

OPERATION WARP SPEED OUTLINES PLAN FOR COVID-19 VACCINE DISTRIBUTION, ADMINISTRATION, MONITORING, AND COMMUNICATIONS

On September 16, 2020, the Trump Administration announced its plan for distributing and administering a COVID-19 vaccine once one becomes available. The release materials are two-fold, containing first a [Report to Congress](#) on its overall strategy, along with a complementary [operational playbook](#) for states. Overall, the plan discusses elements around plans for centrally distributing the vaccine; how state and local governments will be partners in this effort; how phased-in administration of the vaccine will target prioritized populations first; why communications around vaccine promotion are necessary for broad uptake; and its approach for monitoring vaccine distribution and administration in real-time.

While this is the most comprehensive plan seen from the administration to-date, stakeholders may still be left with certain questions around specific details. For example, Senator Patty Murray (D-WA) remarked at a Labor, Health and Human Services, Education [hearing](#) earlier this morning that the report does not represent a “comprehensive, end-to-end national plan” that she and others have called for. Specifically, she noted that “important details on research and review – like what standards FDA would use to authorize a vaccine for emergency use; development – like how we make sure disparities are addressed in clinical trials; and manufacturing – like how we address supply chain issues and avoid bottle necks” are still needed.

Details on the distribution plan follow.

Report to Congress: In its [report](#), the Trump Administration outlines how Operation Warp Speed (OWS) plans to distribute a COVID-19 vaccine once one is available. The strategy consists of four key components: vaccine distribution; engaging with local governments and stakeholders; vaccine administration; and data monitoring. We detail the administration’s plans for each of these components below.

- **Distribution:** The report states that a distribution plan must be able to deliver vaccines immediately upon FDA authorization or licensure to all possible administration endpoints. It must also be flexible enough to accommodate a variety of factors, including timelines, volume of production, and others. Along these lines, OWS states it is currently developing cooperative plans for centralized distribution to be executed in phases by the federal government and all 50 states and territories. Specifically, OWS is:
 - **Establishing partnerships with state and local governments to allocate and distribute vaccines:** OWS notes that the Centers for Disease Control and Prevention (CDC) awarded grants through the CARES Act to aid with immunization programs once a vaccine is available. In addition, the report states that a multi-agency federal team is working with pilot jurisdictions in California, Florida, Minnesota, North Dakota, and Philadelphia to implement a basic plan for administering vaccines, tailored to their specific areas.
 - **Centralized Distribution:** Here, OWS states it has an existing contract with McKesson to perform a distributor contract. The report notes the distribution system will be scalable to

meet demand, and will account for vaccines that need to be rapid distribution of doses of refrigerated and frozen vaccines.

- **Ordering and Tracking Systems:** The report states that the U.S. Department of Health and Human Services (HHS) will use its Vaccine Tracking System (VTrckS) to assist with allocation and centralized distribution. VTrckS is a secure, web-based IT system that integrates the publicly funded vaccine supply chain from purchasing and ordering through distribution to participating state, local, and territorial health departments and providers.

On p. 5 of the report, OWS further outlines a potential phased structure for the distribution plan.

- **Administration:** Here, the report states that effective administration requires identifying prioritized populations and working with local governments to ensure those populations receive vaccines first. Specifically, OWS states its plan for vaccine administration will include:
 - **Delivery and Cost:** OWS notes that its contact with McKesson is such that no American will be charged for the COVID-19 vaccine or its distribution.
 - **Ancillary Supplies:** OWS is also procuring and assembling 6.6 million ancillary supply kits that are required for vaccine administration. The report states this would support vaccination of up to 660 million doses.
 - **Administration Sites:** The report states that administration sites may be more limited to settings that can optimize reaching the target population at the earlier phases of the distribution plan. The site locations may expand in later phases of the distribution plan. OWS also notes that it will work with the CDC to ensure rural populations receive the vaccine as well.
- **Monitoring:** OWS notes that the vaccine program will require extensive data monitoring infrastructure to incorporate claims and payment processes, identify when an individual needs a potential second dose, monitor outcomes and adverse events, and account for federal spending. The monitoring program will require data from federal and local stakeholders to ensure efficient management, it adds. OWS' progress on this front is outlined on p. 9 of the report.
- **Engagement:** The report states that a stakeholder engagement plan is required to promote vaccine uptake and support vaccine distribution. OWS states it is working to establishing partnerships with organizations that are trusted sources for target audiences to aid public understanding of eventual vaccines. To do this, OWS states it is engaging public, nonprofit, and private partnerships, along with state health departments, health care systems, the vaccine industry, health insurance plans, and "non-traditional partners."
 - **Partnerships:** First, OWS states it is building baseline capacity for distribution and administration through successful partnerships between the CDC and state, local, and tribal health departments. The HHS Office of Intergovernmental and External Affairs is also establishing communication channels with nearly 30 private sector organizations in the health care sector to provide regular updates on the work of OWS. OWS also notes it has begun work with organizations representing minority populations and vulnerable communities, including faith-based organizations, to encourage broader participation in the vaccination program.
 - **Communications:** Here, the report outlines that HHS' public affairs department will develop messaging to promote vaccine safety and efficacy, and will target key populations and communities to ensure greater uptake of the vaccine. It states that it recognizes

promoting the right message, targeting outreach to vulnerable populations, and countering misinformation will be necessary to achieve high coverage.

State Playbook: The administration also released a [playbook](#) for states outlining steps for operationalizing a vaccination response to COVID-19 within their local jurisdictions, accounting for the need to prioritize distribution of a limited supply of doses in the earlier phases of the Vaccination Program. Moreover, OWS intends recipients of CDC Immunization and Vaccines for Children Cooperative Agreements to use this plan to develop their own vaccination plans. **Funding recipients should submit their vaccination plans to their CDC project officers by Oct. 16, 2020.**

Specific highlights of the playbook include:

- On p. 11, the playbook notes that initial doses of the vaccine will have to be distributed in a limited manner, and that distribution must go to the populations of focus first.
- On p. 14, the playbook outlines how the federal government is working to identify critical populations of focus for the vaccine. It states the CDC has established an Advisory Committee on Immunization Practices (ACIP) workgroup to review evidence on COVID-19 epidemiology and burden to provide recommendations on vaccine distribution and prioritization. The playbook outlines the following potential populations that may be considered critical:
 - Infrastructure workforce;
 - People at increased risk for severe COVID-19 illness;
 - People at increased risk for acquiring or transmitting COVID-19; and
 - People with limited access to routine vaccination services.
- On p. 24, OWS outlines how it will determine the number of COVID-19 vaccines to be allotted for each jurisdiction. Factors that will determine this include:
 - 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 the vaccine and related supplies; and
 - Other local factors.

Additional details are included on vaccine program communications (p. 35); regulatory considerations (p. 39); and vaccine safety monitoring (p. 40), among others.