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# 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 federal government for administration exclusively by [enrolled providers](#) through the CDC COVID-19 Vaccination Program.

This page provides information about the **CDC COVID-19 Vaccination Program** — with vaccine being provided by the federal government — to ensure all people in the United States who wish to be vaccinated can receive vaccine without barriers, to the greatest extent possible.

This page also serves as repository for any updates to the **CDC COVID-19 Vaccination Provider Agreement** including recommendations, requirements, and other useful information for vaccination providers participating in the program.

[How to Enroll as a COVID-19 Vaccination Provider](#)



[Vaccines for Children Program vs. CDC COVID-19 Vaccination Program](#)



[FAQs for Private & Public Healthcare Providers About Implementing the CDC COVID-19 Vaccination Program in Provider Practices](#)



[FAQs for Federal Retail Pharmacy Program Participants](#)



## CDC COVID-19 Vaccination Program Provider Agreement

- 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 web links incorporated in the agreement.
- Vaccination providers and organizations must check this site regularly. A [sign up is available below](#) to receive emails any time this page is updated.

## 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 10/25/2022)



[www.cdc.gov/vaccines/hcp/acip-recs/index.html](https://www.cdc.gov/vaccines/hcp/acip-recs/index.html)

## CDC Requirements

### ***Mask Distribution Initiative*** (January 20, 2022)

As a subcomponent of the CDC COVID-19 Vaccination Program, designated enrolled providers are authorized to receive from the Department of Health and Human Services Strategic National Stockpile (SNS) N95 masks (also known as respirators) that are approved by the National Institute for Occupational Safety and Health (NIOSH) for free distribution to people in the United States.

1. Designated providers will provide shipping and other necessary information to the SNS to receive shipments of the masks, in addition to the name, title, and contact information for the individual who will coordinate the provider's participation in this initiative. HHS is responsible to ship, at U.S. Government (USG) expense, USG-purchased masks to agreed-upon distribution points designated by the provider.
2. Such masks will be distributed by the provider at locations readily accessible to the public. Subject to receiving adequate supply from the U.S. government:
  - a. Providers should have supply in every store that offers COVID-19 vaccine.
  - b. Providers should prioritize maintaining highest inventory in stores servicing high socially vulnerable (SVI) populations and stores with the highest demand.
3. Providers may direct bulk quantities of the masks to long-term care facilities for free distribution to their residents and communities at no cost subject to the requirements of this section.
4. USG will have the sole responsibility for any reporting of inventory throughput or other data.
5. Providers distributing USG-purchased N95 masks provided through this initiative agree to provide the masks at no charge, for use by individuals. Receipt of masks cannot be conditioned on purchase of other products or services. Provider shall not be required to engage in any fit testing, medical evaluations, or training, regardless of whether individuals obtain masks for employment or other purposes.
6. Absent willful misconduct by provider, provider shall have no responsibility for individual usage of masks or other conduct. Providers are not responsible for monitoring or enforcing those that choose to take masks nor confirm that they are for personal versus business or other usage.
7. Providers will post a web link to a USG and/or manufacturer URL, provided by HHS, on their websites to instructions for proper fit and use. In addition, providers will post notice visible to the public at the site of any mask distribution under this initiative utilizing uniform signage that will be provided electronically by HHS, which, at a minimum, will address:
  - a. The masks have been provided by the U.S. Department of Health and Human Services for free distribution.
  - b. The masks are provided for personal use only.
  - c. And, the public notice will include a QR code and/or weblink that can be used by recipients of the masks to obtain user instructions.

### **U.S. Government Property**

Masks provided through this initiative are U.S. government property and remain U.S. government property until received by the individual who intends to wear the mask. Any sale, diversion, or other distribution of these masks for payment, whether direct or indirect, is prohibited and may be subject to civil or criminal prosecution.

Provider may terminate its participation in the Mask Distribution Initiative by notifying the SNS without impacting participation in the CDC COVID-19 Vaccination Program. Any remaining inventory of USG-purchased N95 masks will be distributed in conformance with Agreement.

### **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).

10/25/22 Update:

### ***Novavax COVID-19 Vaccine Booster Doses***

Pursuant to October 19, 2022, CDC recommendations:

- Providers in the CDC COVID-19 Vaccination Program shall make available and administer, upon request, a single Novavax COVID-19 vaccine booster dose for persons ages 18 years and older, without history of prior booster dose, who are unable or unwilling to receive an mRNA bivalent booster dose, at least six months after completion of a COVID-19 primary series vaccination.
- When unable to fulfill a request from an age-eligible person for a booster dose of Novavax COVID-19 Vaccine, Adjuvanted, notify the requesting person that providers having the vaccine can be located through the website <https://www.vaccines.gov/>.

10/12/22 Update (Revises the 9/1/22 update to reference younger children 5 years and older who are now eligible to receive the bivalent booster):

### ***Single Bivalent COVID-19 Vaccine Booster Doses***

Pursuant to September 1 and October 12, 2022, CDC/ACIP recommendations and the September 2 and October 13, 2022, Secretarial Directives on Bivalent COVID-19 Vaccine Booster Doses, all providers in the CDC COVID-19 Vaccination Program shall make immediately available and administer, upon request, a single booster dose of:

- Pfizer-BioNTech COVID-19, Bivalent (Original and Omicron BA.4/BA.5) vaccine to individuals ages 5 years and older at least 2 months after receipt of a primary series or prior monovalent booster dose with any COVID-19 vaccine.
- or
- Moderna COVID-19, Bivalent (Original and Omicron BA.4/BA.5) vaccine to individuals ages 6 years and older at least 2 months after receipt of a primary series or prior monovalent booster dose with any COVID-19 vaccine.

*Bivalent COVID-19 vaccine booster dose recommendations are without regard to the number of previous monovalent booster doses received.*

Monovalent COVID-19 vaccine booster doses are no longer recommended for persons ages 5 years and older.

### ***Heterologous (mix and match) booster doses***

- Among the groups recommended by CDC to receive bivalent booster vaccination after a primary series of Pfizer-BioNTech, Moderna, Novavax, or Janssen COVID-19 vaccine, a single booster dose of the bivalent Pfizer-BioNTech or Moderna COVID-19 vaccines may be provided as a heterologous bivalent booster dose, as age-eligible.

7/22/22 Update

### ***Novavax COVID-19 Vaccination of Persons 18 Years of Age and Older***

Pursuant to CDC/ACIP recommendations and the July 21, 2022, Secretarial Directive, as of July 25, 2022, CDC COVID-19 Vaccination Program enrolled providers shall:

- If they have the vaccine in stock, make immediately available and administer upon request a two-dose Novavax COVID-19 Vaccine, Adjuvanted primary series for persons ages 18 years and older.
- When unable to fulfill a request from an age-eligible person for Novavax COVID-19 Vaccine, Adjuvanted, notify the requesting person that providers having the vaccine can be located through the website

[https://www.vaccines.gov/.](https://www.vaccines.gov/)

6/23/22 Update (replaces 6/18/22 update; and revised to be a consolidated update that addresses all primary series pediatric COVID-19 vaccination; 6/23/22 update also adds availability of age-appropriate Moderna COVID-19 Vaccine for 6 years through 17 years of age):

#### ***COVID-19 Vaccination of Children 6 Months through 17 Years of Age***

Pursuant to CDC/ACIP recommendations and Secretarial Directives:

All authorized providers in the CDC COVID-19 Vaccination Program shall make immediately available and administer upon request –

- a two-dose series using the age-appropriate Moderna COVID-19 Vaccine product for children ages 6 months through 17 years
- a three-dose series using the age-appropriate Pfizer-BioNTech COVID-19 Vaccine product for children ages 6 months through 4 years
- a two-dose series using the age-appropriate Pfizer-BioNTech COVID-19 Vaccine product for children ages 5 years through 17 years

6/23/22 Update (replaces 6/18/22, 1/6/22, 9/14/21 and 10/7/21 updates; additional eligible group noted in ***bold italics***; Updated on 10/12/22 to remove reference to the purple cap Pfizer-BioNTech vials which are no longer available):

#### ***Third Dose for Recipients of Pfizer-BioNTech or Moderna COVID-19 Vaccine Who Are Immunocompromised***

Pursuant to CDC/ACIP recommendations and Secretarial Directives, a third primary dose of an mRNA COVID-19 vaccine should be administered using the same mRNA COVID-19 vaccine as was administered for the 2-dose primary series to persons who are moderately to severely immunocompromised at least 28 days after completing the two-dose primary series:

- Pfizer-BioNTech COVID-19 Vaccine –
  - Orange cap to children 5 through 11 years of age
  - Gray cap to people 12 years and older
- Moderna COVID-19 Vaccine –
  - Dark blue cap/magenta border to children 6 months through 5 years of age
  - Dark blue cap/purple border to children ***6 years through 11 years of age***
  - Red cap/light blue border to people ***12 years and older***

5/31/22 Update:

#### ***COVID-19 Vaccination Under the CDC Interim Clinical Considerations and Emergency Use Instructions***

Providers may also administer COVID-19 vaccines as described in CDC guidance as updated from time to time:

- [Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States](#)
- [Emergency Use Instructions](#) (see vaccine Fact Sheets)

5/23/22 Update (revision of 5/19/22 update to add reference to the May 23, 2022, Secretarial Directive; © 2022. All rights reserved. This document contains neither recommendations nor conclusions that have been formally approved by CDC. The document is being made available to the public to facilitate timely access to important information.

9/1/22 revision noted in ***bold italics*** to clarify that booster doses available to this age group are monovalent):

### ***COVID-19 Vaccine Booster Doses for Children 5 through 11 Years of Age***

Pursuant to CDC/ACIP recommendations and the May 23, 2022, Secretarial Directive on Pediatric and Second COVID-19 Vaccine Booster Doses, all providers in the CDC COVID-19 Vaccination Program shall make immediately available and administer a single ***monovalent*** booster dose of Pfizer-BioNTech COVID-19 vaccine to individuals seeking such a dose as follows:

- Children ages 5 through 11 years should receive a single ***monovalent*** Pfizer-BioNTech COVID-19 vaccine booster dose at least 5 months after completion of a Pfizer-BioNTech COVID-19 vaccine primary series.

2/11/22 Update:

### ***Second Dose for Recipients of Janssen COVID-19 Vaccine Who are Immunocompromised***

As provided in the February 11, 2022 Emergency Use Instructions, an additional dose, using an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna), should be administered to recipients of primary Janssen COVID-19 vaccination who are moderately or severely immunocompromised at least 28 days after receipt of the primary Janssen dose.

9/1/22 Update (Revises 2/11/22 Update to add reference to bivalent COVID-19 vaccine booster doses):

### ***Third primary dose/booster dose COVID-19 vaccination of persons in the United States who received COVID-19 vaccination outside of the United States or as part of a clinical trial***

All providers are required to offer third primary doses or bivalent booster doses of the Pfizer-BioNTech or Moderna COVID-19 vaccine to qualifying persons who received particular non-FDA authorized/approved COVID-19 vaccines outside of the United States or as part of certain COVID-19 clinical trials as described in the Emergency Use Instructions issued by CDC on November 17, 2021, and February 11, 2022: [Pfizer EUI](#) , [Moderna EUI](#)  , and Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html>).

11/3/21 Update (reference to Pfizer-BioNTech COVID-19 vaccination of children 5-11 years of age consolidated into 6/23/22 pediatric primary series update):

### ***COVID-19 Vaccination of Children 5 through 11 Years of Age***

5/12/21 Update (On 6/23/22 the 5/12/21 reference to Pfizer-BioNTech COVID-19 vaccination of adolescents 12-15 years of age was moved to consolidated 6/23/22 pediatric primary series update)

4/19/21 Update:

With regard to the 3/17/21 Update, as of April 19, 2021, all persons qualified under the terms of the applicable COVID-19 vaccine Emergency Use Authorization are eligible to be vaccinated, as that list of qualified persons may change over time. This is not intended to prevent prioritizing particular populations for specific vaccination clinics/events with the purpose of promoting health equity.

**3/1/21 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.

***Provision of Information to Vaccine Recipients (Updated 2/9/22 to reference Moderna's COVID-19 vaccine BLA approval)***

Before administering COVID-19 Vaccine, providers must provide an approved FDA Emergency Use Authorization (EUA) Fact Sheet, FDA Vaccine Information Fact Sheet, or CDC Vaccine Information Statement (VIS), as applicable, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.

In lieu of CDC developing a separate COVID-19 Vaccine Information Statement (VIS) at this time for the licensed Pfizer vaccine, FDA has issued a combination [COVID-19 Vaccine Information Fact Sheet for Recipients and Caregivers](#) to address both the FDA authorized (EUA) Pfizer-BioNTech COVID-19 Vaccine and the FDA Biologics License Application (BLA) approved (licensed) Pfizer-BioNTech COMIRNATY COVID-19 Vaccine. The vaccines have identical formulations. When administering the Pfizer-BioNTech COVID-19 vaccine under either the EUA or under BLA approval, providers must give each vaccine recipient, adult caregiver accompanying the recipient, or other legal representative, a copy of the age-appropriate Pfizer-BioNTech COVID-19 Vaccine Information Fact Sheet.

Similarly, in lieu of a separate COVID-19 VIS for the licensed Moderna vaccine, FDA has issued a combination [Moderna COVID-19 Vaccine Fact Sheet for Recipients and Caregivers](#) to address both the FDA authorized (EUA) Moderna COVID-19 Vaccine and the FDA BLA approved (licensed) Moderna SPIKEVAX COVID-19 Vaccine. The vaccines have identical formulations. When administering the Moderna COVID-19 vaccine under either the EUA or under BLA approval, providers must give each vaccine recipient, adult caregiver accompanying the recipient, or other legal representative, a copy of the combined Moderna COVID-19 Vaccine Information Fact Sheet.

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

***Diversion of COVID-19 Vaccines Prohibited (updated 06/11/2021)***

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 and all related ancillary supplies, including the COVID-19 Vaccination Cards, remains U.S. government property until vaccine is administered to the recipient. Inherent in the reference to COVID-19 vaccine remaining property of the United States Government, all USG-furnished ancillary materials, including COVID-19 Vaccination Record Cards, have remained property of the United States Government for exclusive use in the CDC COVID-19 Vaccination Program since the program's inception. This includes COVID-19 Vaccination Record Cards that have been printed by agents on behalf of CDC, including the jurisdictions.

USG-provided COVID-19 Vaccination Record Cards remain property of the United States Government until provided to the vaccine recipient following vaccination through the CDC COVID-19 Vaccination Program. The COVID-19 Vaccination Record Cards may not be reproduced by anyone other than authorized jurisdictions or without written permission of CDC. Any use or unauthorized reproduction of the COVID-19 Vaccination Cards outside of the CDC COVID-19 Vaccination Program, or production or use of similar facsimiles of such cards, is prohibited. Any such unauthorized production or use constitutes fraud and is subject to criminal or civil prosecution for violation of 18 U.S.C. § 1001, 42 U.S.C. § 1320b-10, or other relevant federal statutes.

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.

#### *Use of Vaccine Recipient Data for Commercial Marketing Purposes Prohibited (5/18/2021)*

Notwithstanding uses or disclosures otherwise allowed by law, providers are prohibited from using or disclosing data collected from vaccine recipients for and through the CDC COVID-19 Vaccination Program for commercial marketing purposes or for any other purpose not allowed under this updated provision of the COVID-19 Vaccination Provider Agreement. Such data include COVID-19 vaccination registration information and vaccine administration data. These data are collected solely for the purposes of the CDC COVID-19 Vaccination Program and must be maintained in a manner that protects the integrity of the CDC COVID-19 Vaccination Program by only being used or disclosed for the purposes of the COVID-19 Vaccination Program and other limited purposes that promote public health, advance positive patient outcomes, and promote health equity.

This prohibition is not intended to limit communications by health care providers to vaccine recipients with whom the provider has an existing relationship prior to contact about COVID-19 vaccination.

The following are not included in the above prohibition:

- Communications regarding receipt of a second dose, or potential booster dose(s), of COVID-19 vaccine
- Communications to vaccine recipient for public health purposes
- Communications to vaccine recipients involving pharmacy or clinical services of the provider, personalized to the vaccine recipient's medical needs, even if those services are not directly related to COVID-19 vaccination
- Availability of other vaccines (e.g., shingles, pneumococcal conjugate, seasonal influenza, routine childhood vaccines)
- Clinical emails
- Disease screening services
- Communications about the availability of programs to manage particular health conditions (e.g., asthma, diabetes, heart disease)

In addition, de-identified, aggregate datasets can be used by providers and shared with other partners for public health, population health, and health equity purposes.

Communications with COVID-19 vaccine recipients involving the store component of any pharmacy or other provider participating in the CDC COVID-19 Vaccination Program are considered prohibited commercial marketing. For example, text, e-mail, mail, or other communications to COVID-19 vaccine recipients about products on sale in the store are prohibited as commercial marketing.

COVID-19 vaccination registration information and vaccine administration data collected in the course of participation in the CDC COVID-19 Vaccination Program cannot be sold, for direct or indirect remuneration, even with permission of the vaccine recipient.

#### *Reporting Suspected Fraud or Abuse*

Individuals becoming aware of any suspected fraud or abuse or 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](https://TIPS.HHS.GOV).

#### *COVID-19 Vaccine Administration Fees (updated 4/8/2022)*

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 Coverage Assistance Fund for underinsured vaccine recipients (unavailable as of 11:59 ET on April 5, 2022, due to lack of supplemental funding)
  - HRSA COVID-19 Uninsured Program for non-insured vaccine recipients (unavailable as of 11:59 ET on April 5, 2022, due to lack of supplemental funding)
- 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:

- CMS Guidance – <https://www.cms.gov/covidvax-provider> ↗

#### CDC Statement on Exhaustion of Funding for the Uninsured Program and Coverage Assistance Fund

Due to the lack of supplemental funding from Congress, HRSA stopped accepting claims for reimbursement of costs associated with administering COVID-19 vaccines to uninsured and underinsured individuals as of 11:59 PM ET on April 5, 2022. CDC strongly encourages providers to stay in the CDC COVID-19 Vaccination Program and CDC expects participating providers will continue to administer these lifesaving vaccines at no cost to patients to ensure equitable access for all individuals. Where CDC becomes aware of a provider engaging in any of the following, CDC will consider taking any and all appropriate measures, including the possibility of rescinding the CDC provider agreement:

- Administering COVID-19 Vaccine at any out-of-pocket cost to the recipient
- Denying anyone vaccination, or differentially reducing appointment access, based on the vaccine recipient's coverage status or network status
- Charging an office visit or other fee if COVID-19 vaccination is the sole medical service provided
- Requiring additional medical services to receive COVID-19 vaccination
- Seeking any reimbursement, including through balance billing, from the vaccine recipient

#### ACIP Recommendations (9/7/2021)

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:

- Use of COVID-19 Vaccines After Reports of Adverse Events Among Adult Recipients of Janssen (Johnson & Johnson) and mRNA COVID-19 Vaccines (Pfizer-BioNTech and Moderna): Update from the Advisory Committee on Immunization Practices — United States, July 2021
- Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021
- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years — United States, May 2021
- Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021
- Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021
- 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](https://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 (Updated 9/13/2022)

(<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.

The reporting requirements for COVID-19 vaccines are the same for those authorized under emergency use (EUA) or approved under a Biologics License Application (BLA). Healthcare providers who administer COVID-19 vaccines are **required** to report the following to VAERS:

- Vaccine administration errors; whether or not associated with an adverse event (AE)
  - If the incorrect mRNA COVID-19 vaccine product was inadvertently administered for a second dose in a 2-dose series, **VAERS reporting is required**.
  - If a different product from the primary series is inadvertently administered for the additional or booster (third dose), **VAERS reporting is required**.
  - **VAERS reporting is not required for the following situations:**
    - If a mixed series is given intentionally (e.g., due to hypersensitivity to a vaccine ingredient)
    - Mixing and matching of booster doses intentionally (as of October 21, 2021, mixing and matching of booster doses is allowed)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
  - Death
  - A life-threatening AE
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect

- 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 myocarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine
- Cases of pericarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if unsure whether 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's Emergency Use Authorization (EUA) or as outlined in the [Fact Sheet for Healthcare Providers](#) for any approved COVID-19 Vaccine.

## Requirements for Quality Assurance Monitoring (Updated 10/18/2021)



COVID-19 vaccination providers perform vital functions within the CDC COVID-19 Vaccination Program, including properly storing, handling, and managing vaccine supply, as well as correctly administering vaccine to intended recipients. Thus, it is essential for providers to have a clear understanding of COVID-19 Vaccination Program requirements. Training, site visits, and other oversight measures are important for maintaining or improving providers' adherence to these requirements. Site visits are a key opportunity for quality assurance monitoring and training (as necessary) enrolled providers. The goals of site visits are to:

- Assess COVID-19 vaccination provider adherence to program requirements and recommendations.
- Identify and address areas where providers are doing well and areas needing additional follow-up.
- Identify and address educational needs of COVID-19 vaccination providers to help them meet program requirements.
- Ensure that vaccine recipients are receiving properly managed and viable vaccine.

CDC and/or state/local public health staff are required to conduct certain provider oversight activities in each jurisdiction. **COVID-19 vaccination providers and depot locations that store or redistribute COVID-19 vaccine must accommodate these staff and participate in COVID-19 quality assurance site visits and other educational opportunities associated with COVID-19 vaccination program requirements.**

## Requirements for COVID-19 Vaccination Program Providers

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

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

- **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
- 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](https://TIPS.HHS.GOV).

## Data and Reporting

### 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., [Immunization Information Systems \(IIS\)](#)] as soon as practicable and no later than 72 hours after administration.

All COVID-19 vaccination providers must report COVID-19 vaccine inventory weekly into [Vaccines.gov](#).

In some jurisdictions, providers may report vaccine inventory to the jurisdiction's IIS for the jurisdiction to upload into [Vaccines.gov](#). 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](#)
- [Add the COVID-19 vaccine label to your VTrckS profile](#)
- [See CDC's Reporting Requirements](#)

### Additional Resources

[Vaccination Program Operational Guidance](#)

[COVID-19 Vaccination](#)

[How to Enroll as a COVID-19 Vaccine Provider](#)

[COVIDVaxView](#)

[Training and Education](#)

Last Reviewed: October 26, 2022