

COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations

**Centers for Disease Control and
Prevention (CDC)**

**September 16, 2020
Version 1.0**



**U.S. Department of
Health and Human Services**
Centers for Disease
Control and Prevention

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020

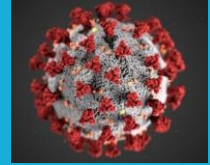
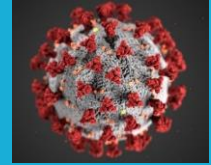


Table of Contents

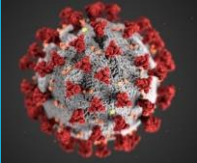
Executive Summary	5
Section 1: Public Health Preparedness Planning	6
Improvement Planning	6
COVID-19 Vaccination Program Planning	6
Section 2: COVID-19 Organizational Structure and Partner Involvement.....	8
Planning and Coordination Team (Internal)	8
State-Local Coordination	8
Tribal Communities.....	8
COVID-19 Vaccination Program Implementation Committee (Internal and External).....	9
Related Guidance and Reference Materials	9
Section 3: Phased Approach to COVID-19 Vaccination	10
Phase 1: Potentially Limited COVID-19 Vaccine Doses Available	11
Phase 2: Large Number of Doses Available; Supply Likely to Meet Demand	12
Phase 3: Likely Sufficient Supply	12
Related Guidance and Reference Materials	13
Section 4: Critical Populations	14
Identifying and Estimating Critical Populations	14
Estimating Population Groups for Initial COVID-19 Vaccine Distribution During Phase 1	15
Describing and Locating Critical Populations.....	15
Related Guidance and Reference Materials	16
Section 5: COVID-19 Vaccination Provider Recruitment and Enrollment	17
Vaccination Provider Recruitment.....	17
Vaccination Provider Enrollment	18
COVID-19 Vaccination Provider Training	20
Role of Commercial and Federal Partners	21
Related Guidance and Reference Materials	21
Section 6: Understanding a Jurisdiction’s COVID-19 Vaccine Administration Capacity.....	22
Related Guidance and Reference Materials	23
Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management	24
Allocation	24
Ordering	24
Distribution	25

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Inventory Management	26
COVID-19 Vaccine Recovery	26
Section 8: COVID-19 Vaccine Storage and Handling	27
Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations	27
Section 9: COVID-19 Vaccine Administration Documentation and Reporting	29
Section 10: COVID-19 Vaccination Second-Dose Reminders	30
Section 11: COVID-19 Requirements for Immunization Information Systems or Other External Systems	31
System Infrastructure	32
COVID-19 Vaccination Provider Preparation	32
Data Management	32
Ordering and Inventory	33
Related Guidance and Reference Materials	33
Section 12: COVID-19 Vaccination Program Communication	35
COVID-19 Vaccination Communication Objectives	35
Key Audiences	35
Broad Communication Planning Phases	35
Communication Activities	36
Messaging Considerations	36
Communication Channels	36
Partners and Trusted Sources	37
Crisis and Risk Communication	37
Related Guidance and Reference Materials	38
Section 13: Regulatory Considerations for COVID-19 Vaccination	39
Emergency Use Authorization Fact Sheets	39
Vaccine Information Statements	39
Section 14: COVID-19 Vaccine Safety Monitoring	40
Vaccine Adverse Event Reporting System	40
Vaccine Safety Datalink	40
Clinical Immunization Safety Assessment Project	40
Section 15: COVID-19 Vaccination Program Monitoring	41
CDC Dashboards	41
Resources	41
Messaging	42

**COVID-19 VACCINATION PROGRAM
INTERIM PLAYBOOK FOR JURISDICTION
OPERATIONS – September 16, 2020**



Local Jurisdictions 42

Appendix A: COVID-19 Vaccination Planning Assumptions for Jurisdictions (revised 9/15/2020)..... 43

Appendix B: COVID-19 Vaccination Scenarios for Jurisdictional Planning—Phase 1, Q4 2020 (updated 9/15/2020)
..... 47

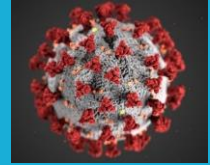
Appendix C: Phase 1 Population Group Worksheet Example 52

Appendix D: CDC IIS Data Requirements for COVID-19 Vaccine Monitoring..... 53

Appendix E: Countermeasures Injury Compensation Program..... 55

Appendix F: Liability Immunity for Covered Persons 56

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Executive Summary

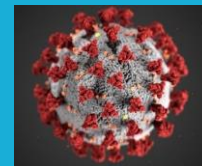
Immunization with a safe and effective COVID-19 vaccine is a critical component of the United States strategy to reduce COVID-19-related illnesses, hospitalizations, and deaths and to help restore societal functioning. The goal of the U.S. government is to have enough COVID-19 vaccine for all people in the United States who wish to be vaccinated. Early in the COVID-19 Vaccination Program, there may be a limited supply of COVID-19 vaccine, and vaccination efforts may focus on those critical to the response, providing direct care, and maintaining societal function, as well as those at highest risk for developing severe illness from COVID-19.

This document serves as an interim playbook for state, territorial (including the US-affiliated Pacific Islands [USAPI] of American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their jurisdictions. The document's sections cover specific areas of COVID-19 vaccination program planning and implementation and provide key guidance documents and links to resources to assist those efforts. Many, but not all, of the COVID-19 Vaccination Program activities described may overlap with routine activities; routine immunization and pandemic influenza program activities can serve as a foundation for COVID-19 vaccination planning.

Centers for Disease Control and Prevention (CDC) Immunization and Vaccines for Children Cooperative Agreement funding recipients (i.e., "awardees") should use this document to develop their COVID-19 vaccination plans. Within their vaccination plans, awardees must address all requirements outlined in the playbook and clearly describe their responsibility for ensuring activities are implemented. Awardees should submit their plans to their CDC project officer by October 16, 2020.

Information in this interim playbook will be updated as new information (e.g., recommendations for pregnant women or pediatric populations) becomes available.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 1: Public Health Preparedness Planning

Pandemic vaccination response planning requires collaboration among a wide range of public- and private-sector partners, including immunization and 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, doctors' offices). Many of these partners are engaged regularly in seasonal influenza and other outbreak vaccination campaigns, and many served as vaccination providers¹ during the 2009 H1N1 pandemic. However, significant additional planning is needed to operationalize a vaccination response to COVID-19, which is much larger in scope and complexity than seasonal influenza or other previous outbreak-related vaccination responses. Following the planning and improvement guidance below can assist in developing a jurisdiction's baseline readiness to launch the COVID-19 Vaccination Program.

Improvement Planning

Improvement planning is the identification of strengths, areas for improvement, and corrective actions that results from workshops, exercises, or real-world events. Jurisdictions should use a consistent approach for improvement-related activities across each of their COVID-19 vaccination preparedness planning components. Gaps in program planning are often identified when plans are tested, whether through a real event, such as a hepatitis A outbreak, or a full-scale vaccination exercise. Jurisdictions should test their COVID-19 vaccination program plans, and after testing, assign roles and responsibilities with target completion dates for specific tasks to ensure that corrective actions are fully implemented. Periodic review and revision of plans are integral to the improvement process. Jurisdictions should support continuous quality improvement as they move through different phases of workshops, exercises, and actual COVID-19 vaccination program implementation, making and operationalizing improvements in an ongoing manner.

COVID-19 Vaccination Program Planning

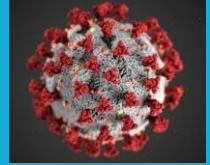
Prior to plan development, it is important for jurisdictions to have full situational awareness. There are many unknowns and unanswered questions at this time. For example, it is not yet known which vaccines will be available, in what volumes, at what time, with what efficacy, and with what storage and handling requirements. However, jurisdictions should review all current planning assumptions to assist with early planning efforts. (See *Appendix A: COVID-19 Vaccination Planning Assumptions for Jurisdictions.*)

In addition to current situational awareness, there is much to learn from past experiences. Jurisdictions may find it helpful to review their 2009 H1N1 pandemic vaccination response plans and lessons learned. After-action reports and improvement plans from that time provide an opportunity for jurisdictions to build on prior strengths and determine any gaps that may need to be addressed.

After plans have been drafted, it is important to identify any weaknesses by conducting exercises, including workshops or tabletop, functional, or full-scale exercises. This may be particularly valuable for any activities planned with external partners. For example, vaccination clinics in temporary or off-site settings, such as those planned for essential workers, are an excellent opportunity for exercises. Specific procedures to assess could include cold chain management, vaccine administration and documentation, traffic flow, or social distancing and sanitation measures. The Federal Emergency Management Agency (FEMA) has posted information on its

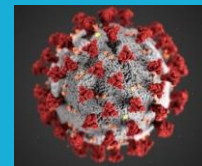
¹ For the purposes of this document, "vaccination provider" refers to any facility, organization, or healthcare provider licensed to possess/administer vaccine or provide vaccination services. A "COVID-19 vaccination provider" is any vaccination provider who has been enrolled in the COVID-19 Vaccination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

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



[Homeland Security Exercise and Evaluation](#) program that jurisdictions may find useful as they plan their own exercises.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 2: COVID-19 Organizational Structure and Partner Involvement

Pandemic vaccination planning is a combined state and local responsibility that requires close collaboration between public health, external agencies, and community partners. Depending on the specific jurisdiction's governance structure, the jurisdiction may play a key role in ensuring readiness at all levels. It is imperative that both state and local jurisdictions as well as tribal organizations and their planning partners clearly understand each other's roles and responsibilities in the COVID-19 Vaccination Program.

Planning and Coordination Team (Internal)

An internal COVID-19 Vaccination Program planning and coordination team is critical to ensure the vaccination response to COVID-19 is thoughtfully planned and successfully executed. A wide array of expertise should be represented among team members. Jurisdictions should consider broad inclusion from the immunization program, preparedness program, legal affairs, media/public affairs, and crisis and emergency risk communication (see *Section 12: COVID-19 Vaccination Program Communication* for additional information on crisis communication planning). In addition, the team should include clinical expertise as well as representatives of programs that serve the early populations of focus (e.g., Bureau of Aging, state licensing board, HIV/AIDS program, rural health office). It may even be helpful to include representation from a local public health jurisdiction for implementation perspective. Team members should be assigned responsibilities based on their individual expertise to best enhance plan development and activities coordination before and during the response. To mitigate any unexpected situations affecting a team member, each team member should have a backup representative to ensure coverage of each specialty area remains intact throughout the COVID-19 Vaccination Program. For any roles that are not adequately staffed, efforts should be made to recruit for and fill any team member vacancies as early as possible.

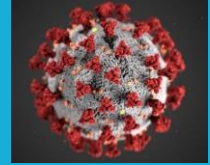
State-Local Coordination

State governance structures vary from centralized to decentralized. In a centralized state, legal authority is concentrated in the central state government, which makes decisions and performs most functions. Conversely, in a decentralized state, authority and responsibilities are dispersed and distributed across regions and areas. Regardless of the jurisdiction's governance structure, it is imperative that state and local authorities combine and coordinate efforts. State-level personnel must closely monitor activities at the local level to ensure the COVID-19 Vaccination Program is implemented throughout the jurisdiction in adherence with federal guidance and requirements, and that there is equitable access to COVID-19 vaccination 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 COVID-19 Vaccination Program.

Tribal Communities

Although CDC is working directly with the Indian Health Service (IHS) at the federal level, plans have not been finalized. It is important that jurisdictions include tribal leaders and tribal organizations in their planning efforts. While IHS may provide vaccination services to the populations they serve, plans are currently in development regarding vaccine distribution to tribal health facilities, including urban facilities, that are not officially connected to IHS. Those facilities may need to work through their jurisdiction to receive vaccine. It is also critical that jurisdictions reach out to any non-federally recognized tribes in their area to ensure they have access to vaccination services, since these groups will likely not be served by IHS.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



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

Reaching intended vaccine recipients is essential to achieving desired levels of COVID-19 vaccination coverage. To ensure equitable access to vaccinations, information about populations within a jurisdiction and the logistical requirements for providing them access to COVID-19 vaccination services will require collaboration with external entities and community partners who are familiar with how they obtain healthcare and other essential services. Jurisdictions should establish a COVID-19 Vaccination Program implementation committee to enhance development of plans, reach of activities, and risk/crisis response communication messaging and delivery. Committee membership should include leadership from the jurisdiction's COVID-19 planning and coordination team as well as representatives from key COVID-19 vaccination providers for critical population groups identified by CDC (see *Section 4: Critical Populations*), as well as representatives from other sectors within the community, such as:

- Emergency management agencies
- Healthcare coalitions
- Immunization coalitions
- Local health departments
- Health systems and hospitals (including critical access hospitals for rural areas, in-patient psychiatric facilities)
- Community health centers
- Rural Health Clinics (RHCs)
- Pharmacies
- Long-term care facilities (LTCFs; includes nursing home, assisted living, independent living (e.g., intermediate care facilities for individuals with intellectual and developmental disabilities), skilled nursing facilities)
- Businesses and occupational health organizations
- Health insurance issuers and plans
- 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
- Entities involved in COVID-19 testing center organization

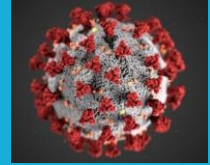
This committee will be helpful in advocating for and developing strategies to ensure equitable access to COVID-19 vaccination services. If needed, a Memorandum of Understanding (MOU) between the jurisdiction and partners can help to cement roles, responsibilities, and the level of support to be provided.

Related Guidance and Reference Materials

CDC's [public health preparedness resources](#) can assist jurisdictions and tribal organizations with strategic planning to strengthen their public health capabilities.

[Pandemic influenza-specific resources](#) on vaccine and other medical countermeasures may be helpful in strategizing for other COVID-19-related situations.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 3: Phased Approach to COVID-19 Vaccination

Due to changing vaccine supply levels at various points during the COVID-19 Vaccination Program, planning needs to be flexible but as specific as possible to accommodate a variety of scenarios. A key point to consider is that vaccine supply will be limited at the beginning of the program, so the allocation of doses must focus on vaccination providers and settings for vaccination of limited critical populations as well as outreach to these populations. The vaccine supply is projected to increase quickly over the proceeding months, allowing vaccination efforts to be expanded to additional critical populations and the general public. It is important to note that recommendations on the various population groups to receive initial doses of vaccine could change after vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors.

Final decisions are being made about use of initially available supplies of COVID-19 vaccines. These decisions will be partially informed by the proven efficacy of the vaccines coming out of Phase 3 trials, but populations of focus for initial COVID-19 vaccination may include: (see *Section 4: Critical Populations*)

- Healthcare personnel likely to be exposed to or treat people with COVID-19.
- People at [increased risk for severe illness](#) from COVID-19, including those with underlying medical conditions and people 65 years of age and older
- Other essential workers

Jurisdictions should be planning in terms of three phases:

1. Phase 1: Potentially limited supply of COVID-19 vaccine doses available

- Focus initial efforts on reaching the critical populations listed above. Ensure vaccination locations selected can reach populations, manage cold chain requirements, and meet reporting requirements for vaccine supply and uptake.

2. Phase 2: Large number of vaccine doses available

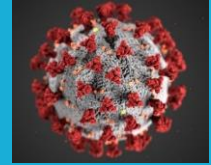
- Focus on ensuring access to vaccine for members of Phase 1 critical populations who were not yet vaccinated as well as for the general population; expand provider network.

3. Phase 3: Sufficient supply of vaccine doses for entire population (surplus of doses)

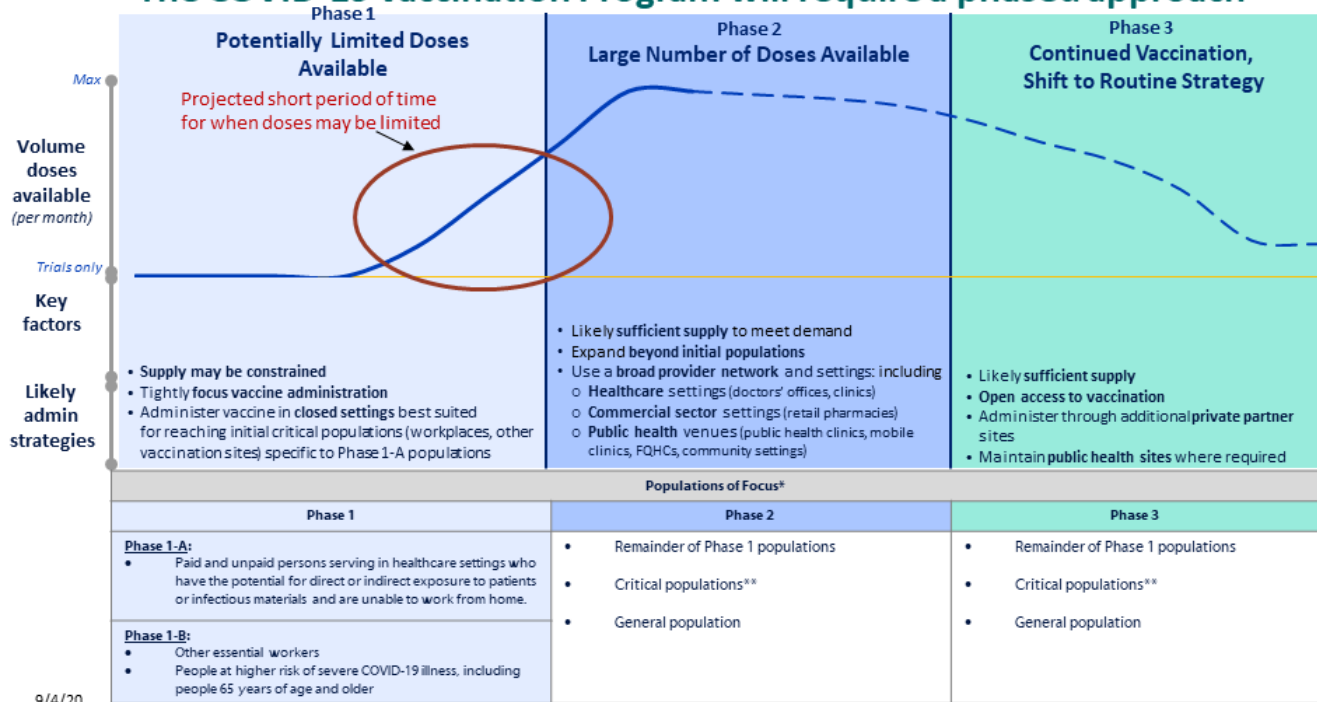
- Focus on ensuring equitable vaccination access across the entire population. Monitor vaccine uptake and coverage; reassess strategy to increase uptake in populations or communities with low coverage.

The following graph illustrates the three phases of the COVID-19 Vaccine Program and populations of focus in each phase.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



The COVID-19 Vaccination Program will require a phased approach



9/4/20

*Planning should consider that there may be initial age restrictions for vaccine products.

**See Section 4: Critical Populations for information on Phase 1 subset and other critical population groups.

Phase 1: Potentially Limited COVID-19 Vaccine Doses Available

In the initial phase, or Phase 1, of the COVID-19 Vaccination Program, initial doses of vaccine will likely be distributed in a limited manner, 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:

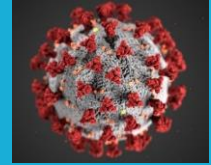
- COVID-19 vaccine supply may be limited.
- COVID-19 vaccine administration efforts must concentrate on the initial populations of focus to achieve vaccination coverage in those groups.
- Inventory, distribution, and any repositioning of vaccine will be closely monitored through reporting to ensure end-to-end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

Jurisdictions can employ strategies to address these constraints, including:

- Concentrating early COVID-19 vaccine administration efforts on the initial critical populations identified above and in *Section 4: Critical Populations*.
- Providing COVID-19 vaccination services in closed point-of-dispensing (POD) settings that allow for the maximum number of people to be vaccinated while maintaining social distancing and other infection control procedures (e.g., large hospitals and [satellite, temporary, or off-site settings](#))

Jurisdictions should prioritize enrollment activities for vaccination providers and settings who will administer COVID-19 vaccine to the populations of focus for Phase 1, giving consideration to those who live in remote, rural areas and may have difficulty accessing vaccination services. Simultaneously, jurisdictions should develop operational procedures for any temporary or mobile clinics planned for Phase 1 prior to receipt of vaccine.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Additional information on COVID-19 vaccination provider outreach and clinic settings is located in *Section 5: COVID-19 Provider Recruitment and Enrollment*.

Three scenarios are provided in *Appendix B: COVID-19 Vaccination Scenarios for Jurisdictional Planning – Phase 1, Q4 2020* to assist with planning for Phase 1. 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.

As jurisdictions are performing Phase 1 activities, they should be thinking ahead to Phase 2. Jurisdictions may consider the need for additional vaccinators to staff PODs, contract needs for vaccination services, and reviewing state practice acts to allow for expanded professional practice, if necessary.

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:

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

The key considerations in planning for Phase 2 are:

- COVID-19 vaccine supply will likely be sufficient to meet demand for critical populations as well as the general public.
- Additional COVID-19 vaccine doses available will permit an increase in vaccination providers and locations.
- A surge in COVID-19 vaccine demand is possible, so a broad vaccine administration network for surge capacity will be necessary.
- Low COVID-19 vaccine demand is also a possibility, so jurisdictions should monitor supply and adjust strategies to minimize vaccine wastage.

Jurisdictions should adapt to the increase in COVID-19 vaccine supply levels by:

- Expanding vaccination efforts beyond initial population groups in Phase 1 with emphasis on equitable access for all populations.
- Administering vaccine through:
 - Commercial and private sector partners (pharmacies, doctors' offices, clinics)
 - Public health sites (mobile clinics, Federally Qualified Health Centers [FQHCs], RHCs, public health clinics, temporary/off-site clinics)

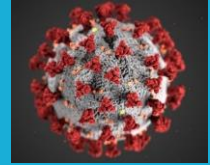
Phase 3: Likely Sufficient Supply

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:

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

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



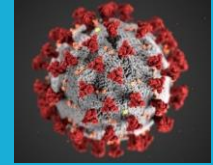
Strategies that jurisdictions should consider:

- Continuing to focus on equitable vaccination access to vaccination services
- Monitoring COVID-19 vaccine uptake and coverage in critical populations and enhancing strategies to reach populations with low vaccination uptake or coverage
- Partnering with commercial and private entities to ensure COVID-19 vaccine and vaccination services are widely available
- Monitoring supply and repositioning refrigerated vaccine products to minimize vaccine wastage

Related Guidance and Reference Materials

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. The document also includes tools and resources for tracking progress on critical workforce vaccination planning and activities within a jurisdiction. Though currently specific to an influenza pandemic, it may help to inform the approach for COVID-19 vaccination planning for critical workforce.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 4: Critical Populations

CDC's Advisory Committee on Immunization Practices (ACIP), the National Institutes of Health, and the National Academies of Sciences, Engineering, and Medicine (NASEM) are working to determine populations of focus for COVID-19 vaccination and ensure equity in access to COVID-19 vaccination availability across the United States. CDC has established an ACIP work group to review evidence on COVID-19 epidemiology and burden as well as COVID-19 vaccine safety, vaccine efficacy, evidence quality, and implementation issues to inform recommendations for COVID-19 vaccination policy. A key policy goal is to determine critical populations for COVID-19 vaccination, including those groups identified to receive the first available doses of COVID-19 vaccine when supply is expected to be limited.

After a short period of potentially limited vaccine supply, supply will likely increase quickly, allowing vaccination efforts to be expanded to include additional critical populations as well as the general public. Jurisdictions should develop plans to ensure equitable access to vaccination for each of the critical populations identified below.

Identifying and Estimating Critical Populations

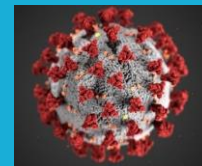
The first step in planning is to identify and estimate the critical populations within a jurisdiction. These populations (listed in no particular order) may include but are not limited to:

- Critical infrastructure workforce
 - Healthcare personnel (i.e., paid and unpaid personnel working in healthcare settings, which may include vaccinators, pharmacy staff, ancillary staff, school nurses, and EMS personnel)
 - Other essential workers (see additional guidance from the Cybersecurity and Infrastructure Security Agency [[CISA](#)])

Note: The critical infrastructure workforce varies by jurisdiction. Each jurisdiction must decide which groups to focus on when vaccine supply is limited by determining key sectors that may be within their populations (e.g., port-related workers in coastal jurisdictions)
- People at increased risk for severe COVID-19 illness
 - LTCF residents (i.e., nursing home, assisted living, independent living facility residents)
 - People with [underlying medical conditions](#) that are risk factors for severe COVID-19 illness
 - People 65 years of age and older
- People at increased risk of acquiring or transmitting COVID-19
 - People from racial and ethnic minority groups
 - People from tribal communities
 - People who are incarcerated/detained in correctional facilities
 - People experiencing homelessness/living in shelters
 - People attending colleges/universities
 - People who work in educational settings (e.g., early learning centers, schools, and colleges/universities)
 - People living and working in other congregate settings
- People with limited access to routine vaccination services
 - People living in rural communities
 - People with disabilities
 - People who are under- or uninsured

Estimates of these groups should be as accurate as possible to minimize potential waste of vaccine, constituent products, or ancillary supplies. Partner agencies and organizations may be helpful in determining accurate

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



estimates of these population groups. Such organizations might include the jurisdiction's emergency management agency, labor department, chamber of commerce, healthcare coalitions, and chronic disease/nutrition groups, as well as the [U.S. Department of the Interior](#), federal executive boards, and the [Association of Continuity Professionals](#).

Estimating Population Groups for Initial COVID-19 Vaccine Distribution During Phase 1

In the event that the jurisdiction's allocation during Phase 1 is insufficient to vaccinate all those included in the [initial populations of focus](#), it is important for jurisdictions 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. Jurisdictions can review [current ACIP work group considerations](#) for assistance in identifying, prioritizing, and estimating Phase 1 sub-population groups.

Jurisdictional considerations for Phase 1 subset groups may include, for example:

- ❖ **Phase 1-A:** Paid and unpaid people serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home.
- ❖ **Phase 1-B:** People who play a key role in keeping essential functions of society running and cannot socially distance in the workplace (e.g., healthcare personnel not included in Phase 1-A, emergency and law enforcement personnel not included in Phase 1-A, food packaging and distribution workers, teachers/school staff, childcare providers), and people at increased risk for severe COVID-19 illness, including people 65 years of age or older.

There may be insufficient COVID-19 vaccine supply initially to vaccinate all those who fall into the Phase 1-A subset, so jurisdictions should plan for additional subsets within that group. Phase 1-B and Phase 2 planning may also benefit from identifying subsets of population groups if there is high demand for vaccine. The U.S. Department of Labor's Occupational Safety and Health Administration has [information](#) on classifying workers at risk (low to very high based on position within an organization) for exposure to SARS-CoV-2. This information could prove helpful in determining subsets of critical populations for vaccination.

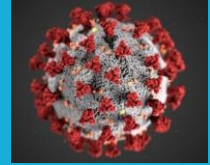
Describing and Locating Critical Populations

To improve vaccination among critical population groups, jurisdictions must ensure these groups have access to vaccination services. To inform COVID-19 vaccination provider outreach efforts, jurisdictions need to know where these groups are located. Jurisdictions should create visual maps of these populations, including places of employment for the critical infrastructure workforce category, to assist in COVID-19 vaccination clinic planning, especially for satellite, temporary, or off-site clinics. The federal government will release a dashboard that includes a mapping tool that may assist jurisdictions with this task. Additional information on the dashboard will be shared when available.

Public health programs should establish procedures to communicate key messages and coordinate vaccination logistics for these groups. Programs should establish points of contact (POCs) for each organization, employer, or community (as appropriate) within the critical population 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:

- Community Health Centers
- FQHCs
- RHCs
- Critical access hospitals
- Pharmacies

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



- Organizations and businesses that employ critical workforce
- First responder organizations
- Non-traditional providers (e.g., community health workers, doulas) and locations (e.g., dialysis centers, community centers) serving people at higher risk for severe illness
- Other locations or facilities for shared or congregate housing serving people at higher risk for severe illness (e.g., homeless shelters, group housing, correctional facilities, senior living facilities)
- Locations where people 65 years of age and older gather (e.g., senior centers, food pantries)
- Religious groups and other community groups
- In-home care organizations
- Schools and institutions of higher learning

Jurisdictions should prioritize describing and locating the Phase 1 [initial populations of focus](#) (see above) in their planning efforts, as these groups will be the first to be vaccinated before other critical populations.

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

[Related Guidance and Reference Materials](#)

[Advisory Committee on Immunization Practices](#)

[NASEM Preliminary Framework for Equitable Allocation of COVID-19 Vaccine](#)

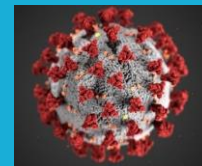
[Johns Hopkins Center for Health Security Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States](#)

The HHS Office for Civil Rights (OCR) [webpage](#) on Civil Rights and COVID-19 has several resources, including:

- [BULLETIN: Civil Rights, HIPAA, and the Coronavirus Disease 2019 \(COVID-19\)](#)
- [BULLETIN: Ensuring the Rights of Persons with Limited English Proficiency in Health Care During COVID-19](#)
- [BULLETIN: Civil Rights Protections Prohibiting Race, Color, and National Origin Discrimination During COVID-19: Application of Title VI of the Civil Rights Act of 1964](#)
- Information on the resolution of complaints filed with HHS OCR such as those that allege age and disability discrimination due to a state's crisis standards of care guidelines, etc.

[Mapping Medicare Disparities Tool](#) can be used to identify areas of disparities between subgroups of Medicare beneficiaries in health outcomes, utilization, and spending. It can assist with investigating geographic and racial and ethnic differences in health outcomes and inform decisions to focus on certain populations and geographies.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 5: COVID-19 Vaccination Provider Recruitment and Enrollment

An adequate network of trained, technically competent COVID-19 vaccination providers in accessible settings is critical to COVID-19 Vaccination Program success. For this reason, COVID-19 vaccination provider recruitment and enrollment may be the most critical activity conducted before vaccine becomes available. Jurisdictions and tribal organizations should concentrate early planning efforts on engaging those vaccination providers and services that can rapidly vaccinate initial populations of focus (see *Section 4: Critical Populations*) as soon as a COVID-19 vaccine is available (Phase 1). Subsequent planning should include measures for recruiting and enrolling enough providers to vaccinate additional critical populations and eventually the general population when sufficient vaccine supply is available (Phases 2 and 3).

Vaccination Provider Recruitment

Jurisdictions are encouraged to immediately reach out to potential COVID-19 vaccination providers and target the appropriate settings so that COVID-19 vaccination services are accessible to the initial populations of focus when the first COVID-19 vaccine doses arrive. Providers and settings that maximize the number of people who can be vaccinated should be prioritized for enrollment; however, jurisdictions should ensure social distancing and other infection control procedures can be maintained in selected settings (see *CDC guidance on [vaccination during a pandemic](#)*). All providers/settings, especially those enrolled for Phase 1, must be able to meet the reporting requirements discussed in *Section 9: COVID-19 Vaccine Administration Documentation and Reporting* and *Section 11: COVID-19 Requirements for Immunization Information Systems or Other External Systems*. Jurisdictions should consider partnering with the private sector and with local hospitals or health systems to provide COVID-19 vaccination in the closest proximity possible to the initial populations of focus. For example, partnering with critical access hospitals will be key to vaccinating Phase 1 populations in rural areas. Suggested early COVID-19 vaccination providers/settings include:

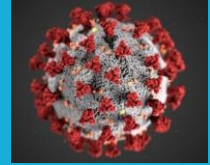
- Large hospitals and health systems
- Commercial partners* (e.g., pharmacies)
- Mobile vaccination providers
- Occupational health settings for large employers
- Critical access hospitals, RHCs, community health centers, or other central locations that can provide vaccination services for a broad area

**CDC is working to engage large pharmacy partners to assist with on-site vaccination in LTCFs. These partners have existing distribution and administration infrastructure (including cold chain) and relationships with some LTCFs to provide medication and, in some cases, vaccination services (e.g., seasonal influenza) for staff and residents in LTCFs; this may reduce burden on jurisdictional health departments. CDC will ensure jurisdictions have visibility on this work with large pharmacy partners.*

Jurisdictions should recruit additional COVID-19 vaccination providers to expand equitable access to COVID-19 vaccination when vaccine supply increases. Enrollment activities should be tracked so vaccination providers are not approached multiple times. Establishing and building upon existing relationships with community partners and collaborating with medical societies, state licensing boards, the state Medicaid agency, state rural health office, IHS/tribal health entities, and health insurance issuers and plans in the area, may assist jurisdictions in identifying COVID-19 vaccination providers and the population groups they serve. Jurisdictions should consider engaging both traditional and nontraditional vaccination providers and settings, including:

- In-patient healthcare facilities
 - Large hospitals could potentially operate as open PODs.
- LTCFs (e.g., nursing home, assisted living, independent living, and skilled nursing facilities)

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



- Doctors' offices and other outpatient facilities (particularly those treating patients at higher risk of severe COVID-19 illness)
- Pharmacies
- Occupational health settings
- Organizations serving people at higher risk for severe illness from COVID-19 (e.g., dialysis centers, social service organizations)
- In-home care provider organizations
- Congregate settings (e.g., correctional facilities)
- Colleges and universities
- Homeless shelters
- Locations where people 65 years of age and older gather (e.g., senior centers, food pantries)
- FQHCs and RHCs

Jurisdictions and tribal organizations should determine the need for additional vaccination services such as [satellite, temporary, or off-site clinics](#) to meet demand/need not met by other enrolled COVID-19 vaccination providers. These clinics may operate as either closed or open PODs.

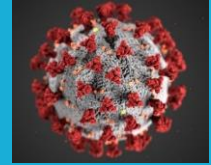
It is important to consider [infection control](#) measures that are currently necessary when selecting COVID-19 vaccination clinic settings:

- Providing specific appointment times or other strategies to manage patient flow and avoid crowding and long lines.
- Ensuring sufficient staff and resources to help move patients through the clinic flow as quickly as possible
- Limiting the overall number of clinic attendees at any given time, particularly for people at higher risk for [severe illness from COVID-19](#)
- Setting up a unidirectional site flow with signs, ropes, or other measures to direct site traffic and ensure physical distancing between patients
- When feasible, arranging a separate vaccination area or separate hours for people at increased risk for severe illness from COVID-19, such as older adults and people with underlying medical conditions
- Making available a point of contact for any reasonable accommodation needs for people with disabilities
- Ensuring vaccination locations are accessible to individuals with disabilities consistent with disability rights statutes such as the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973
- Selecting a space large enough to ensure a minimum distance of 6 feet between patients in line or in waiting areas for vaccination, between vaccination stations, and in postvaccination monitoring areas.
Note: ACIP [recommends that providers consider observing patients for 15 minutes after vaccination](#) to decrease the risk for injury should they faint. For mobile or drive-through vaccination clinics, it is important to assess parking to accommodate vaccine recipients as they wait after vaccination.

Vaccination Provider Enrollment

To receive/administer COVID-19 vaccine, constituent products, and ancillary supplies, vaccination provider facilities/organizations must enroll in the federal COVID-19 Vaccination Program coordinated through their jurisdiction'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*. These conditions are detailed in the agreement itself:

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



1. Administer COVID-19 vaccine in accordance with ACIP recommendations. (*Note: ACIP will review data on the safety and efficacy of each available COVID-19 vaccine and vote on recommendations for use.*)
2. Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. (See *Appendix D: CDC IIS Data Requirements for COVID-19 Vaccine Monitoring*). The provider must maintain the vaccine administration records for at least 3 years following vaccination, or longer if required by state, local, or territorial law. These records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
3. Not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies provided by the federal government.
4. Administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay.
5. Provide an Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as applicable, to each vaccine recipient/parent/legal representative prior to vaccination.
6. Comply with CDC requirements for vaccine management, including storage and handling, temperature monitoring at all times, complying with jurisdiction's instructions for dealing with temperature excursions, and monitoring expiration dates. Providers must keep all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by law.
7. Report COVID-19 vaccines and adjuvants that were unused, spoiled, expired, or wasted as required by the jurisdiction's immunization program.
8. Comply with federal instruction regarding disposal of unused COVID-19 vaccine and adjuvant.
9. Report adverse events to the Vaccine Adverse Event Reporting System ([VAERS](#)).
10. Provide a completed COVID-19 vaccination record card to every vaccine recipient/parent/legal representative.
11. Comply with the U.S. Food and Drug Administration's requirements, including [EUA-related requirements](#), if applicable. Providers must also administer COVID-19 vaccine in compliance with all applicable state and territorial vaccine laws.

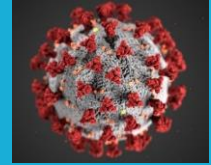
Failure of any enrolled COVID-19 vaccination provider organization or vaccination location under its authority to meet the conditions of the agreement may impact whether COVID-19 vaccine product orders are fulfilled and may result in legal action by the federal government.

Enrolled COVID-19 vaccination providers must also fully complete the *CDC COVID-19 Vaccination Provider Profile* form for each location where COVID-19 vaccine will be administered. The profile form collects the following variables for each location:

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

The profile form includes a field where the brand/model/type of storage unit is to be listed, requiring an attestation from the medical/pharmacy director or vaccine coordinator that each unit will maintain the relevant

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



required temperatures (i.e., refrigerated [2°C to 8°C], frozen [-15° to -25°C], ultra-cold [-60° to -80°C]). If desired, the immunization program may request photos of vaccine storage units for confirmation.

Both forms (agreement and profile) may be submitted to the jurisdiction electronically, and it is permissible for an immunization program to develop and administer these forms in the IIS or other system.

*Note: A **vaccine coordinator** is the POC for receiving vaccine shipments, monitoring storage unit temperatures, managing vaccine inventory, etc. Immunization programs should encourage enrolled facilities/organizations to designate a vaccine coordinator role at each location as well as a back-up vaccine coordinator.*

Provider enrollment activities that immunization programs must complete include:

- Ensure provider agreement, profile form, and redistribution agreement (if applicable) are thoroughly and accurately completed by each enrolled provider, retained on file for a minimum of 3 years, and made available to CDC upon request
- Verify COVID-19 vaccination providers (prescribers only, e.g., MD, DO, RPh, NP, PA) have active, valid licensure/credentials to possess and administer vaccine.
- Onboard COVID-19 vaccination providers to the jurisdiction's IIS or other external system using an expedited process.
- Enter ship-to site information for each enrolled COVID-19 vaccination provider location in the Vaccine Tracking System (VTrckS) via direct upload or extensible XML information set (ExIS).
- Report COVID-19 vaccination provider enrollment data electronically to CDC twice a week (i.e., Monday and Thursday by 9:00pm EST), using CDC-provided Comma Separated Values (CSV) and JavaScript Object Notation (JSON) templates to report via a Security Access Management Services (SAMS)–authenticated mechanism. CDC will monitor provider enrollment progress (see *Section 15: COVID-19 Vaccination Program Monitoring*).
- Ensure that all COVID-19 vaccination providers have been trained appropriately and have the appropriate equipment at their location to manage any serious adverse events. (*Note: For new vaccination providers and nontraditional provider settings, it will be helpful to furnish [vaccination clinic planning guidance](#) to ensure optimum staffing, layout, [supplies](#), and [infection control](#) procedures are in place.*)

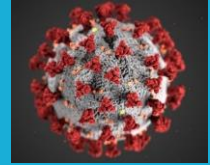
COVID-19 Vaccination Provider Training

Training of COVID-19 vaccination providers is vital to ensure the success of the COVID-19 Vaccination Program. CDC will have many educational resources available for use (even some for co-branding), but immunization programs may develop or use other materials in conjunction with CDC materials. Jurisdictions should determine the most efficient methods for training delivery and tracking. Jurisdictions will not be required to provide training for federal entities and commercial partners receiving direct vaccine allocations from CDC.

COVID-19 vaccination providers must understand the following:

- ACIP COVID-19 vaccine recommendations, when available
- How to order and receive COVID-19 vaccine
- COVID-19 vaccine storage and handling (including transport requirements)
- How to administer vaccine, including reconstitution, use of adjuvants, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration, etc.
- How to document and report vaccine administration via the jurisdiction's IIS or other external system
- How to manage vaccine inventory, including accessing and managing product expiration dates (see *Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management*)

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



- How to report vaccine inventory
- How to manage temperature excursions
- How to document and report vaccine wastage/spoilage
- Procedures for reporting moderate and severe adverse events as well as vaccine administration errors to VAERS
- Providing EUA fact sheets or VISs to vaccine recipients
- How to submit facility information for COVID-19 vaccination clinics to CDC's [VaccineFinder](#) (particularly for pharmacies or other high-volume vaccination providers/settings)

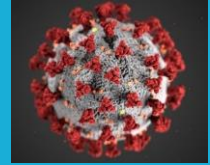
Role of Commercial and Federal Partners

Some multijurisdictional vaccination providers (e.g., select large drugstore chains, some IHS locations, Veterans Administration clinics and hospitals, and other federal providers) will enroll directly with CDC to order and receive COVID-19 vaccine. CDC will notify jurisdictions of any entities receiving direct allocations within their areas. These direct partners will be required to report vaccine supply and uptake information to each respective jurisdiction. Jurisdictions may partner with commercial entities that are enrolled directly with CDC to reach their populations. Large drugstore chains, for example, may be particularly helpful in conducting PODs as well as vaccinating LTCF residents and staff. Health insurance issuers and plans may also assist in informing their enrollees about vaccination efforts.

Related Guidance and Reference Materials

[HHS authorization for state-licensed pharmacists to administer vaccines](#)

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 6: Understanding a Jurisdiction's COVID-19 Vaccine Administration Capacity

Occupational health settings, temporary vaccination clinics, and closed PODs may be particularly useful for vaccination of critical infrastructure workers and other select critical populations early in the COVID-19 vaccination response when vaccine supply may be limited. However, once vaccine supply increases, leveraging a wide variety of potential community COVID-19 vaccination providers and settings is essential to providing equitable access to COVID-19 vaccination for all people in all communities. Public health programs should understand their jurisdiction's overall potential COVID-19 vaccine administration capacity, using a variety of COVID-19 vaccination provider types and settings.

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

Box 1: Key Public and Private Sector Vaccination Settings

- Healthcare provider offices and other outpatient clinics
- Public health clinics
- Chain and independent pharmacies
- School-based health centers
- Worksites and other occupational health clinics
- Hospitals
- Temporary or off-site vaccination clinics*
- Mobile vaccinators

**Community locations where state and local agencies dispense and administer medical countermeasures [MCMs] to the public, also known as “points of dispensing” [PODs]*

Important elements to consider in estimating vaccination capacity:

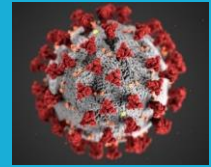
- Estimated number of existing vaccination provider locations in the jurisdiction, by type or vaccination setting, and the populations served (e.g., adults, children)
- Estimated potential weekly COVID-19 vaccine administration capacity (throughput)
- Estimated vaccination provider participation rate in the COVID-19 Vaccination Program

When assessing vaccine administration capacity, other important factors to consider include:

- COVID-19 vaccine storage capacity at a given location (e.g., quantity of COVID-19 vaccine that can be stored, storage equipment and temperature monitoring devices that meet CDC requirements)
- Existing vaccine administration capacity during seasonal influenza or other high vaccination periods
- Current staffing levels
- Routine immunization programs being conducted simultaneously that may affect throughput for COVID-19 vaccination in certain vaccination provider settings
- Infection control measures (i.e., scheduling, distancing, donning and doffing personal protective equipment, cleaning/sanitation procedures) that may slow the vaccination process
- Timing and duration of COVID-19 vaccination provider participation due to changes in staffing or other resources throughout the response
- Clinic closure due to environmental or other factors (e.g., seasonal weather, wildfires, holidays)

Jurisdictions should seek input from a variety of COVID-19 vaccination providers to inform this process. Previous vaccination exercises or campaigns may also provide helpful information.

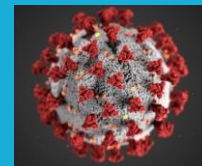
COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Related Guidance and Reference Materials

CDC has developed a tool to assist with estimating vaccination capacity. A pandemic influenza version of this tool, [the PanVax Tool for Pandemic Vaccination Planning](#), is available on the CDC website. The tool is currently being updated.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

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. Populations of focus for initial COVID-19 vaccine doses are expected to include healthcare workers (including ancillary staff, vaccinators, and staff in LTCFs), other essential workers, and people at higher risk for severe COVID-19 illness². 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.

Allocation

The federal government will determine the amount of COVID-19 vaccine designated for each jurisdiction. The jurisdiction's immunization program will then be responsible for managing and approving orders from enrolled providers within their jurisdiction using this allotment. The amount allotted will change over time, which may be based on critical populations recommended for vaccination by ACIP (with input from NASEM), COVID-19 vaccine production and availability, and overall population of the jurisdiction.

Federal agencies and additional commercial partners will also receive allocations directly from CDC once larger volumes of vaccine are available. 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.

Immunization programs should develop allocation methods for critical populations of focus in early- and limited-supply scenarios. Prior to receiving an initial vaccine supply, jurisdictions should determine COVID-19 vaccine order allowances among their vaccination providers based on the critical populations they serve. Allotments of doses to vaccination providers within a jurisdiction should be based on:

- ACIP recommendations (when available)
- Estimated number of doses allocated to the jurisdiction and timing of availability
- Populations served by vaccination providers and geographic location to ensure distribution throughout the jurisdiction
- Vaccination provider site vaccine storage and handling capacity
- Minimizing the potential for wastage of vaccine, constituent products, and ancillary supplies
- Other local factors

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

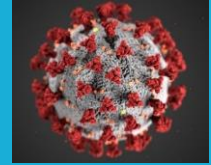
Ordering

COVID-19 vaccination providers enrolled by the jurisdiction will order COVID-19 vaccine through their jurisdiction's immunization program. Most jurisdictions will ask COVID-19 vaccination providers to place orders using systems and procedures routinely used for ordering publicly funded vaccines (e.g., IIS/ExIS upload to CDC's VTrckS for provider direct order entry), though some jurisdictions may have augmented systems.

CDC will provide jurisdictions with regular updates on the available vaccine supply and vaccine product-specific allocations for their 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

² Subject to any vaccine product-specific age restrictions

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



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. CDC will share more information on these shipments as it becomes available.

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:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 105 per kit
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators, per kit
- 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.

Distribution

COVID-19 vaccines and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will use its centralized distribution contract to fulfill orders for most vaccine products and associated ancillary supplies. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site.

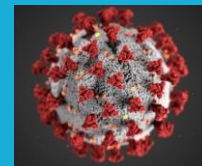
Jurisdictions should ensure accurate and complete shipping information (e.g., shipment address, provider contact information, shipping hours) is available in VTrckS for all vaccine shipments to enrolled vaccination providers.

COVID-19 vaccine (and diluent or adjuvant, if required) will be shipped to vaccination provider sites enrolled by the jurisdiction'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.

The federally contracted vaccine distributor uses validated shipping procedures to maintain COVID-19 vaccine cold chain and minimize the likelihood of vaccine loss or damage during shipment. Once a vaccine product has been shipped to a COVID-19 vaccination provider site, the federal government will neither redistribute the product nor take financial responsibility for its redistribution. (See *Section 8: COVID-19 Vaccine Storage and Handling* for more information.)

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 jurisdiction's immunization program, to redistribute COVID-19 vaccine, if validated cold-chain procedures are in place in accordance with the

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling. These entities must sign and agree to conditions in the *CDC COVID-19 Vaccine Redistribution Agreement* for the sending facility/organization and have a fully completed and signed *CDC COVID-19 Vaccination Provider Profile* form for each receiving location. Jurisdictions should be extremely judicious in allowing redistribution and limit any redistribution to refrigerated vaccines only.

Immunization programs 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 8: COVID-19 Vaccine Storage and Handling* for more information.)

Inventory Management

COVID-19 vaccination providers will be required to report inventory of COVID-19 vaccines, and jurisdictions must ensure this inventory information is submitted with each order.

It is anticipated COVID-19 vaccines will initially be authorized under an EUA. Vaccines *authorized* under an EUA will contain slight variations from *approved* Food and Drug Administration (FDA) products, including:

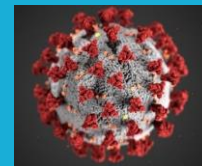
- **Expiration Date:** The vaccine vials and cartons will not contain a printed expiration date. Expiration dates may be updated based on vaccine stability studies occurring simultaneously with COVID-19 vaccine distribution and administration. Current expiration dates by vaccine lots for *all authorized* 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.
- **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.
- **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.
- **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.

COVID-19 Vaccine Recovery

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

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 8: 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. Jurisdictions should work with staff at each COVID-19 vaccination provider site to ensure appropriate vaccine storage and handling procedures are established and followed.

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). Ongoing stability testing may impact these requirements. *Note: These temperatures are based on information available as of 9/04/2020. Updated information will be provided as it becomes available.*

For a reliable cold chain, three elements must be in place:

- Well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

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. Jurisdictions and 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 for redistribution. 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. If redistributing vaccine, jurisdictions must adhere to all cold chain requirements and should limit transport of frozen or ultra-cold vaccine products.

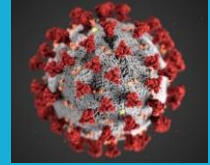
An addendum to the [Vaccine Storage and Handling Toolkit](#) that specifically addresses COVID-19 vaccines is currently being developed in addition to other training materials.

Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations

Satellite, temporary, or off-site clinics in collaboration with community or mobile vaccinators may assist jurisdictions in providing equitable access for COVID-19 vaccination. However, these situations require additional oversight and enhanced storage and handling practices, including:

- 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.
- 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.
- Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020

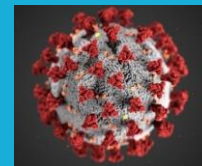


- Temperature data must be reviewed and documented according to guidance in the upcoming COVID-19 addendum to CDC’s *Vaccine Storage and Handling Toolkit*.
- At the end of the clinic day, temperature data must be assessed prior to returning vaccine to fixed storage units to prevent administration of vaccines that may have been compromised.
- As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions³ at any time, the temperature excursion should be documented and reported according to the jurisdiction 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.

Jurisdictions and tribal organizations should review CDC’s revised [Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](#) as well as [Vaccination Guidance During a Pandemic](#). These resources provide information on additional considerations that are necessary during the COVID-19 pandemic, including social distancing, PPE use, and enhanced sanitation efforts.

³ 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.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 9: COVID-19 Vaccine Administration Documentation and Reporting

CDC requires that vaccination providers enrolled in the COVID-19 Vaccination Program report certain data elements for each dose administered within 24 hours of administration. (See *Appendix D: CDC IIS Data Requirements for COVID-19 Vaccine Monitoring*). Jurisdictions should assess the capability of COVID-19 vaccination providers to meet federal and jurisdiction-specific reporting requirements before or upon enrollment. The required data elements are located on the ISD Awardees SharePoint site. COVID-19 vaccination providers may view the data requirements on CDC's [IIS website](#). Jurisdictions should be prepared to provide additional support or technical assistance for smaller vaccination providers or rural clinic settings.

Jurisdictions must facilitate and monitor IIS reporting by enrolled vaccination providers. Each vaccination location should be ready (including trained staff, necessary equipment, and internet access) to report vaccine administration data to the IIS or other external system at the time of vaccination. If data will be entered off site, vaccination providers must ensure the required data are reported to the IIS or other designated system within 24 hours. Reporting data may be transmitted daily from the jurisdiction's designated system to the CDC via the IZ Gateway⁴ "Connect" component. Additional information on the reporting process and specifications will be shared as soon as they have been finalized. Jurisdictions will not be responsible for reporting data from federal agencies or commercial partners who receive vaccine allocations directly from CDC.

In addition to reporting vaccine administration, jurisdictions must put processes in place to match first and second doses including addressing the need to exchange data with or query other jurisdiction's systems and/or the Immunization Data Lake⁵ to obtain immunization history, if applicable.

Jurisdictions should ensure redundant measures and procedures are in place for recording vaccine administration data in instances of connectivity problems or failures in the jurisdiction's IIS or other system. The jurisdiction's IIS should collect, report, and submit data directly to CDC's Immunization Data Lake and jurisdictional reporting requirements. (Additional information on CDC data requirements is forthcoming.) Planning activities should include onboarding to IZ Gateway Connect and Share⁶ (if feasible) components; exchanging data with other jurisdictions through the IZ Gateway; generating coverage reports for use within the jurisdiction; and providing data to CDC that meet defined standards.

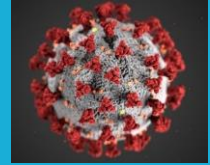
⁴ The Immunization Gateway (IZ Gateway) facilitates electronic messaging of IZ vaccination records in a secure infrastructure allowing IIS systems across the nation to share vaccine administration data not only between jurisdictions, but also with provider organizations (e.g., Department of Defense, Federal Bureau of Prisons, IHS, Department of Veterans Affairs) that do not exchange data with the IIS today.

⁵ The Immunization Data Lake is a cloud-hosted data repository to receive, store, and manage COVID-19 vaccination data for doses administered, vaccination coverage, ordering, inventory, and distribution. The Data Lake will provide a catalogue of different COVID-19 vaccine-related data sources that can be used to aid in monitoring COVID-19 vaccine ordering, distribution, coverage, and uptake. Data streams currently being onboarded to the Data Lake include provider enrollment data, VTrckS, and VaccineFinder.

⁶ There are multiple ways to onboard to the IZ Gateway, including Connect and Share.

- **Connect** enables large national and non-traditional vaccination systems for satellite/temporary/off-site clinic settings to report and query immunization data with IISs, using the gateway's centralized data exchange, avoiding multiple individual, and point-to-point connections.
- **Share** allows exchange of immunization data between IIS jurisdictions by automating message triggers through the IIS for patients immunized outside of their jurisdiction, to route messages to the patient's state of residence through the IZ Gateway.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



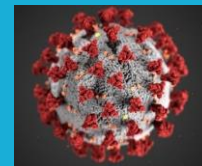
Section 10: COVID-19 Vaccination Second-Dose Reminders

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 the IIS or other system 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.

Redundant methods and systems should be used to remind vaccine recipients about their need for second doses. Jurisdictions should assess current practices for patient reminder/recall in existing healthcare provider organizations. Public health programs should work with occupational health providers and partners to consider the most appropriate and effective method of issuing second-dose reminders. A jurisdiction's IIS can be particularly useful for centralized reminder/recall (see *Section 11: COVID-19 Requirements for IIS or Other External Systems*). Many pharmacies and healthcare systems have their own systems for patient notifications and reminders, some using functionality within their electronic health record (EHR) systems. Jurisdictions may consider exploring the use of automated patient phone calls ("robocalls"), emails, and SMS text message-based systems. Health plans may also help to notify their enrollees about second doses based on claims information.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 11: COVID-19 Requirements for Immunization Information Systems or Other External Systems

IISs, also known as “vaccine registries,” are confidential, population-based, computerized databases for recording information on vaccine doses. IISs are maintained by a jurisdiction’s immunization program.

IISs have a range of capabilities. Many IISs can exchange data with EHRs, so that documentation of vaccine administration is automatically uploaded through bidirectional data exchange between EHRs and the IIS. EHRs that interface with jurisdiction IISs may improve the pace and accuracy of vaccine administration data capture. Some EHRs may leverage 2D barcoding technology on vaccine vials and VISs to allow for rapid, accurate, and automatic capture of vaccine administration data, such as vaccine lot number, vaccine manufacturer, and expiration date. In many jurisdictions, routine vaccination providers enroll in public vaccine programs, order vaccines, report inventory, document vaccine spoilage/wastage, and remind patients when vaccine doses are due using the IIS.

Using the IIS to document COVID-19 vaccine dose administration is beneficial on many fronts. When using the IIS, vaccination providers are able to determine if a patient is due for the first or second dose of vaccine. 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. Based on a jurisdiction’s discretion and IIS functionality, COVID-19 vaccination providers may use IISs to:

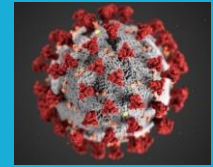
- Preregister or enroll in the COVID-19 vaccination program
- Place orders for COVID-19 vaccine
- Document vaccine administration
- Manage and report vaccine inventory
- Report vaccine spoilage/wastage
- Provide reminders to COVID-19 vaccine recipients indicating when the next dose of a multidose vaccine is due

CDC is making available a vaccination clinic mobile application that may be used to register patients and record dose-level vaccination data that meets CDC reporting requirements. IIS and other external systems that support COVID-19 response efforts must have solid infrastructure, engaged partners, high-quality data, and efficient processes for managing vaccination. The objectives for these areas are described below.

Immediate Priorities for Immunization Programs Related to Data Reporting:

- Determine and implement a solution for documenting vaccine administration in temporary or high-volume settings (e.g., CDC mobile app, IIS or module that interfaces with the IIS, or other jurisdiction-based solution)
- Ensure system capacity for data exchange, security, storage, and reporting
- Enroll vaccination provider facilities/organizations anticipated to vaccinate essential workers
- Connect IIS to the IZ Gateway
- Establish required data use agreements
- Assess and improve data quality
 - Ensure data are available, secure, complete, timely, valid, accurate, consistent, and unique

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



System Infrastructure

Jurisdictions should take certain steps to ensure the IIS or other external system's infrastructure is ready to support the COVID-19 Vaccination Program. Each jurisdiction should ensure their IIS infrastructure meets COVID-19 response data exchange, storage, and reporting requirements. The hardware and software on which the IIS depends should be up to date. For IISs that use a vendor platform, the IIS should be on the latest version of the platform.

The jurisdiction's IIS must operate as expected to appropriately support COVID-19 vaccination tracking efforts. The jurisdiction should prioritize testing and implement fixes for defects and enhancements that impact the IIS's ability to support COVID-19 response efforts.

The jurisdiction must use a system that supports dose-level accountability—from the time vaccine leaves the distributor until the vaccine is administered or unused vaccine is returned—and provides data to CDC that meet defined standards. Jurisdictions will need to have a solution (either leveraging existing or new) for extracting required data from their IIS as a contingency for network outages. The specifications to support the data extracts will be provided by CDC to ensure data submissions align with the format required for submission to the COVID-19 clearing house (a secure data lake). Jurisdictions should also develop and test backup solutions for offline use if the internet is unavailable.

Jurisdictions should explore and implement available IIS functionality for sending second-dose reminders (see *Section 10: COVID-19 Vaccination Second-Dose Reminders*) for vaccine recipients. This will be critical to ensure recipients complete the COVID-19 vaccine series.

COVID-19 Vaccination Provider Preparation

As jurisdictions enroll providers in the COVID-19 Vaccination Program (see *Section 5: COVID-19 Vaccination Provider Recruitment and Enrollment*), it is critical that they onboard providers to the IIS. Jurisdictions should have expedited processes in place to rapidly onboard vaccination providers expected to support Phase 1 activities and efficient processes to onboard vaccination providers expected to support expanded efforts in Phases 2 and 3.

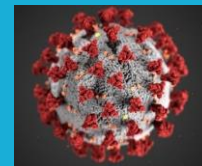
Jurisdictions may conduct nontraditional COVID-19 vaccination clinics, such as temporary, off-site, or mobile vaccination clinics to reach critical populations, particularly during early vaccination efforts. This may require jurisdictions to identify, enroll, and train additional partners to report doses administered in the system designated to support those efforts.

Data Management

The jurisdiction's IIS should collect and report data to satisfy CDC and jurisdictional reporting requirements. (Additional information on CDC data requirements is forthcoming.) Planning activities should include onboarding COVID-19 providers to the IIS, ensuring adequate IIS capacity, and establishing processes to ensure provider reporting within 24 hours of administration. IISs should also consider leveraging the IZ Gateway **Connect** and **Share** (if feasible) components for exchanging data with and/or querying other jurisdictions to obtain a consolidated vaccination record; using systems designed to support satellite, temporary, or off-site vaccination clinics; and generating coverage reports for use within the jurisdiction. Jurisdictions should be prepared to update their Clinical Decision Support (CDS) systems when CDC CDSi (Clinical Decision Support for immunizations) resources are updated.

Jurisdictions must have necessary policies in place to facilitate data collection and sharing with CDC and other jurisdictions. Jurisdictions onboarding to the IZ Gateway will be required to sign the Data Use Agreement (DUA) with Association of Public Health Laboratories (APHL) to participate in both IZ Gateway **Connect** and IZ Gateway

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Share. Jurisdictions will also need to execute the MOU to share data with other jurisdictions through the IZ Gateway.

- [APHL – Jurisdiction DUA IZ Gateway \(3August2020revision\)](#) When executed, the APHL and jurisdiction DUA allows for the jurisdiction to participate in the Connect component and to identify which (if any) other components to enable (*Share, Provider-initiated Multi-jurisdictional Data Exchange, Access and/or Access: Consumer-initiated Multi-jurisdictional Data Exchange*). This document was updated Aug 3, 2020 for this expanded use.
- [Memorandum of Understanding between Jurisdictions to Exchange Data](#) The Share component enables the exchange of immunization information across IIS jurisdictions. To enable the Share component, a jurisdiction must execute an Interjurisdictional MOU with jurisdictions with which it will exchange data. The MOU allows data exchange to occur through the IZ Gateway or an alternative mechanism with any state or jurisdiction that signed the MOU.

Jurisdictions will also need to execute a DUA with CDC so CDC can access their IIS data for national coverage data analysis. CDC will make the CDC-IIS DUA template available when it is finalized.

Ordering and Inventory

Jurisdictions must have processes in place for managing and tracking COVID-19 vaccine ordering and inventory. Planning activities should include reviewing business processes and IIS functionality to identify and implement improvements; developing a plan to order, monitor, and manage COVID-19 vaccine inventory in the IIS using CDC standards; and exploring opportunities to adopt 2D barcoding technology to improve data quality.

Related Guidance and Reference Materials

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*)

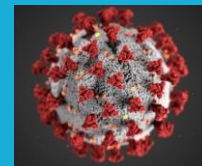
Provider Onboarding

- [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, EHR 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

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

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



- [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.

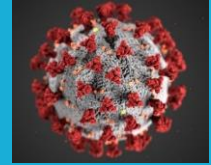
Immunization Gateway (IZ Gateway)

- 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*)

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.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 12: COVID-19 Vaccination Program Communication

Starting before COVID-19 vaccines are available, clear, effective communication will be essential to implementing a successful COVID-19 Vaccination Program. 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 Vaccination Program will have lasting effects on the nation's immunization system and overall vaccination efforts in the future. Using risk communication principles along with the CDC's recently developed [Vaccinate with Confidence](#) framework, jurisdictions can develop and implement timely, evolving plans as the foundation for their overall COVID-19 vaccination communication efforts.

COVID-19 Vaccination Communication Objectives

- Educate the public about the development, authorization, distribution, and execution of COVID-19 vaccines and that situations are continually evolving.
- Ensure public confidence in the approval or authorization process, safety, and efficacy of COVID-19 vaccines.
- Help the public to understand key differences in [FDA emergency use authorization](#) and [FDA approval](#) (i.e., licensure).
- Engage in dialogue with internal and external partners to understand their key considerations and needs related to COVID-19 vaccine program implementation.
- 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.
- Provide guidance to local health departments, clinicians, and other hosts of COVID-19 vaccination provider locations.
- Track and monitor public receptiveness to COVID-19 vaccination messaging.

Key Audiences

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

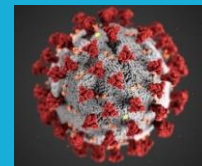
- Healthcare personnel (i.e., organizations and clinicians who will receive information about receiving and administering vaccine)
- Health insurance issuers and plans (coverage for vaccine, in-network providers)
- Employers
- Government and community partners and stakeholders
- Public/consumers
 - Essential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

Broad Communication Planning Phases

Messaging should be timely and applicable for the current phase of the COVID-19 Vaccination Program.

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

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Communication Activities

- Communicate early about the safety of vaccines in general and have easily accessible, government information to address myths, questions, and concerns.
- Keep the public, public health partners, and healthcare providers well-informed about COVID-19 vaccine(s) development, recommendations, and public health's efforts.
- 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.
- Communicate proactively whenever possible, anticipating issues and forecasting possible problems before they reach broad awareness.
- 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.
- Use information and education campaigns to extend reach and increase visibility of vaccine recommendations and resources.
- Work closely with partner agencies, representatives of local communities with critical populations, and intermediaries to achieve consensus on actions, consistency in messages, and coordinated communication activities.
- Communicate transparently about COVID-19 vaccine risks and recommendations, immunization recommendations, public health recommendations, and prevention measures.

Messaging Considerations

Public health messages and products should be tailored for each audience and developed with consideration for health equity. It is important to use plain language that is easily understood. Information should be presented in culturally responsive language and available in languages that represent the communities. Jurisdictions should be careful to address all people inclusively, with respect, using non-stigmatizing, bias-free language. Insufficient consideration of culture in developing materials may unintentionally result in misinformation, errors, confusion, or loss of credibility. When developing/utilizing materials, jurisdictions should check for the following:

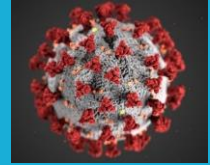
- Are there words, phrases, or images that could be offensive to or stereotypical of the cultural or religious traditions, practices, or beliefs of the intended audience?
- Are there words, phrases, or images that may be confusing, misleading, or have a different meaning for the intended audience (e.g., 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?

These considerations and any others that emerge during message development and deployment should be reviewed again when material is translated.

Communication Channels

Even perfectly developed messages and materials will provide no benefit if they are not received by the intended audience. Jurisdictions and tribal organizations should explore how specific groups are most likely to

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



access information with the communication methods available to them. Feedback mechanisms such as a web page or e-mail account to allow the audience to express concerns, ask questions, and request assistance are extremely important, and creating such mechanisms should be a priority for jurisdictions.

Traditional media channels

- Print
- Radio
- TV

Digital media

- Internet
- Social media
- Text messaging

Partners and Trusted Sources

Working to engage and empower partners is critical to reinforcing COVID-19 vaccination messages. Efforts with partners and trusted sources should be integrated into other channels in addition to programmatic and community engagement efforts. These partners include:

- State and local government
- Employers
- Healthcare providers (including federally funded safety net and in-home care providers)
- Health insurance issuers and plans
- Educators
- Unions and professional organizations
- Organizations serving minority populations and people with disabilities
- Community and faith-based groups

Crisis and Risk Communication

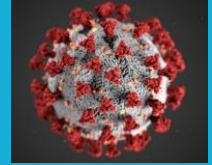
Crisis and emergency risk communication (CERC) is the application of evidence-based principles to effectively communicate during emergencies. These principles are used by public health professionals and public information officers to provide information that helps people, stakeholders, and entire communities make the best possible decisions for themselves and their loved ones. CERC recognizes that during emergencies, we work under impossible time constraints and must accept the imperfect nature of our choices.

CERC principles include:

- Be First
- Be Right
- Be Credible
- Express Empathy
- Show Respect

Jurisdictions must have communication messaging before, during, and after 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.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



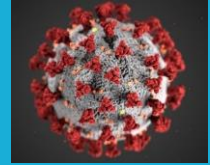
Related Guidance and Reference Materials

Jurisdictions should regularly review available [CDC COVID-19 Communication Resources](#). CDC has developed [COVID-19 One-Stop Shop Toolkits](#) for communication, including toolkits tailored for different populations as well as a social media toolkit. To reach essential workers for vaccination, jurisdictions may need to assist industry and businesses in communicating with employees about vaccination clinics. CDC's [COVID-19 Communications Plan for Select Non-Healthcare Critical Infrastructure Employers](#) may be helpful for this purpose.

CDC's CERC manual is available online, including online trainings, and examples of how CERC is applied during emergencies, at <https://emergency.cdc.gov/cerc/manual/index.asp>.

The World Health Organization has developed a [guide](#) that provides strategies and tools to support effective communication planning and management in response to vaccine safety events.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 13: Regulatory Considerations for COVID-19 Vaccination

Initially available COVID-19 vaccines may be authorized for use under an EUA issued by FDA or approved as licensed vaccines.

Emergency Use Authorization Fact Sheets

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](#).

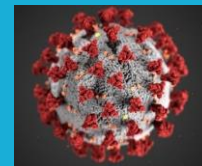
Product-specific EUA fact sheet for COVID-19 vaccination providers will be made available that will include information on the specific vaccine product and instructions for its use. An **EUA fact sheet for vaccine recipients** will also be developed, and both will likely be made available on the FDA 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.

Vaccine Information Statements

VISs are required only if a vaccine is added to the Vaccine Injury Table. Optional VISs may be produced, but only after a vaccine has been licensed (e.g., such as with zoster vaccines). Plans for developing a VIS for COVID-19 vaccine are not known at this time but will be communicated as additional information becomes available.

Additional information on VISs is located at <https://www.cdc.gov/vaccines/hcp/vis/current-vis.html>.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 14: 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.

Vaccine Adverse Event Reporting System

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 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 IHS healthcare facilities are being coordinated through the federal government. Jurisdictions should ensure that the COVID-19 vaccination providers they enroll understand the procedures for reporting adverse events to VAERS. More information on submitting a VAERS report electronically can be found at <https://vaers.hhs.gov/reportevent.html>.

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

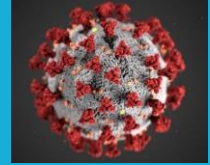
Vaccine Safety Datalink

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.

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.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Section 15: COVID-19 Vaccination Program Monitoring

Continuous monitoring for situational awareness throughout the COVID-19 Vaccination Program is crucial for a successful outcome. Prior to receiving COVID-19 vaccine, jurisdictions should establish procedures for monitoring various critical program planning and implementation elements, including performance targets, resources, staffing, and activities.

CDC Dashboards

To provide situational awareness for jurisdictions and the general public throughout the COVID-19 vaccination response, 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:

- Data for planning (e.g., estimates of critical population categories, number and attributes of healthcare providers and facilities)
- Implementation data (e.g., number of enrolled COVID-19 vaccination providers, COVID-19 vaccine supply and distribution, COVID-19 vaccine administration locations)
- COVID-19 vaccine administration data

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.

Resources

Jurisdictions and tribal organizations should regularly monitor their resources to avoid unexpected obstacles to the progress of their COVID-19 Vaccination Programs.

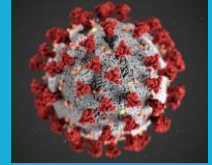
Staffing

Having enough adequately trained staff with current situational awareness is key to a successful COVID-19 Vaccination Program. Specialized expertise is required, and it is important to have backups in each specialty area to guard against interruption of activities because of illness or other personal situations. For example, if staff are supporting temporary or off-site COVID-19 vaccination clinics, the hours are likely to be long and physically taxing. Managers and supervisors need to regularly check in with and support assigned staff's wellness and overall resilience to perform the assigned tasks.

Inventory

Important activities during the COVID-19 Vaccination Program might be halted if certain supplies are depleted without replenishment. Jurisdictions may find it helpful to develop lists and track inventory for various program components (e.g., temporary/off-site clinics, vaccination provider enrollment and training, vaccine management). Regular monitoring of such records will foster early prompts to order and replenish supplies and ensure availability as needed. For example, jurisdictions will need to project and monitor use of PPE throughout the response and have ordering and procurement protocols in place for securing additional supplies.

COVID-19 VACCINATION PROGRAM INTERIM PLAYBOOK FOR JURISDICTION OPERATIONS – September 16, 2020



Messaging

CDC will provide timely messaging throughout the COVID-19 vaccination response via all-jurisdiction calls, regular e-mail communication, and website updates. Jurisdictions and tribal organizations should routinely monitor both CDC and local-level messaging to inform their communications efforts. Variations in messaging can create confusion and hamper the effective implementation of the vaccination program. Messaging must be clear, current, and received as intended by the audience. Monitoring social media can be helpful in assessing message delivery and reception and dispelling inaccurate information.

Local Jurisdictions

Constant communication and coordination with local jurisdictions and tribal organizations are instrumental during all phases of the COVID-19 Vaccination Program in both centralized and decentralized operational structures. Long before the vaccination program begins, roles and responsibilities should be established and well understood at all levels. This will help avoid misperceptions as well as gaps in planning and implementation. Throughout the COVID-19 Vaccination Program, jurisdictions should monitor and maintain awareness of local-level strategies and activities, providing technical assistance as needed. This visibility can help ensure local jurisdictions and providers adhere to recommendations and guidance from CDC and state and local authorities.

Appendix A: COVID-19 Vaccination Planning Assumptions for Jurisdictions (revised 9/15/2020)

Many COVID-19 vaccine candidates are in development, and clinical trials are being conducted simultaneously with large-scale manufacturing. It is not known which vaccines may be approved or authorized for use by FDA or when such authorizations or approvals will take place. COVID-19 Vaccination Program plans must be flexible and accommodate multiple scenarios. For the purpose of initial planning, consider the following assumptions.

COVID-19 VACCINE

- Limited COVID-19 vaccine doses may be available by early November 2020 if a COVID-19 vaccine is authorized or licensed by FDA by that time, but COVID-19 vaccine supply may increase substantially in 2021.
- Initially available COVID-19 vaccines will either be approved as licensed vaccines or authorized for use under an [Emergency Use Authorization \(EUA\)](#) issued by the U.S. Food and Drug Administration.
- Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold (-60°C to -80°C) temperatures, and ongoing stability testing may impact these requirements. *Note: These temperatures are based on information available as of September 15, 2020. Updated information will be provided as it becomes available.*
- Jurisdictions should develop strategies to ensure the correct match of COVID-19 vaccine products and dosing intervals. Once authorized or approved by the FDA, two doses of COVID-19 vaccine, separated by either 21 or 28 days, will be needed for most COVID-19 vaccine products, and second-dose reminders for patients will be necessary. Both doses will need to match each other (i.e., be the same vaccine product).
- Some COVID-19 vaccine products will likely require reconstitution with diluent or mixing adjuvant at the point of administration.

COVID-19 VACCINE ALLOCATION

- Final decisions are being made about use of initially available supplies of COVID-19 vaccines. These decisions will be partially informed by the proven efficacy of the vaccines coming out of Phase 3 trials, but populations of focus for initial COVID-19 vaccination may include:
 - Healthcare personnel likely to be exposed to or treat people with COVID-19
 - People at increased risk for severe illness from COVID-19, including those with underlying conditions and people 65 years of age and older
 - Other essential workers
- Allocation of COVID-19 vaccine to jurisdictions will be based on multiple factors, including:
 - Critical populations recommended by the Advisory Committee on Immunization Practices (with input from the National Academies of Sciences, Engineering, and Medicine)
 - Current local spread/prevalence of COVID-19
 - COVID-19 vaccine production and availability
- Jurisdictions should anticipate that allocations may shift during the response based on supply, demand, and risk.
- Each jurisdiction should plan for high-demand and low-demand scenarios.

COVID-19 VACCINATION PROVIDER OUTREACH AND ENROLLMENT

- To receive and administer COVID-19 vaccine and ancillary supplies, vaccination providers must enroll in the United States Government (USG) COVID-19 Vaccination Program, coordinated through their jurisdiction's immunization program, by signing and agreeing to conditions outlined in the *CDC COVID-19 Vaccination Program Provider Agreement*.
- CDC will make this agreement available to each jurisdiction's immunization program for use in conducting outreach and enrolling vaccination providers. Jurisdictions will be required to maintain these agreements on file for a minimum of 3 years.
- Jurisdictions will be required to collect and submit to CDC information on each enrolled vaccination provider/site, including provider type and setting, patient population (i.e., number and type of patients served), refrigerated/frozen/ultra-cold temperature storage capacity, and logistical information for receiving COVID-19 vaccine shipments.
- Some multijurisdictional vaccination providers (e.g., select large drugstore chains, the Indian Health Service, other federal providers) will enroll directly with CDC to order and receive COVID-19 vaccine. These direct partners will be required to report vaccine supply and uptake information back to each respective jurisdiction. CDC will share additional information when available on these procedures to ensure jurisdictions have full visibility for planning and documentation purposes.
- Jurisdictions may choose to partner with commercial entities to reach the initial populations of focus.
- Routine immunization programs will continue.

To be determined:

- *Specific multijurisdictional providers to be served directly by CDC*

COVID-19 VACCINE ORDERING AND DISTRIBUTION

- COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will share more information about reimbursement claims for administration fees as it becomes available.
- CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction immunization programs. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer.
- Jurisdiction-enrolled vaccination providers will follow the jurisdiction's vaccine ordering procedures.
- COVID-19 vaccination providers will be required to report COVID-19 vaccine inventory each time a COVID-19 vaccine order is placed.
- Vaccine orders will be approved and transmitted in CDC's Vaccine Tracking System (VTrckS) by jurisdiction immunization programs for vaccination providers they enroll.
- Vaccine (and adjuvant or diluent, if required) will be shipped to provider sites within 48 hours of order approval by the immunization program, if supply is available. Ancillary supply kits and diluent (if required) will ship separately from the vaccine due to different cold chain requirements, but shipment will be timed to arrive with or before the vaccine.
- Ancillary supply kits will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators.
 - Each kit will include supplies needed to administer 100 doses of vaccine.
 - Jurisdictions may need to plan for additional PPE, depending on vaccination site needs.

-
- For COVID-19 vaccines that require reconstitution with diluent or mixing adjuvant at the point of administration, these ancillary supply kits will include additional necessary syringes, needles, and other supplies for this purpose.
 - Sharps containers, gloves, bandages, and other supplies will not be included.
 - Minimum order size for CDC centrally distributed vaccines will be 100 doses per order for most vaccines. Minimum order size for direct-ship vaccines may be much larger. CDC will provide more detail as it becomes available.
 - Vaccine will be sent directly to vaccination provider locations for administration or designated depots for secondary distribution to administration sites (e.g., chain drugstores' central distribution).
 - Once vaccine products have been shipped to a provider site, the federal government will not redistribute product.
 - Jurisdictions will be allowed to redistribute vaccines while maintaining the cold chain. However, with the challenge of meeting cold chain requirements for frozen or ultra-cold vaccines, jurisdictions should be judicious in their use of redistribution and limit any redistribution to refrigerated vaccines only.
 - Jurisdictions are **not** advised to purchase ultra-cold storage equipment at this time. Ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice. These coolers should be repacked with dry ice within 24 hours of receipt of shipment and repacked again within 5 days.

To be determined:

- *Vaccine disposal/recovery procedures*

COVID-19 VACCINE ADMINISTRATION DATA REPORTING

- Jurisdictions will be required to report CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours). CDC will provide information on these data elements to jurisdictions.
- All vaccination providers may be required to report and maintain their COVID-19 vaccination information on CDC's [VaccineFinder](#).
- CDC has prioritized jurisdiction onboarding to the Immunization (IZ) Gateway* to allow Immunization Information Systems (IISs) to receive data directly from national providers, nontraditional vaccination providers, and other external systems, as well as to report vaccine administration data to CDC.
- Data Use Agreements (DUAs) will be required for data sharing via the IZ Gateway and other methods of vaccine administration data sharing with CDC and will be coordinated by each jurisdiction's immunization program.

To be determined:

- *Jurisdiction responsibility/involvement concerning reporting of data from multijurisdictional providers*
- *Method and frequency for vaccination providers to report information to VaccineFinder*

COMMUNICATION

- CDC will develop communication resources for jurisdictions and tribal organizations to use with key audiences. These resources will be available on a public-facing website currently under development, but jurisdictions and tribal organizations will likely need to tailor messaging and resources specific to special populations in their communities.
- CDC will work with national organizations to disseminate key messages.

- Communication and educational materials about COVID-19 vaccination provider enrollment, COVID-19 vaccine ordering, COVID-19 vaccine storage, handling, administration (i.e., reconstitution, adjuvant use, administration techniques), etc. will be available in a variety of formats.
- When vaccine supply is available for expanded groups among the general population, a national COVID-19 vaccine finder will be available on the public-facing [VaccineFinder](#).
- A screening tool on the CDC website will help people determine their own eligibility for COVID-19 vaccine and direct them to VaccineFinder.

COVID-19 VACCINE SAFETY

- Clinically important adverse events following any vaccination should be reported to the Vaccine Adverse Event Reporting System ([VAERS](#)).
- Adverse events will also be monitored through electronic health record- and claims-based systems (e.g., [Vaccine Safety Datalink](#)).
- Additional vaccine safety monitoring may be required under the EUA.

* The IZ Gateway is a portfolio of project components that share a common IT infrastructure. The IZ Gateway aims to rapidly onboard IISs to support readiness for COVID-19 vaccine response through data exchange, both among IIS and between IIS and federal providers, mass vaccination reporting, and consumer access tools. The IZ Gateway aims to increase the availability and volume of complete and accurate immunization data stored within IIS and available to providers and consumers regardless of their jurisdictional boundaries.

Appendix B: 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>SHIPMENT <i>3 separately acquired components (mixed on site)</i></p> <ol style="list-style-type: none"> Vaccine <ul style="list-style-type: none"> Direct to site from manufacturer (on dry ice) Multidose vials (5 doses/vial) Diluent <ul style="list-style-type: none"> Direct to site from the US Government (USG) at room temperature) Ancillary supply kits (for administration and mixing) <ul style="list-style-type: none"> Direct to site from USG (at room temperature) 	<p>ON-SITE VACCINE STORAGE <i>Frozen (-70 °C ± 10 °C)</i></p> <ul style="list-style-type: none"> Must be used/recharged within 10 days Storage in shipping container OK (replenish dry ice within 24 hours of receiving shipment and again 5 days later) <p><i>Thawed but NOT reconstituted (2–8 °C)</i></p> <ul style="list-style-type: none"> Must use within 5 days (discard unused doses after 5 days) <p><i>Reconstituted (room temperature)</i></p> <ul style="list-style-type: none"> Must use within 6 hours (discard any unused, reconstituted vaccine after 6 hours)
<p>ORDERS <i>Large quantities, to large administration sites only</i></p> <ul style="list-style-type: none"> Minimum order: ~1,000 doses Maximum order: ~5,000 doses 	<p>ADMINISTRATION <i>2-dose series (21 days between doses)</i></p> <ul style="list-style-type: none"> On-site mixing required; reconstitute with diluent just prior to administration Administer by intramuscular (IM) injection
<p>INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES</p> <p><i>Healthcare personnel</i> — public health, closed point of dispensing (POD), temporary/off-site vaccination clinics + potential for mobile clinics</p> <p><i>Other essential workers</i> — public health, closed POD, temporary/off-site vaccination clinics + potential for mobile clinics</p> <p><i>People at higher risk of severe COVID-19 illness</i> — potential for mobile clinics to long-term care facilities (LTCFs)</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.
- 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	
SHIPMENT <i>2 separately shipped components</i> 1. Vaccine <ul style="list-style-type: none"> To central distributor (at -20 °C) Multidose vials (10 doses/vial) 2. Ancillary supply kits <ul style="list-style-type: none"> Direct to site from USG (at room temperature) 	ON-SITE VACCINE STORAGE Frozen (-20 °C) <ul style="list-style-type: none"> Storage in shipping container OK Refrigerated (2–8 °C) <ul style="list-style-type: none"> Must use within 14 days Room temperature <ul style="list-style-type: none"> Must use within 6 hours (discard any unused vaccine after 6 hours)
ORDERS <i>Central distribution capacity required</i> <ul style="list-style-type: none"> Required by Dec 2020 Maintained at -20 °C 	ADMINISTRATION <i>2-dose series (28 days between doses)</i> <ul style="list-style-type: none"> No on-site mixing required Administer by IM injection
INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES Healthcare personnel — healthcare clinics + healthcare occupational health clinics + public health, closed POD, temporary/off-site vaccination clinics + mobile clinics Other essential workers (specifics TBA) — occupational health + hospital clinics + public health, closed POD, temporary/off-site vaccination clinics People at higher risk of severe COVID-19 illness (e.g., LTCF residents) — commercial pharmacy partners + mobile clinics	

Additional Considerations for Early Vaccination Planning

<ul style="list-style-type: none"> “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 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 critical populations with as much throughput as possible. 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. 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.

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)
Total	~3M doses	20M–30M doses	35M–45M doses	

Distribution, Storage, Handling, and Administration Assumptions

Vaccine A	
<p>SHIPMENT <i>3 separately acquired components (mixed on site)</i></p> <ol style="list-style-type: none"> Vaccine <ul style="list-style-type: none"> Direct to site from manufacturer (on dry ice) Multidose vials (5 doses/vial) Diluent <ul style="list-style-type: none"> Direct to site from USG (at room temperature) Ancillary supply kits <ul style="list-style-type: none"> Direct to site from USG (at room temperature) 	<p>ON-SITE VACCINE STORAGE <i>Frozen (-70 °C ± 10 °C)</i></p> <ul style="list-style-type: none"> Must be used/recharged within 10 days Storage in shipping container OK (replenish dry ice within 24 hours of receiving shipment and again 5 days later) <p><i>Thawed but NOT reconstituted (2–8 °C)</i></p> <ul style="list-style-type: none"> Must use within 5 days (discard unused doses after 5 days) <p><i>Reconstituted (room temperature)</i></p> <ul style="list-style-type: none"> Must use within 6 hours (discard any unused, reconstituted vaccine after 6 hours)
<p>ORDERS <i>Large quantities, to large administration sites only</i></p> <p>Minimum order: ~1,000 doses Maximum order: ~5,000 doses</p>	<p>ADMINISTRATION <i>2-dose series (21 days between doses)</i></p> <ul style="list-style-type: none"> On-site mixing required; reconstitute with diluent just prior to administration Administer IM injection
<p>PRIORITIZED POPULATIONS AND ANTICIPATED VACCINE ADMINISTRATION SITES</p> <p><i>Healthcare personnel</i> — public health, closed POD temporary/off-site vaccination clinics + potential for mobile clinics <i>Other essential workers (specifics TBA)</i> — public health, closed POD temporary/off-site vaccination clinics + potential for mobile clinics <i>LTCF residents & staff</i> — potential for mobile clinics to facilities</p>	
Vaccine B	
<p>SHIPMENT <i>2 separately shipped components</i></p> <p>Vaccine</p> <ul style="list-style-type: none"> To central distributor (at -20 °C) Multidose vials (10 doses/vial) <p>Ancillary supply kits</p> <ul style="list-style-type: none"> Direct to site from USG (at room temperature) 	<p>ON-SITE VACCINE STORAGE <i>Frozen (-20 °C)</i></p> <ul style="list-style-type: none"> Storage in shipping container OK <p><i>Refrigerated (2–8 °C)</i></p> <ul style="list-style-type: none"> Must use within 14 days <p><i>Room temperature</i></p> <ul style="list-style-type: none"> Must use within 6 hours (discard any unused vaccine after 6 hours)

<p>ORDERS</p> <p>Central distribution capacity required</p> <ul style="list-style-type: none"> • Required by Dec 2020 • Maintained at -20 °C 	<p>ADMINISTRATION</p> <p>2-dose series (28 days between doses)</p> <ul style="list-style-type: none"> • No on-site mixing required • Administer by intramuscular (IM) injection
<p>INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES</p> <p>Healthcare personnel — healthcare clinics + healthcare occupational health clinics + public health, closed POD, temporary/off-site vaccination clinics + mobile clinics</p> <p>Other essential workers (specifics TBA) — occupational health + hospital clinics + public health, closed POD, temporary/off-site vaccination clinics</p> <p>People at higher risk of severe COVID-19 illness — 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.

Appendix C: Phase 1 Population Group Worksheet Example

PHASE 1-A POPULATION GROUP: HEALTHCARE PERSONNEL

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	townnh@gmail.com	Direct Care Staff	50
	County Nursing Home	John White	123-789-1234	conursinghome@co.gov	Direct Care Staff	50
Hospitals	ABC Hospital	Joe Admin	123-555-6666	jadmin@abchosp.com	ICU Staff	50
					Direct Care Staff	200
	City X Hospital	Sue Jones	123-666-5555	cityx@hospital.com	Direct Care Staff	300
Public Health	Anywhere Health Dept.	Ann Stewart	123-222-1234	astewart@cohd.gov	Clinic Staff	50
					Staff Providing Direct Care	40
Other Healthcare Essential Workers	County Emergency Services	Sam Stone	123-555-9876	sstone@coems.gov	Ambulance Staff	25
	Medical Reserve Corp	Mike Reserve	123-777-8888	mrcmike@mrc.com	Clinic Volunteers	30

Appendix D: CDC IIS Data Requirements for COVID-19 Vaccine Monitoring

CDC IIS DATA REQUIREMENTS FOR COVID-19 VACCINE ADMINISTRATION

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

Required Data Element	Mass Vaccination or Standard
<i>Data elements required for IIS to report</i>	<i>Mass Vaccination = may require mass vaccination module or enhancement Standard = IIS Core Data Element commonly collected during routine vaccination</i>
Administered at location: facility name/ID	Standard
Administered at location: type	Standard
Administration address (including county)	Standard
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
<i>Data elements optional for IIS to report (e.g., state mass vaccination tool collects this information)</i>	<i>Mass Vaccination = may require mass vaccination module or enhancement Standard = IIS Core Data Element commonly collected during routine vaccination</i>
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*

Appendix E: 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, email cicp@hrsa.gov, or call 1-855-266-CICP (1-855-266-2427).

Appendix F: 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 Advisory Committee on Immunization Practices (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.”