Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

CDC COVID-19 Vaccination Program Provider Requirements and Support

At this time, all COVID-19 vaccine in the United States has been purchased by the United States Government for administration exclusively by enrolled providers through the CDC COVID-19 Vaccination Program. Vaccine remains U.S. government property until administered to the vaccination recipient. Learn how to enroll as a COVID-19 vaccination provider.

COVID-19 vaccination providers participating in the CDC COVID-19 Vaccination Program are required to sign a CDC COVID-19 Vaccination Program Provider Agreement. Providers are responsible for adhering to all requirements outlined in the agreement, including updated recommendations, requirements, and other guidance provided in the footnoted weblinks incorporated in the agreement. This webpage serves as repository for any updates to the provider agreement including recommendations, requirements, and other guidance. Vaccination providers and organizations must check this site regularly and can sign up below to receive emails any time this page is updated. In addition, this webpage provides other useful information for vaccination providers participating in the program.

UPDATES - CDC COVID-19 Vaccination Program Provider Agreement Requirements

Centers for Disease Control and Prevention Requirements and Advisory Committee on Immunization Practices (ACIP) Recommendations (Updated 03/17/2021)

www.cdc.gov/vaccines/hcp/acip-recs/index.html

CDC Requirements

Prioritization

Providers must administer COVID-19 vaccine in accordance with prioritization groups determined by appropriate public health authorities (*i.e.*, HHS/CDC/ACIP, state/territorial health department in coordination with the state/territorial governor, Indian Health Service, Tribal Health Programs, Urban Indian Organizations, the Freely Associated States).

3/17/21 Update:

Prioritization for receipt of COVID-19 vaccine in the early months of the CDC COVID-19 Vaccination Program was necessary given limited supplies of vaccine. Supplies of COVID-19 vaccine doses are rapidly increasing. Effective May 1, 2021, in conformance with the Secretary's March 17, 2021 directive to transition beyond priority groups, all persons qualified under the terms of the applicable COVID-19 vaccine Emergency Use Authorization are eligible to be vaccinated. CDC COVID-19 Vaccination Program providers are required to make available and administer COVID-19 vaccine to all such persons. This requirement is not intended to prevent prioritizing particular populations for specific vaccination clinics/events with the purpose of promoting health equity.

3/12/21 Update:

Notwithstanding the above, in order to fulfill the purpose of the Secretary's directive issued on March 2, 2021, any CDC COVID-19 Vaccination Program provider must, effective immediately, make available and administer, as one of the currently eligible groups, COVID-19 vaccine to all teachers, school staff, and child care workers, as defined below.

In addition, pharmacies are asked to prioritize vaccinating teachers, school staff and childcare workers through March 31, 2021. This could include providing teachers exclusive access to booking appointments online or utilizing mobile and pop-up locations, as feasible, to reach this population.

Teachers, school staff, and child care workers are defined as: those who work in pre-primary, primary, and secondary schools, as well as Head Start and Early Head Start programs (including teachers, staff, and bus drivers) and those who work as or for licensed child care providers, including center-based and family care providers.

[Additions to CDC COVID-19 Vaccination Program Provider Agreements, Paragraph 1.]

Diversion of COVID-19 Vaccines Prohibited (updated 02/25/2021)

At this time, all COVID-19 vaccine in the United States has been purchased by the United States Government for administration exclusively through the CDC COVID-19 Vaccination Program. The vaccine remains U.S. government property until administered to the recipient. COVID-19 vaccination providers are prohibited from selling USG-purchased COVID-19 vaccine (and ancillary materials purchased by the USG for use in the Vaccination Program), soliciting or receiving any inducement, whether direct or indirect, for vaccinating (or providing COVID-19 vaccine to be used for vaccinating) any individual who is not currently eligible to receive COVID-19 vaccine as a member of a group currently authorized under prioritization specified by HHS/CDC/ACIP, the state/territory's governor or other relevant public health authority, or otherwise diverting COVID-19 vaccine from the CDC COVID-19 Vaccination Program. Such use constitutes fraud and is a violation of the terms of the provider agreement. It shall be cause for immediate termination from the CDC COVID-19 Vaccination Program and criminal or civil prosecution for violation of 18 U.S.C. § 1001 or other relevant federal statutes.

Note that transfer of COVID-19 Vaccine through the CDC authorized redistribution process from one enrolled provider to another enrolled provider for authorized vaccination is not considered to be diversion of COVID-19 vaccine.

Further, a good faith judgment call by an enrolled provider to administer excess doses to individuals outside of authorized prioritization groups, without malintent and without direct/indirect receipt of inducement, will not be considered a prohibited diversion if such vaccine doses have been prepared for scheduled administration and would otherwise be wasted due to expiration.

Reporting violations of provider agreement requirements:

Individuals becoming aware of any potential violations of provider agreement requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services at 1-800-HHS-TIPS or TIPS.HHS.GOV.

COVID-19 Vaccine Administration Fees (updated 02/25/2021)

All organizations and providers participating in the CDC COVID-19 Vaccination Program:

- **must** administer COVID-19 Vaccine at no out-of-pocket cost to the recipient
- may **not** deny anyone vaccination based on the vaccine recipient's coverage status or network status
- may **not** charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided
- may **not** require additional medical services to receive COVID-19 vaccination
- **may** seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient, such as:
  - vaccine recipient's private insurance company
  - Medicare or Medicaid reimbursement
  - HRSA COVID-19 Uninsured Program for non-insured vaccine recipients
- may **not** seek any reimbursement, including through balance billing, from the vaccine recipient

For additional information on filing claims for reimbursement of COVID-19 vaccine administration fees, go to:

- HRSA COVID-19 Uninsured Program – https://www.hrsa.gov/CovidUninsuredClaim
- CMS Guidance – https://www.cms.gov/covidvax-provider

ACIP Recommendations

The Advisory Committee on Immunization Practices (ACIP) comprises 15 medical and public health experts who develop evidence-based recommendations for use of vaccines in the United States. The recommendations stand as public health guidance for the safe use of vaccines and related biological products. COVID-19 vaccination providers are required to implement all recommendations of the ACIP, adopted by the CDC Director, relevant to COVID-19 vaccination including:

- Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine, United States 2020
- Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine, United States, December 2020
- Interim Recommendation for Use of Moderna COVID-19 Vaccine, United States, December 2020
- Updated Interim Recommendation for Allocation of COVID-19 Vaccine, United States, December 2020

COVID-19 Vaccine Administration and Reporting Requirements

Find more information about vaccine administration and reporting requirements.

For those provider agreements not specifying vaccine administration data to be recorded or reported, the following applies:

After administering a dose of COVID-19 vaccine, record to the extent not already recorded in the vaccine recipient's record all information marked below by an asterisk and report the following required vaccine administration data, or other data elements if revised by CDC, to the appropriate entity noted in the agreement:

a. Administered at location/facility name/ID
b. Administered at location type
c. Administration address (including Company)*
d. Recipient name and ID*
e. Recipient date of birth*
f. Recipient sex*
g. Recipient race
h. Recipient ethnicity
i. Recipient address*
j. Administration date*
k. CVX (product)*
l. NDC (national drug code)
m. Dose number*
n. Lot number (Unit of Use [UoU] or Unit of Sale [UoS])*
o. MVX (manufacturer)*
p. Sending organization (name of the Agency submitting the report)
q. Vaccine administering provider's name and suffix*
r. Administering provider's address, if different than the administration address*
s. Vaccine administration site (on the body)*
t. Vaccine expiration date*
u. Vaccine route of administration*
v. Vaccine series

Requirements for Safe Immunization Services Practices During the COVID-19 Pandemic

www.cdc.gov/vaccines/pandemic-guidance/index.html

The COVID-19 pandemic has caused healthcare providers to change how they operate to continue to provide essential services to patients. CDC has issued interim guidance for healthcare personnel in a variety of clinical and alternative settings for the safe administration of vaccines during the COVID-19 pandemic. COVID-19 vaccination providers are required to implement this guidance on safe vaccination practices, including COVID-19 safety measures (e.g., social distancing, mask wearing, hand hygiene), when providing COVID-19 vaccine.

Requirements for COVID-19 Vaccine Storage and Handling

http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

Vaccines must be stored and handled properly from the time they are manufactured until they are administered to maintain the cold chain, thus protecting the potency and effectiveness of the vaccine and ensuring vaccine recipients are fully and safely protected from vaccine-preventable diseases.

As part of the COVID-19 Vaccination Provider Agreement, providers are required to:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance in the Vaccine Storage and Handling Toolkit.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in the toolkit.
- Comply with immunization program guidance for handling temperature excursions.
- Monitor and comply with COVID-19 vaccine expiration dates.
- Preserve all records related to COVID-19 vaccine management for a minimum of three years, or longer as required by the agreement or law of the jurisdiction.
- Comply with CDC instructions and timelines for disposing of COVID-19 vaccine and diluent, including used doses.

Find detailed information regarding COVID-19 Vaccine storage and handling requirements at CDC Vaccine Storage and Handling Toolkit.

Requirements for Reporting to VAERS

(https://vaers.hhs.gov/reportevent.html)

The Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in vaccines used in the United States. VAERS accepts and analyzes reports of adverse events (AEs) after a person has received a vaccination. Anyone can report an adverse event to VAERS. Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention.

Healthcare providers are **required** to report to VAERS the following adverse events after COVID-19 vaccination, under Emergency Use Authorization (EUA), and other adverse events if later revised by CDC:

- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Cases of COVID-19 that result in hospitalization or death
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
  1. Death;
  2. A life-threatening AE;
  3. Inpatient hospitalization or prolongation of existing hospitalization;
  4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
  5. A congenital anomaly/birth defect;
  6. An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Cases of Multisystem Inflammatory Syndrome

Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.

Also report any additional select AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an EUA.

Data and Reporting

All COVID-19 vaccination providers must report COVID-19 vaccine inventory daily into VaccineFinder. In some jurisdictions, providers may report vaccine inventory to the jurisdiction's IIS for the jurisdiction to upload into VaccineFinder. If you have questions about the process for your jurisdiction, please contact your jurisdiction's immunization program.

Enrolling in your jurisdiction/state-based IIS system

See CDC's Reporting Requirements

Add the COVID-19 vaccine label to your VTrckS profile

Vaccine Administration Documentation

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration, and use their best efforts to report administration data to the relevant system for the jurisdiction (i.e., IIS) as soon as practicable and no later than 72 hours after administration.

COVID-19 Vaccine is Provided at 100% No Cost to Recipients

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- may **not** charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided
- may **not** require additional medical services to receive COVID-19 vaccination
- **may** seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient, such as:
  - vaccine recipient's private insurance company
  - Medicare or Medicaid reimbursement
  - HRSA COVID-19 Uninsured Program for non-insured vaccine recipients
- may **not** seek any reimbursement, including through balance billing, from the vaccine recipient

Individuals aware of any potential violations of these requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, by calling 1-800-HHS-TIPS or the website TIPS.HHS.GOV.

Additional Resources

Vaccination Program Operational Guidance

How to Enroll as a COVID-19 Vaccine Provider

Training and Education

Inventory Management Best Practices

COVID-19 Vaccination

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