

# ALL HAZARDS PUBLIC HEALTH EMERGENCY RESPONSE PLAN (PHERP)



## Functional Annex 6: Mass Vaccination Plan

October 2020

**DRAFT**

*For Official Use Only*

## Promulgation

The Connecticut Department of Public Health (DPH) All Hazards Public Health Emergency Response Plan (PHERP) establishes the basis for coordination of the DPH resources and response to provide public health and medical services during an emergency or disaster. The fundamental assumption is that a significant emergency or disaster may overwhelm the capability of local government or the healthcare system to carry out operations necessary to save lives and protect public health. Consequently, resources of the DPH are used to provide public health and medical services assistance throughout the state.

Connecticut follows the [State Response Framework](#) (SRF) to prepare for and respond to natural hazards or disasters that may occur. The PHERP is the Emergency Support Function #8 (ESF #8): Public Health and Medical Annex to the SRF. The PHERP is written and promulgated pursuant to [Connecticut General Assembly Chapter 368a](#) and the [C.G.S. § 19a-176, PA 03-236. An Act Concerning Public Health Emergency Response Authority](#).

The DPH agrees to implement planning efforts and exercise these plans in order to maintain the overall DPH preparedness and response capability. I hereby adopt this PHERP and direct the head of each designated DPH section to implement its directives. All previous versions of the PHERP are hereby rescinded.

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Deidre S. Gifford, MD, MPH, Acting Commissioner  
Connecticut Department of Public Health

## Approval and Implementation

The Connecticut Department of Public Health (DPH) All Hazards Public Health Emergency Response Plan (PHERP) Functional Annex 6: Mass Vaccination Plan describes the distribution and management of vaccine in response to a pandemic. Planning teams comprised of subject matter experts, planners, and representatives of stakeholder organizations contributed to this plan. This Mass Vaccination Plan supersedes the previous Vaccine Distribution Plan, and a revision was completed in September 2020.

This Mass Vaccination Plan incorporates guidance from the U.S. Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC), Office of the Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Homeland Security (DHS) and Federal Emergency Management Agency (FEMA). The Mass Vaccination Plan builds on lessons learned from planned events, disasters, emergencies, trainings, and exercises.

This Annex:

- Defines the DPH emergency response roles and responsibilities, as outlined in the Emergency Support Function (ESF) #8: Public Health and Medical Services annex to the State of Connecticut State Response Framework (SRF).
- Aligns the basic structures, processes, and protocols of the National Response Framework (NRF) guidelines into DPH's response plans.
- Incorporates National Incident Management System (NIMS) concepts and guidelines utilizing integrated command and control guidelines for local, regional, and/or national response coordination in the event of a public health or medical emergency.
- Provides a basis for unified training and exercises.

The Functional Annex 6: Mass Vaccination Plan was created to centralize response procedures that would be common amongst any mass vaccination campaign. The appendices to this annex highlight specific mass vaccination scenarios and considerations for response.

This Mass Vaccination Plan is hereby approved. This plan is effective immediately and supersedes all previous editions. The following signatories agree to support the Mass Vaccination Plan and to carry out their functional responsibilities described in this plan.

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Deidre S. Gifford, MD, MPH, Acting Commissioner

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Ellen Blaschinski, MBA, RS, Branch Chief  
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**Appendix 2: COVID-19 Mass Vaccination Plan**

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## I. Purpose, Scope, Situation, and Assumptions

### A. Purpose

The COVID-19 Mass Vaccination Plan Appendix describes and documents the expected response by the Connecticut Department of Public Health (DPH) and its local public health and healthcare partners to safely prepare for, activate, and implement an effective statewide COVID-19 mass vaccination initiative to reduce COVID-19 related illnesses, hospitalizations, and deaths in the state of Connecticut. Using response guidance issued by the Centers for Disease Control and Prevention (CDC), the DPH's Office of Public Health Preparedness and Response (OPHPR) and Immunization Program will work closely with other DPH programs, local health departments and districts, hospitals, the healthcare industry, and other state and federal partners to prepare and implement this COVID-19 mass vaccination initiative.

This Appendix will be modified and updated as more information about the COVID-19 vaccine, mass vaccination strategies, and additional guidance become available from the CDC. Many, but not all, of the COVID-19 mass vaccination initiative activities described may overlap with routine immunization activities. Routine immunization and pandemic influenza program activities have served as a foundation for COVID-19 mass vaccination planning.

### B. Scope

This COVID-19 Mass Vaccination Plan applies to the vaccines manufactured and distributed for COVID-19. Although there are themes that apply to other mass vaccination efforts, the details contained in this document apply only to COVID-19.

The COVID-19 Mass Vaccination Plan is part of the Mass Vaccination Annex to the All Hazards Public Health Emergency Response Plan (PHERP). The PHERP is the Emergency Support Function #8 (ESF #8): Public Health and Medical Annex to Connecticut's [State Response Framework](#) (SRF). DPH serves as the lead agency for ESF #8 response and is designated as the primary and coordinating agency for public health and medical response to an emergency, disaster, or event. Per [Governor's Executive Order No. 34](#), the state of Connecticut uses the [National Incident Management System \(NIMS\)](#) as the standard system for the management of domestic incidents that affect the health, welfare, safety, and security of the residents of Connecticut.

### C. Situation Overview

#### *2019-Present Novel Coronavirus Disease 2019 (COVID-19) Outbreak*

The outbreak of 2019 novel coronavirus disease (COVID-19) was first reported on December 31, 2019 in Wuhan, China. Within a few weeks, the virus had spread rapidly throughout China and to several other countries. On March 11, 2020, the novel coronavirus disease (COVID-19) was declared a pandemic by the World Health Organization. On March 13, 2020, a national emergency was declared in the United States concerning the COVID-19 outbreak. The unprecedented COVID-19 pandemic prompted the CDC to activate its emergency operations center (EOC) to help coordinate technical assistance and control activities with partners. For more about the CDC response to this outbreak and mass vaccination planning, see the [CDC Coronavirus \(COVID-19\) Site](#).

### D. Connecticut DPH Planning Assumptions:

The DPH is operating under the current guidance from the CDC including the planning

assumptions for jurisdictions listed in the [CDC COVID-19 Vaccination Program Interim Playbook or Jurisdiction Operations](#).

## II. Concept of Operations

### A. Preparedness

Pandemic vaccination response planning requires collaboration among a wide range of public- and private-sector partners, including immunization programs, public health emergency preparedness programs, emergency management agencies, healthcare organizations, industry groups that include critical infrastructure sectors, policy makers, and community vaccination providers (e.g. pharmacies, occupational health settings, physicians' offices). Many of these partners are engaged regularly in seasonal influenza and other outbreak response vaccination campaigns, and many served as vaccination providers<sup>1</sup> during the 2009 H1N1 pandemic. However, significant additional planning is needed to operationalize a vaccination response to COVID-19 as its scope and complexity is more significant than seasonal influenza or other previous outbreak-related vaccination initiative.

For the purposes of this plan, the activities and efforts described in the Preparedness Section are activities and efforts that take place prior to any vaccine allocation or mass vaccination initiative.

#### **REFERENCES:**

- CISA's [Critical Infrastructure Sectors](#)

### 1. COVID-19 Vaccination Planning Activities

The Connecticut DPH planning strategy for mass vaccination is a collaborative effort at all levels of government and requires close collaboration between public health, healthcare, tribal nations, and community partners in the public and private sector. Information and guidance from the U.S. Department of Health and Human Services (DHHS) and other governing entities is evolving rapidly, and the DPH is adapting to these evolutions. Additional resources may be required to further these efforts.

Based on existing vaccination efforts and previous experience with mass vaccination campaigns (like seasonal influenza and H1N1), the DPH has applied the following lessons learned to current planning efforts:

- a. Future events should improve on identification of populations served by providers who pre-register. Develop a pre-registration packet to include additional information about patient population served. The provider profile should query for the approximate number of patients they provide primary care for within each of the targeted populations.
- b. Develop a system to monitor vaccine administered in real time.
- c. Develop an educational message for providers outlining vaccine preparations and procedures for vaccine ordering.

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<sup>1</sup> For the purposes of this document, "vaccination provider" refers to any facility, organization, or healthcare provider licensed to possess/administer vaccine or provide vaccination services. A "COVID-19 vaccination provider" is any vaccination provider who has been enrolled in the COVID-19 Vaccination Program.

- d. Future efforts should include analysis of access by provider type per geographic area and an analysis of provider types by total numbers in the state.
- e. The DPH should develop a pre-registration provider profile agreement to include patient profile served by practice type and specialty of practice.
- f. The DPH should evaluate mass vaccination plans for each of the state's geographic planning regions (i.e., Department of Emergency Services and Public Protection, Division of Emergency Management and Homeland Security (DESPP-DEMHS) regions) and evaluate each region's efforts in providing the services in the plan. Each region should have a schedule of "clinics" to be activated when vaccine is available.

Additional lessons learned can be found in the H1N1 Influenza Pandemic Response After Action Report dated July 30, 2010.

Current COVID-19 vaccination planning activities include:

- a. Establishing a Public Health COVID-19 Vaccination Workgroup that includes staff from the DPH (OPHPR, Immunization Program, FLIS, Commissioner's Office, Legislative Liaison, Epidemiology, IT, OEMS); Yale New Haven Health System (YNHHS); the Department of Consumer Protection (DCP) Drug Control Division; the Military Department; the CT Governor's Office of Communications; the DESPP-DEMHS; the Connecticut Healthcare Coalition; ESF-15 media/public affairs; and crisis and emergency risk communications to develop plans and coordinate activities.
- b. Establishing a Governor's Vaccine Advisory Group comprised of partners with expertise in vaccine safety, healthcare, and access issues for critical populations,
- c. Identifying gaps in preparedness based on CDC-provided planning assumptions, previous real-world events (like H1N1), and exercise after action reports.
- d. Assessing the capacity of CT's Immunization Information System (CT WiZ) and other reporting systems.
- e. Identifying critical populations and critical workforce for Phase 1 vaccinations. Identifying sub-groups of these populations for when vaccine supply is extremely limited.
- f. Identifying additional vaccination providers and locations for rapid vaccination of early critical populations/critical workforce.
- g. Matching those critical populations with vaccination providers, where applicable and as needed.
- h. Planning for expanded vaccination provider outreach, enrollment, training, and onboarding.
- i. Finalizing the vaccine allocation strategy for identified critical populations in early and limited supply scenarios.
- j. ESF 7 – resource support planning logistics for deliveries and distribution
- k. Developing a communications plan to ensure frequent and culturally appropriate messages to vaccination partners and the community.
- l. Hiring a consultant to apply the DPH strategies and procedures into a COVID-19 Mass Vaccination Plan.

As planning efforts continue, events may be scheduled to test written plans and ensure continuous quality improvement. Specific exercise needs are currently being assessed by the DPH and its partners and will be developed as needed.

2. **COVID-19 Organizational Structure and Partner Involvement**

The Connecticut DPH is the lead agency in the COVID-19 response for the state of Connecticut and is the lead agency for ESF 8, as defined in the SRF and PHERP. To plan for and manage the mass vaccination initiative, the DPH OPHPR has established a working group consisting of representatives of the DPH Commissioner's Office, Legal, Epidemiology, Public Information, Preparedness, Hospital Preparedness, Healthcare Acquired Infections, Healthcare Facility Licensing, and Emergency Medical Services (EMS). The State Emergency Operations Center (SEOC) may be opened to engage and coordinate with other state agencies.

To ensure a streamlined effort in planning and implementation of the mass vaccination initiative, clear roles and responsibilities have been delineated.

a. **Organizational Structure and Committee Members**

Under the direction of the Commissioner, the DPH is comprised of eight branches and several specialized offices (e.g., general counsel, communications). Each branch is managed by an executive management team member (Branch Chief) who reports to the Commissioner or Deputy Commissioner. Each branch is comprised of several sections. Each section includes multiple programs.

The Immunization Program and Healthcare Acquired Infections Program reside in the Infectious Disease Branch. The Office of Public Health Preparedness and Response and Office of Local Health Administration reside in the TB, HIV, STD, Viral Hepatitis and Public Health Preparedness and Local Health Branch. Facility Licensing and Investigations Section, and Office of Emergency Medical Services reside in the Healthcare Quality and Safety Branch.

b. **Planning and Coordination Team (Internal)**

The Public Health COVID-19 Vaccination Work Group is critical to ensure the mass vaccination initiative to COVID-19 is thoughtfully planned and successfully executed. A wide array of expertise is represented among team members. While CDC guidance recommends an internal planning and coordination team, DPH has included external partners integral to this initiative. The work group is comprised of subject matter experts from the DPH (OPHPR, Immunization Program, FLIS, Commissioner's Office, Legislative Liaison, Epidemiology, IT, OEMS); Yale New Haven Health System (YNHHS); the Department of Consumer Protection (DCP) Drug Control Division; the Military Department; the CT Governor's Office of Communications; the DESPP-DEMHS; the Connecticut Healthcare Coalition; ESF-15 media/public affairs; and crisis and emergency risk communications. Refer to Attachment B Workgroup Organizational Representative Chart or the complete list of agencies involved in the Public Health COVID-19 Vaccination Workgroup.

OPHPR provides subject matter expertise to support the DPH and its partners to prepare for, respond to and recover from public health emergencies. OPHPR administers and manages the Public Health Emergency Preparedness (PHEP) Cooperative Agreement from the Centers for Disease Control and Prevention (CDC), the Healthcare Preparedness Program (HPP) Cooperative Agreement from the Office of Assistant Secretary for Preparedness and Response (ASPR), and several other 'crisis cooperative agreements' as awarded. OPHPR also works closely with local health departments and districts (LHDs) to meet their public health preparedness deliverables, including mass dispensing and mass vaccination planning. Throughout the COVID-19 response, OPHPR has continually evaluated and refined agency's objectives.

The Immunization Program of the Infectious Diseases Branch provides subject matter expertise on immunization best practices, including storage and handling. The Immunization Program engages a diverse group of immunization providers to enroll to receive and administer pandemic vaccines to patients, while ensuring that CT residents can find a vaccine provider, once vaccine is available. The Program provides training to providers on ordering, managing vaccine inventory, and reporting vaccine doses administered in CT WiZ. The Program communicates frequently with enrolled providers about current priority populations and vaccine availability. The Program provides oversight and accountability for vaccines provided by the federal government.

**c. COVID-19 Vaccination Program Implementation Committee (Internal and External)**

In Connecticut, the Governor's COVID-19 Vaccine Advisory Group has been established to ensure equitable access to vaccinations, information about populations, and the logistical requirements for providing access to COVID-19 mass vaccination initiative. This will require collaboration with external entities and community partners who are familiar with how they obtain healthcare and other essential services. The Governor's COVID-19 Vaccine Advisory Group consists of healthcare providers, scientific subject matter experts, community faith-based leaders, state and local leaders, legislative caucus chairs, and public health professionals. In addition to the main advisory group, three subcommittees have been created to address specific issues of communication, allocation and science. Each member of the main advisory group will also serve on a subcommittee, whose membership is expanded to include additional subject matter experts. Recommendations will be made at the subcommittee level, brought to the main advisory group for consideration and presented to the Governor for final approval.

**d. Coordination Efforts Between State, Local, and Territorial Authorities**

i. Connecticut is made up of 169 municipalities and two tribal nations (described in subsection ii. Below) and follows a decentralized state governance structure. City and town governments are responsible for all people and property within their boundaries and jurisdictions to the limits

of their resources. Emergency operations will be carried out principally by local officials and resources, supported by mutual aid, then, if requested, state forces, and, as available and needed, by military and/or federal forces. Mutual aid agreements between local governments in effect at the time of the emergency are the first means of obtaining assistance when a city or town's resources are exhausted or nearly exhausted. Requests by local governments for State assistance shall be made through the appropriate DEMHS Region Offices. State resources may include, but not be limited to, activation of volunteer civil preparedness force members, including Medical Reserve Corps (MRC) volunteers, in accordance with Title 28 of the Connecticut General Statutes. During emergencies and disasters, coordination between the Governor and local chief elected officials occurs routinely through conference calls and emails. Connecticut does not have county government; regional planning and coordination is done within the five DEMHS regions. Planning is documented in Local Emergency Operations Plans, Regional Emergency Support Plans and the Interstate Mutual Aid Compact. Coordination between the Governor and local chief executive officers (not elected) and other local officials occurs through the State Emergency Operations Center, in accordance with the SRF.

The 169 towns in Connecticut receive public health services through 65 LHDs. The DPH Office of Local Health Administration (OLHA) is responsible for ensuring the delivery of public health services at the local level. The mission of OLHA is to work with local partners to fulfill Connecticut General Statutes and Regulations thereby providing essential public health services statewide.

Connecticut's local public health infrastructure encompasses a mixture of municipal health departments and regional health districts. All health districts provide full-time public services to their communities. Connecticut's local public health system is decentralized. Local health agencies are autonomous and under the jurisdiction of the towns/municipality or health district served. Local health agency staff are hired and employed by their respective local health agency. The DPH Commissioner reviews the credentials of the director of health for the local health agency to assure minimum qualifications are met, pursuant to Connecticut General Statute (CGS) Section 19a-200 (municipal) and Section 19a-244 (district).

Currently, Connecticut has 65 [local health agencies](#) serving the State's entire population, 53 of which employ a full-time director of health (aka a full-time local health agency) and 12 of which employ a part-time director of health (aka a, part-time local health agency). The full-time local health agencies include 33 independent municipal health departments and 20 health districts with jurisdictions spanning from two to 20 towns.

- ii. State-level personnel must closely monitor activities at the local level to ensure the COVID-19 Vaccination Program (CoVP) is implemented

throughout the jurisdiction in adherence with federal guidance and requirements, and that there is equitable access to COVID-19 vaccine across all areas. Local personnel likely have a better understanding of perceptions, unique challenges, and successful mitigation strategies within their communities. Aligning areas of responsibility as well as specific tasks can help to complement rather than duplicate efforts at either level, maximizing the efficient use of resources and overall quality of the CoVP.

e. **Coordination and Engagement with Tribal Nations**

Although CDC is working directly with the Indian Health Service (IHS) at the federal level, plans have not been finalized. The DPH has memoranda of agreement (MOA) with the two tribal nations located in the state of Connecticut. The tribal nations operate as their own sovereign nations but voluntarily abide by the public health code. The majority of the members of the tribal nations in Connecticut do not live on designated tribal lands and are served by the health districts in that regional planning area of Connecticut. The Uncas Health District and LedgeLight Health District are located in the geographic area of the two tribal nations located in Connecticut. The two tribal nations' Directors of Health are invited to all Region 4 public health planning meetings and are offered PHEP funding annually. All public health alerts sent by the DPH to Directors of Health are concurrently sent to the tribal nations' public health contacts.

The IHS does not provide vaccination services so tribal health services are planning for vaccination of their population with the local health department where they are located. Additionally, a pharmacy located on tribal lands is working with the Immunization Program to ensure they plan to enroll in the CoVP, vaccinate tribal members, and report doses administered.

f. **Key Partners for Critical Populations**

Per CDC guidance, planning should include leadership from the DPH's COVID-19 Vaccine Work Group, representatives from key COVID-19 vaccination providers for critical population groups identified by CDC (See Section 4: Critical Populations), and representatives from other sectors within the community. The DPH has engaged with representatives from organizations and agencies that include:

- Local and state Emergency Management Agencies
- Connecticut Healthcare Coalition (CT HCC)
- Immunization coalitions
- Local health departments and districts
- Health systems and hospitals (including critical access hospitals for rural areas and inpatient psychiatric facilities)
- Community health centers
- Pharmacies
- First responders
- Long-term care facilities including nursing home, assisted living service agencies, residential care homes, and independent living facilities (e.g.,

intermediate care facilities for individuals with intellectual and developmental disabilities)

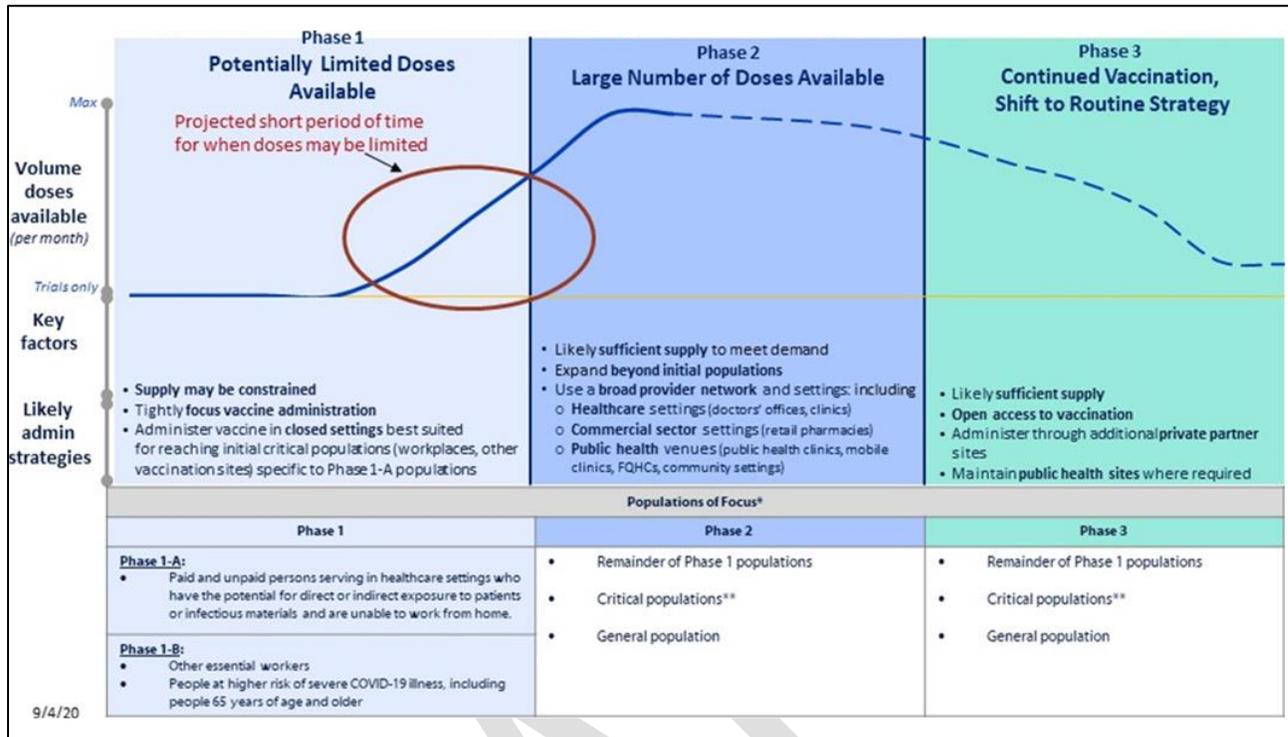
- Businesses and occupational health organizations
- Education agencies and providers
- Correctional facilities
- Churches or religious leaders and institutions
- Tribal leaders
- Organizations serving racial and ethnic minority groups
- Organizations serving people with disabilities
- Organizations serving people with limited English proficiency
- Community representatives

**REFERENCES:**

- CDC's [Public Health Preparedness Resources](#) : Assist with strategic planning to strengthen public health capabilities.
- CDC's [Pandemic Influenza-Specific Resources](#) on vaccine and other medical countermeasures may be helpful in strategizing for other COVID-19 related situations.
- CDC's COVID-19 [Vaccination Guidance During a Pandemic](#)

**3. Phased Approach to COVID-19 Vaccination**

Due to changing vaccine supply levels at various points during the COVID-19 mass vaccination initiative, planning needs to be flexible but as specific as possible to accommodate a variety of scenarios. The Connecticut DPH is planning for three phases of vaccination and to allocate limited vaccine resources to critical populations. The following graph illustrates the three phases of the COVID-19 mass vaccination initiative and populations of focus in each phase.



Source: [COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#)

a. **Phase 1: Potentially Limited COVID-19 Vaccine Doses Available**

In Phase 1 of the COVID-19 mass vaccination initiative, initial doses of vaccine will likely be distributed in a limited manner and with the goal of maximizing vaccine acceptance and public health protection while minimizing waste and inefficiency. The key considerations in planning for this phase are:

- i. COVID-19 vaccine supply may be limited.
- ii. COVID-19 vaccine administration efforts must concentrate on the initial populations of focus to achieve vaccination coverage in those groups.
- iii. Inventory, distribution, and any repositioning of vaccine will be closely monitored through reporting to ensure end-to-end visibility of vaccine doses.

The Connecticut DPH Mass Vaccination Strategy for Phase 1:

The CT DPH will prioritize enrollment activities for mass vaccination providers who serve the populations that must be vaccinated during the early phases of this initiative. Vaccinators are identified and recruited by the DPH. Once vaccinators have expressed an interest, they must agree to and sign the terms of the [CDC COVID-19 Vaccination Program \(CoVP\) Provider Agreement](#) and are onboarded into the CT WiZ system. Given the volume of adult vaccine providers that must enroll in the CT WiZ system, the DPH's efforts are simultaneously directed towards enrolling pharmacies and healthcare providers.

Sometimes, vaccinators and the settings for mass vaccination initiatives are co-located (e.g. acute care hospitals and their healthcare workforce) while others

are not (e.g. home health agencies). Therefore, DPH is working to match vaccinators with priority populations in diffuse settings or at smaller facilities. Planning efforts for Phase 1 take into consideration underserved populations who may have difficulty accessing vaccination services (e.g. low-income populations in areas with limited public transit). The DPH is working closely with local public health jurisdictions (considered mass vaccinators) to plan and further develop or refine operational procedures for any temporary or mobile clinics planned for Phase 1 prior to receipt of vaccine.

See Attachment C: COVID-19 Vaccination Scenarios for Jurisdictional Planning – Phase 1, Q4 2020. Each hypothetical scenario presents variations in product availability, number of vaccine doses allocated, storage and handling requirements, and administration by theoretical vaccine product. These three scenarios may be especially helpful in conducting any workshops or exercises.

**b. Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand**

As the supply of available vaccine increases, distribution will expand, increasing access to vaccination services for a larger population. When larger quantities of vaccine become available, there will be two simultaneous objectives:

- i. Provide equitable access to COVID-19 vaccination for all critical populations to achieve high COVID-19 vaccination coverage in these populations in the jurisdiction.
- ii. Ensure high uptake in specific populations, particularly in groups that are [higher risk for severe outcomes from COVID-19 disease](#).

The Connecticut DPH Mass Vaccination Strategy for Phase 2:

In Phase 2, COVID-19 vaccine supply will likely be sufficient to meet demand for critical populations as well as the general public. To meet the Phase 2 objectives, CT DPH will develop a broad vaccine administration network that goes beyond the Phase 1 vaccine providers. Recruitment of providers will focus on ensuring equitable access for all populations. The expanded network will include private practices, federally qualified health centers (FQHCs) and pharmacies. It will include both primary care providers, and specialty providers that can reach populations that have health conditions that put them at high risk for severe COVID-19. Development of the network will be monitored to ensure that vaccine is available in all geographical areas of the state and can be accessed by those without a medical home.

**c. Phase 3: Likely Sufficient Supply, Slowing Demand**

Ultimately, COVID-19 vaccine will be widely available and integrated into routine vaccination programs, run by both public and private partners. The key considerations in planning for Phase 3 are:

- i. Likely sufficient COVID-19 vaccine supply where supply might exceed demand
- ii. Broad vaccine administration network for increased access

The Connecticut DPH Mass Vaccination Strategy for Phase 3:

The CT DPH will seek to maintain a broad network of providers to ensure that all who want vaccine can have access to it. The amount of vaccine ordered and the use of vaccine that has been ordered will be monitored to identify places where supply may exceed demand. If supply exceeds demand, adjustments to the provider network may be made.

**REFERENCES:**

- CDC's [Roadmap to Implementing Pandemic Influenza Vaccination of Critical Workforce](#). Provides additional information and tools for state and local planners on how to operationalize and implement specific plans for targeting critical workforce groups during an influenza pandemic response.

**4. Critical Populations**

Based on the CDC's guidance, critical workforce is defined as workers who provide response functions and essential services to communities and whose absence would significantly disrupt or collapse the critical infrastructure. To identify the number of individuals in each critical workforce group (CWG), the DPH has contacted other state agencies, hospitals, long-term care facilities, critical infrastructure sector entities, LHDs, and other state, regional and local partners to identify critical workforce and report back to DPH. Within OPHPR, each staff member has been assigned a particular sector on which to collect data. OPHPR and the Immunization Program collaborate on this data collection to ensure a consistent approach to the process and avoidance of gaps. The information collected will further inform the vaccination planning process.

**a. Identifying, Estimating, and Locating Critical Populations**

Connecticut will identify priority groups for early vaccination based on the recommendations of the Advisory Committee on Immunization Practices (ACIP). Target populations will likely include essential workers (medical and nonmedical) and people at high risk of severe COVID-19. Once identified, DPH will coordinate the planned settings for COVID-19 vaccine administration and the populations that they would be expected to serve in Phases 1 and 2. The determination of which characteristics confer [increased risk of severe COVID-19](#) is based on information provided by the CDC.

**b. Defining and Estimating Population Groups Initial COVID-19 Vaccine Distribution**

- i. Healthcare personnel likely to be exposed to or to treat people with COVID-19
- ii. People at increased risk of severe illness from COVID-19, including those with underlying medical conditions and people over 65 years of age
- iii. Other essential workers

Numerous data sources are being used to estimate the size of populations at high risk for COVID-19 in Connecticut. These sources include the results of the Connecticut Behavioral Risk Surveillance Surveys, the DataHaven Community Wellbeing Surveys, Medicare records, and the decennial US census and the American Community Survey. Survey data on the willingness of Connecticut residents to get vaccinated may be used to adjust estimates for different uptake scenarios using Data Haven Survey and other available data. Once the data has been finalized, the DPH will work with GIS experts to provide visual representation of the key populations.

**c. Sub-Prioritization within Jurisdiction when Vaccine Supply is Limited**

In the event that the Connecticut DPH allocation during Phase 1 is insufficient to vaccinate all those included in the initial populations of focus, it is important to identify and estimate the subset groups (i.e. Phase 1-A, Phase 1-B) within these initial populations of focus to determine who will receive the first available doses of COVID-19 vaccine.

Allocation decisions and sub-allocation decisions (should they be necessary) will be made by the Governor in consultation with the Department of Public Health, other state agencies, the Vaccine Advisory Group, and others as indicated. These decisions will be guided by ACIP recommendations. Allocation decisions may also take into account the indications and contraindications of available vaccines, and the current epidemiology of COVID-19.

**d. Establishing Points of Contact (POCs) and Communication Methods for Organizations, Employers, or Communities within the Critical Population Groups**

The DPH will issue any communications through the channels outlined in the State Response Framework and through the SEOC. The DPH utilizes the state alert system (Everbridge) to communicate key messages with public health partners. As noted above, the DPH is also identifying key vaccine provider points of contact for all state agencies and healthcare provider types (licensed by the DPH and other agencies). This is accomplished by working with designated state agency leads and the Cities Readiness Initiative (CRI) leads who reach out to their respective stakeholder groups. Partnerships with trusted community organizations can facilitate early agreement on communication channels and methods for rapidly disseminating information and ultimately ensuring these groups have access to vaccination. (See Section 12: COVID-19 Vaccination Program Communication.) Some of these partners could include:

- i. FQHCs / Community Health Centers (CHCs)
- ii. Acute care hospitals
- iii. Pharmacies (through DCP)
- iv. Organizations and businesses that employ critical workforce through a variety of state agency leads
- v. Municipal and state first responders

- vi. Non-traditional providers, and locations (e.g., dialysis centers, community centers) serving people at higher risk for severe illness
- vii. The DPH licensed healthcare congregate settings
- viii. Group homes or congregate settings that house people at higher risk for severe illness (e.g., homeless shelters, group housing, senior living facilities)
- ix. Department of Corrections facilities (prisons)
- x. Locations where people 65 years of age and older gather (e.g., senior centers, food pantries)
- xi. Faith-based organizations and other community groups
- xii. Home health agencies, and other home-based healthcare providers (through social services agencies)
- xiii. Universities, colleges, and institutions of higher learning
- xiv. Private boarding schools

Efforts by the DPH are focused on working with entities likely to be vaccinated during Phase 1-A, 1-B, and early Phase 2. Correspondence and surveys sent to these agencies, organizations, and establishments are designed to obtain information on workforce numbers, ability to vaccinate, and contact information.

A sample worksheet for collecting critical population POCs and other pertinent information is in Attachment D: Phase 1 Population Group Worksheet Example.

**REFERENCES:**

- CISA's [Critical Infrastructure Sectors](#)

**5. COVID- 19 Provider Recruitment and Enrollment**

An adequate network of trained, technically competent COVID-19 vaccination providers in accessible settings is critical to the success of the COVID-19 mass vaccination initiative. For this reason, COVID-19 vaccination provider recruitment and enrollment may be the most critical activity conducted before vaccine becomes available.

**a. Vaccination Provider Recruitment**

A number of different strategies are being used to recruit providers in traditional and non-traditional settings to join the COVID-19 Vaccine Program (CoVP) to administer COVID-19 vaccine. Providers that will likely play a role in Phase 1 are being prioritized for enrollment in the CoVP include hospitals, local health departments and districts, pharmacies and clinics that can achieve high throughput.

The DPH is working with the Connecticut Hospital Association to recruit hospitals throughout Connecticut. Hospitals will likely play a key role in vaccinating their staff. They may also serve as central vaccination locations for other medical essential workers. The contribution of hospitals as a central vaccination location could be particularly important if the minimum order for vaccine in Phase 1 is

1,000 doses as is specified in COVID-19 Vaccination Scenario 1 for Jurisdictional Planning.

It is expected that LHDs will play an important role in immunizing essential municipal workers in Phase 1. Under the State Response Framework, the state of Connecticut is divided into five (5) planning regions; the DPH has also organized under the same regional approach for LHD vaccination initiative efforts. The DPH is working with the CRI leads to ensure that all LHDs have a plan to vaccinate their municipal workers (either alone, in collaboration with neighboring LHDs, or by contracting with an outside agency). LHDs and other vaccinators are being invited to enroll in the CoVP.

Connecticut statute requires healthcare providers who administer pediatric vaccines (children age 18 and younger) to enroll in the CT Vaccine Program (CVP). Most providers in the CVP are pediatric clinics. However, family practice clinics, urgent care clinics, school-based health centers, local health departments/districts, hospital (maternity wards) and FQHCs are also enrolled in the CVP. As providers sign a CVP Provider Agreement, DPH contacts them to determine their interest in enrolling in the CoVP. Each provider was sent a cover letter that explains the likely terms of the CoVP and a SurveyMonkey link where providers can register their interest and provide some information about their clinics. All those who indicate their interest in administering COVID-19 vaccine are added to a list of pre-registered CoVP providers and will be invited to enroll in the CoVP.

The invitation to enroll in CoVP includes adult providers that joined the CVP in preparation for the 2020-2021 influenza season. In the summer of 2020, CDC indicated that it would provide the DPH with supplemental late season influenza vaccine doses to be distributed to providers who could administer them to adults during the 2020-2021 influenza season. These doses were intended for under-vaccinated populations. An email was sent to all local health departments/districts, long-term care facilities, assisted living and FQHCs. Those that indicated the ability to utilize doses are required to enroll in the CVP if they have not done so.

To further expand vaccination capacity for adults who will be vaccinated in both Phases 1 and 2, additional Connecticut providers beyond those in the current programs are also being targeted for recruitment. A recruitment letter was distributed by the DPH Practitioner Licensing via email to practitioners with CT MD, DO, and APRN licenses in September 2020. The letter was also distributed via the professional associations (e.g. Connecticut Medical Association, Connecticut APRN Society, Connecticut Chapter of the American Academy of Family Physicians, Connecticut Hospital Association, American College of Obstetricians and Gynecologists New England Branch, Connecticut Association of Health Care Facilities/Connecticut Center for Assisted Living) and Connecticut State Departments (Consumer Protection, Social Services). The letter explained

the terms of the CoVP and included a SurveyMonkey link where a provider could pre-register interest in administering COVID-19 vaccines. The letter requests that one practitioner per facility complete the survey. All those who pre-register will be invited to enroll in the CoVP.

**REFERENCES:**

- CDC’s [Infection Control Guidance for Healthcare Professionals about Coronavirus \(COVID-19\)](#): Infection control measures that are currently necessary when selecting COVID-19 vaccination clinic settings

**b. Vaccination Provider Types and Settings**

The table below is an example of the provider types and populations reached during Phases 1 and 2.

**Table 1 - CT COVID-19 Program Vaccine Administration Settings with Populations Reached in Phase 1 and Phase 2**

Vaccine administration entities	child or adult	Populations reached
Hospitals (occ health)	adult	Essential hospital personnel
Pharmacies	both	No medical home, urban, those with limited transportation
Private medical practices - urgent care	both	No medical home
LTCF / ASL / residential care/homecare	adult	LTCF residents and staff
Occupational health clinics / private sector employers	adult	Essential personnel
LHDDs	both	Uninsured, urban people of color (some LHDDs), no medical home
VNAs	both	Uninsured, urban people of color (some LHDDs), no medical home
Corrections	both	high risk for COVID
Military clinics		
FQHCs	both	Urban, People of color, Uninsured, Underinsured
Private medical practices - family medicine	both	general public
Private medical practices - internal medicine	adult	general public
Private medical practices - endocrinology	mostly adult	medically high risk for COVID - Diabetes
Private medical practices - gerontology	mostly adult	high risk for COVID - Advanced age
Private medical practices - oncology / hematology	mostly adult	medically high risk for COVID - cancer, immunosuppression
Private medical practices - cardiology	mostly adult	medically high risk for COVID - heart disease
Private medical practices - nephrology	mostly adult	medically high risk for COVID - Renal disease
School based health centers	children	Urban people of color, no medical home, uninsured
Private medical practices - pediatrics	children	general public
Tribal nations		Tribal nation members
Dialysis centers	mostly adult	medically high risk for COVID - Renal disease
Colleges/ Universities/ Residential schools	both	students living in congregate settings, young adults
Homeless shelter	both	congregate setting
Group homes - behavioral health	both	
Hospice	both	

**c. Vaccination Provider Enrollment Data**

To receive/administer COVID-19 vaccine, constituent products, and ancillary supplies, vaccination provider facilities/organizations must enroll in the federal CoVP coordinated through Connecticut DPH’s Immunization Program. Enrolled

COVID-19 vaccination providers must be credentialed/licensed in the jurisdiction where vaccination takes place, and sign and agree to the conditions in the [CDC COVID-19 Vaccination Program Provider Agreement](#). Failure of any enrolled COVID-19 vaccination provider organization or vaccination location under its authority to meet the conditions of the agreement may impact whether COVID-19 vaccine product orders are fulfilled and may result in legal action by the federal government.

Enrolled COVID-19 vaccination providers must also fully complete the *CDC COVID-19 Vaccination Provider Profile* form (included in the [CDC COVID-19 Vaccination Program Provider Agreement](#)) for each location where COVID-19 vaccine will be administered. The profile form collects the following variables for each location:

- i. Address and contact information
- ii. Days and hours of operation
- iii. Vaccination provider type (e.g., medical practice, pharmacy, long-term care facilities)
- iv. Settings where vaccine will be administered (e.g., hospital, university, temporary or off-site clinic)
- v. Number of patients/clients served
- vi. Influenza vaccination capacity during the peak week of the prior (2019–2020) influenza season
- vii. Populations served (e.g., pediatric, adult, military, pregnant women)
- viii. Current Immunization Information Systems (IIS) reporting status
- ix. Vaccine storage unit capacity in volume and ability to maintain required temperatures

Both forms (agreement and profile) must be submitted to the Connecticut DPH electronically through CT WiZ.

All COVID-19 vaccination providers will be required to order COVID-19 vaccine from the CoVP using the CT WiZ web interface, electronically report doses administered to CT WiZ either directly or indirectly through the CDC's Vaccine Administration Management System (VAMS) and to maintain dose level vaccine accountability.

The DPH Immunization Program will contact the person designated by facilities that expressed interest in enrolling in the CoVP to initiate the process. The steps of the process will be:

- i. Immunization Program staff enter clinic level information in CT WiZ using information shared in the pre-registration survey by interested providers.
- ii. CT WiZ staff create the clinic in CT WiZ and assign a PIN number.
- iii. Immunization Program staff email the contact with an invitation link to request a user account associated with the clinic access to CT WiZ.
- iv. Clinic staff request user accounts by completing and submitting a [CT WiZ User Agreement](#).

- v. Designated CT WiZ staff approve or deny the requests. Requests that match the name and email contact from the pre-registration documents will be approved. If a request does not match, the Immunization Programs will attempt to contact the clinic to ensure the request is valid.
- vi. The clinic director reviews and signs the [CDC COVID-19 Vaccination Program Provider Agreement](#) in CT WiZ. This includes specifying a designated CoVP Coordinator and Backup Coordinator.
- vii. CT WiZ IT staff work with clinic IT staff to onboard the clinic to CT WiZ (establish bi-directional communication of vaccine administration and inventory information with the clinic's electronic health record (I)). If this is not possible, because the clinic's I does not support data exchange or the clinic does not have an I, clinic staff can access the CT WiZ user interface via the [internet](#). Providers participating in mass vaccination during Phase 1 can use VAMS to electronically report doses administered.

*\*Note: [This text captures current practices that will likely be maintained in Phase 2.]*

d. **Provider Verification**

The DPH CoVP enrollment efforts, and corresponding memoranda and surveys are sent out to only currently licensed healthcare practitioners who can administer vaccines in Connecticut. The state's e-licensing system and practitioner rosters were used to distribute these materials.

e. **COVID-19 Vaccination Provider Training**

Training of COVID-19 vaccination providers is vital to ensure the success of the COVID-19 mass vaccination initiative.

Once a clinic is enrolled in the CoVP, a member of the CT WiZ training staff contacts the designated CoVP Vaccine Coordinator about training. The Coordinator and Back-up Coordinators are directed to the [CT WiZ training website](#) where they can complete self-directed training on navigating the CT WiZ IIS and managing patient information. They then must complete web-based video conference training on using CT WiZ for ordering vaccines and managing vaccine inventory. Reports on provider participation will be pulled from CT WiZ and analyzed by DPH to ensure providers are trained before receiving and dispensing vaccine.

Before ordering vaccine, the CoVP Coordinator and Backup Coordinator are required to complete CDC's COVID-19 training module which will be a web-based training course (currently under development—topics will include storage/handling, vaccine indications, contraindications/precautions, administration and documentation). They are also required to review *The Guide for Providers Enrolled in the CoVP* that is accessed on the Connecticut DPH CoVP Provider webpage.

COVID-19 vaccination providers must understand the following:

- i. ACIP COVID-19 vaccine recommendations, when available
  - ii. COVID-19 vaccine indications, contraindications and precautions for each vaccine product being administered
  - iii. How to order and receive COVID-19 vaccine
  - iv. COVID-19 vaccine storage and handling (including transport requirements)
  - v. How to administer vaccine, including preparation (e.g. reconstitution, use of adjuvants), appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration, etc.
  - vi. How to document and report vaccine administration via the jurisdiction's IIS or other external system
  - vii. How to manage vaccine inventory, including accessing and managing product expiration dates
  - viii. How to report vaccine inventory
  - ix. How to manage temperature excursions
  - x. How to document and report vaccine wastage/spoilage
  - xi. Procedures for reporting moderate and severe adverse events as well as vaccine administration errors to the Vaccine Adverse Event Reporting System (VAERS)
  - xii. Providing Emergency Use Authorization (EUA) fact sheets or Vaccine Information Sheets (VIS) to vaccine recipients
  - xiii. How to submit facility information for COVID-19 vaccination clinics to CDC's VaccineFinder (particularly for pharmacies or other high-volume vaccination providers/settings)
- f. **Strategy for Redistribution of Vaccine**  
Vaccine ordered by a CoVP enrolled provider will be sent from the central distributor or manufacturer (for ultra-cold vaccine) to the delivery location specified in CT WiZ for that provider under the agreement. Under limited circumstances, a provider that receives vaccine may redistribute it to another CoVP enrolled provider. This means that custody of vaccine will be transferred from one CoVP enrolled provider to another. For example, vaccine may be delivered to an LHD and some of that order may be redistributed to another LHD or vaccinator, such as a Visiting Nurse Association (VNA). This may occur when a jurisdiction's needs fall below the minimum allowable order or because COVID-19 vaccination by LHDs is organized by region. In such a case, the entity that ordered the vaccine will be required to sign a COVID-19 Redistribution Agreement. Each site receiving redistributed vaccine must sign a [CDC COVID-19 Vaccination Program Provider Agreement](#) and complete the required trainings. Upon redistribution of vaccine, a transfer of inventory must occur in CT WiZ to allow for vaccine tracking. Patient-level doses administered must be reported to CT WiZ within 24 hours.
- g. **Strategy to Ensure Equitable Access**  
The Governor's Advisory Group is working to finalize a strategy to ensure equitable access to vaccine and to combat vaccine hesitancy. The preliminary strategy is to place more clinics in population-dense areas of the state. To

accomplish this, the address of each enrolled CoVP provider will be geocoded and mapped to show the geospatial distribution of clinics by type for Phase 1 and 2. The maps will show clinics as points on the map and show clinic density per population to adjust for variations in population density across the state. These maps will be reviewed to identify areas where additional providers will need to be recruited to ensure equitable access to COVID 19 vaccine.

**h. Recruitment Strategy for Pharmacies**

Some multijurisdictional vaccination providers (e.g., select large drugstore chains, some I locations, Veterans Administration clinics and hospitals, and other federal providers) will enroll directly with CDC in Phase 1-B and 2 through a Memorandum of Understanding (MOU) to order and receive COVID-19 vaccine. CDC will notify the DPH of any entities receiving direct allocations within their areas. These direct partners will be required to report vaccine supply and uptake information to Connecticut DPH.

The DPH may enroll some pharmacies in the CoVP to administer vaccine in Phase 1, depending upon gaps that may exist in reaching critical populations identified for this Phase, and the ability of pharmacies to meet storage and handling requirements. Pharmacies may be engaged as off-site mass vaccinators (mobile clinics) or for in-pharmacy vaccination of critical populations identified through VAMS.

**REFERENCES:**

- [VaccineFinder](#): Online service for users to search for locations that offer vaccinations. VaccineFinder works with partners such as clinics, pharmacies, and health departments to provide accurate and up-to-date information about vaccination services.
- Health and Human Services (HHS) [Authorization for State-Licensed Pharmacists to Administer Vaccines](#): HHS Expands Access to Childhood Vaccines during COVID-19 Pandemic

**6. COVID-19 Vaccine Administration Capacity**

“Vaccine administration capacity” is defined as the maximum achievable vaccination throughput regardless of public demand for vaccination. By having a good understanding of the COVID-19 vaccination providers and locations and their vaccine administration capacities, the Connecticut DPH can generate rough estimates of COVID-19 vaccine administration capacity in their jurisdiction and their ability to reach various COVID-19 mass vaccination initiative coverage goals.

**a. Vaccine Estimates**

CT DPH has a number of sources of information available to estimate the vaccine throughput of enrolled COVID-19 providers. Vaccine throughput is the number of doses of vaccine that can be administered per a unit time. LHDs provide the DPH with estimates of throughput that result from exercises. Vaccine ordering and CT WiZ data can be used to examine the capacity of providers enrolled in the CVP.

The recruitment surveys and the provider agreement ask for estimates of throughput.

**b. Provider Estimates**

For Phase 1, vaccine providers will be matched with groups that will likely require vaccination to ensure sufficient capacity. For Phase 2, the total throughput that can be achieved by enrolled providers in each region will be estimated using the data described above. These estimates will be used to determine whether the number of enrolled providers is likely to be sufficient to vaccinate those not designated for Phase 1 vaccination on a timely basis. This will be done periodically as providers enroll. Where gaps are noted strategies for targeted recruitment to increase total throughput in a region will be developed and implemented.

To meet the potential demand for vaccinators, the DPH is proposing that additional practitioners be allowed to administer vaccine under medical orders from a medical doctor or doctor of osteopathy. The Commissioner of the DPH has the authority under existing executive orders to suspend certain licensure or regulatory requirements under the scope of the agency that could enable vaccine to be administered by dentists paramedics, medical assistants, and emergency medical technicians.

**REFERENCES:**

- CDC's [PanVax Tool for Pandemic Vaccination Planning](#): CDC developed a tool to assist with estimating vaccine capacity.

**B. Activation**

Refer to Section II. Concept of Operations, C. Activation of the Connecticut DPH Functional Annex 6: Mass Vaccination Plan. Activation of this plan will occur when the delivery of the vaccine and related supplies is imminent.

**C. Response**

Once this Mass Vaccination Plan is officially activated, the DPH will serve in the lead role to manage the response using the Incident Command System (ICS), and DEMHS is the lead support agency. Additional response structures may be activated at the state and local levels to support the response.

For the purposes of this Plan, the activities and efforts described in the Response section are activities and efforts that will be activated when vaccine supplies arrive and when the mass vaccination initiative begins in Connecticut.

Initial supplies of COVID-19 vaccine may be available in fall 2020. Early dose distribution will be limited; therefore, phased allocation of early vaccine doses will likely be necessary. According to the COVID-19 Vaccination Program Interim Playbook for Jurisdictional Operations Populations of focus for initial COVID-19 vaccine doses are expected to include healthcare workers (including ancillary staff, vaccinators, and staff in long-term care facilities),

other essential workers, and people at higher risk for severe COVID-19 illness 2. See Section 4: Critical Populations for more information. Jurisdictions should anticipate allocations to shift during the response based on supply, demand, vaccine characteristics, and disease epidemiology and should plan for high-demand and low-demand scenarios.

Based on guidance from the CDC, initial doses of a COVID-19 vaccine will first be administered to critical workforce and high-risk populations as supplies allow. Vaccine will be administered to these targeted groups at small, local clinics such as workplaces, community/senior centers or mobile clinics. These mass vaccination clinics may be run by local health departments, employers, hospitals, health care providers or others. As vaccine becomes more available, vaccination will be expanded to additional essential workers, those at high risk for complications of COVID-19 and will be made available to the general public. Most of the vaccine for the general population will be provided through private sector providers (e.g., private practitioners, pharmacies) and FQHCs

## 1. Vaccine Allocation, Ordering, Distribution, and Inventory Management

### a. Allocation

The federal government will determine the allocation of COVID-19 vaccine designated for each jurisdiction based on population. The Connecticut DPH's Immunization Program is responsible for managing and approving orders from enrolled vaccination providers based on this allocation. The amount allocated will change over time, which may be based on critical populations recommended for vaccination by ACIP (with input from National Academy of Science, Engineering, and Medicine), COVID-19 vaccine production and availability, and overall population of the jurisdiction.

In addition to the State, Federal agencies such as Department of Defense, Bureau of Prisons, and the Department of Veterans Affairs, starting in Phase 1, and commercial partners such as pharmacies, starting in Phase 1b, will receive allocations directly from CDC. CDC is currently developing procedures to ensure that jurisdictions and tribes have full visibility of COVID-19 vaccine supply and vaccination activities among these entities located within their boundaries.

The Connecticut DPH Immunization Program developed allocation principles for critical populations of focus in early- and limited- supply scenarios. Allotments of doses to vaccination providers within Connecticut are based on:

- i. ACIP recommendations (when available)
- ii. Estimated number of doses allocated to the jurisdiction and timing of availability
- iii. The Food and Drug Administration (FDA) indications of the available vaccine product and its match to the target population served by the provider
- iv. Target populations served by vaccination providers and geographic location to ensure distribution throughout the jurisdiction
- v. Vaccination provider site vaccine storage and handling capacity and throughput

- vi. Minimizing the potential for wastage of vaccine, constituent products, and ancillary supplies
- vii. Other local factors

See Section A. 4: Critical Populations for more information.

**b. Assessing Cold Chain Capability**

Each enrolled provider is required to complete a [CDC COVID-19 Vaccination Program Provider Agreement](#) which contains a profile for each clinic location that will be administering COVID-19 vaccine at any phase of the campaign. On the Provider Profile, the provider is required to specify a ship-to and receiving time information for each clinic location. The provider is also required to list all storage devices that will be used to store COVID-19 vaccine at each clinic location. Before providers can order vaccine, they will be required to demonstrate that each listed storage unit where CoVP vaccine will be stored can maintain temperatures within the required range for at least 72 hours. Providers will demonstrate this by emailing a readout (printout) of a digital data logger that has been placed in each device. A digital data logger with a current valid certificate of calibration is required in each device containing COVID-19 vaccine, at all times. The provider is also required to have a back-up data logger with a current valid certificate of calibration. The temperature of each storage device containing COVID-19 vaccine must be checked, and temperatures recorded at least 2 time per day. Excursions from the temperature requirements must be immediately reported to the Connecticut DPH Immunization Program as soon as possible. Vaccine that has been exposed to out-of-range temperatures must be labeled and stored separately from other vaccines but remain at the required temperature until it can be determined whether it is viable or whether it must be discarded.

Each facility is required to complete an Emergency Vaccine Storage Back-up Plan that can be activated in case a storage device fails to maintain temperatures in the required range or if there is a power outage.

**c. Ordering**

COVID-19 vaccination providers enrolled in Connecticut will order COVID-19 vaccine through the DPH's Immunization Program. Provider clinics will place their orders in CT WiZ. These orders must be approved by a CT WiZ staff member before they are loaded into the CDC's Vaccine Tracking System (VTrckS) for transmission to CDC. If an order is not approved, in whole or in part, the provider is notified via CT WiZ. Decisions about whether or not to approve an order will be based on factors including:

- i. A demonstrated ability of the provider to meet the storage requirements of available vaccine.
- ii. The number of doses available.
- iii. Whether or not the facility serves patients that have been prioritized for vaccine (especially in Phase 1).
- iv. Throughput (especially in Phase 1)

CDC will provide the Connecticut DPH with regular updates on the available vaccine supply and vaccine product-specific allocations for the enrolled COVID-19 vaccination providers in VTrckS. During Phase 1 of the vaccination program, when there is limited vaccine supply for critical populations, immunization programs should approve orders based on the likely populations served by a vaccination provider, the provider's capability to store and handle various COVID-19 vaccine products, and existing inventory. The minimum order size and increment for centrally distributed vaccines will be 100 doses per order; though early in the response, some ultra-cold (-60°C to -80°C) vaccine (if authorized for use or approved) may be shipped directly from the manufacturer in larger quantities.

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. Each kit will contain supplies to administer 100 doses of vaccine, including:

- i. Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
- ii. Syringes, 105 per kit
- iii. Alcohol prep pads, 210 per kit
- iv. 4 surgical masks and 2 face shields for vaccinators, per kit
- v. COVID-19 vaccination record cards for vaccine recipients, 100 per kit

For COVID-19 vaccines that require reconstitution with diluent or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies will also be included. Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.

Facilities ordering outside of their jurisdiction's allocation (i.e., commercial and federal entities with federal MOUs in place) will order directly from CDC, and CDC will be responsible for approval of those orders.

Once a vaccine order is placed, approved, and transmitted to CDC, vaccine is shipped directly from the distributor/manufacturer to the provider. The [CDC COVID-19 Vaccination Program Provider Agreement](#) specifies which days and times clinic staff are present to receive the vaccine. Providers must acknowledge receipt of vaccine received in CT WiZ.

d. **Distribution**

COVID-19 vaccine (and diluent or adjuvant, if required) will be shipped to vaccination provider sites enrolled by the Connecticut DPH's Immunization Program within 48 hours of order approval. Because of cold chain requirements, ancillary supply kits (and diluent, if applicable) will ship separately from vaccine but should arrive before or on the same day as vaccine.

Whenever possible, vaccine should be shipped to the location where it will be

administered to minimize potential breaks in the cold chain. However, there may be circumstances where COVID-19 vaccine needs to be redistributed beyond the identified primary CDC ship-to sites (i.e., for orders smaller than the minimum order size or for large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations). In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers may be allowed, if approved by the Connecticut DPH's Immunization Program, to redistribute COVID-19 vaccine, if validated cold-chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling.

The provider who has ordered the vaccine and who intends to redistribute it must sign and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement for the sending facility/organization. The provider receiving the vaccine must also have a fully completed and signed [CDC COVID-19 Vaccination Program Provider Agreement](#) for each receiving location.

Connecticut DPH's Immunization Program may occasionally allow local transport of vaccines from one location to another within their jurisdictions, if adherence to cold chain and tracking requirements are maintained. CDC does not pay for or reimburse jurisdictions, COVID-19 vaccination provider organizations, facilities, or other entities for any redistribution beyond the initial designated primary CDC ship-to location, or for any vaccine-specific portable refrigerators and/or qualified containers and pack-outs. (See Section 5: COVID-19 Vaccine Storage and Handling below for more information.)

It is expected that vaccine distribution will be coordinated by the Immunization Program's Vaccine Coordinator. It is planned that COVID-19 vaccine ordering and distribution will utilize the existing vaccines for children (VFC) distribution infrastructure. However, the state is ready to utilize its existing medical countermeasures infrastructure to support the distribution of vaccine, if necessary. Other state logistics resources (e.g., ESF 7) will be used as well.

Should a vaccine supply need to be urgently moved to a new location, the DPH will communicate with the provider(s) to ensure that cold chain management and redistribution is possible. (Refer to earlier portions of this plan that include details on cold chain management and redistribution/provider agreements).

**e. Inventory Management:**

CT WiZ will be used to document the number of doses in specific storage locations, wasted, transferred, and administered. All COVID-19 vaccination providers will be required to report inventory of COVID-19 vaccines in CT WiZ, and dose-level accountability is required of all providers that order vaccine from the CoVP program.

Documentation of dose administration may occur in VAMS for clinics using this

interface, and information in VAMS will be transmitted to CT WiZ via the IZ Gateway. Inventory reconciliation is required monthly in CT WiZ, and vaccine orders are not approved by the Connecticut DPH Immunization Program staff until reconciliation is complete.

It is anticipated COVID-19 vaccines will initially be authorized under an EUA. Vaccines authorized under an EUA will contain slight variations from approved FDA products, including:

- i. **Expiration Date:** The vaccine vials and cartons will not contain a printed expiration date. Expiration dates may be updated based on vaccine stability studies occurring simultaneously with COVID-19 vaccine distribution and administration. Current expiration dates by vaccine lots for all authorized COVID-19 vaccines will be posted on a US Department of Health and Human Services (HHS) website (weblink pending), accessible to all COVID-19 vaccination providers. To ensure that information systems continue to work as expected, CDC has worked with FDA and the manufacturers to include a two-dimensional (2D) barcode on the vaccine vial (if possible) and carton (required) labels that includes a National Drug Code (NDC), lot number, and a placeholder expiration date of 12/31/9999 to be read by a scanner. The placeholder 12/31/9999 expiration date is not visible on the vaccine packaging nor found anywhere else; it is only to facilitate information system compatibility. CDC is developing “beyond use date” (BUD) tracker labels to assist clinicians with tracking expiration dates at the point of vaccine administration. The label templates will be available on the CDC website.
- ii. **Manufactured Date:** A manufactured date will be on the packaging and should not be used as the expiration date when documenting vaccine administration. This date is provided to help with managing stock rotations; however, expiration dates should also be considered (see above) as using manufactured date alone could have some limitations.
- iii. **2D Barcode:** The 2D barcode available on the vaccine carton (also on the vials for some vaccines) will include NDC, lot number, and a placeholder expiration date of 12/31/9999.
- iv. **QR Code:** Each vaccine manufacturer will include a Quick Response (QR) code on the vaccine carton for accessing FDA-authorized, vaccine product-specific EUA fact sheets for COVID-19 vaccination providers and COVID-19 vaccine recipients.

A list of authorized COVID-19 vaccine products with corresponding EUA fact sheets for healthcare providers and vaccine recipients, and up-to-date expiration information by vaccine lot will be available on an HHS website.

## 2. **COVID-19 Vaccine Storage and Handling**

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness.

It is expected that cold chain storage and handling requirements for COVID-19 vaccine products will vary in temperature from refrigerated (2°C to 8°C) to frozen (-15 to -25°C) to ultra-cold (-60°C to -80°C) in the freezer or within the dry ice shipping container in which product was received). *Note: These temperatures are based on information available as of 9/04/2020. Updated information will be provided as it becomes available.*

The cold chain begins at the COVID-19 vaccine manufacturing plant, includes delivery to and storage at the COVID-19 vaccination provider site, and ends with administration of COVID-19 vaccine to a person. Vaccination providers are responsible for maintaining vaccine quality from the time a shipment arrives at a vaccination provider site until the dose is administered. To minimize opportunities for breaks in the cold chain, most COVID-19 vaccine will be delivered from CDC's centralized distributor directly to the location where the vaccine will be stored and administered, although some vaccine may be delivered to secondary depots based upon Redistribution Agreements. Certain COVID-19 vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site.

- a. Individual providers will be required to follow the storage and handling requirements as described in the [CDC COVID-19 Vaccination Program Provider Agreement](#) and the specific storage requirements of the individual vaccines.
- b. Satellite, temporary, and off-site clinics in collaboration with community or mobile vaccinators may assist the Connecticut DPH in providing equitable access for COVID-19 vaccination. However, these situations require additional oversight and enhanced storage and handling practices, including:
  - i. The quantity of COVID-19 vaccine transported to a satellite, temporary, or off-site COVID-19 vaccination clinic should be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and transport the vaccine appropriately. This is essential to minimizing the potential for vaccine wastage and spoilage.
  - ii. COVID-19 vaccines may be transported—not shipped—to a satellite, temporary, or off-site COVID-19 vaccination clinic setting using vaccine transportation procedures outlined in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit. The procedures will include transporting vaccines to and from the provider site at appropriate temperatures, using appropriate equipment, as well as monitoring and documenting temperatures.
  - iii. Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.
  - iv. Temperature data must be reviewed and documented according to guidance in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit.

- v. At the end of the clinic day, temperature data must be assessed prior to returning vaccine to fixed storage units to prevent administration of vaccines that may have been compromised.
  - vi. As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions<sup>2</sup> at any time, the temperature excursion should be documented and reported according to CT's Immunization Program's procedures. The vaccines that were exposed to out-of-range temperatures must be labeled "do not use" and stored at the required temperature until further information on usability can be gathered or further instruction on disposition or recovery is received.
- c. Any redistributing of vaccine (planned or unplanned) will adhere to all cold chain requirements and should limit transport of frozen or ultra-cold vaccine products. The DPH will manage and approve any and all redistribution efforts.

**REFERENCES:**

- CDC's [Vaccine Storage and Handling Toolkit](#): A comprehensive guide that reflects best practices for vaccine storage and handling from Advisory Committee on Immunization Practices (ACIP) recommendations, product information from vaccine manufacturers, and scientific studies.
- CDC's [Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](#): guidance is to assist with jurisdictional planning and implementation of satellite, temporary, or off-site vaccination clinics by public and private vaccination organizations
- CDC's [Vaccination Guidance During Pandemic](#)

**3. Dispensing Coordination (Operations)**

Connecticut maintains five CRI regions, which align with the five Connecticut DEMHS regions. Each CRI region has a lead local health department, which coordinates with other health departments in their region to develop strategies to distribute vaccine, including plans for points of vaccination (POVs) within their respective region that meet federal criteria (e.g., throughput, security, safety, equipment).

**a. Closed POVs**

Most Phase 1 mass vaccination will be carried out through closed point of vaccination sites. Each municipality, agency and business would designate their unique POV, which is not publicized or shared with the general public.

**b. Open POVs**

Open Point of Vaccination sites are likely to include large chain pharmacies, CHCs and FQHCs, private healthcare practices, hospitals, and select LHDs during Phase 2 when an ample supply of vaccine is available.

**c. Hospitals**

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<sup>2</sup> A "temperature excursion" is an event in which the COVID-19 vaccine is exposed to temperatures outside the range(s) prescribed for storage and/or transport.

Acute care hospitals are likely to operate as closed POVs for employees during Phase 1 and may provide services to surrounding communities during Phase 2 as open POVs.

**d. Pharmacies**

Pharmacies who engage in agreements with the federal government to offer vaccination to residents in long-term care and assisted living facilities will operate as closed POVs during Phase 1b. Pharmacies that receive vaccine through the DPH may operate as close POVs during Phase 1a or 1b, and also as open POVs during Phase 2.

Pharmacy chains that are part of an interstate chain Memorandum of Agreement (MOA) and that receive vaccine directly from the Federal Government outside of the Connecticut allocation will be required to report doses administered to CT WiZ directly or via VAMS or another platform. Other pharmacies intend to administer vaccine will follow the normal procedure for enrolling, ordering, documenting doses administered and accounting for inventory.

**e. Clinical Support and Vaccine Safety Monitoring**

**i. Dosage and contraindications**

Vaccine dosing information, indications and contraindication will not be available for specific vaccines until they are approved/authorized by FDA and recommendations have been made by ACIP concerning their use. The [CDC COVID-19 Vaccination Program Provider Agreement](#) requires providers to administer vaccine as recommended by ACIP. The DPH will provide this information to CoVP program members when it becomes available.

**ii. COVID-19 Vaccine Safety Monitoring**

An “adverse event following immunization” is an adverse health problem or condition that happens after vaccination (i.e., a temporally associated event). It might be truly caused by the vaccine or it might be purely coincidental and not related to vaccination.

CDC continuously monitors the safety of vaccines given to children and adults in the United States. VAERS, co-administered by CDC and FDA, is the national frontline monitoring system for vaccine safety.

**(i) Vaccine Adverse Event Reporting System (VAERS)**

Healthcare providers should report clinically important adverse events following COVID-19 vaccination to VAERS. VAERS is a national early warning system to detect possible safety problems with vaccines. Anyone—a doctor, nurse, pharmacist, or any member of the general public—can submit a report to VAERS. VAERS is not designed to detect whether a vaccine caused an adverse event, but it can identify “signals” that might indicate

possible safety problems requiring additional investigation. The main goals of VAERS are to:

- Detect new, unusual, or rare adverse events that happen after vaccination
- Monitor for increases in known side effects
- Identify potential patient risk factors for particular types of health problems related to vaccines
- Assess the safety of newly licensed vaccines
- Detect unexpected or unusual patterns in adverse event reports

Per the CDC [CDC COVID-19 Vaccination Program Provider Agreement](#), COVID-19 vaccination providers are required to report adverse events following COVID-19 vaccination and should report clinically important adverse events even if they are not sure if the vaccination caused the event. Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention. VAERS data-sharing agreements with Department of Defense and I healthcare facilities are being coordinated through the federal government. The Connecticut DPH ensure that the COVID-19 vaccination providers they enroll understand the procedures for reporting adverse events to VAERS.

Healthcare providers are required by law to report to VAERS:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations.
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.
- Healthcare providers are strongly encouraged to report to VAERS:
- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event.
- Vaccine administration errors

The *Guide for Providers Enrolled in the CoVP* includes information on VAERS, the report requirements and a copy of the VAERS Table of Reportable Events Following Vaccination.

The CT Immunization Vaccine Coordinator is designated as the program safety officer. All vaccine adverse events reported by providers or members of the public to the Connecticut DPH Immunization Program will be forwarded to him. He will notify the Connecticut DPH leadership via the ICS structure, advise on

VAERS reporting and may assist in data collection on behalf of the VAERS system.

**REFERENCES:**

- [Vaccine Adverse Event Reporting System](#): Information on submitting a VAERS report electronically.

The following two programs require no actions from the Connecticut DPH but are provided for informational purposes only to help in fielding questions about COVID-19 vaccine safety monitoring.

(ii) **Vaccine Safety Datalink**

The [Vaccine Safety Datalink](#) (VSD) is a collaboration between CDC's Immunization Safety Office and nine healthcare organizations. This active surveillance system monitors electronic health data on vaccination and medical illnesses diagnosed in various healthcare settings and conducts vaccine safety studies based on questions or concerns raised from medical literature and VAERS reports.

(iii) **Clinical Immunization Safety Assessment Project**

CDC's [Clinical Immunization Safety Assessment Project](#) is a national network of vaccine safety experts from CDC's Immunization Safety Office and seven medical research centers. This project conducts clinical research and assesses complex adverse events following vaccination. Healthcare providers can request a consultation for a complex vaccine safety issue with an individual patient at [CISAeval@cdc.gov](mailto:CISAeval@cdc.gov).

(iii) CDC is planning for enhanced vaccine safety surveillance, such as Vaccine safety assessment for essential workers (V-SAFE) and enhanced VAERS reporting through National Healthcare Safety Network (NHSN) sites

**REFERENCES:**

- CDC's National Center for immunization & Respiratory Diseases: [Enhanced Safety Monitoring for COVID-19 Vaccines in Early Phase Vaccination](#)

4. **COVID-19 Requirements for IISs or Other External Systems**

Immunization Information Systems (IIS), formerly known as "vaccine registries," are confidential, population-based, computerized databases for exchanging vaccine information with healthcare providers. Connecticut's IIS, CT WiZ, is maintained by the DPH's Immunization Program.

Consistent documentation of COVID-19 doses administered in CT WiZ is a federal requirement of enrollment in the CoVP and important for several reasons.

- Patient level information is important should it be necessary to trace back to the precise lot number which vaccine was administered, to help ensure patient safety and monitor for adverse events. Additionally, it is important for enabling patient

reminders for the second dose of vaccine which must be the same type of vaccine given for first dose. This is especially helpful in a pandemic situation when people may receive first and second vaccine doses at different locations. The IIS will also help to ensure that first and second doses are administered using the same vaccine product and appropriately spaced according to ACIP-recommended intervals.

- Reporting doses to CT WiZ will also allow the State to monitor at the population level that we are reaching the populations we are targeting for vaccination.

Based on Connecticut DPH's discretion and IIS functionality, COVID-19 vaccination providers may use IISs to:

- a. Enroll in the COVID-19 vaccination program
- b. Place orders for COVID-19 vaccine
- c. Document vaccine administration
- d. Manage and report vaccine inventory
- e. Report vaccine spoilage/wastage
- f. Provide reminders to COVID-19 vaccine recipients indicating when the next dose of a multidose vaccine is due

The VAMS application contains three interfaces: the patient interface will allow patient registration and appointment management, the clinic interface will allow clinic management and recording of vaccine administration, and the public health interface will allow data reporting and analysis. VAMS is being made available by the CDC.

Using VAMS, employers and organizations can identify people designated for immunization in Phase 1. A point of contact from the employers or organizations will be invited by the DPH to establish an account in VAMS. These organizations will then use VAMS to upload rosters of people who should be vaccinated in phase 1. Provider clinics enrolled in the CoVP will be invited by the DPH to establish an account in VAMS. These clinics will then use VAMS to do the following:

- a. Set up appointments to administer vaccine to those listed on an essential staff or high-risk patient roster.
- b. Gain consent for immunization and conduct medical screening before the appointment.
- c. Sign in vaccinees at the clinic
- d. Record doses administered
- e. Document and decrement vaccine inventory. Vaccines can be hand keyed in to populate clinic inventory or scanned in and matched to the vaccine via 2D bar code technology.
- f. Set up and send out a reminder a required second dose of vaccine, if applicable.

These facilities will be required to order vaccine in CT WiZ.

During Phase 2, facilities will use CT WiZ to place vaccine orders and to manage inventory. Clinics which have established electronic data exchange with CT WiZ will

document doses administered in their electronic health record (EHR) and this information will be transmitted to CT WiZ. Facilities that do not have electronic data exchange will be required to document doses of COVID-19 vaccine administered via the web-based CT WiZ user interface or VAMS.

**REFERENCES:**

- CDC Vaccination Clinic Mobile Application: Vaccine Administration Management System (VAMS)
- VAMS: An overview of the functionality of the four VAMS modules: IIS jurisdictions, employers/organizations, clinics, and vaccine recipients. (Located in SharePoint)

As the Connecticut DPH enrolls providers in the COVID-19 mass vaccination initiative (see Section 6: COVID-19 Vaccination Provider Recruitment and Enrollment), it is critical providers are onboarded to the CT WiZ.

**REFERENCES:**

**Provider Onboarding**

- [CDC Provider IIS Participation Community of Practice](#): An overview of the CDC Provider IIS Participation Community of Practice and ideas for addressing important provider IIS participation issues, including onboarding, assistance, data quality, and provider training and outreach presented as a webinar on April 10, 2019.
- [American Immunization Registry Association \(AIRA Data Validation Guide – for the IIS Onboarding Process \(2017\)\)](#): A guide with recommendations on the data validation process within onboarding
- [Onboarding Consensus-Based Recommendations \(2018\)](#): A guide for improving and standardizing onboarding intended for technical and programmatic staff that make up IIS onboarding teams and for program administrators responsible for allocation of onboarding resources

**5. Data Management (Submission of Required Data to the CDC)**

CT WiZ will be used to collect and report data to satisfy CDC and jurisdictional reporting requirements.

During Phase 1 and 2, required data points will be reported through either VAMS or CT WiZ. Data on administered vaccines by VAMS users/clinics will be transmitted via VAMS to CDC. The records will then be transmitted to CT WiZ via the Immunization Gateway (IZ Gateway), a system that allows for the secure flow of immunization data between IISs, large multi-jurisdictional provider organizations to IIS, and from IIS to consumers. Clinics not using VAMS will report to CT WiZ; CT WiZ data will be submitted to CDC directly.

**REFERENCES:**

**Data Quality**

- [IIS Data Quality Blueprint](#) — A guide to help immunization program awardees address and advance data quality within IISs
- [Data Quality Assurance in Immunization Information Systems: Incoming Data \(2008\)](#): A

summary of best practice guidelines and immediate actions an IIS can take to improve data quality

- [IIS Data Quality Practices to Monitor and Evaluate Data at Rest \(2018\)](#): Practical guidance on techniques, methodologies, and processes for IISs to use in assessing the quality of data at rest, including demographic and immunization record information that is currently in the live, production environment (e.g., database or other data store). The primary audience for the guide includes IIS managers and staff with responsibility for ensuring IIS data quality.
- [Consolidating Demographic Records and Vaccination Event Records \(2017\)](#): Consensus-based best practice recommendations to support the process of consolidating demographic and vaccination event records.

#### **Immunization Gateway**

- Immunization Gateway Information Sheet (Located in SharePoint available to immunization programs)
- Immunization Gateway Overview (Located in SharePoint available to immunization programs)
- Immunization Gateway Q&As for IIS Awardees (Located in SharePoint available to immunization programs)

#### **6. Ordering and Inventory**

See Section 2. Ordering and Section 4. Inventory found in the Response Section above.

#### **REFERENCES:**

##### **Ordering and Inventory**

- [Immunization Information System Inventory Management Operations \(2012\)](#): Consensus-based best practice recommendations for IISs to support immunization program requirements for provider organizations' vaccine inventory management and associated IIS reports that support the vaccine inventory management needs of provider organizations and grantee immunization programs.
- [Decrementing Inventory via Electronic Data Exchange \(2016\)](#): Consensus-based best practice recommendations to support the process of decrementing inventory via electronic data exchange.
- [Guidance on Unit of Sale/Unit of Use Lot Numbers \(2018\)](#): Clarifications to the process and expectations for management of vaccine lot numbers.
- [Vaccine Code Set Considerations \(2020\)](#): A general overview of vaccine code sets and brief description of how code sets support multiple and varied IIS functions, including electronic data exchange with EHRs and other health information systems and vaccine ordering and inventory management.

#### **7. COVID-19 Vaccination Second-Dose Reminders**

For most COVID-19 vaccine products, two doses of vaccine, separated by 21 or 28 days, will be needed. Because different COVID-19 vaccine products will not be interchangeable, a vaccine recipient's second dose must be from the same manufacturer as their first dose. Second-dose reminders for vaccine recipients will be critical to ensure compliance with vaccine dosing intervals and achieve optimal

vaccine effectiveness. COVID-19 vaccination providers should make every attempt to schedule a patient's second-dose appointment when they get their first dose.

COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. Vaccination providers should be highly encouraged to complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each patient who receives vaccine to ensure a basic vaccination record is provided. Vaccination providers should encourage vaccine recipients to keep the card in case VAMS or CT WiZ is not available when they return for their second dose. The card provides room for a written reminder for a second-dose appointment. If vaccine recipients have a smartphone, they may consider documenting their vaccine administration with a photo of their vaccination record and entering the date the next vaccine dose is due on their electronic calendar.

Providers that administer COVID-19 will be encouraged to conduct reminder recall for those vaccinated with an initial dose. VAMS includes a mechanism for reminding those who have been vaccinated with one dose of COVID-19 vaccine of the need for a second dose, after 21 or 28 days depending on the vaccine. Providers not using VAMS will be encouraged to use existing methods or they may use the reminder/recall functionality in CT WiZ. Training on the use of the module is available on the CT WiZ training webpage.

**a. System Training for Enrolled Providers**

See Section A.6.iii: COVID-19 Vaccination Provider Training in Section II. Concept of Operations.

**8. COVID-19 Vaccine Program Monitoring**

Continuous monitoring for situational awareness throughout the COVID-19 Vaccination Program is crucial for a successful outcome.

**a. CDC Dashboards**

To provide situational awareness for the Connecticut DPH and the general public throughout the COVID-19 mass vaccination initiative, CDC will have two dashboards available.

The Weekly Flu Vaccination Dashboard will include weekly estimates of influenza vaccination for adults, children, and pregnant women (when approved for these groups) using existing (National Immunization Survey [NIS]-Flu) and new (IQVIA) data sources. Data and estimates from additional sources will be added, as available.

The COVID-19 Vaccination Response Dashboard will include:

- i. Data for planning (e.g., estimates of critical population categories, number and attributes of healthcare providers and facilities)

- ii. Implementation data (e.g., number of enrolled COVID-19 vaccination providers, COVID-19 vaccine supply and distribution, COVID-19 vaccine administration locations)
- iii. COVID-19 vaccine administration data
- iv. The COVID-19 Vaccination Response Dashboard will be implemented in stages based on data availability and shareability. Both dashboards will include a view tailored for jurisdictions, available through SAMS, and a view for the general public on CDC's website.

**b. Connecticut Monitoring Systems**

The DPH Immunization Program is creating dashboards to document the process of provider engagement. The dashboards will summarize information on providers that have pre-registered and enrolled in the CoVP, including clinic number, type, location, and estimated throughput. Enrolled providers will be mapped to show their geographical distribution.

Once COVID-19 vaccine becomes available, the Immunization Program will query CT WiZ daily to examine the number and geographical distribution of doses administered.

**c. Resources**

The Connecticut DPH will regularly monitor resources to avoid unexpected obstacles to the progress of their COVID-19 mass vaccination initiative.

**i. Staffing**

Having enough adequately trained staff with current situational awareness is key to a successful COVID-19 mass vaccination initiative. Managers and supervisors will regularly check in with and support assigned staff's wellness and overall resilience to perform the assigned tasks.

**ii. Inventory**

Important activities during the COVID-19 mass vaccination initiative might be halted if certain supplies are depleted without replenishment. The Connecticut DPH will be regularly monitoring inventory to order and replenish supplies and ensure availability when needed.

**d. Communications and Public Messaging**

The Connecticut DPH routinely monitors both CDC and local-level messaging to inform their communications efforts. Information will be pushed to the local level once it is received. See Section 9: COVID-19 Mass Vaccination Initiative Communication.

**e. Local Jurisdictions and Situational Awareness**

Constant communication and coordination with local jurisdictions and tribal organizations are instrumental during all phases of the COVID-19 mass vaccination initiative. Throughout the COVID-19 mass vaccination initiative, the

Connecticut DPH will monitor and maintain awareness of local-level strategies and activities, providing technical assistance as needed.

f. **Vaccination Program Metrics**

DPH will report twice weekly on administration, distribution and provider enrollment metrics as required by CDC.

9. **COVID-19 Mass Vaccination Initiative Communication**

Starting before COVID-19 vaccines are available, clear, effective communication will be essential to implementing a successful COVID-19 mass vaccination initiative. Building vaccine confidence broadly and among groups anticipated to receive early vaccination, as well as dispelling vaccine misinformation, are critical to ensure vaccine uptake.

A successful COVID-19 mass vaccination initiative will have lasting effects on Connecticut's immunization system and overall vaccination efforts in the future; messaging is a significant component of a successful program. Messaging will be developed using risk communication principles as well as guidelines and products from the CDC Vaccinate with Confidence Framework, the FEMA coordinated New England Messaging Collaborative and with Connecticut specific messaging in development.

a. **Communication Roles**

All vaccination communication strategies will be coordinated with the Department of Public Health, the Office of the Governor in conjunction with Emergency Support Function (ESF 15). These entities will coordinate public messaging related to COVID-19 Vaccination.

i. **Office of the Governor (OTG)**

(i) Traditionally, during emergencies, messaging flows up and out through the OTG. OTG will determine which entity (OTG, DPH, or in some cases another agency) is best suited to release information.

(ii) OTG Communication staff will be informed of all messaging before it is released.

ii. **State Department of Public Health (Subject Matter Expert Lead)**

(i) The State Department of Public Health is the lead subject matter expert agency during mass vaccination initiatives.

(ii) Messaging will be confirmed with the DPH subject matter experts prior to distribution.

(iii) The Department of Public Health, through its many internal units, will be liaison to local public health, providers, hospitals, long term care facilities and other entities with direct, tactical messaging.

**iii. Emergency Support Function 15 (Public Information/Outreach)**

- (i) Under the State Response Framework (SRF), Connecticut has an established ESF-15 to coordinate planning, messaging development and amplification, diverse community outreach with all appropriate agencies and organizations.
- (ii) If activated under a Public Health or Civil Preparedness Emergency, ESF-15 may provide communications planning and operational support to DPH and the Office of the Governor with regards to COVID-19 Mass Vaccination messaging.

**b. COVID-19 Vaccination Communication Objectives**

- i. Educate the public about the development, authorization, safety monitoring, distribution, and execution of COVID-19 vaccines and that situations are continually evolving.
- ii. Ensure public confidence in the approval or authorization process, safety, and efficacy of COVID-19 vaccines.
- iii. Help the public to understand key differences in FDA emergency use authorization and FDA approval (i.e., licensure).
- iv. Engage in dialogue with internal and external partners to understand their key considerations and needs related to COVID-19 vaccine program implementation.
- v. Ensure active, timely, accessible, and effective public health and safety messaging along with outreach to key state/local partners and the public about COVID-19 vaccines.
- vi. Provide guidance to local health departments, clinicians, and other hosts of COVID-19 vaccination provider locations.
- vii. Track and monitor public receptiveness to COVID-19 vaccination messaging.

**c. Key Audiences**

Messaging should be tailored for each audience to ensure communication is effective.

- i. Healthcare personnel (i.e., organizations and clinicians who will receive information about receiving and administering vaccine)
- ii. Health insurance issuers and plans (coverage for vaccine, in-network providers)
- iii. Employers
- iv. Government and community partners and stakeholders
- v. Public/consumers
  - (i) Essential workers
  - (ii) Those in groups at risk for severe outcomes from COVID-19 infection
  - (iii) Those in groups at increased risk of acquiring or transmitting COVID-19
  - (iv) Those with limited access to vaccination services
  - (v) Community based services organizations, and other local leaders such as places of worship

- (vi) Mono-lingual communities
- (vii) Communities with limited access to the internet and other mainstream communications

**d. Broad Communication Planning Phases**

Messaging should be timely and applicable for the current phase of the COVID-19 mass vaccination initiative.

- i. Before vaccine is available
- ii. Vaccine is available in limited supply for certain populations of early focus (Phase 1)
- iii. Vaccine is increasing and available for other critical populations and the general public (Phase 2)
- iv. Vaccine is widely available (Phase 3)

**e. Communication Activities**

- i. Communicate early about the safety of vaccines in general and have easily accessible, government information to address myths, questions, and concerns.
- ii. Keep the public, public health partners, and healthcare providers well-informed about COVID-19 vaccine(s) development, recommendations, and public health's efforts.
- iii. Engage and use a wide range of partners, collaborations, and communication and news media channels to achieve communication goals, understanding that channel preferences and credible sources vary among audiences and people at higher risk for severe illness and critical populations, and channels vary in their capacity to achieve different communication objectives.
- iv. Ensure that communications meet the requirements of the Americans with Disabilities Act, the Rehabilitation Act, the Patient Protection and Affordable Care Act, the Plain Language Act, and other applicable disability rights laws for accessibility.
- v. Communicate transparently about COVID-19 vaccine risks and recommendations, immunization recommendations, public health recommendations, and prevention measures.

**f. Messaging Considerations**

Public health messages and products will be tailored for each audience and developed with consideration for health equity. Every effort will be made to use plain language that is easily understood. Information will be presented in culturally responsive language and available in languages that represent the communities. Messaging will be created to address all people inclusively, with respect, using non-stigmatizing, bias-free language.

When developing/utilizing materials, the following checklist will be used:

- Are there words, phrases, or images that could be offensive to or stereotypical of the cultural or religious traditions, practices, or beliefs of the intended audience?
- Are there words, phrases, or images that may be confusing, misleading, or have a different meaning for the intended audience (e.g., if abstract images are used, will the audience interpret them as intended)?
- Are there images that do not reflect the look or lifestyle of the intended audience or the places where they live, work, or worship?
- Are there health recommendations that may be inappropriate or prohibited for the social, economic, cultural, or religious context of the intended audience?
- Are any toll-free numbers or reference web pages in the message in the language of the intended audience?

Engaging every community, including our underserved communities with COVID-19 vaccination messaging, and messaging planning is of utmost importance. These communities include the access and functional needs communities in Connecticut, as well as our many culturally and ethnically diverse communities.

**Means of Ensuring Continued Inclusion:**

- i. Utilize the ESF-15 Diverse Communities Outreach List. This list consists of community organizations and ethnic media sources. This list is used to amplify messaging to ethnic media sources, as well as access and functional needs communities.
  - ii. Engage culturally specific media, including hyperlocal media sources to ensure our messaging reaches everyone. Encourage media participation at all press events.
  - iii. Ensure continued interpreter presence at each press conference related to COVID-19, including vaccination.
  - iv. Continue to engage diverse communities' leadership in the planning process for our messaging campaigns.
- g. Communication Channels**  
Even perfectly developed messages and materials will provide no benefit if they are not received by the intended audience.
- i. Traditional media channels**
    - (i) Print (Including hyperlocal and ethnic media sources)
    - (ii) Radio (Including hyperlocal and ethnic media sources)
    - (iii) TV
  - ii. Digital media**
    - (i) Google ads
    - (ii) Website
    - (iii) Social media including but not limited to Facebook, Twitter, Instagram, and SnapChat

(iv) Text messaging systems

**h. Partners and Trusted Sources**

Working to engage and empower partners is critical to reinforcing COVID-19 vaccination messages. Partners will be engaged throughout the vaccination rollout phases as needed to ensure unified messaging and two-way information sharing.

Partners will be engaged through community outreach meetings, through involvement within both the COVID-19 Mass Vaccination Planning Group and the Governor's COVID-19 Vaccination Advisory Committee. Efforts with partners and trusted sources are integrated into other channels in addition to programmatic and community engagement efforts.

These partners include:

- i. State and local government
- ii. Employers
- iii. Healthcare providers (including federally funded safety net and in-home care providers)
- iv. Health insurance issuers and plans
- v. Educators
- vi. Unions and professional organizations
- vii. Organizations serving minority populations, people with disabilities, and those with limited access to basic necessities like food and housing
- viii. Community and faith-based groups
- ix. Ethically and culturally diverse media

**i. Crisis and Risk Communications**

Connecticut deploys crisis and emergency risk communication strategies (CERC) to effectively communicate during all-hazard emergencies. This is done collaboratively with many state and local partners and stakeholders. Emergency public information is disseminated before, during and after an emergency or disaster. In addition to providing situational information to the public, it also frequently provides protective action recommendations or directives to be taken by the general public. This information is deployed to help people, stakeholders, and entire communities make the best possible decisions for themselves and their loved ones.

CT DPH, OTG and partner agencies will deploy communication messaging before, during, and after the COVID-19 vaccine is available to help communities understand the importance of vaccination as well as the benefits and risks. Communicating what is currently known, regularly updating this information, and continuing dialogue with media and other partners throughout the vaccine distribution and administration process is essential to establish and maintain trust and credibility.

**j. Tactical Communications**

The Connecticut DPH Immunization Program uses the following methods to communicate with providers who administer vaccine as part of the CVP: CT WIZ web interface news banner, CVP newsletter, Everbridge mass notification and the Connecticut DPH Immunization Program Website. These methods will also be used to communicate with CoVP providers. Once a clinic has registered to administer COVID-19 vaccine, designated staff will receive regular communications concerning the CoVP on topics such as vaccine availability, storage, and handling requirements. CoVP providers may also access information on the CoVP Provider webpage (<https://portal.ct.gov/DPH/Immunizations/COVID-19-Vaccine-Providers>).

**k. Public Information Officers Action Checklist**

The Public Information Officer (PIO) is the lead for public facing communications within state agencies. DPH is the lead subject matter expert agency with support from the Office of the Governor and ESF-15 PIOs as necessary.

Agency Contacts:

- Public Information Officer, Office of the Governor
- Public Information Officer, Office of the Governor and Chief Operating Officer
- Public Information Officer, Connecticut Department of Public Health
- Public Information Officer, Connecticut Division of Emergency Management and Homeland Security (ESF-15 Representative)

**i. Pre-Vaccination Messaging Checklist**

- DPH Communications, in collaboration with OTG and other agencies as needed, will monitor and determine if any messaging is required prior to a vaccine being made available.
- DPH Immunizations will inform the DPH Communications Office of vaccination status and delivery date, DPH will inform other communications stakeholders.
- DPH will work with partner agencies to develop and deploy messaging across multiple platforms and outreach means. This messaging should:
  - Set expectations early for what to expect during different vaccine rollout phases (i.e. Observation period, number of immunizations required and prioritization methodology etc.).
  - Clearly explain the type of trials used to develop and rollout the vaccine and what that means.
  - Communicate risks and the safety of vaccines with transparent messaging and continue to update the public as new information is made available on safety and efficacy.

- Ensure this messaging reaches Connecticut’s vulnerable, critical, and diverse populations.

ii. **Vaccine Arrival and deployment Messaging (Applying to Each Planning Phase)**

- DPH Communications, in collaboration with OTG and other agencies as needed, will monitor, and determine the frequency and level of messaging required when the vaccine is deployed and made available.
- As we enter each phase, DPH Immunizations will inform the DPH Communications Office of the vaccination deployment strategy approved by the Governor for the current phase.
- DPH will work with partner agencies to develop and deploy messaging across multiple platforms and outreach means. This messaging should:
  - Communicate the phase of deployment and who can get the vaccine during that phase.
  - Communicate the methodology for deployment if not available to the general public.
  - Communicate locations to receive vaccines (depending on phase).
  - Communicate risks, benefits, and the safety of vaccines with transparent messaging, and continue to update the public as new information is made available on safety and efficacy.
  - Ensure messaging reaches Connecticut’s vulnerable, critical, and diverse populations.

**REFERENCES:**

- CDC’s [Communication Resources](#)
- CDC’s [COVID-19 One-Stop Shop Toolkits](#): Toolkits tailored for different populations as well as a social media toolkit.
- CDC’s [COVID-19 Communications Plan for Select Non-Healthcare Critical Infrastructure Employers](#): Guidance on assisting industry and businesses in communication with employees about vaccination clinics.
- CDC’s [CERC manual](#): Includes online trainings, and examples of how CERC is applied during emergencies.
- WHO’s [Vaccine Safety Events: managing the communications response](#): A guide that provides strategies and tools to support effective communication planning and management in response to vaccine safety events.
- [Connecticut State Response Framework](#): The SRF is Connecticut’s All-Hazards disaster response plan. See Appendix 15 for ESF-15 related considerations.
- [Connecticut Diverse Communities Outreach List](#)
- Connecticut Diverse Communities by County document
- Connecticut’s COVID-19 Resource Landing Page: [www.ct.gov/coronavirus](http://www.ct.gov/coronavirus)
- Connecticut’s Community Resources Landing Page:

<https://portal.ct.gov/Coronavirus/CommunityResources>

#### D. Demobilization and Recovery

##### 1. Coordination of Returned Assets (COVID-19 Vaccine Recovery)

Details of COVID-19 vaccine recovery are still being finalized and will be communicated when available.

The Connecticut DPH Vaccine Ordering Standard Operating Procedure (SOP) describes the usual procedures for vaccine returns. A Clinic that intends to return vaccine must complete the Vaccine Return form. Returns must be reviewed and approved by the CVP Vaccine Coordinator. Once the request to return vaccine is approved, a member of the Inventory Support staff enters the return into VTrckS. A return label is sent to the email address supplied by the clinic. The clinic has 30 days to print and use the return label to return the vaccines. After 30 days the label expires. If it is determined by the Vaccine Coordinator that the clinic must pay restitution, the clinic is notified and the clinic's status in CVP is changed to "Suspended" until restitution is made.

##### 2. Dormancy

Demand will be monitored regularly. If supply is exceeding demand overall or within specific regions, the Connecticut DPH Immunization Program will consider reducing the number of doses providers are authorized to receive and/or ending the supply of vaccine to non-traditional dispensing locations that were established as part of the COVID-19 vaccine initiative.

#### II. Administration, Finance, and Logistics

##### A. COVID-19 Vaccination Administration Documentation and Reporting

CDC requires that vaccination providers enrolled in the COVID-19 mass vaccination initiative report certain data elements for each dose administered within 24 hours of administration. See Attachment F: CDC IIS Data Requirements for COVID-19 Vaccine Monitoring. The required data elements are located on the Immunization Services Division Awardees SharePoint site. COVID-19 vaccination providers may view the Core Data Elements for IIS Functional Standards v4.0 at CDC's [IIS website](#).

The Connecticut DPH facilitates and monitors reporting to CT WiZ by enrolled vaccination providers. Each vaccination location should be ready (including trained staff, necessary equipment, and internet access) to report vaccine administration data to CT WiZ or VAMS at the time of vaccination. If data will be entered off site, vaccination providers must ensure the required data are reported to CT WiZ or VAMS within 24 hours. Reporting data may be transmitted daily from CT WiZ to the CDC via the IZ Gateway<sup>3</sup> "Connect" component. The

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<sup>3</sup> The Immunization Gateway (IZ Gateway) facilitates electronic messaging of vaccination records in a secure infrastructure allowing IIS systems across the nation to share vaccine administration data not only between jurisdictions, but also with provider organizations (e.g., Department of Defense, Federal Bureau of Prisons, IHS, Department of Veterans Affairs) that do not exchange data with the IIS today.

Connecticut DPH will not be responsible for reporting data from federal agencies or commercial partners who receive vaccine allocations directly from CDC.

**B. Finance, Billing, and Reimbursement**

As per the [CDC COVID-19 Vaccination Program Provider Agreement](#), providers may not seek payment or reimbursement for COVID-19 vaccine provided by the Federal Government. Providers may seek reimbursement for vaccine administration costs.

The terms of the [CDC COVID-19 Vaccination Program Provider Agreement](#) are material conditions of payment for COVID-19 Vaccine-administration claims submitted by [the Provider] organization to any federal healthcare benefit program, including but not limited to Medicare and Medicaid, or submitted to any HHS-sponsored COVID-19 relief program, including the Health Resources & Services Administration Program. Reimbursement for administering COVID-19 Vaccine is not available under any federal healthcare program if the Provider's organization fails to comply the terms of the [COVID-19 Vaccine Provider Agreement] [CDC COVID-19 Vaccination Program Provider Agreement](#) requirements with respect to the administered COVID-19 Vaccine dose. Each time the [Provider] Organization submits a reimbursement claim for COVID-19 Vaccine administration to any federal healthcare program, [the Provider] Organization expressly certifies that it has complied with the requirement of the [CDC COVID-19 Vaccination Program Provider Agreement](#) with respect to their administered dose. Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349. Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services. Reimbursement for vaccine administration under an EUA is being determined.

**III. Regulatory Considerations for COVID-19 Vaccination**

Initially, in Phase 1 of the mass vaccination initiative, COVID-19 vaccines may be authorized for use under an EUA issued by the FDA or approved as licensed vaccines. The facility administering the vaccine will be required to provide the person receiving the vaccine with the most recent EUA factsheet at the time of administration. See Section 5: COVID- 19 Provider Recruitment and Enrollment.

**A. Emergency Use Authorization Fact Sheets**

1. The EUA authority allows FDA to authorize either (a) the use of an unapproved medical product (e.g., drug, vaccine, or diagnostic device) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. The EUA will outline how the COVID-19 vaccine should be used and any conditions that must be met to use the vaccine. FDA will coordinate with CDC to confirm these "conditions of authorization." Vaccine conditions of authorization are expected to include distribution requirements, reporting requirements, and safety and monitoring requirements. The EUA will be authorized for a specific time period to meet response needs (i.e., for the duration of the COVID-19 pandemic). Additional

information on EUAs, including guidance and frequently asked questions, is located on the FDA [website](#).

2. Product-specific EUA fact sheet for COVID-19 **vaccination providers** will be made available that will include information on the specific vaccine product and instructions for its use. An **EUA fact sheet for vaccine recipients** will also be developed, and both will likely be made available on the FDA website and through the CDC website. Jurisdictions should ensure providers know where to find both the provider and recipient fact sheets, have read and understand them, and are clear on the requirement to provide the recipient fact sheet to each client/patient prior to administering vaccine.

**B. Vaccine Information Sheets (VISs)**

All vaccine providers, public or private, are required by the National Vaccine Childhood Injury Act (NCVIA – 42 U.S.C. § 300aa-26) to give the appropriate VIS to the patient (or parent or legal representative) prior to every dose of specific vaccines. Optional VISs may be produced, but only after a vaccine has been licensed (e.g., such as with zoster vaccines). For more information on VISs, please see the link below.

**REFERENCES:**

- CDC's [Vaccine Information Statements \(VISs\)](#)

**IV. Acronyms**

Acronym	Definition
ACIP	Advisory Committee on Immunization Practices
APRN	Advanced Practice Registered Nurse
ASPR	Assistant Secretary for Preparedness and Response
CDC	U.S. Centers for Disease Control and Prevention
CHC	Community Health Centers
CoVP	COVID-19 Vaccination Program
CRI	Cities Readiness Initiative
CT	Connecticut
CVP	Connecticut Vaccine Provider
DCP	Department of Consumer Protection
DEMHS	Connecticut Division of Emergency Management and Homeland Security
DESPP	Department of Emergency Services and Public Protection
DPH	Connecticut Department of Public Health
DHS	U.S. Department of Homeland Security
DO	Doctor of Osteopathic Medicine
EOC	Emergency Operations Center
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
FQHC	Federally Qualified Health Centers
HCC	Healthcare Coalition
ICS	Incident Command System
IIS	Immunization Information System
HHS	U.S. Department of Health and Human Services
HPP	Hospital Preparedness Program
LHD	Local Health Department
LTCF	Long-Term Care Facilities
MD	Medical Doctor
MOA	Memorandum of Agreement
OPHPR	Office of Public Health Preparedness and Response
PHEP	Public Health Emergency Preparedness
POC	Point of Contact
POV	Point of Vaccination
PPE	Personal Protective Equipment
QR	Quick Response
SEOC	State Emergency Operations Center
SOP	Standard Operating Procedure
VAERS	Vaccine Adverse Event Reporting System
VAMS	CDC's Vaccine Administration Management System
VIS	Vaccine Information Sheet
VNA	Visiting Nurse Association
VSD	Vaccine Safety Datalink
VTrcks	CDC's Vaccine Tracking System
YNHHS	Yale New Haven Health System

**Attachment A: Crosswalk to CDC Plan Template**

This Attachment can be used to crosswalk the elements in the CDC’s [COVID19 Vaccination Program Interim Playbook for Jurisdiction Operations](#) and it’s corresponding plan template. This Crosswalk will be updated as the DPH plan develops.

Color Scale

0-10% complete (red)

10-50% complete (orange)

50-99% complete (yellow)

100% complete (green)

Instruction	DPH Plan Location	Status	NOTES (10/15)
<b>Section 1: COVID-19 Vaccination Preparedness Planning</b>			
A. Describe your early COVID-19 vaccination program planning activities, including lessons learned and improvements made from the 2009 H1N1 vaccination campaign, seasonal influenza campaigns, and other responses to identify gaps in preparedness.	II. Concept of Operations A. Preparedness 1. COVID-19 Vaccination Planning Activities		
B. Include the number/dates of and qualitative information on planned workshops or tabletop, functional, or full-scale exercises that will be held prior to COVID-19 vaccine availability. Explain how continuous quality improvement occurs/will occur during the exercises and implementation of the COVID-19 Vaccination Program.	II. Concept of Operations A. Preparedness 1. COVID-19 Vaccination Planning Activities		Sentence added but no specific dates or events.
<b>Section 2: COVID-19 Organizational Structure and Partner Involvement</b>			
A. Describe your organizational structure.	II. Concept of Operations A. Preparedness 2. COVID-19 Organizational Structure and Partner Involvement a. Organizational Structure and Committee		

Instruction	DPH Plan Location	Status	NOTES (10/15)
	Members		
B. Describe how your jurisdiction will plan for, develop, and assemble an internal COVID-19 Vaccination Program planning and coordination team that includes persons with a wide array of expertise as well as backup representatives to ensure coverage.	II. Concept of Operations A. Preparedness 2. COVID-19 Organizational Structure and Partner Involvement b. Planning and Coordination Team (Internal) Attachment B		Add chart - Attachment B
C. Describe how your jurisdiction will plan for, develop, and assemble a broader committee of key internal leaders and external partners to assist with implementing the program, reaching critical populations, and developing crisis and risk communication messaging.	II. Concept of Operations A. Preparedness 2. COVID-19 Organizational Structure and Partner Involvement c. COVID-19 Vaccination Program Implementation Committee (Internal and External)		
D. Identify and list members and relevant expertise of the internal team and the internal/external committee.	II. Concept of Operations A. Preparedness 2. COVID-19 Organizational Structure and Partner Involvement a. Organizational Structure and Committee Members		
E. Describe how your jurisdiction will coordinate efforts between state, local, and territorial authorities.	II. Concept of Operations A. Preparedness 2. COVID-19 Organizational Structure and Partner Involvement d. Coordination Efforts Between State, Local, and Territorial Authorities		Add info about coordinating with the locals
F. Describe how your jurisdiction will engage and coordinate efforts with leadership from tribal communities, tribal health organizations, and urban Indian organizations.	II. Concept of Operations A. Preparedness 2. COVID-19 Organizational Structure and Partner Involvement e. Coordination and Engagement with Tribal		

Instruction	DPH Plan Location	Status	NOTES (10/15)
<p>G. List key partners for critical populations that you plan to engage and briefly describe how you plan to engage them, including but not limited to:</p> <ul style="list-style-type: none"> <li>• Pharmacies</li> <li>• Correctional facilities/vendors</li> <li>• Homeless shelters</li> <li>• Community-based organizations</li> </ul>	<p>Nations</p> <p>II. Concept of Operations</p> <p>A. Preparedness</p> <p>2. COVID-19 Organizational Structure and Partner Involvement</p> <p>f. Key Partners for Critical Populations</p>		
<b>Section 3: Phased Approach to COVID-19 Vaccination</b>			
<p>A. Describe how your jurisdiction will structure the COVID-19 Vaccination Program around the three phases of vaccine administration:</p> <ul style="list-style-type: none"> <li>• Phase 1: Potentially Limited Doses Available</li> <li>• Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand</li> <li>• Phase 3: Likely Sufficient Supply, Slowing Demand</li> </ul>	<p>II. Concept of Operations</p> <p>A. Preparedness</p> <p>3. Phased Approach to COVID-19 Vaccination</p>		
<b>Section 4: Critical Populations</b>			
<p>A. Describe how your jurisdiction plans to: 1) identify, 2) estimate numbers of, and 3) locate (e.g., via mapping) critical populations. Critical population groups may include:</p> <ul style="list-style-type: none"> <li>• Healthcare personnel</li> <li>• Other essential workers</li> <li>• Long-term care facility residents (e.g., nursing home and assisted living facility residents)</li> <li>• People with underlying medical conditions that are risk factors for severe COVID-19 illness</li> <li>• People 65 years of age and older</li> </ul>	<p>II. Concept of Operations</p> <p>A. Preparedness</p> <p>4. Critical Populations</p> <p>a. Identifying, Estimating, and Locating Critical Populations</p>		<p>Missing info on how to “estimate numbers” and “locate critical populations” (#2 and #3 of the requirement).</p>

Instruction	DPH Plan Location	Status	NOTES (10/15)
<ul style="list-style-type: none"> <li>• People from racial and ethnic minority groups</li> <li>• People from tribal communities</li> <li>• People who are incarcerated/detained in correctional facilities</li> <li>• People experiencing homelessness/living in shelters</li> <li>• People attending colleges/universities</li> <li>• People living and working in other congregate settings</li> <li>• People living in rural communities</li> <li>• People with disabilities</li> <li>• People who are under- or uninsured</li> </ul>			
<p>B. Describe how your jurisdiction will define and estimate numbers of persons in the critical infrastructure workforce, which will vary by jurisdiction.</p>	<p>II. Concept of Operations                      A. Preparedness                      4. Critical Populations                      b. Defining and Estimating Population Groups                      Initial COVID-19 Vaccine Distribution</p>		
<p>C. Describe how your jurisdiction will determine additional subset groups of critical populations if there is insufficient vaccine supply.</p>	<p>II. Concept of Operations                      A. Preparedness                      4. Critical Populations                      c. Sub-Prioritization within Jurisdiction when Vaccine Supply is Limited</p>		
<p>D. Describe how your jurisdiction will establish points of contact (POCs) and communication methods for organizations, employers, or communities (as appropriate) within the critical population groups.</p>	<p>II. Concept of Operations                      A. Preparedness                      4. Critical Populations                      d. Establishing Points of Contact (POCs) and Communication Methods for Organizations, Employers, or Communities within the Critical Population Groups</p>		
<b>Section 5: COVID-19 Provider Recruitment and Enrollment</b>			
<p>A. Describe how your jurisdiction is currently recruiting</p>	<p>II. Concept of Operations</p>		

Instruction	DPH Plan Location	Status	NOTES (10/15)
<p>or will recruit and enroll COVID-19 vaccination providers and the types of settings to be utilized in the COVID-19 Vaccination Program for each of the previously described phases of vaccine availability, including the process to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.</p>	<p>A. Preparedness                      5. Provider Recruitment and Enrollment                      a. Vaccination Provider Recruitment</p>	<p>Green</p>	
<p>B. Describe how your jurisdiction will determine the provider types and settings that will administer the first available COVID-19 vaccine doses to the critical population groups listed in Section 4.</p>	<p>II. Concept of Operations                      A. Preparedness                      5. Provider Recruitment and Enrollment                      b. Vaccination Provider Types and Settings</p>	<p>Green</p>	
<p>C. Describe how provider enrollment data will be collected and compiled to be reported electronically to CDC twice weekly, using a CDC-provided Comma Separated Values (CSV) or JavaScript (JSON) template via a SAMS-authenticated mechanism.</p>	<p>II. Concept of Operations                      A. Preparedness                      5. Provider Recruitment and Enrollment                      c. Vaccination Provider Enrollment Data</p>	<p>Yellow</p>	<p>Missing how provider enrollment data will be collected and compiled to be reported electronically to CDC twice weekly</p>
<p>D. Describe the process your jurisdiction will use to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.</p>	<p>II. Concept of Operations                      A. Preparedness                      5. Provider Recruitment and Enrollment                      d. Provider Verification</p>	<p>Green</p>	
<p>E. Describe how your jurisdiction will provide and track training for enrolled providers and list training topics.</p>	<p>II. Concept of Operations                      A. Preparedness                      5. Provider Recruitment and Enrollment                      e. COVID-19 Vaccination Provider Training</p>	<p>Green</p>	
<p>F. Describe how your jurisdiction will approve planned redistribution of COVID-19 vaccine (e.g., health systems or commercial partners with depots, smaller vaccination providers needing less than the minimum order requirement).</p>	<p>II. Concept of Operations                      A. Preparedness                      5. Provider Recruitment and Enrollment                      f. Strategy for Redistribution of Vaccine</p>	<p>Green</p>	

Instruction	DPH Plan Location	Status	NOTES (10/15)
G. Describe how your jurisdiction will ensure there is equitable access to COVID-19 vaccination services throughout all areas within your jurisdiction.	II. Concept of Operations A. Preparedness 5. Provider Recruitment and Enrollment g. Strategies for Equitable Access		
H. Describe how your jurisdiction plans to recruit and enroll pharmacies not served directly by CDC and their role in your COVID-19 Vaccination Program plans.	II. Concept of Operations A. Preparedness 5. Provider Recruitment and Enrollment h. Recruitment Strategy for Pharmacies		
<b>Section 6: COVID-19 Vaccine Administration Capacity</b>			
A. Describe how your jurisdiction has or will estimate vaccine administration capacity based on hypothetical planning scenarios provided previously.	II. Concept of Operations A. Preparedness 6. COVID-19 Vaccine Administration Capacity a. Vaccine Estimates		
B. Describe how your jurisdiction will use this information to inform provider recruitment plans.	II. Concept of Operations A. Preparedness 6. COVID-19 Vaccine Administration Capacity b. Provider Estimates		
<b>Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management</b>			
A. Describe your jurisdiction's plans for allocating/assigning allotments of vaccine throughout the jurisdiction using information from Sections 4, 5, and 6. Include allocation methods for populations of focus in early and limited supply scenarios as well as the variables used to determine allocation.	II. Concept of Operations c. Response 1. Vaccine Allocation, Ordering, Distribution, and Inventory Management a. Allocation		
B. Describe your jurisdiction's plan for assessing the cold chain capability of individual providers and how you will incorporate the results of these assessments into your plans for allocating/assigning allotments of COVID-19 vaccine and approving	II. Concept of Operations c. Response 1. Vaccine Allocation, Ordering, Distribution, and Inventory Management b. Assessing Cold Chain Capability		

Instruction	DPH Plan Location	Status	NOTES (10/15)
orders.			
C. Describe your jurisdiction’s procedures for ordering COVID-19 vaccine, including entering/updating provider information in VTrckS and any other jurisdictional systems (e.g., IIS) used for provider ordering. Describe how you will incorporate the allocation process described in step A in provider order approval.	II. Concept of Operations c. Response 1. Vaccine Allocation, Ordering, Distribution, and Inventory Management c. Ordering		
D. Describe how your jurisdiction will coordinate any unplanned repositioning (i.e., transfer) of vaccine.	II. Concept of Operations c. Response 1. Vaccine Allocation, Ordering, Distribution, and Inventory Management d. Distribution		
E. Describe jurisdictional plans for monitoring COVID-19 vaccine wastage and inventory levels.	II. Concept of Operations c. Response 1. Vaccine Allocation, Ordering, Distribution, and Inventory Management e. Inventory Management		
<b>Section 8: COVID-19 Vaccine Storage and Handling</b>			
A. Describe how your jurisdiction plans to ensure adherence to COVID-19 vaccine storage and handling requirements, including cold and ultracold chain requirements, at all levels: <ul style="list-style-type: none"> <li>• Individual provider locations</li> <li>• Satellite, temporary, or off-site settings</li> <li>• Planned redistribution from depots to individual locations and from larger to smaller locations</li> <li>• Unplanned repositioning among provider locations</li> </ul>	II. Concept of Operations c. Response 2. COVID-19 Vaccine Storage and Handling		
B. Describe how your jurisdiction will assess provider/redistribution depot COVID-19 vaccine	II. Concept of Operations c. Response		

Instruction	DPH Plan Location	Status	NOTES (10/15)
storage and temperature monitoring capabilities.	2. COVID-19 Vaccine Storage and Handling		
<b>Section 9: COVID-19 Vaccine Administration Documentation and Reporting</b>			
A. Describe the system your jurisdiction will use to collect COVID-19 vaccine doses administered data from providers.	II. Concept of Operations c. Response 1. Vaccine Allocation, Ordering, Distribution, and Inventory Management e. Inventory Management		
B. Describe how your jurisdiction will submit COVID-19 vaccine administration data via the Immunization (IZ) Gateway.	II. Concept of Operations c. Response 1. Vaccine Allocation, Ordering, Distribution, and Inventory Management e. Inventory Management		
C. Describe how your jurisdiction will ensure each COVID-19 vaccination provider is ready and able (e.g., staff is trained, internet connection and equipment are adequate) to report the required COVID-19 vaccine administration data elements to the IIS or other external system every 24 hours.	II. Concept of Operations c. Response 1. Vaccine Allocation, Ordering, Distribution, and Inventory Management e. Inventory Management		
D. Describe the steps your jurisdiction will take to ensure real-time documentation and reporting of COVID-19 vaccine administration data from satellite, temporary, or off-site clinic settings.	II. Concept of Operations c. Response 1. Vaccine Allocation, Ordering, Distribution, and Inventory Management e. Inventory Management		
E. Describe how your jurisdiction will monitor provider-level data to ensure each dose of COVID-19 vaccine administered is fully documented and reported every 24 hours as well as steps to be taken when providers do not comply with documentation and reporting requirements.	II. Concept of Operations c. Response 1. Vaccine Allocation, Ordering, Distribution, and Inventory Management e. Inventory Management		
F. Describe how your jurisdiction will generate and use COVID-19 vaccination coverage reports.	II. Concept of Operations c. Response		Missing how DPH will use/generate vax

Instruction	DPH Plan Location	Status	NOTES (10/15)
	1. Vaccine Allocation, Ordering, Distribution, and Inventory Management e. Inventory Management		coverage reports
<b>Section 10: COVID-19 Vaccination Second-Dose Reminders</b>			
A. Describe all methods your jurisdiction will use to remind COVID-19 vaccine recipients of the need for a second dose, including planned redundancy of reminder methods.	II. Concept of Operations c. Response 7. COVID-19 Vaccination Second Dose Reminders		
<b>Section 11: COVID-19 Requirements for IISs or Other External Systems</b>			
A. Describe your jurisdiction’s solution for documenting vaccine administration in temporary or high-volume vaccination settings (e.g., CDC mobile app, IIS or module that interfaces with the IIS, or other jurisdiction-based solution). Include planned contingencies for network outages or other access issues.	II. Concept of Operations c. Response 4. COVID-19 Requirements for IIS or Other External Systems		Missing plans for outage
B. List the variables your jurisdiction’s IIS or other system will be able to capture for persons who will receive COVID-19 vaccine, including but not limited to age, race/ethnicity, chronic medical conditions, occupation, membership in other critical population groups.	II. Concept of Operations c. Response 4. COVID-19 Requirements for IIS or Other External Systems		Missing specific demographic details captured
C. Describe your jurisdiction’s current capacity for data exchange, storage, and reporting as well as any planned improvements (including timelines) to accommodate the COVID-19 Vaccination Program.	II. Concept of Operations c. Response 4. COVID-19 Requirements for IIS or Other External Systems		Missing capacity info
D. Describe plans to rapidly enroll and onboard to the IIS those vaccination provider facilities and settings expected to serve healthcare personnel (e.g., paid and unpaid personnel working in healthcare settings, including vaccinators, pharmacy staff, and	II. Concept of Operations c. Response 4. COVID-19 Requirements for IIS or Other External Systems		

Instruction	DPH Plan Location	Status	NOTES (10/15)
ancillary staff) and other essential workers.			
E. Describe your jurisdiction’s current status and plans to onboard to the IZ Gateway Connect and Share components.	II. Concept of Operations c. Response 4. COVID-19 Requirements for IIS or Other External Systems		
F. Describe the status of establishing: <ul style="list-style-type: none"> <li>• Data use agreement with the Association of Public Health Laboratories to participate in the IZ Gateway</li> <li>• Data use agreement with CDC for national coverage analyses</li> <li>• Memorandum of Understanding to share data with other jurisdictions via the IZ Gateway Share component</li> </ul>	II. Concept of Operations c. Response 4. COVID-19 Requirements for IIS or Other External Systems		Missing data use info
G. Describe planned backup solutions for offline use if internet connectivity is lost or not possible.	II. Concept of Operations c. Response 4. COVID-19 Requirements for IIS or Other External Systems		Missing backup info
H. Describe how your jurisdiction will monitor data quality and the steps to be taken to ensure data are available, complete, timely, valid, accurate, consistent, and unique.	II. Concept of Operations c. Response 4. COVID-19 Requirements for IIS or Other External Systems		Missing how data is monitored
<b>Section 12: COVID-19 Vaccination Program Communication</b>			
A. Describe your jurisdiction’s COVID-19 vaccination communication plan, including key audiences, communication channels, and partner activation for each of the three phases of the COVID-19 Vaccination Program	II. Concept of Operations c. Response 9. COVID-19 Vaccination Program Communication		
B. Describe your jurisdiction’s expedited procedures for risk/crisis/emergency communication, including	II. Concept of Operations c. Response		

Instruction	DPH Plan Location	Status	NOTES (10/15)
timely message development as well as delivery methods as new information becomes available.	9. COVID-19 Vaccination Program Communication		
<b>Section 13: Regulatory Considerations for COVID-19 Vaccination</b>			
A. Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers are aware of, know where to locate, and understand the information in any Emergency Use Authorization (EUA) fact sheets for providers and vaccine recipients or vaccine information statements (VISs), as applicable.	III Regulatory Considerations for COVID-19 Vaccination		
B. Describe how your jurisdiction will instruct enrolled COVID-19 vaccination providers to provide Emergency Use Authorization (EUA) fact sheets or vaccine information statements (VISs), as applicable, to each vaccine recipient prior to vaccine administration.	III Regulatory Considerations for COVID-19 Vaccination		
<b>Section 14: COVID-19 Vaccine Safety Monitoring</b>			
A. Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers understand the requirement and process for reporting adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).	II. Concept of Operations c. Response 3. Dispensing Coordination e. Clinical Support and Vaccine Safety Monitoring ii. COVID-19 Vaccine Safety Monitoring (i)Vaccine Adverse Event Reporting System		
<b>Section 15: COVID-19 Vaccination Program Monitoring</b>			
A. Describe your jurisdiction’s methods and procedures for monitoring progress in COVID-19 Vaccination Program implementation, including: <ul style="list-style-type: none"> <li>• Provider enrollment</li> <li>• Access to COVID-19 vaccination services by population in all phases of implementation</li> <li>• IIS or other designated system performance</li> </ul>	II. Concept of Operations c. Response 8. COVID-19 Vaccine Program Monitoring b. Connecticut monitoring systems		

Instruction	DPH Plan Location	Status	NOTES (10/15)
<ul style="list-style-type: none"> <li>• Data reporting to CDC</li> <li>• Provider-level data reporting</li> <li>• Vaccine ordering and distribution</li> <li>• 1- and 2-dose COVID-19 vaccination coverage</li> </ul>			
<p>B. Describe your jurisdiction’s methods and procedures for monitoring resources, including:</p> <ul style="list-style-type: none"> <li>• Budget</li> <li>• Staffing</li> <li>• Supplies</li> </ul>	<p>II. Concept of Operations            c. Response            8. COVID-19 Vaccine Program Monitoring            c. Resources</p>		<p>Need budget mgmt info            Need staffing plan            Need inventory plan</p>
<p>C. Describe your jurisdiction’s methods and procedures for monitoring communication, including:</p> <ul style="list-style-type: none"> <li>• Message delivery</li> <li>• Reception of communication messages and materials among target audiences throughout jurisdiction</li> </ul>	<p>II. Concept of Operations            c. Response            8. COVID-19 Vaccine Program Monitoring            d. Communications</p>		
<p>D. Describe your jurisdiction’s methods and procedures for monitoring local-level situational awareness (i.e., strategies, activities, progress, etc.).</p>	<p>II. Concept of Operations            c. Response            8. COVID-19 Vaccine Program Monitoring            b. Connecticut monitoring systems</p>		
<p>E. Describe the COVID-19 Vaccination Program metrics (e.g., vaccination provider enrollment, doses distributed, doses administered, vaccination coverage), if any, that will be posted on your jurisdiction’s public-facing website, including the exact web location of placement.</p>	<p>II. Concept of Operations            c. Response            8. COVID-19 Vaccine Program Monitoring            f. Vaccination program metrics</p>		<p>Need metrics</p>

**Attachment B: Workgroup Organizational Representative Chart**

DRAFT

**Attachment C: COVID-19 Vaccination Scenarios for Jurisdictional Planning – Phase 1, Q4 2020  
 (Updated 9/15/2020)**

The planning scenarios described below should be used by state and local jurisdictions to develop operation plans for early COVID-19 vaccination when vaccine supply may be constrained. The scenarios describe potential COVID-19 vaccine requirements, early supply estimates in the event that a vaccine is authorized under EUA, and populations that may be recommended for vaccination during this early period. These scenarios are designed to support jurisdictional, federal, and partner planning, but they are still considered hypothetical. The COVID-19 vaccine landscape is evolving and uncertain, and these scenarios may change as more information is available.

Planners should assume that by January 2021, significantly more COVID-19 vaccine may be available for distribution and plans will need to evolve to address additional vaccine availability. Please refer to COVID-19 vaccine planning assumptions and additional guidance from the Centers for Disease Control and Prevention.

**Scenario 1: FDA has authorized vaccine A for Emergency Use Authorization (EUA) in 2020**

**Availability Assumptions**

Vaccine availability under EUA by				
Candidate	End of Oct 2020	End of Nov 2020	End of Dec 2020	Notes
Vaccine A	~2 million (M) doses	10M–20M doses	20M–30M doses	Ultra-cold (-70 °C) storage requirements, for large sites only

**Distribution, Storage, Handling, and Administration Assumptions**

Vaccine A	
<p><b>SHIPMENT</b>  <i>3 separately acquired components (mixed on site)</i></p> <ol style="list-style-type: none"> <li>Vaccine                             <ul style="list-style-type: none"> <li>Direct to site from manufacturer (on dry ice)</li> <li>Multidose vials (5 doses/vial)</li> </ul> </li> <li>Diluent                             <ul style="list-style-type: none"> <li>Direct to site from the US Government (USG) at room temperature)</li> </ul> </li> <li>Ancillary supply kits (for administration and mixing)                             <ul style="list-style-type: none"> <li>Direct to site from USG (at room temperature)</li> </ul> </li> </ol>	<p><b>ON-SITE VACCINE STORAGE</b>  <i>Frozen (-70 °C ± 10 °C)</i></p> <ul style="list-style-type: none"> <li>Must be used/recharged within 10 days</li> <li>Storage in shipping container OK (replenish dry ice within 24 hours of receiving shipment and again 5 days later)</li> </ul> <p><i>Thawed but NOT reconstituted (2–8 °C)</i></p> <ul style="list-style-type: none"> <li>Must use within 5 days (discard unused doses after 5 days)</li> </ul> <p><i>Reconstituted (room temperature)</i></p> <ul style="list-style-type: none"> <li>Must use within 6 hours (discard any unused, reconstituted vaccine after 6 hours)</li> </ul>
<p><b>ORDERS</b>  <i>Large quantities, to large administration sites only</i></p> <ul style="list-style-type: none"> <li>Minimum order: ~1,000 doses</li> <li>Maximum order: ~5,000 doses</li> </ul>	<p><b>ADMINISTRATION</b>  <i>2-dose series (21 days between doses)</i></p> <ul style="list-style-type: none"> <li>On-site mixing required; reconstitute with diluent just prior to administration</li> <li>Administer by intramuscular (IM) injection</li> </ul>

## Vaccine A

### INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES

**Healthcare personnel** — public health, closed point of dispensing (POD), temporary/off-site vaccination clinics + potential for mobile clinics

**Other essential workers** — public health, closed POD, temporary/off-site vaccination clinics + potential for mobile clinics

**People at higher risk of severe COVID-19 illness** — potential for mobile clinics to long-term care facilities (LTCFs)

### Additional Considerations for Early Vaccination Planning

- “Healthcare personnel” includes paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to people with COVID-19 or infectious materials.
- Jurisdictions should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine A can be stored in the ultra-cold shipment box.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach critical populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine A; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the critical populations as possible, given limitations with the product. For example: Vaccine A may be administered through mobile clinics if multiple mobile clinics are planned over a short period of time to ensure sufficiently high throughput.

## Scenario 2: FDA has authorized vaccine B for EUA in 2020

### Availability Assumptions

Vaccine availability under EUA by				
Candidate	End of Oct 2020	End of Nov 2020	End of Dec 2020	Notes
Vaccine B	~1M doses	~10M doses	~15M doses	Central distributor capacity required (-20 °C)

### Distribution, Storage, Handling, and Administration Assumptions

Vaccine B	
<p><b>SHIPMENT</b>  <i>2 separately shipped components</i></p> <p>1. Vaccine</p> <ul style="list-style-type: none"> <li>To central distributor (at -20 °C)</li> <li>Multidose vials (10 doses/vial)</li> </ul> <p>2. Ancillary supply kits</p> <ul style="list-style-type: none"> <li>Direct to site from USG (at room temperature)</li> </ul>	<p><b>ON-SITE VACCINE STORAGE</b></p> <p><i>Frozen (-20 °C)</i></p> <ul style="list-style-type: none"> <li>Storage in shipping container OK</li> </ul> <p><i>Refrigerated (2–8 °C)</i></p> <ul style="list-style-type: none"> <li>Must use within 14 days</li> </ul> <p><i>Room temperature</i></p> <ul style="list-style-type: none"> <li>Must use within 6 hours (discard any unused vaccine after 6 hours)</li> </ul>
<p><b>ORDERS</b>  <i>Central distribution capacity required</i></p> <ul style="list-style-type: none"> <li>Required by Dec 2020</li> <li>Maintained at -20 °C</li> </ul>	<p><b>ADMINISTRATION</b>  <i>2-dose series (28 days between doses)</i></p> <ul style="list-style-type: none"> <li>No on-site mixing required</li> <li>Administer by IM injection</li> </ul>
<p><b>INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES</b></p> <p><i>Healthcare personnel</i> — healthcare clinics + healthcare occupational health clinics + public health, closed POD, temporary/off-site vaccination clinics + mobile clinics</p> <p><i>Other essential workers (specifics TBA)</i> — occupational health + hospital clinics + public health, closed POD, temporary/off-site vaccination clinics</p> <p><i>People at higher risk of severe COVID-19 illness (e.g., LTCF residents)</i> — commercial pharmacy partners + mobile clinics</p>	

### Additional Considerations for Early Vaccination Planning

<ul style="list-style-type: none"> <li>“Healthcare personnel” includes paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to people with COVID-19 or infectious materials.</li> <li>Jurisdictions should plan for real-time shipment of doses.</li> <li>Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine B can be stored at 2–8 °C.</li> <li>Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach critical populations with as much throughput as possible.</li> <li>Stability testing is ongoing for Vaccine B; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.</li> <li>Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the prioritized populations as possible, given limitations with the product.</li> </ul>
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### Scenario 3: FDA has authorized vaccines A and B for EUA in 2020

#### Availability Assumptions

Vaccine availability under EUA by				
Candidate	End of Oct 2020	End of Nov 2020	End of Dec 2020	Notes
Vaccine A	~2M doses	10M–20M doses	20M–30M doses	Ultra-cold (-70 °C), for large sites only
Vaccine B	~1M doses	~10M doses	~15M doses	Central distribution capacity required (-20 °C)
<b>Total</b>	<b>~3M doses</b>	<b>20M–30M doses</b>	<b>35M–45M doses</b>	

#### Distribution, Storage, Handling, and Administration Assumptions

Vaccine A	
<p><b>SHIPMENT</b>  <b>3 separately acquired components (mixed on site)</b></p> <ol style="list-style-type: none"> <li>Vaccine           <ul style="list-style-type: none"> <li>Direct to site from manufacturer (on dry ice)</li> <li>Multidose vials (5 doses/vial)</li> </ul> </li> <li>Diluent           <ul style="list-style-type: none"> <li>Direct to site from USG (at room temperature)</li> </ul> </li> <li>Ancillary supply kits           <ul style="list-style-type: none"> <li>Direct to site from USG (at room temperature)</li> </ul> </li> </ol>	<p><b>ON-SITE VACCINE STORAGE</b>  <b>Frozen (-70 °C ± 10 °C)</b></p> <ul style="list-style-type: none"> <li>Must be used/recharged within 10 days</li> <li>Storage in shipping container OK (replenish dry ice within 24 hours of receiving shipment and again 5 days later)</li> </ul> <p><b>Thawed but NOT reconstituted (2–8 °C)</b></p> <ul style="list-style-type: none"> <li>Must use within 5 days (discard unused doses after 5 days)</li> </ul> <p><b>Reconstituted (room temperature)</b></p> <ul style="list-style-type: none"> <li>Must use within 6 hours (discard any unused, reconstituted vaccine after 6 hours)</li> </ul>
<p><b>ORDERS</b>  <b>Large quantities, to large administration sites only</b></p> <p>Minimum order: ~1,000 doses          Maximum order: ~5,000 doses</p>	<p><b>ADMINISTRATION</b>  <b>2-dose series (21 days between doses)</b></p> <ul style="list-style-type: none"> <li>On-site mixing required; reconstitute with diluent just prior to administration</li> <li>Administer IM injection</li> </ul>
<p><b>PRIORITIZED POPULATIONS AND ANTICIPATED VACCINE ADMINISTRATION SITES</b></p> <p><b>Healthcare personnel</b> — public health, closed POD temporary/off-site vaccination clinics + potential for mobile clinics</p> <p><b>Other essential workers (specifics TBA)</b> — public health, closed POD temporary/off-site vaccination clinics + potential for mobile clinics</p> <p><b>LTCF residents &amp; staff</b> — potential for mobile clinics to facilities</p>	

<b>Vaccine B</b>	
<p><b>SHIPMENT</b></p> <p><b>2 separately shipped components</b></p> <p>Vaccine</p> <ul style="list-style-type: none"> <li>To central distributor (at -20 °C)</li> <li>Multidose vials (10 doses/vial)</li> </ul> <p>Ancillary supply kits</p> <ul style="list-style-type: none"> <li>Direct to site from USG (at room temperature)</li> </ul>	<p><b>ON-SITE VACCINE STORAGE</b></p> <p><b>Frozen (-20 °C)</b></p> <ul style="list-style-type: none"> <li>Storage in shipping container OK</li> </ul> <p><b>Refrigerated (2–8 °C)</b></p> <ul style="list-style-type: none"> <li>Must use within 14 days</li> </ul> <p><b>Room temperature</b></p> <ul style="list-style-type: none"> <li>Must use within 6 hours (discard any unused vaccine after 6 hours)</li> </ul>
<p><b>ORDERS</b></p> <p><b>Central distribution capacity required</b></p> <ul style="list-style-type: none"> <li>Required by Dec 2020</li> <li>Maintained at -20 °C</li> </ul>	<p><b>ADMINISTRATION</b></p> <p><b>2-dose series (28 days between doses)</b></p> <ul style="list-style-type: none"> <li>No on-site mixing required</li> <li>Administer by intramuscular (IM) injection</li> </ul>
<p><b>INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES</b></p> <p><b>Healthcare personnel</b> — healthcare clinics + healthcare occupational health clinics + public health, closed POD, temporary/off-site vaccination clinics + mobile clinics</p> <p><b>Other essential workers (specifics TBA)</b> — occupational health + hospital clinics + public health, closed POD, temporary/off-site vaccination clinics</p> <p><b>People at higher risk of severe COVID-19 illness</b> — commercial pharmacy partners + mobile clinics</p>	

### Additional Considerations for Early Vaccination Planning

- “Healthcare personnel” includes paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to people with COVID-19 or infectious materials.
- Jurisdictions should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine A can be stored in the ultra-cold shipment box or Vaccine B can be stored at 2–8 °C.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach prioritized populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine A and Vaccine B; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the prioritized populations as possible, given the limitations with the product. For example: Vaccine A may be administered through mobile clinics if multiple mobile clinics are planned over a short period of time to ensure sufficiently high throughput.

**Attachment D: Phase 1 Population Group Worksheet Example**

Sub-Group	Agency/Organization	Point of Contact (POC)	POC Number	Contact e-mail	Key Group	Estimate # in Key Group
Long Term Care	Town Nursing Home	Jane Smith	123-456-7899	<a href="mailto:townnh@gmail.com">townnh@gmail.com</a>	Direct Care Staff	50
	County Nursing Home	John White	123-789-1234	<a href="mailto:conursinghome@co.gov">conursinghome@co.gov</a>	Direct Care Staff	50
Hospitals	ABC Hospital	Joe Admin	123-555-6666	<a href="mailto:jadmin@abchosp.com">jadmin@abchosp.com</a>	ICU Staff	50
	City X Hospital	Sue Jones	123-666-5555	<a href="mailto:cityx@hospital.com">cityx@hospital.com</a>	Direct Care Staff	200
					Direct Care Staff	300
Public Health	Anywhere Health Dept.	Ann Stewart	123-222-1234	<a href="mailto:astewart@cohd.gov">astewart@cohd.gov</a>	Clinic Staff	50
					Staff Providing Direct Care	40
Other Healthcare Essential Workers	County Emergency Services	Sam Stone	123-555-9876	<a href="mailto:sstone@coems.gov">sstone@coems.gov</a>	Ambulance Staff	25
	Medical Reserve Corp	Mike Reserve	123-777-8888	<a href="mailto:mrcmike@mrc.com">mrcmike@mrc.com</a>	Clinic Volunteers	30

**Attachment E: CDC IIS Data Requirements for COVID-19 Vaccine Monitoring**

**CDC IIS Data Requirements for COVID-19 Vaccine Monitoring**

**BACKGROUND AND PURPOSE**

The ongoing, rapid monitoring of COVID-19 vaccine uptake will be a critical part of the nation’s COVID- 19 response efforts. Immunization programs and immunization information systems (IIS) will play a critical role in vaccine delivery, the monitoring of vaccine doses administered, and generation of vaccination coverage estimates among several different population groups.

A strong, nationally coordinated approach is critical to collecting, tracking, and analyzing vaccination data, especially in early phases of vaccine administration, which is expected to occur in non-traditional settings. This document outlines the anticipated vaccine administration data elements IIS will report to CDC. The required data elements in this document represent demographic and vaccination information routinely captured by an IIS during a vaccination event. In addition to the ability to collect and report these data elements, IIS will also be required to report information from these data elements 1) in a timely fashion (within 24 hours of administration) and 2) through a connection to the Immunization Gateway (IZ Gateway) or data lake. This will enable CDC to reliably track COVID-19 vaccinations and analyze vaccination coverage by demographic factors once vaccine supplies are available. The vaccine administration data elements in this document will continue to evolve to include inventory and distribution elements as those parameters are finalized.

**DISCRETE DATA ELEMENTS**

Table 1 includes each data element that IIS will be required to report to CDC. Table 2 includes each data element that will be optional for IIS to report to CDC. Optional data requirements will support additional national coverage analysis and vaccination monitoring efforts. Data elements are also categorized as “Mass Vaccination” or “Standard”. Standard data elements are likely already collected by IIS, whereas Mass Vaccination data elements are likely to require enhancements or a Mass Vaccination module for data collection and reporting. Any identifiable data elements will be used to facilitate deduplication of data within the Immunization Data Lake, an analytic environment that will be used to consolidate, deduplicate, and reconcile vaccine administration information from multiple sources (e.g. jurisdictional immunization programs, pharmacies, Department of Defense, Veterans Affairs, Bureau of Prisons, Indian Health Service). Identifiable elements will not be stored in the Data Lake environment.

**Table 1. Required Data Elements**

<b>Required Data Element</b>	<b>Mass Vaccination or Standard</b>
<b><i>Data elements required for IIS to report</i></b>	<b><i>Mass Vaccination = may require mass vaccination module or enhancement</i></b> <b><i>Standard = IIS Core Data Element commonly collected during routine vaccination</i></b>
Administered at location: facility name/ID	Standard
Administered at location: type	Standard
Administration address (including county)	Standard

Required Data Element	Mass Vaccination or Standard
<b>Data elements required for IIS to report</b>	<b>Mass Vaccination = may require mass vaccination module or enhancement Standard = IIS Core Data Element commonly collected during routine vaccination</b>
Administration date	Standard
CVX (Product)	Standard
Dose number	Standard
IIS Recipient ID*	Standard
IIS vaccination event ID	Standard
Lot Number: Unit of Use and/or Unit of Sale	Standard
MVX (Manufacturer)	Standard
Recipient address*	Standard
Recipient date of birth*	Standard
Recipient name*	Standard
Recipient sex	Standard
Sending organization	Standard
Vaccine administering provider suffix	Standard
Vaccine administering site (on the body)	Standard
Vaccine expiration date	Standard
Vaccine route of administration	Standard
Vaccination series complete	Mass Vaccination

\*Identifiable Information

**Table 2. Optional Data Elements**

Optional Data Element	Mass Vaccination or Standard
<b>Data elements optional for IIS to report (e.g., state mass vaccination tool collects this information)</b>	<b>Mass Vaccination = may require mass vaccination module or enhancement Standard = IIS Core Data Element commonly collected during routine vaccination</b>
Comorbidity status (Y/N)	Mass Vaccination
Recipient ethnicity	Standard
Recipient race	Standard
Recipient missed vaccination appointment (Y/N)	Mass Vaccination
Serology results (Presence of Positive Result, Y/N)	Mass Vaccination
Vaccination Refusal (Y/N)	Standard

\*Identifiable Information

## Attachment F: Countermeasures Injury Compensation Program

The [Public Readiness and Emergency Preparedness Act](#) (PREP Act) authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under a PREP Act declaration. The CICP also may provide benefits to certain survivors of individuals who die as a direct result of the administration or use of such covered countermeasures. The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are:

- Any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used:
  - To treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or
  - To limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause; or
- Any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the Federal Food, Drug, and Cosmetic Act (FD&C Act), and the Public Health Service Act, or a respiratory protective device approved by National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary of the Department of Health and Human Services determines to be a priority for use during a public health emergency declared under section 319 of the Public Health Service Act.

For more information about the CICP, visit the program's website at [www.hrsa.gov/cicp](http://www.hrsa.gov/cicp), email [cicp@hrsa.gov](mailto:cicp@hrsa.gov), or call 1-855-266-CICP (1-855-266-2427).

### Attachment G: Liability Immunity for Covered Persons

The Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for Medical Countermeasures Against COVID-19 provides liability immunity to covered persons. The third amendment to the declaration defines “covered persons” as follows:

#### “V. Covered Persons

#### [42 U.S.C. 247d–6d\(i\)\(2\), \(3\), \(4\), \(6\), \(8\)\(A\) and \(B\)](#)

Covered Persons who are afforded liability immunity under this Declaration are “manufacturers,” “distributors,” “program planners,” “qualified persons,” and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I [the Secretary] have determined that the following additional persons are qualified persons:

- (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency;
- (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;
- (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act; and
- (d) a State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy), vaccines that the ACIP recommends to persons ages three through 18 according to ACIP’s standard immunization schedule.

Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

- The vaccine must be FDA authorized or FDA-approved.
- The vaccination must be ordered and administered according to ACIP’s standard immunization schedule.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.

- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa-10 et seq. are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures."