COVID-19 Vaccine Provider FAQs

We are actively monitoring COVID-19 vaccine developments. Below you will find helpful information and answers to some of the most frequently asked questions about COVID-19 vaccines.

Magellan Complete Care has a COVID-19 Vaccine Taskforce comprised of experts, including clinicians, health plan leadership, and pharmacy network team members that meets regularly to discuss the latest developments and plan support. We are monitoring government guidance at the federal and state levels. We are taking steps to ensure you have the information you need as the information and guidelines are made available by federal and state agencies.

Vaccine Development and Distribution

Operation Warp Speed (OWS) was set up by the White House to coordinate efforts among federal government entities, states, and private sector partners. It aims to accelerate the testing, supply, development, and distribution of safe and effective vaccines, therapeutics, and diagnostics.

There are many government agencies involved in helping with the COVID-19 pandemic. A few of the key agencies are listed below for your reference:

- **Food and Drug Administration (FDA) –** The FDA reviews and approves or authorizes safe and effective vaccines.
- **Centers for Disease Control and Prevention (CDC)** – The CDC is responsible for controlling the introduction and spread of infectious diseases.
- **Advisory Committee on Immunization Practices (ACIP) –** ACIP is a committee within the CDC that provides advice and guidance on effective control of vaccine-preventable diseases in the U.S. civilian population.
- **National Academies of Science Engineering & Medicine (NASEM) –** The National Institutes of Health (NIH) and CDC have tasked NASEM to develop a plan for equitable allocation of vaccines. They make recommendations for vaccine administration priority among the population.
- **Biomedical Advanced Research and Development Authority (BARDA) –** BARDA is a U.S. Department of Health and Human Services (HHS) office responsible for the procurement and development of medical countermeasures. BARDA also procures and maintains stockpiles of materials, such as drugs, personal protective equipment (PPE) and vaccines for the Strategic National Stockpile.
- **World Health Organization (WHO) –** WHO is a specialized agency of the United Nations responsible for international public health.

Frequently Asked Questions

Q: Is the COVID-19 vaccine safe?

A: Yes. Clinical trials used to evaluate any COVID-19 vaccine are conducted with thousands of study participants to generate scientific data and other information for the Food and Drug Administration (FDA) to determine their safety and effectiveness. These clinical trials are conducted according to the rigorous standards set forth by the FDA. Once the FDA determines that a vaccine meets its safety and effectiveness standards, it provides its approval. Then the CDC/ACIP review for recommendation of use in the United States. All vaccines made available have undergone clinical trials and approval for both safety and effectiveness.

Q: Can children get the vaccine?

A: The vaccine is now available for children ages 12 and older. Studies are ongoing for children under the age of 12.

Q: How many doses of a COVID-19 vaccine will be needed?

A: Both single and two-step vaccines have EUA from the FDA currently. Please ensure patients understand if and when they need to return to get a second injection. Vaccination cards will be provided when the patient gets their COVID-19 vaccine which will provide the patient with a record of the vaccine type, manufacturer information, date of first vaccine, and date the patient needs to receive the second injection, if applicable. ***It is very important patients receive both injections of a two-step vaccines for it to work.***

Q: What are the side effects of a COVID-19 vaccine?

A: This vaccine is safe. Safety and effectiveness are evaluated during the FDA's review and approval process. Those receiving the vaccine may have some side effects. These are normal signs the body is building protection. The most common side effects are pain and swelling at the injection site. In addition, vaccine recipient may have fever, chills, tiredness, and headache. Most side effects are generally mild and last a few days.

Q: What safety monitoring measures are in place for the COVID-19 vaccine?

A: Vaccine Adverse Event Reporting System (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.
- Per the CDC COVID-19 Vaccination Program Provider Agreement, COVID-19 vaccination providers are required to report the following to VAERS:
    - Vaccine administration errors (whether associated with an adverse event or not),
    - Serious adverse events (even if they are not sure if the vaccination caused the event)
    - Multisystem inflammatory syndrome (MIS) in children or adults, and
    - Cases of COVID-19 that result in hospitalization or death to VAERS.
- More information on submitting a VAERS report electronically can be found at https://vaers.hhs.gov/reportevent.html.

V-Safe

- CDC will implement V-safe, a new smartphone-based tool that uses text messaging and web surveys to check in with vaccinated individuals for adverse events after a COVID-19 vaccination. V-safe will also provide second-dose reminders (if needed) and live telephone follow up by CDC if vaccinated individuals report a medically significant event during a V-safe check-in.

Vaccine Safety Datalink

- The Vaccine Safety Datalink (VSD) is a collaboration between the CDC's Immunization Safety Office and nine healthcare organizations. This active surveillance system monitors electronic health data on vaccinations and medical illnesses diagnosed in various healthcare settings and conducts vaccine safety studies based on questions or concerns raised from medical literature and findings from VAERS monitoring.

Clinical Immunization Safety Assessment Project

- The CDC's Clinical Immunization Safety Assessment (CISA) Project is a national network of vaccine safety experts from the CDC's Immunization Safety Office and seven medical research centers. This project conducts clinical research, assesses complex events following vaccination, and provides consultations to U.S. healthcare providers and public health partners.

Q: Can people get sick with COVID-19 from the vaccine?

A: No. There is no live COVID-19 virus in any vaccine currently available. There is no risk of being infected as a direct result of getting the vaccine. Those receiving the vaccine may have some side effects. These are normal signs the body is building protection. The most common side effects are pain and swelling at the injection site. In addition, vaccine recipient may have fever, chills, tiredness, and headache. Most side effects are generally mild and last a few days.

Q: Do people need to wear a mask when they get a COVID-19 vaccine? Do people need to wear a mask after getting the vaccine?

A: Yes. The CDC recommends people wear a mask that covers their nose and mouth. You should do this when in contact with others outside your household, when in healthcare facilities, and when receiving any vaccine. Once you receive all vaccine doses, it's important for everyone to continue using all the tools available to us to help stop this pandemic. This includes:

- Covering your mouth and nose with a mask
- Washing your hands often
- Staying at least 6 feet away from others

Q: If someone has already had COVID-19 and recovered, do they still need to get a vaccine?

A: Yes. Due to the severe health risks associated with COVID-19 and the possibility of reinfection, you should be vaccinated even if you have had COVID-19. This is because experts don't yet know how long you are protected from getting sick again after recovering from COVID-19.

If you have COVID-19 you should wait to get vaccinated until you are no longer sick and are not in isolation. Talk to your doctor if you have more questions about getting a COVID-19 vaccine.

Q: How much will the COVID-19 vaccine cost?

A: There are two important parts to a vaccine when we think about cost: How much will the product (vaccine dose) cost, and how much will it cost to administer the vaccine?

Per the CDC, vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. However, vaccination providers will be able to charge an administration fee for administering the shot to someone. Vaccine providers can get this fee reimbursed by the patient's public or private insurance company. For uninsured patients, vaccine providers can get this fee reimbursed by the Health Resources and Services Administration's Provider Relief Fund.

Vaccine Dose Cost

The federal government has already purchased these vaccines and we are expecting the product cost to be $0 for patients for most lines of business. Medicaid may have other state requirements.

Vaccine Administration Cost: Pharmacy Claim

Please note: Pharmacy providers with questions around vaccine administration costs and processing, please see appropriate pharmacy help desk info below:

Health Plan	Pharmacy Vendor	Phone Number
SWH NY	ESI	1-800-922-1557

Vaccine Administration Cost: Medical Claim

According to CMS, Medicare payment rates for COVID-19 vaccine administration will be $28.39 to administer single-dose vaccines. For a COVID-19 vaccine requiring a series of 2 or more doses, the initial dose(s) administration payment rate will be $16.94, and $28.39 for the administration of the final dose in the series. These rates recognize the costs involved in administering the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients answering any questions they may have about the vaccine. These rates will also be geographically adjusted. For Medicaid, Commercial, and other lines of business, the administration fees will be expected to be set to rates that are similar to CMS vaccine administration for Medicare.

Patient Costs				
	Commercial	**Medicare**	**Medicaid**	**Uninsured**
Vaccine Product Cost	$0	$0	$0*	$0
Vaccine Administration Cost	$0	$0	$0*	$0
Details	Covered under the ACA for ACIP recommended vaccines. Per guidance insurers should cover administrative costs	Covered under Part B for vaccine and administration	*There may be differences in coverage based on state and population	Administration will be reimbursed through the Provider Relief Fund[1]

1. The Provider Relief Fund is administered by the Health Resources and Services Administration (HRSA). https://www.cms.gov/newsroom/press-releases/trump-administration-acts-ensure-coverage-life-saving-covid-19-vaccines-therapeutics

Q: **How do I code for the COVID-19 vaccine:**

A: CMS has information on their website on the **Medicare Part B Payment for COVID-19 Vaccines**, please visit their website for the most up-to-date information.

Vaccine Administration Cost: Medical Claim

COVID Vaccine CPT Codes

Vaccine Coding: Pharmacy Claim

For Medicaid, DSNP and specialty plans, please call the pharmacy help desk with questions regarding submitting vaccines as a pharmacy claim.

Health Plan	Pharmacy Vendor	Phone Number
SWH NY	ESI	1-800-922-1557

Q: My facility wants to distribute the vaccine. What are the steps to becoming a distribution site?

A: In Phase 2, to vaccinate a broader population group, vaccines will be allocated and distributed directly from the federal government to select pharmacy partners. Direct allocation opportunities will be provided to retail chain pharmacies and networks of independent and community pharmacies (those with a minimum of 200 stores).

- 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.
- COVID-19 vaccination providers must sign/agree to the CDC COVID-19 Vaccination Program Provider Agreement. Failure to comply may impact whether COVID-19 vaccine product orders are fulfilled.

  To administer the vaccine, providers must agree to:

  - Administer COVID-19 vaccine in accordance with ACIP recommendations
  - 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.
  - Not sell or seek reimbursement for COVID-19 Vaccine and any diluent, syringes, needles, or other constituent products and ancillary supplies provided by the federal government.
  - Administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay.
  - Provide an Emergency Use Authorization (EUA) fact sheet for recipients or vaccine information statement (VIS), as applicable, to each vaccine recipient/parent/legal representative prior to vaccination.
  - Comply with CDC requirements for vaccine management
  - Report COVID-19 vaccines and diluents that were unused, spoiled, expired, or wasted as required by the jurisdiction's immunization program.
  - Comply with federal instruction regarding disposal of unused COVID-19 vaccine and diluent.
  - Report vaccine administration errors to VAERS
  - Provide a completed COVID-19 vaccination record card to every vaccine recipient/parent/legal representative.
  - Comply with FDA's requirements, including EUA-related requirements described in FDA's Letter of Authorization, as applicable. Providers must also administer COVID-19 vaccine in compliance with all applicable state and territorial vaccine laws.
- 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.
- CDC is developing and updating a variety of clinical educational and training resources for healthcare professionals related to COVID-19 vaccine(s).

Q: How will long-term care facility residents get access to the vaccine?

A: The CDC will collaborate with CVS and Walgreens to provide on-site vaccination clinics for long-term care facility residents as part of Phase 1a per the CDC's Advisory Committee of Immunization Practices (ACIP).

Q: What is the COVID-19 vaccine administration documentation and reporting process?

A: 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 in CDC's Immunization Information System (IIS). In addition to reporting vaccine administration, jurisdictions must put processes in place to match first and second doses. The jurisdiction's IIS should collect, report, and submit data directly to CDC's Immunization Data Lake and jurisdictional reporting requirements.

Q: How will patients be reminded they need to come back for their second injection for two-step vaccinations?

A: Some of the COVID-19 vaccines require two doses, separated by 21 or 28 days. 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.

COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. Vaccination providers must 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.

Q: When will my area/region/state receive the COVID-19 vaccine for distribution? How many vaccines will my area/region/state receive?

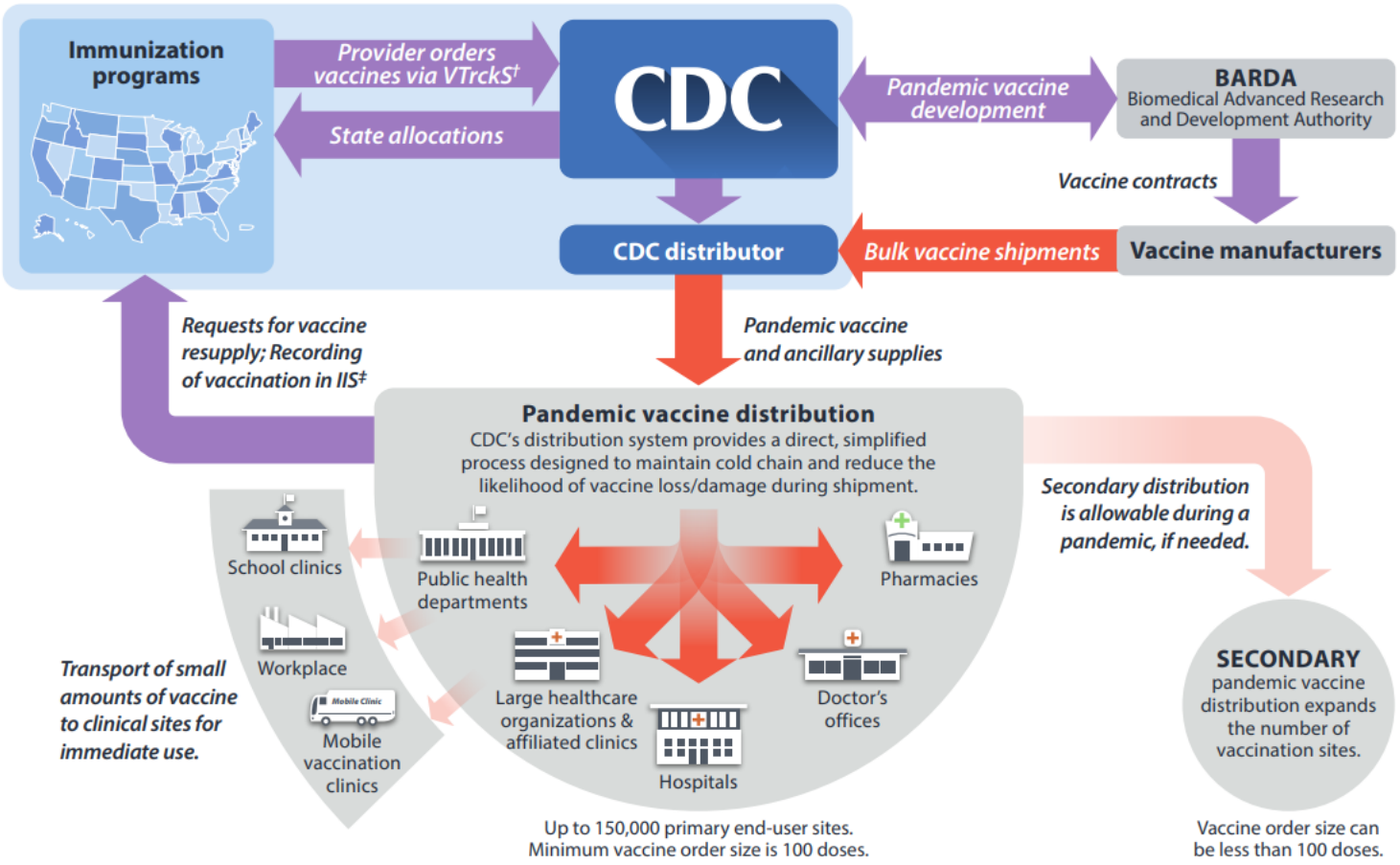
A: The federal government will determine the quantity of COVID-19 vaccines designated for each jurisdiction. The jurisdiction's immunization program will then be responsible for managing and approving orders from enrolled providers within their jurisdiction using this allotment.

- COVID-19 vaccination providers enrolled by the jurisdiction will order COVID-19 vaccine through their jurisdiction's immunization program.
- CDC will provide jurisdictions with regular updates on the available vaccine supply and their assigned vaccine product-specific allocations in VTrckS.
- Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS.
- COVID-19 vaccine (and diluent, if required) will be shipped to vaccination provider sites enrolled by the jurisdiction's immunization program within 48 hours of order approval.
- COVID-19 vaccination providers will be required to report COVID-19 vaccine inventory daily using VaccineFinder.

Q: How will COVID-19 vaccines be stored and handled during the distribution process?

A: 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.

Distribution of pandemic vaccine and supplies



* https://www.cdc.gov/vaccines/hcp/admin/storage/index.html
† The Vaccine Tracking System (VTrcks) is CDC's management and ordering systems for publicly-funded vaccines.
‡ Immunization Information System (IIS)

www.cdc.gov/flu/pandemic-resources/

Interim pandemic distribution plan, 04/20/20

https://www.cdc.gov/flu/pdf/pandemic-resources/pandemic-influenza-vaccine-distribution-9p-508.pdf

Resources:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html
https://www.cdc.gov/vaccines/acip/meetings/slides-2020-12.html
https://www.pfizer.com/science/coronavirus/vaccine
https://www.modernatx.com/sites/default/files/content_documents/mRNA-1273-Update-11-16-20-Final.pdf
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