

# NACO BRIEF: KEY CONSIDERATIONS FOR COUNTIES IN COVID-19 VACCINATION DISTRIBUTION PLANS



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## BACKGROUND

Operation Warp Speed (OWS) is a multi-agency federal partnership led by the Department of Health and Human Services (HHS), that has been tasked with organizing efforts to accelerate the development, manufacturing, and distribution of COVID-19 vaccines and other countermeasures including diagnostics and therapeutics. The goal of this initiative, as outlined by HHS, is to “deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021”.

The Departments of Health and Human Services (HHS) and Defense (DoD) have announced billions of dollars toward the development of six vaccine candidates: *BioNTech SE/Pfizer*, *Moderna*, *AstraZeneca/Oxford*, *Janssen Pharmaceuticals*, *Novavax*, and *Sanofi/GlaxoSmithKline*. Congress has allocated roughly \$10 billion to this effort through supplemental appropriations in previously passed COVID-19 relief bills including the CARES Act.

As of today, *Moderna*, *BioNTech/Pfizer*, and *AstraZeneca/Oxford* have already begun Phase III clinical trials for their respective vaccine candidates, the final stage of clinical development. The other three companies will follow by the end of the year. Following the completion of Phase III trials, vaccine candidates will have to undergo approval by the Food and Drug Administration (FDA).

HHS and OWS are seeking to finalize planning for production and distribution of the vaccine as early as possible so that they may begin distribution immediately following FDA approval and authorization.

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## SUMMARY

On September 16, 2020 HHS announced its COVID-19 vaccine distribution plan. The plan was developed in coordination with the Centers for Disease Control and Prevention (CDC) and the Department of Defense (DoD). The agencies released the plan in the form of a [brief report to Congress](#) outlining a strategic overview of the plan, and [an interim playbook](#) for state, tribal, territorial and local public health programs to begin operationalizing a vaccination response to COVID-19 within their respective jurisdictions.

### The plan outlines four main tenets:

1. Stakeholder engagement and communication with the public to improve vaccine confidence and uptake.
2. Immediate distribution upon FDA approval (within 24 hours).
3. Safe administration and availability of administration supplies.
4. Data monitoring through IT tracking systems.

While many elements of the strategy are still in process pending the outcome of Phase III trials and the timeline for FDA approval, CDC's jurisdictional playbook serves as a framework that outlines many preliminary steps states and localities— especially counties, can be taking now to prepare for vaccine distribution.

The playbook is particularly geared towards CDC Immunization and Vaccines for Children Cooperative Agreement funding awardees. The CDC will distribute federal funding for vaccine preparedness to the 64 jurisdictions with existing cooperative agreements under this program. The agency is also requiring the awardees to **submit detailed vaccine distribution plans to their CDC project officers no later than October 16, 2020.**

**Counties invest heavily in local resident's health and well-being and have been on the front lines of our nation's response to the coronavirus pandemic. Counties support over 900 hospitals, 824 long-term care facilities, and 1,943 local health departments- entities that will play an integral role in the distribution of a COVID-19 vaccine.**

The following sections summarize components of the CDC playbook and key considerations for counties.

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## COVID-19 VACCINATION PROGRAM PLANNING

The playbook outlines the following guidance to assist jurisdictions in operationalizing and launching a COVID-19 Vaccination Program.

**Use of Planning Assumptions & Adaptation.** The playbook emphasizes the importance of “full situational awareness” when planning a vaccine distribution program, which involves balancing the information we have on hand, versus what is not yet known about the vaccine; such as the type of vaccine that will be available, how much of it will be available, and what the

efficacy will be. The resource includes an appendix of planning assumptions, which should be taken into consideration during early planning efforts<sup>1</sup>.

In addition to planning assumptions, the playbook encourages the adaptation of previous vaccination response plans such as those for H1N1, the seasonal flu and childhood immunization programs.

Following the development of a plan, the playbook encourages the use of tabletop exercises to identify weaknesses, especially for plans involving multiple levels of government and cross sectoral partners.

**Development of Internal Planning and Coordination Teams.** The playbook recommends the formation of an internal planning and coordination teams to provide thoughtful insight and expertise from a wide array of state and local jurisdictions. Such jurisdictions may include, but are not limited to:

- Immunization and preparedness professionals
- Legal professionals
- Media and public affairs professionals
- Clinical experts in isolated population fields (e.g. aging, HIV/AIDS, or rural health)
- Local public health jurisdictions

**Development of External Implementation Committees.** In addition to the formation of an internal planning committee, the CDC recommends that jurisdictions leverage external partnerships through the formation of COVID-19 Vaccination Program implementation committees. The members of this committee should represent key COVID-19 vaccination providers for critical population groups, (outlined on page X of this analysis).

**Many of the examples provided by the CDC of stakeholders to be included in external implementation committees are county owned or operated, including:**

- *Emergency management agencies*
- *Local health departments*
- *Health systems & hospitals (including critical access hospitals for rural areas, in-patient psychiatric facilities)*
- *Community Health Centers*
- *Rural Health Clinics (RHCs)*
- *Long-term care facilities, nursing homes, skilled nursing facilities*
- *Correctional facilities*

*\*Please see playbook for full list of suggested stakeholders.*

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## STATE & LOCAL COORDINATION

As states work with counties and other sectors of local government around the planning of a COVID-19 vaccination program plan, the CDC playbook

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<sup>1</sup> See CDC's [COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#), Appendix A: COVID-19 Vaccination Planning Assumptions for Jurisdictions, pages 43- 46

emphasizes the importance of aligning areas of responsibility and specific to maximize resources, quality and efficiency of the program and avoid the duplication of efforts.

*As gatekeepers of the local health and human service safety net, counties will play an essential role in the development and implementation of vaccination programs.*

### **The County Role in Vaccination Program Implementation**

1. **Leveraging Local Expertise.** According to profile data from the National Association of County and City Health Officials (NACCHO), most local health departments provide direct immunization services; 90 percent offer adult immunizations and 88 percent offer childhood immunizations. These departments therefore have a solid foundation of expertise in planning and administering vaccine and immunization programs. *Counties must advocate that states leverage this experience and expertise to ensure COVID-19 vaccination planning efforts make best use of established practices and resources for implementation.*
2. **Increasing Vaccine Confidence.** Vaccine confidence is defined as the trust that parents, patients, or providers have in recommended vaccines, the providers administering those vaccines, and the processes and policies that lead to the development, licensure, manufacturing and recommendations for use.<sup>2</sup> *County officials and local public health agencies must work directly with individuals in their communities to address vaccine hesitancy, combat vaccine misinformation, and increase vaccine confidence.*
3. **Advocating for Necessary Resources.** A [survey conducted in June of 2020](#) by NACCHO revealed that immunization programs in local health departments were the most impacted by COVID-19 through the redirection of funding and the loss of staff. The findings also suggested that while the majority of local health departments (71%) are prepared to give COVID vaccines, *they will need additional resources to do so.*

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## **CRITICAL POPULATIONS**

The CDC has convened a group of professional organizations which include the National Institutes of Health (NIH) and the National Academies of Sciences, Engineering, and Medicine (NASEM), to determine which populations should be prioritized for COVID-19 vaccinations and ensure that there is equitable access to COVID-19 vaccination availability across the U.S.

The working group will decide on priority populations through the continuous review of evidence on COVID-19 epidemiology and burden as well as COVID-19 vaccine safety, efficacy, evidence, quality and implementation findings.

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<sup>2</sup> National Association of County and City Health Officials (2020). Local public health: an integral partner for increasing vaccine confidence. Retrieved September 22, 2020 from [https://www.naccho.org/uploads/full-width-images/factsheet\\_Local-Public-Health-Increasing-Vaccine-Confidence\\_july-2020.pdf](https://www.naccho.org/uploads/full-width-images/factsheet_Local-Public-Health-Increasing-Vaccine-Confidence_july-2020.pdf)

In addition to priority populations, the CDC is encouraging jurisdictions to include a plan to expand vaccine availability beyond priority populations to specific, “critical” populations that jurisdictions are encouraged to consider in their planning efforts:

- **Critical Infrastructure workforce:** frontline healthcare personnel, vaccinators, school nurses EMS personal etc.
- **People at increased risk for severe COVID-19 illness:** nursing home and skilled nursing facility residents, people with underlying medical conditions, people aged 65+
- **People at increased risk of acquiring or transmitting COVID:** racial and ethnic minorities, tribal communities, people incarcerated or detained in correctional facilities, people experiencing homelessness or living in shelters, colleges or universities, people living or working in congregate settings
- **People with limited access to routine vaccination services:** people in rural communities, individuals with disabilities, the uninsured and underinsured.

**Key consideration for counties:**

- Counties officials are trusted public servants in their communities, with the ability to leverage existing partnerships with a variety of stakeholders to rapidly disseminate information through a range of channels.
- County officials should leverage stakeholder partnerships to help identify and communicate with critical populations to ensure equitable vaccine distribution.

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## PHASED VACCINATION APPROACH

The playbook encourages jurisdictions to plan vaccination programs within three possible phases, which outline different scenarios for vaccine supply availability:

1. **Phase 1: A potentially limited supply of COVID-19 vaccine doses.** The CDC recommends that during this phase jurisdictions focus on critical populations outlined above and coordinate the location, storage and reporting requirements for effective distributions.
2. **Phase 2: Large number of vaccine doses available.** During this phase jurisdictions are encouraged to ensure vaccine access critical populations who were not yet vaccinated. as well as for the general population.
3. **Phase 3: Sufficient supply of vaccine doses for entire population.** It is recommended that jurisdictions focus on equitable vaccine access across the entire population as a result of sufficient supply, with a transition to a routine vaccination strategy.

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## VACCINE ALLOCATION, ORDERING, DISTRIBUTION, AND INVENTORY

**Allocation:** Each jurisdiction will be allocated a certain amount of the COVID-19 vaccine by the federal government, which will be managed by the jurisdiction's immunization program. The allotted amount will change over time based on availability and population priority.

**Ordering:** Local distribution sites and enrolled providers will order the COVID-19 vaccine by the jurisdiction's immunization program. The playbook specifies that jurisdictions may use existing IT systems and procedures in place for routine ordering of publicly funded vaccines (e.g., IIS/ExIS upload to CDC's VTrckS for provider direct order entry). Jurisdictions will also use these systems to communicate with CDC about vaccine supply and allocations. Alongside vaccine allocations there will be ancillary supplies sent to jurisdictions which include needles, syringes, and PPE.

**Distribution:** COVID-19 vaccine allotments and ancillary supplies will be provided by the federal government at **no cost to vaccination providers**. The vaccines will be shipped to provider sites that enrolled in the jurisdiction's immunization program within 48 hours of order approval. Because of vaccine storage requirements, ancillary supplies will ship separately from the vaccine.

**Inventory:** The playbook advises that COVID-19 vaccination provider sites will be required to report inventory of COVID-19 vaccines, and jurisdictions will have to ensure this inventory information is submitted with each new order. Vaccines that are *authorized* under an Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) will vary slightly from product that receive an *approval* from the FDA, which has implications for the expiration date of the product.

### Key consideration for counties:

- Determine the entity in your jurisdiction responsible for managing vaccine allotments and orders.
- Ensure that eligible vaccine provider sites in your county (local health departments, clinics, community health centers, etc.) are enrolled in your state's immunization program so that they may receive vaccine allotments.
- Take inventory of existing IT systems used for publicly funded vaccines and ensure all local vaccine provider sites have access to these systems for vaccine ordering and inventory purposes.

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## VACCINE ADMINISTRATION, DOCUMENTATION, AND REPORTING

The playbook specifies that each vaccination provider site is required to report certain data elements for each dose administered and within 24 hours of the administration. Required data elements include detailed information about the vaccine administration site, as well as information about the vaccine recipient (see *page 53 of the playbook for full list of discreet data elements*).

While provider sites may use approved Immunization Information Systems (IIS) or other external systems for tracking, all vaccine administration data must be reported to the CDC's Immunization Data Lake. The CDC recommends that jurisdictions assess the capability of COVID-19 vaccination providers to meet federal and jurisdiction-specific reporting requirements before or upon enrollment, which includes **ensuring that sites have trained staff, necessary equipment, and internet access.**

In addition to reporting vaccine administration, vaccination sites and jurisdictions must implement processes to track first and second vaccine dosages for those vaccines requiring boosters. The information systems being used to track the vaccine administration must also be able to exchange data with other jurisdiction's systems and/or the CDC 's Immunization Data Lake to obtain immunization history, if applicable.

**Key consideration for counties:**

- Assess the vaccine provider site's ability (staff capacity, necessary equipment, and internet access) to adhere to CDC's data reporting requirements. Report resource needs to your jurisdiction project manager.

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**NEXT STEPS**

The CDC is suggesting that states and local jurisdictions use the playbook to develop their COVID-19 vaccination plans. The plans must be submitted to CDC through the corresponding project officer assigned to each of the 64 jurisdictional awardees of the Immunization and Vaccines for Children Cooperative Agreement by **October 16, 2020**. See *Appendix B* for the complete list of the 64 jurisdictions and the corresponding project officers.

**Timeline**

<b>Release of Framework</b>	<b>September 16, 2020</b>
Jurisdiction Vaccination Plan Due to CDC	October 16, 2020
Phase 3 Clinical Trial Completion	End of 2020/ Early 2021
FDA Approval and Authorization	2021
Phased Allocation of Vaccination Doses	2021

**Key next steps for counties:**

- **Reach out to your state's CDC Jurisdiction Project Officer for Vaccine Development** to ensure that your county expertise and resource needs are reflected in jurisdictional plans.
- **Contact your Representative and Senators** to request that Congress provide direct and flexible COVID-19 funding for state and local governments to assist with the acquisition of supplies and resources for vaccine distribution.

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## RESOURCES

### Partner Organizations

- [Local Public Health: An Integral Partner for Increasing Vaccine Confidence \(NACCHO\)](#)
- [NACCHO Infographic: The Impact of COVID-19 Response on Local Health Department Immunization Programs](#)
- [Preliminary Framework for Equitable Allocation of COVID-19 Vaccine \(NASEM\)](#)

### Department of Health and Human Services

- [Fact Sheet: Explaining Operation Warp Speed](#)
- [From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine](#)

### Centers for Disease Control and Prevention

- [COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#)
- [The CDC Advisory Committee on Immunization Practices \(ACIP\)](#)
- [Vaccine Storage and Handling Toolkit](#)
- [Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations](#)
- [Vaccination Guidance During a Pandemic](#)

### Food and Drug Administration

- [Development and Licensure of Vaccines to Prevent COVID-19](#)
- [Emergency Use Authorizations \(EUAs\)](#)



## Appendix A:

### *Federal Funding & Mandates for Vaccine Development and Distribution*

Bill Title (Number)	Funding Amount Allocated	Summary of Provision
<b>Coronavirus Preparedness and Response Supplemental Appropriations Act (P.L. 116-123)</b>	<b>\$61 million</b>	Provided additional funding for FDA "Salaries and Expenses" for COVID-19 response, which includes "the development of necessary medical countermeasures and vaccines".
	<b>\$3.1 billion</b>	Provided additional funding for the HHS "Public Health and Social Services Emergency Fund". The funding was provided to help respond to COVID-19, including the "development of necessary countermeasures and vaccines". These funds can also be used "for the construction, alteration, or renovation of non-Federally owned facilities for the production of vaccines". The bill also instructs the HHS Secretary to use these funds to purchase vaccines.
	<b>\$300 million</b>	Provided additional funding made available to the "Public Health and Social Services Emergency Fund" for the same purposes listed above. However, the funding is only available if the HHS Secretary notifies Congress that the \$3.1 billion allocation "will be obligated imminently and that additional funds are necessary to purchase vaccines...".
<b>Families First Coronavirus Response Act (P.L. 116-127)</b>	<b>Medicaid FMAP assistance increased temporarily by 6.2% for each state/territory</b>	States were only eligible for this temporary increase in federal medical assistance if the State provides "coverage under such plan (or waiver), without the imposition of cost sharing...for any testing services and treatments for COVID-19, including vaccines...".
	<b>\$80 million</b>	Provided additional funding for FDA "Salaries and Expenses" for COVID-19 response, which includes "the development of necessary medical countermeasures and vaccines".
	<b>\$706 million</b>	Provided additional funding for NIH. Mandates that no less than \$156 million of these dollars be used "for the study of, construction of, demolition of, renovation of, and acquisition of equipment for, vaccines and infectious diseases research facilities".

<b>Coronavirus Aid, Relief and Economic Security Act (CARES, P.L. 116-136)</b>	<b>\$3.5 billion</b>	Provided additional funding for the HHS "Public Health and Social Services Emergency Fund". The funding was provided to help respond to COVID-19, including the "development of necessary countermeasures and vaccines". \$3.5 billion of this funding is allocated to the Biomedical Advanced Research and Development Authority for "manufacturing, production and purchase....of vaccines, therapeutics, diagnostics...". These funds can also be used "for the construction, alteration, or renovation of non-Federally owned facilities for the production of vaccines".
	N/A	Required the strategic national stockpile to include PPE and other medical supplies "required for the administration of drugs, vaccines and other biological products".
	N/A	Mandates that the Secretaries of HHS, Labor and Treasury "require group health plans and health insurance issuers...to cover (without cost-sharing) any qualifying coronavirus preventive service", including vaccines. Requires that any licensed COVID-19 vaccine be covered under the Medicare Part B program without cost-sharing