Vaccines For Children Program and CDC COVID-19 Vaccination Program
Comparison

As Emergency Use Authorization of COVID-19 vaccine products expand to include adolescents and children, providers enrolled in the Vaccines for Children (VFC) program are well situated to enroll in the COVID-19 Vaccination Program to ensure equitable access to COVID-19 vaccination services. VFC providers have direct access to the younger patient population and are familiar with vaccine administration and federal vaccine programs. Though the VFC and COVID-19 Vaccination programs are both federal government 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 in order to receive and administer COVID-19 vaccines. The table below will assist VFC providers in understanding the differences in the programs' requirements. **Program differences are in bold.**

	VFC Program	COVID-19 Vaccination Program
Provider Enrollment	▪ Providers enroll via state/local immunization program enrollment system and procedures. ▪ **Providers must complete and sign state/local immunization program Vaccines for Children Program Provider Agreement and VFC Program Provider Profile Form.**	▪ Providers enroll via state/local immunization program enrollment system and procedures. ▪ **Providers must complete and sign CDC COVID-19 Vaccination Program Provider Agreement, Sections A and B.**
Vaccine Ordering	▪ Providers order routine childhood vaccines via state/local immunization program-designated ordering system and procedures. ▪ Providers must be fully trained in vaccine management and storage/handling procedures prior to receiving vaccine supply. ▪ Providers must have the proper equipment **(as defined by the state/local immunization program)** for storing and monitoring vaccine prior to receiving vaccine supply.	▪ Providers order COVID-19 vaccines via state/local immunization program-designated ordering system and procedures. ▪ Providers must be fully trained in vaccine management, storage/handling, preparation, and administration prior to receiving vaccine supply. ▪ Providers must have the proper equipment **(as defined in the Vaccine Storage and Handling Toolkit-March 2021 [cdc.gov])** 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** ○ **American Indian/Alaska Native (AI/AN)** *VFC vaccines do not include COVID-19 vaccines	▪ **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 subject to policy requirements for consent within their own organizations.	▪ 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.

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Provision of Vaccine Information	▪ **Providers must give the appropriate vaccine information statement** to the patient (or parent or legal representative) prior to every dose of specific vaccines covered under the National Vaccine Childhood Injury	▪ **Providers must give the vaccine product-specific Emergency Use Authorization Fact Sheet for Recipients and Caregivers** to the patient or their caregiver prior to every dose of COVID-19 vaccine. ▪ **Providers must provide a COVID-19 Vaccination Record Card to the patient or their caregiver after vaccination (cards are included in the ancillary supply kits provided with the vaccines).**
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 (including through balance billing) 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) programs for underinsured and uninsured patients**
Reporting Vaccine Administration	▪ Providers must document vaccine administration **using the designated system and timeline required** by the state/local immunization program, state/jurisdiction law, or organization policy.	▪ **Providers must document CDC-defined core data elements of 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 system [IIS]) as soon as practicable and no later than 72 hours after administration.**
Reporting Vaccine Inventory	▪ Providers **must report vaccine inventory with every vaccine order, using the system and procedures designated by the state/local immunization program.**	▪ All COVID-19 vaccination providers **must report COVID-19 vaccine inventory daily into Vaccines.gov.** In some jurisdictions, providers may report vaccine inventory to the jurisdiction's IIS for the jurisdiction to upload into Vaccines.gov.

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Vaccine Wastage	■ Providers must document and report vaccine wastage, using the system and procedures designated by the state/local immunization program.	■ Providers must document and report vaccine wastage, using the system and procedures designated by the state/local immunization program.
Vaccine Adverse Event Reporting System (VAERS)	■ Providers are required to report to VAERS: ○ 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) 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 AE** ○ **Cases of COVID-19 that result in hospitalization or death** ○ **Serious AEs regardless of causality. Serious AEs 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 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.**

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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 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.**	▪ 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 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 *Vaccine Storage and 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 vaccines may be transported: ○ 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 *Vaccine Storage and Handling Toolkit*, COVID-19 Vaccine Addendum, pages 53-54. 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).
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.

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Record Retention	■ Providers must retain all records related to the VFC program (both hard copy and electronic copy) for a minimum of three years, or longer if required by state/local law, 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, or longer if required by state/local law 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.