High Level Notes for CDC’s COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations
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BACKGROUND
On September 16, 2020, the U.S. Department of Health and Human Services (HHS) and Department of Defense (DoD) released documents outlining the Trump Administration’s detailed strategy to deliver safe and effective COVID-19 vaccine doses to the American people as quickly and reliably as possible. The documents, developed by HHS in coordination with DoD and the Centers for Disease Control and Prevention (CDC), provide a strategic distribution overview along with an interim playbook for state, tribal, territorial, and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their respective jurisdictions.

The strategic overview lays out four tasks necessary for the COVID-19 vaccine program:

- Engage with state, tribal, territorial, and local partners, other stakeholders, and the public to communicate public health information around the vaccine and promote vaccine confidence and uptake.
- Distribute vaccines immediately upon granting of Emergency Use Authorization (EUA)/Biologics License Application (BLA), using a transparently developed, phased allocation methodology and CDC has made vaccine recommendations.
- Ensure safe administration of the vaccine and availability of administration supplies.
- Monitor necessary data from the vaccination program through an information technology (IT) system capable of supporting and tracking distribution, administration, and other necessary data.

View the strategy: Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine

HIGH LEVEL NOTES FROM THE CDC PLAYBOOK BY SECTION
Below is a summary of notes from the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations that are particularly relevant to local health departments. The notes are categorized by each section of the playbook.

Section 1: Public Health Preparedness Planning

- CDC Immunization Awardees are advised to use the playbook to create and submit state-specific COVID-19 vaccine response plans to their CDC project officer by October 16, 2020. (pg. 5)

- 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 to build upon prior strengths and determine any gaps. (pg. 6)

- 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. (pg. 6)

- **LHD Recommendation/Key Point**: To facilitate coordination across the state and local levels, local health departments should engage with their state contact at this point to ensure coordination in the implementation of the COVID-19 Vaccine Distribution plan.
Section 2: COVID-19 Organizational Structure and Partner Involvement

- An internal COVID-19 Vaccination Program planning and coordination team is critical to ensure 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 (pg. 8).

- 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. (pg. 8)

- COVID-19 Vaccination Program Implementation Committees should include representatives from key COVID-19 vaccination providers for critical population groups identified by CDC. This committee will be helpful in advocating for and developing strategies to ensure equitable access to COVID-19 vaccination services. (pg. 9)

- **LHD Recommendation/Key Point:** Local health departments serve as chief health strategists and conveners within their local communities. Local health departments can contribute this expertise and knowledge as a member of or partner to the overall state COVID-19 vaccine planning and coordination team.

Section 3: Phased Approach to COVID-19 Vaccination

- Jurisdictions should begin planning in terms of three phases (pgs. 10-13):
  - **Phase 1: Potentially Limited COVID-19 Vaccine Doses Available**
    - Inventory, distribution, and any repositioning of vaccine will be closely monitored
    - Provide COVID-19 vaccination in closed point of distribution (POD) settings that allow the maximum number of people to get vaccinated while still maintaining social distancing and other infection control measures
    - Plan for any temporary or mobile clinics that will be operated during phase 1 prior to receiving doses of vaccine
    - Consider and create a plan for those who live in remote and rural areas
  
  - **Phase 2: Large Number of Doses Available; Supply Likely to Meet Demand**
    - Provide equitable access for all critical populations and ensure high uptake in specific populations, particularly those at high risk for severe outcomes
    - Broad vaccine administration network for surge capacity will be necessary
    - Vaccines should be administered through commercial and private sector partners and public health sites.

  - **Phase 3: Likely Sufficient Supply**
    - Broad vaccine administration network for increased access
• Continue to focus on strategies for equitable access to vaccination services
• Monitor coverage and uptake in critical populations and increase outreach to populations with low uptake or coverage

• **LHD Recommendation/Key Point:** The planning and administration for COVID-19 vaccine should be flexible to accommodate a variety of scenarios, including changes in available supply and determinations regarding critical populations.

## Section 4: Critical Populations

• The first step in planning is to identify and estimate the critical populations within a jurisdiction. These populations may include, but are not limited to, the critical infrastructure workforce, people at increased risk for severe COVID-19 illness, people at increased risk of acquiring or transmitting COVID-19, or people with limited access to routine vaccination services. (pg. 14)

• 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 vaccination clinic planning, especially for satellite, temporary, or off-site clinics. (pg. 14)

• Public health programs should establish procedures to communicate key messages and coordinate vaccination logistics for these groups. (pg. 15)

• **LHD Recommendation/Key Point:** Local health departments serve as trusted public health partners and conveners within their communities. It is important for local health departments to leverage these existing partnerships with traditional and non-traditional stakeholders to establish communication and plans for rapid dissemination of COVID-19 vaccine information. Additionally, local health departments may potentially provide valuable assistance and support in the identification and estimation of critical populations within the local jurisdiction.

## Section 5: COVID-19 Vaccination Provider Recruitment and Enrollment

• Jurisdictions are encouraged to immediately reach out to potential COVID-19 vaccination providers and target the appropriate settings so that vaccination services are accessible to the initial populations of focus when the first COVID-19 vaccine doses arrive. (pg. 17)

• All providers/settings, especially those enrolled for Phase 1, must 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. (pg. 17)

• 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 (state) 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. (pg. 18)

- 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. (pg. 19)

- 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. (pg. 20)

- **LHD Recommendation/Key Point:** Local health departments will be key in the vaccination effort as they can rapidly identify and vaccinate initial populations of focus within the community. Focus should be placed on recruiting and enrolling enough providers at the community level to vaccinate critical populations and eventually the general population.

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

- “Vaccine administration capacity” is defined as the maximum achievable vaccination throughput regardless of public demand for vaccination. (pg. 22)

- **LHD Recommendation/Key Point:** Local health departments/public health clinics are considered key public vaccination settings. Local health departments should consider coordinating with state contacts to inform the overall state’s vaccine administration capacity determination process.

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

- The federal government will determine how much vaccine each jurisdiction receives. The (state) jurisdiction’s Immunization Program will be responsible for managing and approving orders for providers in their area within this allotment. (pg. 24)

- COVID-19 vaccination providers enrolled by the (state) jurisdiction will order COVID-19 vaccine through their (state) 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. (pg. 24)

- Ancillary supplies will come in kits in amounts to match vaccine orders. Each kit will contain needles, syringes, alcohol prep pads, surgical masks, face shields, and vaccine record cards for vaccine recipients. If the vax needs reconstitution, mixing kits will be included. They will not provide sharps containers, gloves, or bandages. (pg. 25)
• 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. (pg. 25)

• Because they will likely be authorized under and EUA, vaccines will not have an expiration date. Expiration dates will be posted on an HHS website. (pg. 26)

• **LHD Recommendation/Key Point:** Local health departments should verify with their state how they will register to provide vaccine as well as how to place orders for vaccines and ancillary supplies.

### Section 8: COVID-19 Vaccine Storage and Handling

• 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. (pg. 27)

• Vaccine products that require ultra-cold storage can be stored in their shipping container with dry ice. CDC is working on an addendum to the Vaccine Storage and Handling Toolkit regarding the COVID vaccines. (pg. 27)

• CDC has revised and updated Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations and Vaccination Guidance During a Pandemic (pg. 28)

• **LHD Recommendation/Key Point:** Local health departments often conduct large-scale satellite, temporary and off-site vaccine clinics. It is important to note that these situations will require additional oversight and enhanced storage and handling practices to ensure the integrity and safety of the vaccine. Well-trained staff, reliable storage and temperature monitoring equipment, and accurate vaccine inventory management will be critical to the success of this effort.

### 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 does administered within 24 hours of administration. (pg. 29)

• COVID-19 vaccination providers may view the data requirements on CDC’s [IIS website](https://www.cdc.gov/iis/). (pg. 29)

• **LHD Recommendation/Key Point:** Local health departments should review the data requirements once listed on the CDC’s website and be prepared to collect and input them into their state’s data collection system.
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. (pg. 30)

- 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 received vaccine to ensure a based vaccination record is provided. (pg. 30)

  **LHD Recommendation/Key Point:** As local health departments are preparing their vaccination clinic plans, ensure that completing and providing vaccination record cards is a part of the plan and identifying any additional reminder recall for second dose.

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

- 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 indicated when the next does of a multidose vaccine is due (pg. 31)

- 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. (pg. 31)

  **LHD Recommendation/Key Point:** Communicate with the state to determine which IIS functionalities will be used and ensure staff are trained in the required functions.

Section 12: COVID-19 Vaccination Program Communication

- COVID-19 Vaccination Communication Objectives
  - Educated 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 need 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. (pg. 35)

• Messaging should be tailored for each audience to ensure communication is effective. (pg. 35)

• Messaging should be timely and applicable for the current phase of the COVID-19 Vaccination Program. (pg. 35)

• 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. (pg. 36)

• **LHD Recommendations/Key Point:** Local health departments should be familiar with the state’s communication plan to ensure a unified message is being communicated to the general public. As local health departments know their communities well, they should ensure messaging is tailored to the communities in their area.

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**Section 13: Regulatory Considerations for COVID-19 Vaccination**

• A 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 clients/patient prior to administering vaccine. (pg. 39)

• **LHD Recommendation/Key Point:** Ensure all relevant staff have reviewed and understand both the EUA fact sheet for vaccine providers and recipients. Prepare to provide copies to the recipient fact sheet to all who receive the COVID-19 vaccines. Public Information Officers and other key spokespeople should also be well versed in the plan and vaccine information in order to answer questions on safety/efficacy from the public.

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**Section 14: COVID-19 Vaccine Safety Monitoring**

• 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. (pg. 40)

- **LHD Recommendation/Key Point:** Instruct all staff on how to use and input adverse events into the Vaccine Adverse Event Reporting System (VAERS).

## Section 15: COVID-19 Vaccination Program Monitoring

- To provide situational awareness for jurisdictions and the general public throughout the COVID-19 vaccination response, CDC will have two dashboards available. (pg. 41)

- The Weekly Flu Vaccination Dashboard will include weekly estimates of influenza vaccination for adults, children, and pregnant women. (pg. 41)

- The COVID-19 Vaccination Response Dashboard will include:
  
  o Data for planning (e.g., estimates of critical population categories, number and attributes of healthcare providers and facilities)
  
  o Implementation data (e.g., number of enrolled COVID-19 vaccination providers, COVID-19 vaccine supply and distribution, COVID-19 vaccine administration locations)
  
  o COVID-19 vaccine administration data. (pg. 41)

- Jurisdictions and tribal organization should regularly monitor their resources to avoid unexpected obstacles to the progress of their COVID-19 Vaccination Programs. (pg. 41)

- **LHD Recommendation/Key Point:** Local health departments can leverage the two CDC dashboards to remain current on the vaccination response.

- **LHD Recommendation/Key Point:** Continuously monitor resources to ensure local health departments have adequate staff, inventory, etc. to maintain their vaccination program.