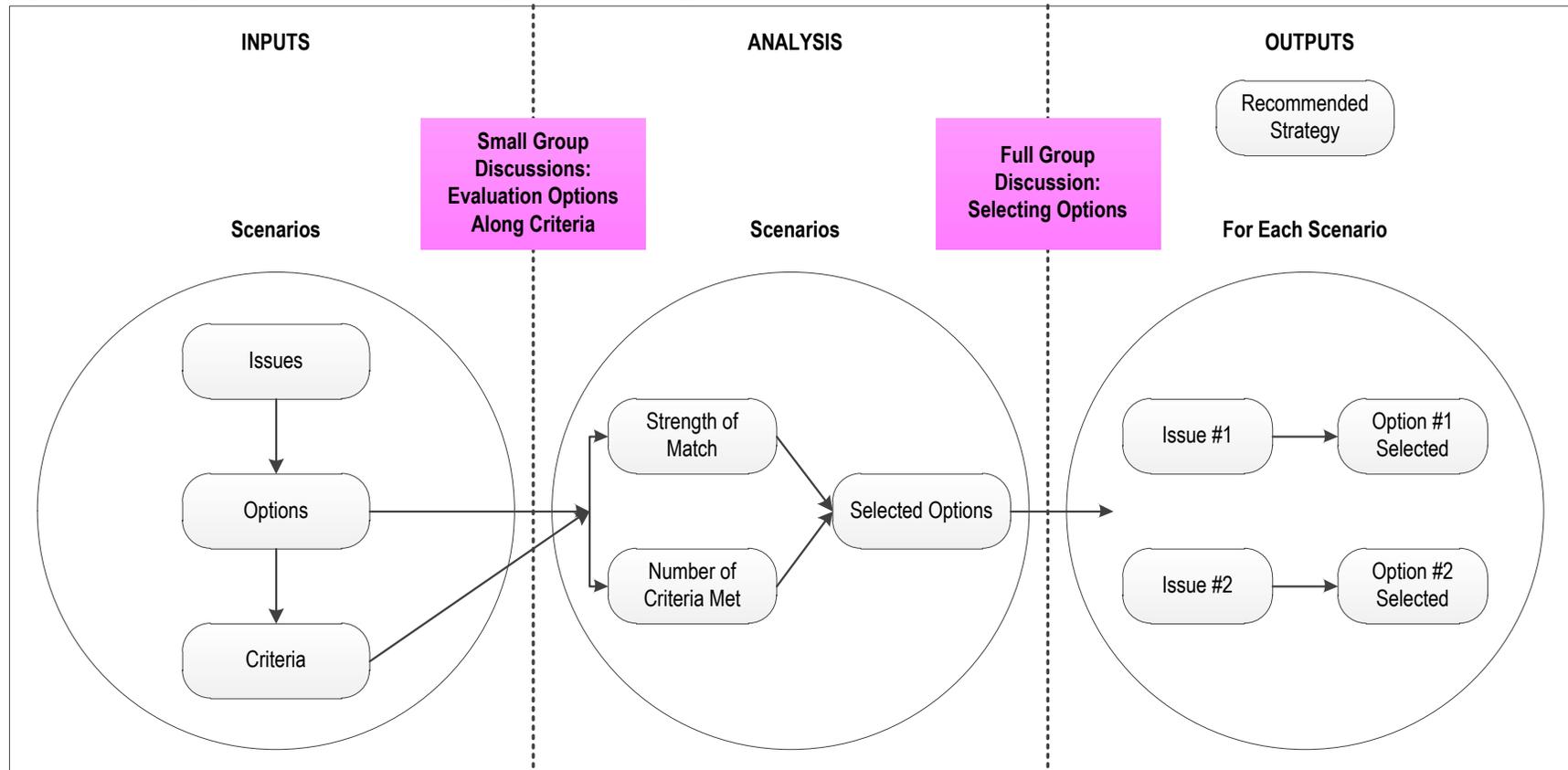
### SD1.2.2: INPUT: DEFINING IMPLEMENTATION ISSUES

Three key implementation issues were presented to the PIVA Advisory Group for discussion including: allocation approach, target group membership verification methods, and dose allotment. Each issue consists of several options. The PIVA Advisory Group examined each issue separately and used the Scoring Tool to select the best option(s) for each implementation scenario and target group type. Table S1.1 presents an example of two of the implementation issues and options discussed by the PIVA Advisory Group. The remainder of this document outlines the methodology that was used to develop membership verification recommendations for role-based target groups (highlighted in yellow).

**Table S1.1 – Example of PIVA Implementation Issues and Options**

Issue	Issue Description	Options
<b>Allocation Approaches</b>	<ul style="list-style-type: none"> <li>• Methods used to allocate (divide) incoming shipments of vaccine to simultaneously vaccinate multiple target groups within a tier</li> <li>• Recommended options differed by vaccination period</li> </ul>	<ol style="list-style-type: none"> <li>1. Sub-prioritization</li> <li>2. Proportionate Allocation</li> <li>3. Hybrid: Sub-prioritization and Proportionate Allocation</li> <li>4. No Designated Allocation</li> </ol>
<b>Target Group Membership Verification Methods</b>	<ul style="list-style-type: none"> <li>• Methods used by vaccine screeners to verify that individuals belong to a given target group before receiving vaccine</li> <li>• Recommended options differed by target group types and vaccination period</li> </ul>	<p><u>Options: Role-based Target Groups</u></p> <ol style="list-style-type: none"> <li>1. Workplace Vaccine Dispensing and Using Employee Lists</li> <li>2. Voucher System</li> </ol> <p><u>Options: Target Groups with Preexisting Medical Conditions</u></p> <ol style="list-style-type: none"> <li>1. Written Doctors' Statements</li> <li>2. Medication Prescriptions</li> <li>3. Self-reported Health Information Forms</li> <li>4. Oral Self-report</li> </ol> <p><u>Options: General Population Target Groups</u></p> <ol style="list-style-type: none"> <li>1. Written Documentation</li> <li>2. Oral Self-report</li> <li>3. No Verification Required</li> </ol>

**Figure S1.1 – Implementation Decision Analysis Methodology Overview**



### SD1.2.3: INPUT: SELECTING EVALUATION CRITERIA

The PIVA Advisory Group evaluated each issue’s implementation options on numerous criteria. These criteria were broken down into a series of determinants which describe the characteristics that the implementation option *must demonstrate* in order to meet that criterion. Table S1.2 presents the evaluation criteria and determinants that were used to evaluate the target group membership verification options for critical role-based target groups.

**Table S1.2 – Evaluation Criteria and Determinants Used to evaluate Critical Role-based Target Group Membership Verification Methods**

Evaluation Criteria	Determinants
<b>Realistic</b>	<ul style="list-style-type: none"> <li>• Realistic dose allotment approach</li> </ul>
<b>Feasible to Implement</b>	<ul style="list-style-type: none"> <li>• Requires limited additional pre-planning (at the local level)</li> <li>• Protects against fraud and abuse</li> <li>• Promotes efficient vaccine dispensing (quick and easy)</li> <li>• Places no undue burden on vaccine recipients</li> </ul>
<b>Transparent</b>	<ul style="list-style-type: none"> <li>• Can be clearly communicated to general public</li> </ul>
<b>Applicable</b>	<ul style="list-style-type: none"> <li>• Can be implemented in “resource rich” local jurisdictions</li> <li>• Can be implemented in “resource limited” local jurisdictions</li> <li>• Can be implemented by large organizations/employers</li> <li>• Can be implemented by medium-small organizations/employers</li> </ul>
<b>Sustainable</b>	<ul style="list-style-type: none"> <li>• Can be executed within the capacity of the local jurisdiction for at least 3 months</li> </ul>
<b>Consistent</b>	<ul style="list-style-type: none"> <li>• Consistent with US federal government’s implementation recommendations</li> </ul>

These determinants were then translated into a series of discussion questions that assess how well the option fulfills that determinant. Figure S1.2 presents an example of the discussion questions for Criterion #3 “Applicable” that were used to evaluate the voucher system membership verification option for critical role-based target group members.

**Figure S1.2 – “Applicable” Criterion Discussion Questions for Critical Role-based Target Groups**

<p>1. Can the option <b>[Voucher System]</b> be implemented in “resource rich” local jurisdictions?</p> <p style="padding-left: 40px;"><input checked="" type="checkbox"/> Yes</p> <p style="padding-left: 40px;"><input type="checkbox"/> No</p>
<p>2. Can the option <b>[Voucher System]</b> be implemented in “resource limited” local jurisdictions?</p> <p style="padding-left: 40px;"><input type="checkbox"/> Yes</p> <p style="padding-left: 40px;"><input checked="" type="checkbox"/> No</p>
<p>3. Can the option <b>[Voucher System]</b> be implemented by large organizations, agencies or employers?</p> <p style="padding-left: 40px;"><input checked="" type="checkbox"/> Yes</p> <p style="padding-left: 40px;"><input type="checkbox"/> No</p>
<p>4. Can the option <b>[Voucher System]</b> be implemented by medium to small organizations, agencies or employers?</p> <p style="padding-left: 40px;"><input type="checkbox"/> Yes</p> <p style="padding-left: 40px;"><input checked="" type="checkbox"/> No</p>

## **SD1.2.4: ANALYSIS: CALCULATING OPTION SCORES**

Calculating implementation option scores takes place in two major steps:

1. Calculating individual criterion scores
2. Calculating final option scores

### **SD1.2.4.1: Step 1. Calculating Individual Criterion Scores**

Strength of Match refers to the degree to which implementation options demonstrate the characteristics of a criterion. Points are assigned to a criterion using a points-based rating scale (range 0-2 points) as follows:

- 2 points: Options that demonstrate all characteristics of a criterion (Yes to all determinants)
- 1 point: Options that demonstrate some characteristics of a criterion (Yes to some determinants, No to some determinants)
- 0 points: Options that contain none of the characteristics of a criterion (No to all determinants)

This process was repeated for each criterion and for each implementation option. Figure S1.3 presents an example of the discussion question that was asked to PIVA group members to determine the “strength of match” for the applicable criterion for critical role-based target group members.

**Figure S1.3 – Applicable Criterion Score- Strength of Match**

<p><b>Criterion Conclusion: How well does the option [Voucher System] fulfill the “Applicable” Criterion for critical role-based target group members?</b></p> <p><input type="checkbox"/> Fully = 2 points (Yes to all determinants)</p> <p><input checked="" type="checkbox"/> <b>Partially = 1 point (Yes to some determinants, No to some determinants)</b></p> <p><input type="checkbox"/> Not all = 0 points (No to all determinants)</p>
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### **SD1.2.4.2: Step 2. Calculating Final Option Scores and Selecting Options**

An option’s criterion scores were summed across the criteria to obtain the final score. This process was repeated for each criterion and each implementation option. The PIVA Advisory Group selected the option or options that received the highest scores (most points) and best fulfilled the evaluation criteria for a given scenario. Figure S1.4 presents the final option scores for the target group membership verification options for critical role-based target group members based on a less limited vaccine supply scenario (1 million CA doses per week).

**Figure S1.4 – Final Option Scores for Critical Role-Based Target Group Verification Methods**

CRITERIA <i>Determinants</i>	ANSWER KEY		OPTION 1. VOUCHERS		OPTION 2. EMPLOYEE LISTS	
			How well does option meet criterion?	Criterion Points	How well does option meet criterion?	Criterion Points
<b>Realistic</b>	Fully, Not at All	0 or 2	<b>Fully</b>	<b>2</b>	<b>Fully</b>	<b>2</b>
<i>Realistic approach</i>	Y/N		Y		Y	
<b>Feasible</b>	Fully, Partial, Not at All	0-2	<b>Partially</b>	<b>1</b>	<b>Fully</b>	<b>2</b>
<i>Requires limited additional planning</i>	Y/N		N		Y	
<i>Efficient administration (quickly)</i>	Y/N		Y		Y	
<i>Efficient administration (easily)</i>	Y/N		Y		Y	
<i>No burden on vaccine recipients</i>	Y/N		Y		Y	
<i>Protects against widespread fraud</i>	Y/N		Y		Y	
<b>Transparent</b>	Fully, Not at All	0 or 2	<b>Fully</b>	<b>2</b>	<b>Fully</b>	<b>2</b>
<i>Clearly communicated to public</i>	Y/N		Y		Y	
<b>Applicable</b>	Fully, Partial, Not at All	0-2	<b>Partially</b>	<b>1</b>	<b>Fully</b>	<b>2</b>
<i>Implemented in “resource rich” jurisdictions</i>	Y/N		Y		Y	
<i>Implemented in “resource limited” jurisdictions</i>	Y/N		N		Y	
<i>Implemented by large employers</i>	Y/N		Y		Y	
<i>Implemented by medium-small employers</i>	Y/N		N		Y	
<b>Sustainable</b>	Fully, Not at All	0 or 2	<b>Fully</b>	<b>2</b>	<b>Fully</b>	<b>2</b>
<i>Executed within existing capacity of local jurisdiction</i>	Y/N		Y		Y	
<b>Consistent</b>	Fully, Not at All	0 or 2	<b>Fully</b>	<b>2</b>	<b>Fully</b>	<b>2</b>
<i>Consistent with federal recommendations</i>	Y/N		Y		Y	
<b>Total Criteria Points</b>		<b>0-12</b>		<b>10</b>		<b>12</b>
<b>SMALL GROUP SELECTION = OPTION 2. EMPLOYEE LISTS</b>						

**SD1.2.5: OUTPUT: DEVELOPING RECOMMENDATIONS**

The recommendations from this systematic decision making process were brought back to the PIVA Advisory Group for final discussion and consensus. The recommendations derived from this process were used by CDPH to develop the “2013 CDPH Interim Guidance: Implementing A Pandemic Influenza Vaccine Immunization Program in California.”

## **SUPPLEMENTAL DOCUMENT 2: PANDEMIC INFLUENZA VACCINE AND ANTIVIRAL ADVISORY GROUP - PARTICIPANT AND STAFF LIST (2008-2009)**

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The Pandemic Influenza Vaccine and Antiviral (PIVA) Advisory Group was comprised of a core group of key statewide pandemic preparedness and emergency response experts from public health, medical, and select critical infrastructure sectors. On the average, approximately 30 members attended each meeting depending on whether the topic of discussion was regarding vaccine or antivirals.

**Table S2.1 – List of Participants by Agency**

<b>First Name</b>	<b>Last Name</b>	<b>Agency</b>
Terry	Adirim	U.S. Department of Homeland Security
Thomas	Ahrens	California Health and Human Services Agency (CHHSA)
Ellie	Anderson	University of California, Davis
Howard	Backer	CHHSA
Deeann	Bagwell	Los Angeles County Department of Public Health
Peter	Baldrige	CHHSA
Bob	Benjamin	Alameda County Department of Public Health
Mark	Chew	Orange County Health Care Agency
Michael	Ciraolo	California Association of Health Facilities
Rupali	Das	CHHSA
Muntu	Davis	Association of Bay Area Health Officers
John	Duffy	Shasta County Public Health Department

<b>First Name</b>	<b>Last Name</b>	<b>Agency</b>
Myrna	Epstein	Yolo County Public Health Department
Calvin	Freeman	Global Vision Consortium
Tonya	Geiger	Riverside County Community Health Agency
Bob	Gerber	California Office of Emergency Services
Michele	Ginsberg	California Conference of Local Health Officers
Jeffery	Goad	California Pharmacists Association
Dana	Grau	CHHSA
Wilfredo	Hernandez	Kaiser Permanente
T. Warner	Hudson	American College of Occupational and Environmental Medicine
Brian	Johnston	CHHSA
Harvey	Kayman	CHHSA
Barbara	Ko	Veterans Administration
Lisa	Koonin	Centers for Disease Control and Preventions
Patricia	Lavalas-Howe	CHHSA, Department of Health Care Services, Indian Health Program
Mary	Massey	California Hospital Association
Janet	Mohle-Boetani	California Prison Health Care Services
Jocelyn	Montgomery	California Association of Health Facilities
Barbara	Morita	California Primary Care Association

<b>First Name</b>	<b>Last Name</b>	<b>Agency</b>
Bob	Nakamura	California Occupational Safety and Health Administration
Jeff	Newman	California Business, Transportation and Housing
Emily	Nourse	California Utilities Emergency Association
Nora	O'Brien	California Primary Care Association
Peter	Ohtaki	Business Executives for National Security
Brit	Oiulfstad	Los Angeles County Public Health Department
Erica	Pan	Bay Area Regional Pandemic Influenza Coordinator
Amy	Pine	San Francisco Department of Public Health
Anne	Reynolds	American Red Cross
Ben	Rich	Bioethicist
Jim	Rooney	Gilead Science
Jill	Rulons	California Grocers Association
Christian	Sandrock	University of California, Davis
Jennifer	Schneider	California Prison Healthcare Services
Ben	Schwartz	Department of Health and Human Services, National Vaccine Program Office
Tom	Shimabukuro	Centers for Disease Control and Preventions
Alexandra	Speer	California Association of Health Facilities
Mike	Stacey	County Health Executives Association of California

<b>First Name</b>	<b>Last Name</b>	<b>Agency</b>
Cathy	West	IBM
David	Witt	Kaiser Permanente

**Table S2.2 – List of Staff by Agency**

<b>First Name</b>	<b>Last Name</b>	<b>Agency</b>
Jeannie	Balido	University of California, Berkeley
Julia	Dysart	University of California, Berkeley
Gwendolyn	Hammer*	CHHSA
Jennifer	Hunter	University of California, Berkeley
Lisa	Goldberg*	University of California, Berkeley
Ann	Roslosnik	CHHSA

\* Dr. Hammer and Ms. Goldberg developed all the documents for the meetings, facilitated the meetings, and co-wrote the guidance.

