VFC vs. CDC COVID-19 Vaccination Program

California COVID-19 Vaccination Program

Though the VFC and COVID-19 vaccination programs are both federal programs, they each have distinct requirements based on the associated funding legislation. For this reason, the provider agreements remain separate, and VFC providers must sign and adhere to the requirements of the *CDC COVID-19 Vaccination Program Provider Agreement* to receive and administer COVID-19 vaccines. **Program differences are in bold.** (CDC Source)

	VFC	COVID-19
Program Enrollment	• Providers enroll using California's MyVFCvaccines.org website. • Providers must complete and sign VFC Provider Agreement and VFC Program Provider Profile Form.	• Provider organizations and locations enroll using California's myCAvax provider system. • Providers must complete and sign CDC COVID-19 Vaccination Program Provider Agreement (Sections A and B).
Vaccine Ordering	• Providers order routine childhood vaccines via MyVFCvaccines.org. • Providers must be fully trained in vaccine management and storage/handling procedures prior to receiving vaccine supply. • Providers must have the proper equipment (see VFC Provider Agreement Addendum) for storing and monitoring vaccine prior to receiving vaccine supply.	• Providers order COVID-19 vaccines via myCAvax. • Providers must be fully trained in vaccine management, storage/handling, preparation, and administration prior to receiving vaccine supply. • Providers must have the proper equipment (see CDC's Storage & Handling Toolkit) for storing and monitoring vaccine prior to receiving vaccine supply.
Vaccine Recipient Eligibility	VFC vaccines may be administered to any child ages 0 through 18 years who is Medicaid-eligible, Uninsured, Underinsured, or American Indian/Alaska Native (AI/AN).	Federally purchased COVID-19 vaccines may be administered to any person, regardless of health benefit coverage status. The age of the vaccine recipient must align with the U.S. Food and Drug Administration (FDA) Emergency Use Authorization or Approval of the vaccine administered.
Consent/Assent	The federal government does not have specific requirements for medical consent for vaccination. Providers should adhere to the medical consent laws of their state/jurisdiction and may also be	The federal government does not have specific requirements for medical consent for vaccination. Providers should adhere to the medical consent laws of their state/jurisdiction and may also be

	subject to policy requirements for consent within their own organizations.	subject to policy requirements for consent within their own organizations.
Provision of Vaccine Information	Providers must give the appropriate Vaccine Information Statement (VIS) to the patient (or parent or legal representative) prior to every dose of specific vaccines covered under the National Vaccine Childhood Injury Act.	Providers must give the vaccine product-specific COVID-19 vaccine Fact Sheet for Recipients and Caregivers to the patient or their caregiver prior to every dose of COVID-19 vaccine.
Administration Fee Reimbursement	• Providers may charge a vaccine administration fee up to the regional maximum established for each state by the Centers for Medicare and Medicaid Services (CMS). • Providers may not deny access to vaccine for a VFC-eligible child if the patient or parent is unable to pay. • Providers may bill vaccine administration fees to patient/parent for uninsured or underinsured patients as well as Medicaid or other third-party payors for Medicaid-eligible or AI/AN patients.	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 and 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, Health Resources & Services Administration (HRSA) Coverage Assistance Fund (for underinsured)*, or COVID-19 Uninsured Program. • May not seek any reimbursement, including through balance billing, from the vaccine recipient *** HRSA will continue to accept claims for COVID-19 vaccine administration until 11:59 PM on April 5, 2022.**
Reporting Vaccine Administration	Providers must document vaccine administration using electronic system or paper usage logs and report doses administered on each vaccine order.	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 CAIR2/SDIR/RIDE using My Turn (or an EHR connected to CAIR) as soon as practicable and no later than 72 hours after administration.

Reporting Vaccine Inventory	VFC providers must report vaccine inventory on every vaccine order using MyVFCvaccines.org.	All COVID-19 vaccination providers must report COVID-19 vaccine inventory to Vaccine Finder daily.
Vaccine Adverse Event Reporting System (VAERS)	The National Childhood Vaccine Injury Act requires all providers to report: • Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine; or • Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination. CDC encourages providers to report any clinically significant adverse event that occurs in a patient following a vaccination, even if the provider is unsure whether a vaccine caused the event.	Providers are required to report to VAERS the following adverse events (AEs) following vaccination with an FDA-authorized or FDA-approved COVID-19 vaccine, and other adverse events if later revised by CDC: • Vaccine administration errors, whether or not associated with an AE • Cases of COVID-19 that result in hospitalization or death • Serious AEs regardless of causality. Serious AEs 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 judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above. • Cases of Multisystem Inflammatory Syndrome 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. Providers should 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.
Vaccine Redistribution	• VFC vaccines should routinely be shipped directly from the CDC distributor to the provider location where the vaccine will be administered. (Note: Exceptions made in Alaska and the United States-Associated Pacific Islands) • If approved by the state/local immunization program, large healthcare systems that use a centralized pharmacy may have vaccine shipped to the pharmacy for redistribution to the	If approved by the state/local immunization program and validated cold-chain procedures are in place according to the manufacturer's instructions and CDC guidance on COVID-19 vaccine storage and handling, providers may be allowed to routinely redistribute vaccine to other provider locations. There must be a signed CDC COVID-19 Vaccine Redistribution Agreement for the provider conducting redistribution and a fully

	clinic(s) only if both the pharmacy and the clinic(s) are on the same campus. • It is not acceptable for a large health care system to use one centralized pharmacy to ship vaccine to clinics throughout the jurisdiction.	completed CDC COVID-19 Vaccination Provider Profile Information form (Section B of the CDC COVID-19 Vaccination Program Provider Agreement) for each receiving vaccination location. CDC cannot reimburse costs of redistribution beyond the initial designated primary CDC ship-to site(s), nor for purchase of any vaccine-specific refrigerators or qualified containers. Therefore, organizations planning for redistribution of COVID-19 vaccine must carefully assess the associated risks and costs (e.g., vaccine loss due to temperature excursions, purchase of vaccine-specific portable refrigerators and/or containers) before planning this activity.
Vaccine Transfers	VFC vaccine transfers can occur only: • With the approval and under direct guidance of the state/local immunization program • When a process is in place to ensure vaccine viability during transfer, as outlined in CDC's Storage & Handling Toolkit. The process must include the use of a digital data logger (DDL) with a current and valid Certificate of Calibration Testing for temperature monitoring during transport, as well as other appropriate equipment. • When temperature monitoring documentation validates the vaccine has not been exposed to a temperature excursion. This documentation must be transported with the vaccine.	COVID-19 vaccine transfers can occur only: • With the approval and under direct guidance of the state/local immunization program • When a process is in place to ensure vaccine viability during transfer, as outlined in CDC's Storage & Handling Toolkit. The process must include the use of a digital data logger (DDL) with a current and valid Certificate of Calibration Testing for temperature monitoring during transport, as well as other appropriate equipment. • When temperature monitoring documentation validates the vaccine has not been exposed to a temperature excursion. This documentation must be transported with the vaccine. • Transport equal amounts of vaccines, diluents, and ancillary supplies (including vaccination record cards and PPE).

Other Reporting Requirements	• VFC providers must document and report vaccine wastage using MyVFCvaccines.org before their next vaccine order. • VFC providers report shipment incidents by faxing Vaccine Receiving Log and Checklist to VFC Call Center. • VFC providers report temperature excursions daily using MyVFCvaccines.org. • VFC providers report transfer events in MyVFCvaccines.org before their next vaccine order.	• Providers must document and report vaccine wastage using myCAvax daily. • COVID-19 providers report shipment incidents in myCAvax. • COVID-19 providers report temperature excursions daily in myCAvax. • COVID-19 providers report redistribution/transfer events in myCAvax within 24 hours of the event.
Vaccine Disposition	• Spoiled or expired VFC vaccines must be returned in their original container (unopened vial or manufacturer-prefilled syringe) within six months of the spoilage or expiration date. • Wasted VFC vaccines (e.g., vaccine in an open vial, drawn into a syringe, or compromised because the container was dropped or broken) should be disposed of following state and local disposal requirements.	• Spoiled, expired, and/or wasted COVID-19 vaccine should not be returned to the distributor or manufacturer. All nonviable or unusable COVID-19 vaccine should be disposed of following state and local disposal requirements.
Record Retention	Providers must retain all records related to the VFC program (both hard copy and electronic copy) for a minimum of three years and make these records available upon request.	Providers must retain all hard copy and electronic copy COVID-19 vaccine-related documentation (e.g., vaccine administration documentation, storage and handling records, etc.) for a minimum of three years and make these records available upon request.
Provider Monitoring	State/local immunization programs are required to conduct VFC compliance site visits with VFC providers every 24 months.	State/local immunization programs are required to conduct CDC COVID-19 Vaccination Program quality assurance site visits with COVID-19 vaccination providers.