

OFFICE OF THE SECRETARY OF STATE

LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON



ARCHIVES DIVISION

STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED

11/27/2024 10:09 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Oregon Immunization Program - Vaccine Access Program. Adds Centers for Disease Control as ALERT IIS user

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 12/23/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Amanda Timmons
503-269-3288
publichealth.rules@odhsoha.oregon.gov

800 NE Oregon St. Suite 370
Portland, OR 97232

Filed By:
Public Health Division
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 12/16/2024

TIME: 2:00 PM - 2:30 PM

OFFICER: Staff

REMOTE HEARING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 971-277-2343

CONFERENCE ID: 318125808

SPECIAL INSTRUCTIONS:

This hearing is being held remotely via Microsoft Teams. To provide oral (spoken) testimony during this hearing, please contact publichealth.rules@odhsoha.oregon.gov to register and receive the link for the Microsoft Teams video conference via calendar appointment, or you may access the hearing using the meeting URL above. Alternatively, you may dial 971- 277-2343, Phone Conference ID 318 125 808# for audio (listen) only.

The hearing will close at the posted time of 2:30PM. You are encouraged to join as close to the beginning of the hearing if you wish to provide oral testimony.

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide free help. Some examples are: sign language and spoken language interpreters, real-time captioning, braille, large print, audio, and written materials in other languages. If you need help with these services, please contact the Public Health Division at 971-673-1222, 711 TTY or publichealth.rules@odhsoha.oregon.gov at least 48 hours before the meeting. All relay calls are accepted. To best ensure our ability to provide a modification please contact us if you are considering attending the meeting and require a modification. The earlier you make a request the more likely we can meet the need.

NEED FOR THE RULE(S)

The Oregon Health Authority, Public Health Division, Oregon Immunization Program (OIP) is adopting the Vaccine Access Program (VAP) in Oregon Administrative Rule. VAP is Oregon's name for the federal 317 vaccine program which has provided vaccines for uninsured people for many years. ALERT IIS rules have received a routine review. Adds a provision that allows an adult to unlock their record once they turn 18 years of age if the record was locked when they were a minor. ALERT IIS records belong to the individual, so once a person reaches 18 years, they have the right to determine whether the record remains locked or not. The Centers for Disease Control and Prevention is being added as an authorized user of ALERT IIS for the purpose of investigating vaccine adverse events.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

42 USC CHAPTER 6A, SUBCHAPTER XIX: VACCINES:

<https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter6A/subchapter19&edition=prelim>

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The Vaccine Access Program (VAP) is being adopted in Oregon Administrative Rules. VAP is Oregon's name for the federal 317 vaccine program which has provided vaccines for uninsured people for many years. These changes are administrative in nature and little impact on racial equity is anticipated. Naming the federal section 317 program as the Oregon Vaccine Access Program may clarify the purpose of the program to potential vaccine recipients.

FISCAL AND ECONOMIC IMPACT:

The VAP provides federally-purchased vaccines for fully uninsured adults. This is anticipated to provide a positive economic impact for uninsured Oregonians.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) No cost of compliance impact is anticipated for state agencies, units of local government, or the public.

(2)(a) Small medical clinics who serve uninsured patients will be subject to these rules. The Oregon Health Authority cannot accurately estimate the number of affected clinics because, though we know how many clinics are in Oregon, we do not know how many specifically serve uninsured individuals.

(b) No anticipated impacts for recordkeeping. Clinics already screen patients for vaccine eligibility and submit an appropriate eligibility code to ALERT IIS.

(c) No equipment, supplies, labor or increased administration will be required for compliance.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small clinics were included in the Rules Advisory Committee. In addition, the Oregon Immunization Program reached out to our Immunization Partner listserv that reaches ~5,000 immunization-related subscribers via email, including public and private health care providers and clinics, Tribal and Urban Indian health centers, health insurance and Medicaid representatives, local public health, legislative staff, and others asking for review and comment.

RULES PROPOSED:

333-046-0010, 333-046-0015, 333-046-0030, 333-046-0040, 333-046-0050, 333-046-0055, 333-046-0060, 333-046-0070, 333-046-0080, 333-046-0090, 333-046-0100, 333-046-0110, 333-046-0120, 333-046-0130, 333-047-0010, 333-049-0010, 333-049-0080

AMEND: 333-046-0010

RULE SUMMARY: Amend OAR 333-046-0010 – Clarifies that unaffordable administration fees must be waived. Takes language from OAR 333-046-0060.

CHANGES TO RULE:

333-046-0010

Purpose of Vaccines for Children (VFC) ¶

The Vaccines for Children (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. If the recipient cannot pay the administration fee, it must be waived.

Statutory/Other Authority: ORS 413.042, 431.250

Statutes/Other Implemented: ORS 413.042, 431.250

ADOPT: 333-046-0015

RULE SUMMARY: Adopt OAR 333-046-0015 – Describes the purpose of the Vaccine Access Program (VAP).

CHANGES TO RULE:

333-046-0015

Purpose of Vaccine Access Program (VAP)

The Vaccine Access Program (VAP) is designed to provide selected vaccines purchased by the Oregon Health Authority to enrolled clinics.¶

(1) Vaccines purchased using funds provided through the federal Section-317 program may be used for adults with no insurance or whose insurance does not include immunization coverage. 317 vaccines must be provided at no cost, besides an administration fee, to the recipient. If the recipient cannot pay the administration fee, it must be waived.¶

(2) Billable vaccines purchased using state funds may be provided to insured patients served at a VAP-enrolled clinic. The cost of the vaccine serum and an administration fee may be billed to the vaccine recipient or their payor.

Statutory/Other Authority: ORS 413.042, ORS 431.250

Statutes/Other Implemented: ORS 413.042, ORS 431.250

AMEND: 333-046-0030

RULE SUMMARY: Amend OAR 333-046-0030 – Adds definitions for billable vaccine, enrolled clinic, 317 vaccine and Vaccine Access Program agreement.

CHANGES TO RULE:

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) "Billable vaccine" means a vaccine purchased by the Authority using state funds for use in insured recipients served at Vaccine Access Program (VAP)-enrolled clinics.¶¶
- (7) "CDC" means the Centers for Disease Control and Prevention.¶¶
- (78) "Clinic" means a facility providing medical services to outpatients. A clinic may have a solo practitioner or be a group practice. Pharmacies and hospitals that provide immunization services are also considered clinics for the purposes of this rule.¶¶
- (89) "Enrolled clinic" means a clinic that is authorized to receive vaccines under OAR 333-046-0040.¶¶
- (10) "FQHC" means a federally-qualified health center.¶¶
- (911) "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.¶¶
- (102) "Prescriber" means a professional with prescription writing privileges currently licensed in Oregon.¶¶
- (113) "RHC" means a federally-designated rural health clinic.¶¶
- (124) "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.¶¶
- (135) "Uninsured" means a person that does not have any kind of health insurance.¶¶
- (146) "Vaccines for Children (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.¶¶
- (157) "VAP Program Agreement" means a document provided by the Authority that sets forth the requirements of the VAP program and allows clinics to indicate the number of patients served annually.¶¶
- (18) "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.¶¶
- (19) "317 vaccine" means a vaccine purchased by the Authority using federal funds for use in adult recipients who are uninsured or whose insurance doesn't provide vaccine coverage.

Statutory/Other Authority: ORS 413.042, 431.250

Statutes/Other Implemented: ORS 413.042, 431.250

AMEND: 333-046-0040

RULE SUMMARY: Amend OAR 333-046-0040 – Clarifies that only authorized prescribers may use Vaccines for Children (VFC), Vaccine Access Program (VAP) or billable vaccines.

CHANGES TO RULE:

333-046-0040

Clinic Enrollment ¶

(1) Only prescribers authorized by the ~~Authority~~Oregon Health Authority (Authority) may receive federally-purchased vaccines provided by the ~~VFC~~Vaccines for Children (VFC) program and Vaccine Access Program (VAP) or state-purchased vaccines for billable vaccine provided by the VAP program.¶

(2) Application for the ~~VFC~~VFC or VAP 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~~VFC or VAP 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~~VFC or VAP 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~~VFC or VAP Program Agreement:¶

(a) Annually; and¶

(b) When the number of ~~children~~patients served changes enough to require an adjustment in the amount of vaccine needed; or¶

(c) ~~The status of the clinic change~~A clinic changes prescribing providers during a calendar year.

Statutory/Other Authority: ORS 413.042, 431.250

Statutes/Other Implemented: ORS 413.042, 431.250

AMEND: 333-046-0050

RULE SUMMARY: Amend OAR 333-046-0050 – Specifies that billable vaccine may only be used for patients who are insured.

CHANGES TO RULE:

333-046-0050

Vaccine Eligibility ¶¶

- (1) Enrolled clinics may only provide Vaccines for Children (VFC) vaccine to children under the age of 19 years.¶¶
- (2) Enrolled clinics may only provide VFC 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 federally-qualified health centers (FQHCs) or rural health clinics (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.¶¶
- (5) Enrolled clinics may only provide 317 vaccines to adults aged 19 years and older without insurance or whose insurance does not have any coverage for immunizations.¶¶
- (6) Enrolled clinics may provide billable vaccine to insured patients who are ineligible for VFC- or 317-provided vaccines.

Statutory/Other Authority: ORS 413.042, 431.250

Statutes/Other Implemented: ORS 413.042, 431.250

ADOPT: 333-046-0055

RULE SUMMARY: Adopt OAR 333-046-0055 – Describes the administrative processes regulating the billable vaccine program, including the process the Oregon Health Authority uses to seek reimbursement for vaccines purchased using state monies.

CHANGES TO RULE:

333-046-0055

Billable Vaccine

(1) Clinics that administer billable vaccines will be billed quarterly for the purchase price of the vaccine by the Oregon Health Authority (Authority).¶

(2) The vaccine price list will be updated biannually by the Authority, on January 1 and July 1.¶

(3) Enrolled clinics must submit payment within 60 days of receiving their quarterly bill.¶

(4) Enrolled clinics may not bill more for the vaccine than the published price in effect on the date of administration.¶

(5) Clinics may charge an administration fee for billable vaccines that covers their cost of providing the service. Billable vaccines are not subject to the administration fee limits imposed on Vaccines for Children (VFC) and 317 vaccines.¶

(6) Clinics may bill a patient's insurer for both the billable vaccine and the administration fee.

Statutory/Other Authority: ORS 413.042, ORS 431.250

Statutes/Other Implemented: ORS 413.042, ORS 431.250

AMEND: 333-046-0060

RULE SUMMARY: Amend OAR 333-046-0060 – Specifies that clinics may not bill for the cost of vaccines provided by the Vaccine Access Program.

CHANGES TO RULE:

333-046-0060

~~Patient Consent and~~Vaccines for Children (VFC) and 317 Vaccine Administration Fees ¶

- (1) Clinics may not bill any insurer or guarantor for the cost of vaccines provided by the Vaccines for Children (VFC) program or purchased with 317 funds for the Vaccine Access Program (VAP). ¶
- (2) Clinics may charge a vaccine administration fee for each VFC or 317 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~~ established 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~~ not deny access to VFC vaccines.

Statutory/Other Authority: ORS 413.042, 431.250

Statutes/Other Implemented: ORS 413.042, 431.250

AMEND: 333-046-0070

RULE SUMMARY: Amend OAR 333-046-0070 – Clinics must adhere to terms detailed in the Vaccine Access Program agreement. The Oregon Health Authority may change the agreement with 30 days written notice.

CHANGES TO RULE:

333-046-0070

Program Compliance ¶¶

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

~~(a) The Authority~~ vaccines for Children (VFC) or Vaccine Access Program (VAP) Program Agreement.¶¶

(a) The Oregon Health Authority (Authority) may, at its discretion, revise the VFC or VAP 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 or VAP 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 or VAP Program Agreement, the prescriber may contact the Oregon ~~VFC~~ Immunization 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. (NCVIA) of 1986 (42 U.S.C. ~~??~~ 300aa-1 to 300aa-34). ¶¶

(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.

Statutory/Other Authority: ORS 413.042, 431.250

Statutes/Other Implemented: ORS 413.042, 431.250

AMEND: 333-046-0080

RULE SUMMARY: Amend OAR 333-046-0080 - Clinics must keep all records related to the Vaccine Access Program for three years.

CHANGES TO RULE:

333-046-0080

Record Keeping ¶

Clinics must keep all records related to the Vaccines for Children (VFC) program or Vaccine Access Program (VAP) for a minimum of three years and make them available to the Oregon Health Authority for review upon request.

Statutory/Other Authority: ORS 413.042, 431.250

Statutes/Other Implemented: ORS 413.042, 431.250

AMEND: 333-046-0090

RULE SUMMARY: Amend OAR 333-046-0090 – The Oregon Health Authority may terminate a clinic's participation in the Vaccine Access Program if a prescriber violates the agreement.

CHANGES TO RULE:

333-046-0090

Provider Sanctions ¶¶

The ~~Authority~~ Oregon Health Authority (Authority) may terminate a clinic's or prescriber's participation in the Vaccines for Children (VFC) program or Vaccine Access Program (VAP) 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~~ their 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 or VAP rules and procedures.

Statutory/Other Authority: ORS 413.042, 431.250

Statutes/Other Implemented: ORS 413.042, 431.250

AMEND: 333-046-0100

RULE SUMMARY: Amend OAR 333-046-0100 – The Oregon Health Authority may offer a clinic participating in the Vaccine Access Program a probationary agreement.

CHANGES TO RULE:

333-046-0100

Clinic Probation ¶

- (1) Except in cases of suspected fraud, when a clinic is sanctioned by the ~~Authority~~Oregon Health Authority (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 Vaccines for Children (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 Oregon 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 or Vaccine Access Program (VAP). If the clinic has not complied with all clauses of the agreement during the probationary period, the clinic will be removed from the VFC or VAP program under OAR 333-046-0110.

Statutory/Other Authority: ORS 413.042, 431.250

Statutes/Other Implemented: ORS 413.042, 431.250

AMEND: 333-046-0110

RULE SUMMARY: Amend OAR 333-046-0110 – Clinics may be removed from the Vaccine Access Program when sanctioned by the Oregon Health Authority.

CHANGES TO RULE:

333-046-0110

Removal from the Vaccines for Children (VFC) Program or Vaccine Access Program (VAP) ¶¶

(1) When a clinic is sanctioned by the ~~Authority~~Oregon Health Authority (Authority) under OAR 333-046-0090 sections (2) through (5), the Authority will immediately remove the clinic, and all associated prescribers, from the Vaccines for Children (VFC) program or Vaccine Access Program (VAP) under the provisions of this rule.¶¶

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

(3) 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.¶¶

(4) Clinics and prescribers that have been removed from the VFC or VAP 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.~~

Statutory/Other Authority: ORS 413.042, 431.250

Statutes/Other Implemented: ORS 413.042, 431.250

AMEND: 333-046-0120

RULE SUMMARY: Amend OAR 333-046-0120 – Clinics may appeal their removal from the Vaccine Access Program.

CHANGES TO RULE:

333-046-0120

Clinic Appeals ¶

(1) A clinic may appeal an ~~Authority~~Oregon Health Authority (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 Vaccines for Children (VFC) program or Vaccine Access Program (VAP).¶

(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.

Statutory/Other Authority: ORS 413.042, 431.250

Statutes/Other Implemented: ORS 413.042, 431.250

AMEND: 333-046-0130

RULE SUMMARY: Amend OAR 333-046-0130 – Clinics may enroll conditionally in the Vaccine Access Program 12 months after their removal.

CHANGES TO RULE:

333-046-0130

Conditional Re-enrollment ¶¶

- (1) Clinics and prescribers that have been removed from the Vaccines for Children (VFC) program or Vaccine Access Program (VAP) 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 or VAP 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 or VAP program in lieu of agreeing to a probationary agreement will be subject to a 12-month waiting period before requesting re-enrollment.
- Statutory/Other Authority: ORS 413.042, 431.250
Statutes/Other Implemented: ORS 413.042, 431.250

AMEND: 333-047-0010

RULE SUMMARY: Amend OAR 333-047-0010 – The Vaccine Access Program is added to the definition of "Receives vaccines."

CHANGES TO RULE:

333-047-0010

Definitions Used in the Vaccine Accountability Rules ¶¶

- (1) All definitions of ORS 433.090 and 433.235 apply to ~~these rules~~ OAR chapter 333, division 47. ¶¶
- (2) In addition to the definitions of ORS 433.090 and 433.235, the following definitions apply: ¶¶
- (a) "Authority" means the Oregon Health Authority. ¶¶
- (b) "Authority's Immunization Registry" means the immunization information system (IIS) established by the Authority under ORS 433.094 and OAR chapter 333, division 49. ¶¶
- (c) "Certify" means to attest, in writing, on a form prescribed by the Oregon Health Authority that at least two employees, owners or partners have completed required vaccine-related trainings as provided or approved by the Oregon Health Authority. ¶¶
- (d) "Entity" means a health clinic or provider, pharmacy or pharmacist who receives state-supplied vaccine. ¶¶
- (e) "Oregon Immunization Program" means the Oregon Health Authority, Public Health Division, Immunization Program. ¶¶
- (f) "Public Health Division" means the Oregon Health Authority, Public Health Division. ¶¶
- (g) "Receives vaccines" means an entity is supplied with vaccines by the Oregon Immunization Program, including vaccines acquired with federal and state funds, including the Vaccines for Children Program (VFC), ~~the Section 317 Vaccine~~ (VFC) program, the Vaccine Access Program (VAP), state Special Project vaccine, and state Billable Project vaccine. ¶¶
- (h) "State supplied vaccine" means vaccine provided by the federal government or the Oregon Immunization Program.

Statutory/Other Authority: ORS 433.103

Statutes/Other Implemented: ORS 433.103

AMEND: 333-049-0010

RULE SUMMARY: Amend OAR 333-049-0010 – Adds the Centers for Disease Control and Prevention as an authorized user when investigating vaccine adverse events.

CHANGES TO RULE:

333-049-0010

Definitions ¶¶

- (1) All definitions of ORS 433.090 and 433.235 apply to these rules OAR chapter 333, division 49. ¶¶
- (2) In addition to the definitions of ORS 433.090 and 433.235, the following definitions apply: ¶¶
- (a) "Authorized user" has the meaning as defined in ORS 433.090(4). Agents of the Centers for Disease Control and Prevention are considered authorized users when requesting information for investigation into adverse events reported to the Vaccine Adverse Events Reporting System. ¶¶
- (b) "Client" has the meaning as defined in ORS 433.090(3). ¶¶
- (c) "Exempt" means the special status of information on certain clients that will limit its disclosure. ¶¶
- (d) "Immunization Information System (IIS)" means a registry of client and vaccination records. ¶¶
- (e) "Manager" means the manager of the statewide IIS or his/~~his~~/their designee. ¶¶
- (f) "Oregon Immunization Program" means the Oregon Health Authority, Public Health Division, Immunization Program. ¶¶
- (g) ~~"Program" means the Oregon Health Authority, Public Health Division, Immunization Program.~~ ¶¶
- (h) "Public Health Division" means the Oregon Health Authority, Public Health Division. ¶¶
- (i) "State Public Health Division Timelines" means the schedule of reporting timelines shown in the Vaccine User Accountability Reporting Table (OAR 333-047-0050), detailing data elements required and when each element must be included for submission. ¶¶
- (j) "State supplied vaccine" means vaccine provided by the federal government or the Oregon Immunization Program.

Statutory/Other Authority: ORS 433.100

Statutes/Other Implemented: ORS 433.100

AMEND: 333-049-0080

RULE SUMMARY: Amend OAR 333-049-0080 – Allows an adult to unlock their ALERT vaccine record that was locked when they were a minor. A minor’s record may be locked at a guardian’s request for personal safety reasons or because the minor has a medical condition which precludes vaccination.

CHANGES TO RULE:

333-049-0080

Limitations on the Transfer of Information from the Immunization Information System ¶¶

(1) Any parent or guardian of a child who has a disease or condition that may preclude administration of some or all immunizations may request a limitation on the child's information that may be transferred from the IIS Immunization Information System (IIS) by providing a written request to the Oregon Immunization Program (program).¶¶

(2) Upon verification of the information in the request, the program shall cause the IIS to flag the client's record and to limit transfer of the information on the client. The program shall also notify the parent or guardian of such action. No information on such children will be disclosed in response to inquiries to the IIS.¶¶

(3) Any parent or guardian of a client may request a limitation on the transfer of child's information by providing a written request to the program when the parent or guardian reasonably believes there is a risk of harm to the child, or other family members, where such person could be located through information from the IIS, and the child or other family members may be harmed if located.¶¶

(a) The request for limitation must include a statement and evidence that supports the request. Such evidence may include any evidence accepted under ORS 192.445(2)(b)(A)-(E).¶¶

(b) Upon receipt of any request under this section, the manager may cause the IIS to flag the child's record for a period of 30 days until the request can be approved.¶¶

(c) Upon receipt of acceptable evidence to support the request, the manager shall cause the IIS to flag the child's record and to limit transfer of the information on the child. The manager shall also notify the parent or guardian of such action.¶¶

(d) After approval of a request under this section, such request will remain in effect until the program receives a written request from the parent or guardian, or upon reaching 18 years, the client, to remove the flag from the child's record.

Statutory/Other Authority: ORS 433.100

Statutes/Other Implemented: ORS 433.100