COVID-19 Pandemic: Vaccination Planning FAQ



November 19, 2020

The U.S. government must ensure access to a COVID-19 vaccine that meets FDA's rigorous and science based standards, for all people in the United States who wish to be vaccinated. The U.S. Department of Health and Human Services (HHS), the U.S. Department of Defense (DOD), and other Federal partners are coordinating support requirements for the distribution, storage, and administration of COVID-19 vaccines. Details on the requirements associated with the distribution and administration of the vaccine are based on the vaccines that are expected to be reviewed, and potentially authorized, by the U.S. Food and Drug Administration (FDA).¹ Such requirements include the type of storage and handling necessary for each approved vaccine, transportation and distribution needs, and specific requirements for properly administering the vaccine. Links are provided at the end of this FAQ for more information and resources about general vaccine planning and support mechanisms.

1. How is the Federal government coordinating support for COVID-19 vaccination across departments and agencies?

Following FDA's determination that the vaccine has met the agency's rigorous and science based standards for quality, safety, and effectivenss, Operation Warp Speed² is planning to deliver authorized COVID-19 vaccines to Americans as expeditiously as possible. Successful implementation of a national COVID-19 vaccination program requires precise and close coordination across the Federal government, as well as state, local, territorial, and tribal (SLTT) governments and among many public and private partners. Operation Warp Speed is a partnership among components of HHS, including the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), the HHS Assistant Secretary for Preparedness and Response (ASPR), and Biomedical Advanced Research and Development Authority (BARDA), as well as DOD, with the objective of a unified government approach in response to the ongoing COVID-19 pandemic. The goal is to produce and deliver 300 million doses

¹ The FDA is expected to authorize COVID-19 vaccines for use under an <u>Emergency Use Authorization</u> or licensed through the Biologics License Application process.

² Fact Sheet: Explaining Operation Warp Speed available at www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html.

of authorized vaccines, with the initial doses available by January 2021 (if not sooner) as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines and therapeutics.³ The Federal Emergency Management Agency (FEMA) is also able to provide supplemental funding through the Public Assistance (PA) Program for eligible work and associated costs when necessary for the distribution and administration of COVID-19 vaccines.⁴

2. What sources of Federal funding are available for COVID-19 vaccines?

COVID-19 vaccines will be procured and distributed by the Federal government at no cost to enrolled COVID-19 vaccine providers.⁵ The vaccine will be administered primarily through established healthcare systems and distribution points approved by Operation Warp Speed. The cost for vaccine administration will be covered by private and public healthcare providers, most insurance, TRICARE, Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and/or other HHS funding sources. Healthcare providers may be reimbursed for administering COVID-19 vaccines to uninsured individuals through HHS's COVID-19 Uninsured Program. Additionally, vaccine providers will be able to charge an administration fee to the program or entity providing reimbursement for COVID-19 vaccines.⁶ However, the CDC Provider Agreement⁷ states that participating providers must administer COVID-19 vaccines regardless of the vaccine recipient's insurance coverage status or ability to pay COVID-19 vaccine administration fees.⁸ Vaccine providers may seek appropriate reimbursement from a program or health plan that covers COVID-19 vaccine administration fees for the individual receiving the vaccine⁹ (e.g., private insurance, Medicare, Medicaid, CHIP, etc.).

Operation Warp Speed is also providing vaccination kits, ¹⁰ at no cost, which includes the needles, syringes, and Personal Protective Equipment (PPE) needed for safe administration of COVID-19 vaccines. CDC has also allocated funding through established mechanisms to support the distribution of COVID-19 vaccines to SLTT

³ <u>Id.</u>

⁴ Work and costs must in accordance with PA program eligibility requirements as outlined in the Public Assistance Program and Policy Guide (PAPPG). Version 3.1 of the PAPPG is applicable to all COVID-19 declarations and is available on the FEMA website at www.fema.gov/sites/default/files/2020-03/public-assistance-program-and-policy-guide_v3.1_4-26-2018.pdf.

⁵ COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, page 30. www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

⁶ Getting Vaccinated: www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html.

⁷ The CDC COVID-19 Vaccination Program Provider Agreement is available at www.mhanet.com/mhaimages/COVID-19/COVID%20Vaccine%20Provider%20Agreement_Fillable.pdf.

⁸ COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, number 4 at page 21. www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

⁹ COVID-19 Vaccine Implementation Planning Update, page 14: www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-10/COVID-Routh.pdf.

¹⁰ Each ancillary supply kit will contain enough supplies to administer up to 100 doses of vaccine. For a list of items, please visit www.hhs.gov/about/news/2020/10/30/trump-administration-producing-supply-kits-safely-administer-covid-19-vaccines-americans.html.

public health departments and the SLTT plans for their administration. FEMA is also able to provide supplemental funding through the PA Program for eligible work and costs necessary for the distribution and administration of COVID-19 vaccines and consistent with PA program authorities. Funding may also be available through the FY 2020 Emergency Management Performance Grant Program – COVID-19 Supplemental (EMPG-S). Funding availability is dependent on the eligibility requirements of each program. With the support of interagency partners, FEMA has developed the COVID-19 Healthcare Recovery Resource Roadmap to assist SLTT leaders and stakeholders with navigating some of the challenges, as well as the resources, associated with the COVID-19 pandemic.

3. Are costs incurred by SLTT governments for the distribution and administration of COVID-19 vaccines eligible for FEMA PA?

Work and associated costs to support the distribution and administration of COVID-19 vaccines may be eligible for PA. The work and associated costs must be in accordance with PA program eligibility requirements as outlined in the Public Assistance Program and Policy Guide (PAPPG).¹¹ For example, costs covered by another source of federal funding or insurance are not eligible for PA. The cost of the vaccine itself will be covered by the Federal government and Operation Warp Speed is providing vaccination kits with supplies to support the administration of the vaccine. The vaccine will be made available through established healthcare delivery and reimbursement systems and HHS has established mechanisms and program funding to support the COVID-19 vaccination effort. There may be additional costs incurred by SLTTs to support the distribution and administration of the vaccine. Such costs may be eligible for PA funding when they are necessary to effectively distribute and administer COVID-19 vaccines consistent with CDC guidance and PA program requirements.

4. What kinds of work and associated costs may be eligible under FEMA PA for COVID-19 vaccines?

Examples of eligible work and costs under FEMA PA include, but are not limited to:

- Personal protective equipment (PPE),¹² other equipment, and supplies required for storing, handling, distributing/transporting, and administering COVID-19 vaccines.
 - PPE includes items necessary for proper handling and administration of vaccines as well as handling dry ice for storage and transportation needs.
 - Equipment includes, coolers, freezers, temperature monitoring devices, and portable vaccine storage units for transportation.

¹¹ Version 3.1 of the PAPPG is applicable to all COVID-19 declarations and is available on the FEMA website at www.fema.gov/sites/default/files/2020-03/public-assistance-program-and-policy-guidev3.1 4-26-2018.pdf.

¹² PPE includes items such as N95 and other filtering respirators, surgical masks, gloves, protective eyewear, face shields, and protective clothing (e.g., gowns).

- Supplies include emergency medical supplies (for emergency medical care needs that may arise in the administration of the vaccine), sharps containers (for medical waste), and supplies necessary for proper storage like cannisters of liquid nitrogen or dry ice.
- Transportation support includes refrigerated trucks and transport security when reasonable and necessary.
- Facility support costs, including leasing space for storage and/or administration of vaccines, utilities, maintenance, and security.
- Additional staff if necessary, including medical and support staff not paid for by another funding source, consistent with FEMA PA labor policies (see *Chapter 2:V.A. Applicant (Force Account) Labor* of the <u>PAPPG</u> (V3.1)).
- Onsite infection control measures including PPE for staff as well as cloth face coverings for patients, temperature scanners, physical barriers (e.g., plexiglass dividers), and disinfection of the facility in accordance with CDC guidance.
- Emergency medical care associated with vaccine administration (e.g., to address allergic reactions to the vaccine or other emergency medical needs that arise in the administration of the vaccine).
- Medical waste disposal.
- Communications to disseminate public information regarding vaccinations.¹³

5. Are there work and associated costs eligible for FEMA PA that are also eligible from other sources of Federal funding?

Eligibility among various programs of Federal assistance depends on the specific statutory and regulatory provisions and criteria that apply to each program. In some cases, there may be overlap among programs regarding what is eligible. FEMA will allow costs that are eligible under PA that are also eligible under other Federal programs as long as funding for the same item of work and associated costs is not provided by another source of Federal funding, insurance, or any other funding source. The FEMA fact sheet Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Coordinating Public Assistance and Other Sources of Federal Funding provides information regarding the coordination of COVID-19 funding between FEMA PA and other sources of Federal funding.

6. Will FEMA require SLTT applicants to seek reimbursement of costs through insurance?

Costs for administering the vaccine to individuals may be covered by other mechanisms, including health insurance, TRICARE, Medicare, Medicaid, and other HHS funding sources for uninsured individuals (*i.e.*, HHS COVID-19 Uninsured Program). Costs for which providers have received or will receive payments from health insurance, TRICARE, Medicare, Medicaid, CHIP, or other Federal programs are not eligible under PA. Applicants

¹³ Dissemination of public information should be consistent with Chapter 2:VI.B of the PAPPG (V3.1) which lists "dissemination of information to the public to provide warnings and guidance about health and safety hazards using various strategies, such as flyers, public service announcements, or newspaper campaigns" as an eligible emergency protective measure.

should follow their normal billing practices and must certify that they have not received and do not anticipate receiving assistance from these sources or any other source for the same work or costs.

7. If obtaining required resources is beyond a SLTT government's capability, can it request Direct Federal Assistance for those resources?

When a SLTT government is unable to secure resources that are necessary to effectively distribute and administer COVID-19 vaccines, it may request the resources directly from the Federal government through Direct Federal Assistance (DFA). FEMA will evaluate such requests to determine if those resources are beyond the capability of SLTT jurisdictions and, if so, the best method of securing those resources. Vaccine distribution and administration activities are also an allowable activity under existing Title 32 Mission Assignments to Department of Defense for Title 32 National Guard deployments in response to the COVID-19 pandemic until the President's authorization expires.

8. What is the best source of information for SLTT emergency managers regarding Federal support for COVID-19 vaccine distribution and administration?

SLTT emergency management agencies should coordinate communications, planning, and logistics for vaccine distribution and administration with their public health director and through existing immunization programs. CDC is providing frequent updates to SLTTs and other jurisdictions through engagement with jurisdictional public health and emergency management staff. SLTT health departments have conducted pandemic vaccination planning with immunization and preparedness funding from CDC for over a decade and have been updating those plans specifically for COVID-19. HHS has also been holding regular calls with intergovernmental partners at the SLTT level with robust dialogue on how the Federal government will successfully partner with them on the COVID-19 vaccination program. At the Federal level, emergency managers may contact their regional HHS/ASPR point of contact for more information:

Region 1: ASPR.R1@hhs.gov
Region 2: ASPR.R2@hhs.gov
Region 3: ASPR.R3@hhs.gov
Region 4: ASPR.R3@hhs.gov
Region 5: ASPR.R4@hhs.gov
Region 5: ASPR.R4@hhs.gov
Region 6: ASPR.R4@hhs.gov
Region 7: ASPR.R8@hhs.gov
Region 9: ASPR.R9@hhs.gov
Region 10: ASPR.R10@hhs.gov

Additional Federal information related to COVID-19 vaccine planning and distribution are provided below:

- 1. <u>CDC Interim Playbook</u> (provides vaccination response planning for SLTT partners)
- 2. Operation Warp Speed Fact Sheet and Vaccine Distribution Strategy
- 3. CDC COVID-19 Vaccine FAQ
- 4. CDC: 8 Things to Know About Vaccine Planning
- 5. COVID-19 Recovery Resource Roadmaps