

OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 46

VACCINES FOR CHILDREN (VFC) PROGRAM

333-046-0010

Purpose

The VFC program is a federally funded program established in 1993 through the Omnibus Budget Reconciliation Act (OBRA). Known as section 1928 of the Social Security Act, the VFC program is an entitlement program for children, age 18 and younger who are categorically eligible. Categories of eligibility are limited to: enrollment in Medicaid; lack of health insurance; American Indian/Alaskan Native heritage; and in federally-qualified health centers and rural health clinics, insurance that does not cover immunizations. The VFC program provides vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) at no cost, besides an administration fee, to the recipient.

Stat. Auth.: ORS 413.042, 431.250

Stats. Implemented: ORS 413.042, 431.250

333-046-0020

Adoption by Reference

Outside standards, listings and publications referred to in these rules are by reference made a part of these rules as if fully set forth.

Stat. Auth.: ORS 413.042, 431.250

Stats. Implemented: ORS 413.042, 431.250

333-046-0030

Definitions

- (1) "ACIP" means the Advisory Committee on Immunization Practices, a group of experts convened by the Centers for Disease Control and Prevention to provide guidance and advice on the immunization of the civilian population.
- (2) "Alaskan Native" means a person who self-identified as having Alaskan Native heritage.
- (3) "ALERT IIS" means the ALERT Immunization Information System.
- (4) "American Indian" means a person who self-identifies as having Native American heritage.
- (5) "Authority" means the Oregon Health Authority.
- (6) "CDC" means the Centers for Disease Control and Prevention.
- (7) "Clinic" means a facility providing medical services to outpatients. A clinic may have a solo practitioner or be a group practice. Pharmacies that provide immunization services are also considered clinics for the purposes of this rule.
- (8) "FQHC" means a federally-qualified health center.
- (9) "Oregon Vaccine Management Guide" means a document produced by the Authority that describes provider requirements for vaccine inventory, management and storage of federally-supplied vaccines.

- (10) "Prescriber" means a professional with prescription writing privileges currently licensed in Oregon.
- (11) "RHC" means a federally-designated rural health clinic.
- (12) "Underinsured" means a person that has health insurance that does not cover immunizations, or health insurance that covers some recommended immunizations but not all recommended immunizations.
- (13) "Uninsured" means a person that does not have any kind of health insurance.
- (14) "VFC Operations Guide" means the document produced annually by the Immunization Services Division of the CDC that outlines the policies and procedures that must be followed by states participating in the federal VFC program.
- (15) "VFC Program Agreement" means a document provided by the Authority in compliance with CDC regulations that sets forth the requirements of the VFC program and allows clinics to indicate the number of patients served annually.
- Stat. Auth.: ORS 413.042, 431.250
Stats. Implemented: ORS 413.042, 431.250

333-046-0040

Clinic Enrollment

- (1) Only prescribers authorized by the Authority may receive federally-purchased vaccines provided by the VFC program.
- (2) Application for the VFC program requires the clinic's principal provider, medical director or clinic administrator to complete a VFC Program Agreement that estimates the number of patients served and documents the prescriber's agreement to ensure that the clinic, and all of its prescribers, complies with all VFC program requirements.
- (3) In a solo practice, forms must be signed by the primary prescriber.
- (4) In a group practice, forms must be signed by the medical director or clinic administrator. The signer will be held accountable for compliance of the entire organization and all prescribers using VFC vaccine in the practice.
- (5) Prior to enrollment, clinics must have an enrollment site visit by the Authority.
- (6) Clinics must re-submit an updated signed VFC Program Agreement:
- (a) Annually; and
 - (b) When the number of children served changes enough to require an adjustment in the amount of vaccine needed ; or
 - (c) The status of the clinic changes during a calendar year.

Stat. Auth.: ORS 413.042, 431.250
Stats. Implemented: ORS 413.042, 431.250

333-046-0050

Vaccine Eligibility

- (1) Enrolled clinics may only provide VFC vaccine to children under the age of 19 years.
- (2) Enrolled clinics may only provide vaccine to children in one of the following categories:
- (a) Children enrolled in the Oregon Health Plan; or
 - (b) Children with American Indian/Alaskan Native heritage; or
 - (c) Uninsured children; or
 - (d) In FQHCs or RHCs only, children who are underinsured.

(3) Clinics may not require patients eligible under subsections (2)(b) or (2)(c) of this rule to prove their eligibility for VFC vaccines.

(4) Clinics designated as an FQHC or RHC must vaccinate any VFC-eligible underinsured patients that present at the clinic for immunization. Clinics that are not FQHCs and RHCs may not be required to vaccinate patients that are not established with the clinic.

Stat. Auth.: ORS 413.042, 431.250

Stats. Implemented: ORS 413.042, 431.250

333-046-0060

Patient Consent and Administration Fees

(1) Clinics may not bill any insurer or guarantor for the cost of vaccines provided by the VFC program.

(2) Clinics may charge a vaccine administration fee for each VFC vaccine provided. The administration fee may not exceed the limit set for Oregon by the United States Department of Health and Human Services.

(3) Vaccine administration fees may be billed to a patient's insurer, if applicable.

(4) If a regular patient of the clinic is unable to pay the administration fee, the prescriber must waive the charges for vaccine administration. Other applicable visit or office fees incurred do not have to be waived.

Stat. Auth.: ORS 413.042, 431.250

Stats. Implemented: ORS 413.042, 431.250

333-046-0070

Program Compliance

(1) Clinics must adhere to all terms detailed in the VFC Program Agreement.

(a) The Authority may, at its discretion, revise the VFC Program Agreement as posted on the Oregon VFC website. The Authority will provide 30 days written notice, via listserv electronic mail, to prescribers of revisions to the VFC Program Agreement.

(b) A prescriber's submission of a vaccine order after receipt of such notice shall be considered the prescriber's acceptance of the agreement revisions. If a prescriber does not wish to accept and be bound by the revisions to VFC Program Agreement, the prescriber may contact the Oregon VFC program to arrange pick-up of any remaining state-supplied vaccine.

(2) Clinics must practice in compliance with the legal requirements of the federal National Childhood Vaccine Safety Act.

(3) Prescribers must chart all vaccinations administered in accordance with federal law.

(4) Prescribers must comply with all provisions of ORS 433.103 and OAR chapter 333, division 47.

(5) Clinics must participate in VFC compliance site visits conducted by the Authority. Participation includes making available, without unreasonable delay, any staff or documentation necessary to answer questions included on the site visit questionnaire provided by the CDC.

(6) Clinics must cooperate with unannounced storage and handling site visits conducted by the Authority.

(7) Clinics must complete all necessary trainings as determined by the Authority.

Stat. Auth.: ORS 413.042, 431.250

Stats. Implemented: ORS 413.042, 431.250

333-046-0080

Record Keeping

Clinics must keep all records related to the VFC program for a minimum of three years and make them available to the Authority for review upon request.

Stat. Auth.: ORS 413.042, 431.250

Stats. Implemented: ORS 413.042, 431.250

333-046-0090

Provider Sanctions

The Authority may terminate a clinic's or prescriber's participation in the VFC program based on the following:

- (1) Violation of the terms of the VFC Program Agreement.
- (2) Conviction of fraud related to any federal, state, or locally financed health care program or commission of an act that is subject to criminal or civil penalties under Medicaid statutes.
- (3) Conviction of interference with the investigation of health care fraud.
- (4) An action by a state licensing authority relating to a prescriber's professional competence, professional conduct, or financial integrity, that results in the prescriber either:
 - (a) Having his or her license suspended or revoked; or
 - (b) Surrendering the license while a formal disciplinary proceeding was pending before a licensing authority.
- (5) Suspension or exclusion from participation in a federal or state-administered health care program for reasons related to professional competence, professional performance, or other reason.
- (6) Improper billing practices, including billing for the cost of state-supplied vaccines, excessive charges or unnecessary vaccination visits.
- (7) Failure to correct deficiencies in operations after receiving written notice of the deficiencies from the Authority.
- (8) The Authority shall consider the following factors in determining the sanctions to be imposed (this list includes but is not limited to these factors):
 - (a) Seriousness of the offenses;
 - (b) Extent of violations by the prescriber;
 - (c) History of prior violations by the prescriber;
 - (d) Prior imposition of sanctions;
 - (e) Prior education provided by the Authority; and
 - (f) Prescriber willingness to comply with VFC rules and procedures.

Stat. Auth.: ORS 413.042, 431.250

Stats. Implemented: ORS 413.042, 431.250

333-046-0100

Clinic Probation

- (1) Except in cases of suspected fraud, when a clinic is sanctioned by the Authority for the first time under OAR 333-046-0090 sections (1), (6) or (7), the Authority will offer a clinic the opportunity to voluntarily sign a probationary agreement before removing the clinic from the VFC program in accordance with OAR 333-046-0110.
- (2) The terms of the probationary agreement will be determined by the violations that have been identified by the Authority. The final probationary agreement will be approved by the Immunization Program manager or their designee.

(3) Failure to return a signed copy of the final probationary agreement within 14 calendar days of receipt of the agreement by the clinic will forfeit any right to a probationary agreement under section (1) of this rule.

(4) A probationary agreement may be in effect for no longer than 12 months before a final resolution is determined. If the clinic has complied with all clauses of the agreement during the probationary period, the clinic will be returned to regular status with the VFC program. If the clinic has not complied with all clauses of the agreement during the probationary period, the clinic will be removed from the VFC program under OAR 333-046-0120.

Stat. Auth.: ORS 413.042, 431.250

Stats. Implemented: ORS 413.042, 431.250

333-046-0110

Removal from the VFC Program

(1) When a clinic is sanctioned by the Authority under OAR 333-046-0090 sections (2) through (5), the Authority will immediately remove the clinic, and all associated prescribers, from the VFC program under the provisions of this rule.

(2) When the Authority determines that a clinic should be removed from the VFC program, written notification will be sent by certified mail to the prescriber who signed the VFC Program Agreement.

(3) Clinics and prescribers that have been removed from the VFC program may apply for conditional re-enrollment no sooner than 12 months after their removal from the program.

(4) The written notification will include the rationale behind the removal and inform the clinic of the right to appeal the decision within 60 calendar days.

Stat. Auth.: ORS 413.042, 431.250

Stats. Implemented: ORS 413.042, 431.250

333-046-0120

Clinic Appeals

(1) A clinic may appeal an Authority decision in which the clinic is directly adversely affected such as the following:

(a) A denial of an application for new or continued participation in the VFC program.

(b) Sanctions imposed, or intended to be imposed, by the Authority on a clinic.

(2) A clinic appeal is initiated by filing a timely request in writing for review by the Authority.

(3) A clinic's appeal request is not required to follow a specific format as long as it provides a clear written rationale from a clinic expressing disagreement with the Authority's decision.

(4) The request must identify the decision made by the Authority that is being appealed and the reason the clinic disagrees with that decision.

(5) A clinic's appeal request is timely if it is received within 60 calendar days of the date of the appealed decision.

(6) In the event a clinic's request for appeal is not timely, the Authority shall determine whether the failure to file the request was caused by circumstances beyond the control of the clinic. In determining whether to accept a late appeal, the Authority requires the request to be supported by a written statement that explains why the request for review is late. In determining timeliness of filing a request for review, the amount of time the Authority determines accounts for circumstances beyond the control of the prescriber is not counted.

(7) The burden of presenting evidence to support a clinic's appeal is on the clinic.

(8) Agency appeal proceedings, if any, shall be held in Portland, unless otherwise stipulated to by all parties and agreed to by the Authority.

Stat. Auth.: ORS 413.042, 431.250

Stats. Implemented: ORS 413.042, 431.250

333-046-0130

Conditional Re-enrollment

(1) Clinics and prescribers that have been removed from the VFC program under OAR 333-046-0110 may apply for conditional re-enrollment 12 months after the removal.

(2) Re-enrollment will be conditional on the clinic correcting any deficiencies that led to their removal from the VFC program.

(3) Clinics accepted for re-enrollment will be subject to a probationary agreement as detailed in OAR 333-046-0100 for a period of 12 months.

(4) Clinics that voluntarily disenroll from the VFC program in lieu of agreeing to a probationary agreement will be subject to a 12 month waiting period before requesting re-enrollment.

Stat. Auth.: ORS 413.042, 431.250

Stats. Implemented: ORS 413.042, 431.250