

Provider Agreement

Replacement Model

Instructions: *The official VFC-registered health care provider signing the agreement must be a practitioner authorized to administer pediatric vaccines* under state law, who will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the provider enrollment agreement. The individual listed here must sign the provider agreement.*

**Note: For the purposes of the VFC Program, the term “vaccine” is defined as any FDA-authorized or licensed, ACIP-recommended product for which ACIP approves a VFC resolution for inclusion in the VFC Program.*

To receive publicly funded vaccines at no cost, I agree to the following conditions on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or practice administrator or equivalent:

1. I will annually submit a provider profile representing the VFC-eligible populations served by my practice/facility and the privately insured (i.e., non-VFC eligible) population I plan to vaccinate. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.

2. I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:

Federally Vaccine-Eligible Children (VFC eligible):

- a) Are an American Indian or Alaska Native;
- b) Are enrolled in Medicaid;
- c) Have no health insurance;
- d) Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only); a child whose insurance does not include first-dollar coverage for a vaccine. Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.

State Vaccine-Eligible Children:

- a) In addition, to the extent that my state designates additional categories of children as “state vaccine-eligible,” I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses to such children.

Children aged 0 through 18 years that do not meet one or more of the federal vaccine eligibility categories (VFC-eligible), are **not** eligible to receive VFC-purchased vaccine.

3.	For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless: a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child; or b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
4.	I agree not to use VFC vaccine inventory to vaccinate my non-VFC-eligible population. Non-VFC-eligible populations include: a) Fully insured children b) Other underinsured children (served by a provider/facility that is not a FQHC/RHC or a deputized provider) c) Enrolled in CHIP
5.	I will maintain all records related to the VFC program for a minimum of three years, and upon request, make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
6.	I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.
7.	I will not charge a vaccine administration fee to non-Medicaid VFC-vaccine eligible children that exceeds the administration fee cap of \$26.03 per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
8.	I will not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
9.	I will distribute the current Vaccine Information Statement (VIS) each time a vaccine included in the National Vaccine Injury Compensation Program (VICP) is administered and maintain records in accordance with VICP, which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). <i>Note: For any vaccine that does not yet have a Vaccine Information Statement available, a provider may use the manufacturer's package insert, written FAQs, or any other document – or produce their own information materials – to inform patients about the benefits and risks of that vaccine. Once a VIS is available it should be used for any vaccine included in the VICP; but providers should not delay use of an included vaccine because of the absence of a VIS.</i> <i>For VFC monoclonal antibody immunizing products (e.g., nirsevimab), when not co-administered with other vaccines, report all suspected adverse reactions to MedWatch. Report</i>

	<i>suspected adverse reactions following coadministration of a VFC monoclonal antibody immunizing products (e.g., nirsevimab) with any vaccine to the Vaccine Adverse Event Reporting System (VAERS).</i>
10.	I will comply with the requirements for vaccine management including: a) Order vaccine and maintain appropriate vaccine inventories; b) Not storing vaccine in dormitory-style units OR in the freezer compartment of household combination units at any time; c) Store vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet the California Department of Public Health Vaccines for Children (VFC) Program storage and handling recommendations and requirements; and d) Return all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.
11.	I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program: Fraud: an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law. Abuse: provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.
12.	I will participate in VFC program compliance site visits, including unannounced visits and other educational opportunities associated with VFC program requirements.
13.	For specialty providers, such as pharmacies, urgent care, school-located vaccine clinics, or birthing hospitals, I agree to: a) Vaccinate all "walk-in" VFC-eligible children and b) Will not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee. <i>Note: "Walk-in" refers to any VFC-eligible child who presents requesting a vaccine, not just established patients. "Walk-in" does not mean that a provider must serve VFC patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive vaccinations, then the policy would apply to VFC patients as well. "Walk-in" may also include VFC-eligible newborn infants at a birthing facility.</i>
14.	I agree to replace vaccine purchased with federal funds that are deemed non-viable due to provider negligence on a dose-for-dose basis.

15.	I will enter all vaccines doses administered in my practice, regardless of patient's age or eligibility status, into the California Immunization Registry (CAIR), or an approved Immunization Information system, in accordance with all specified elements of AB1797. Vaccine administration submission shall include specifics about the vaccine (including manufacturer, lot number, and NDC), funding source, patient's eligibility category by dose, and should occur within the same day of administration, but no later than 14 days, and prior to submission of vaccine orders. Doses administered reported as part of vaccine ordering should match quantities reported to the immunization registry.
16.	For providers with approval to implement the vaccine order replacement model, I agree to: a) Provide proof of the means to purchase the initial vaccine supply for all pediatric populations served to the California Department of Public Health Vaccines for Children (VFC) Program; b) Have an electronic medical record (EMR) or another electronic means of documenting and submitting dose-level eligibility via HL7 messaging and is actively transmitting data bidirectionally with IIS; c) Submit monthly of dose-level accountability (i.e., administration and eligibility) data and replacement vaccine orders to the California Department of Public Health Vaccines for Children (VFC) Program; d) Report a calculated virtual vaccine inventory of public doses on hand with each vaccine replacement request. Calculated inventory shall be based on the percentage of location's VFC-eligible population applied to current private inventory; e) Not violate the CDC depot policy—distribution of doses outside of an approved location (campus) is not allowed; and f) Adhere to all program requirements related to proper vaccine management and storage—my facility will maintain one vaccine inventory supply for private and public patients and inventories may be comingled.
17.	I understand this facility, or the California Department of Public Health Vaccines for Children (VFC) Program, may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the California Department of Public Health Vaccines for Children (VFC) Program.

By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.

Medical Director or Equivalent Name (print):

Signature:

Date: