



## Alaska

# Vaccines for Children Requirements Manual

CDC Fiscal Year 7.1.24-6.30.25



Alaska Immunization Program Vaccines for Children 907-269-8088 (Anchorage) or 1-888-430-4321 vfc@alaska.gov

## **Table of Contents**

INTRODUCTION	3
VFC VACCINE DEFINITION	4
VFC PROGRAM REQUIREMENTS	4
Provider Management Plan.	4
Records Retention.	4
Provider Criteria and Staffing	4
Facility/Staff Information	5
Childhood Vaccine Eligibility	5
Fees for Vaccines and Vaccine Administration	6
Vaccine Administration Documentation	6
Vaccine Storage and Temperature Monitoring	6
Immunization Standards	8
Vaccine Inventory	8
Temporary, Off-site, Satellite, Mobile, & Mass Vaccination Clinics	11
VFC Quality Assurance	11
Enrollment and Unenrollment.	12
Enrollment	12
Unenrollment.	13
CDC approved VFC Provider Agreement language	14

## Introduction

Thank you for your interest in receiving pediatric vaccines in partnership with the Alaska Immunization Program.

Since the establishment of a <u>program to distribute pediatric vaccines</u> was implemented, the <u>Vaccines for Children (VFC) Program</u> has represented an unprecedented approach to improving vaccine availability for VFC-eligible children. Federal funds support the VFC Program at the national and local level. These funds are used by the Centers for Disease Control and Prevention (CDC) to purchase vaccine at a discount from manufacturers so that they may be administered to VFC-eligible children and are awarded to the Immunization Program to implement and oversee Alaska's VFC program.

Eligible providers who demonstrate they are willing and able to maintain compliance with program requirements found in this manual and attached links, may enroll with the Immunization Program to receive federally purchased vaccines.

Children who are not VFC-eligible and adults who meet select eligibility criteria may receive vaccines funded through the <u>Alaska Vaccine Assessment Program (AVAP)</u>, a public-private partnership used to purchase and distribute vaccines through the Immunization Program.

Providers who enroll into the VFC Program automatically have access to AVAP funded vaccines for AVAP-eligible patients. (No separate enrollment to receive AVAP funded vaccines is required for VFC enrolled providers.)

Providers who do not have a VFC population but serve AVAP only eligible children and adults may look into enrolling into the AVAP only.

VFC Program enrolled providers are known as "VFC Providers" even with their additional AVAP enrollment. All vaccine supplied by the Immunization Program through these funding sources are known as "state-supplied" vaccines.

When contacting the Alaska Immunization Program, VFC enrolled providers must include their facility name and PIN. Omitting this information when calling, emailing, or faxing the Alaska Immunization Program can delay a response time. VFC staff members may be indisposed if you reach out to us individually, however, staff who are available monitor and can be reached through vfc@alaska.gov.

## VFC Vaccine Definition

From CDC's VFC Program dated 10.2023: For the purposes of the federal VFC Program, the term "vaccine" is defined as any FDA-authorized or licensed, Advisory Committee on Immunization Practices (ACIP) recommended product for which ACIP approves a VFC resolution for inclusion in the VFC Program.

All references of "vaccine(s)" within the VFC Program (verbal or written) includes nirsevimab.

## VFC Program Requirements

## Provider Management Plan

This manual, along with the documents and information linked throughout it, provides the information needed for providers to maintain compliance with requirements and acts as each provider's general VFC management plan.

As the VFC Program is a Title XIX Medicaid program, compliance with program requirements is required. Noncompliant providers may find their vaccine orders denied or their vaccine order privileges suspended altogether; may be required to participate in extended training activities; may be unenrolled from program participation; and/or may be subject to Medicaid fraud and abuse investigation.

#### Fraud and Abuse

The following definitions are consistent with "fraud" and "abuse" as defined in Medicaid regulation 42 CFR § 455.2:

- 1. 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.
- 2. 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 healthcare.

## Records Retention

Providers must maintain all records related to the VFC program for a minimum of three years and must make them available upon request by Immunization Program staff. VFC records include, but are not limited to, VFC eligibility documentation, billing records, temperature monitoring documentation, temperature monitor calibration certificates, and temperature excursion documentation.

## Provider Criteria and Staffing

To be eligible to participate in the VFC program, providers must:

- Be licensed in Alaska to administer vaccines to children aged 18 years and younger. (Exception:
  IHS health professionals who are assigned or detailed to tribes or tribal organizations under the IPA
  or MOA are not required to be licensed in the state in which they are assigned or detailed.)
- Be willing and able to follow all VFC program requirements, policies, and procedures, including participation in site visits and educational opportunities.
- Have the capacity to order, receive, manage, store, and monitor the temperature of public vaccines.
- Be open at least four consecutive hours on a day other than a Monday to receive VFC vaccines.

Qualifying providers include: Medical Doctor (MD), Doctor of Osteopathy (DO), Advanced Nurse Practitioner (ANP), Pharmacist certified to administer immunizations, or Physician Assistant (PA) with their signing collaborating physician.

The provider signing the VFC Provider Agreement on behalf of a multi-provider practice must have authority to sign on behalf of the entity and will be held accountable for the entire organization's compliance.

Providers on the Office of Inspector General's (OIG) <u>List of Excluded Individuals and Entities</u> (LEIE), are not eligible to participate in the program.

Certifying Providers must designate at least one on-site staff member for each of the following roles:

- Vaccine Coordinator
- Back-up Coordinator

Vaccine Coordinators and Back-up Coordinators are equally responsible for providing oversight for the VFC program within the facility. They must have the Certifying Provider's supporting authority to implement and enforce program requirements. Should designated staff be out of the office (i.e., on leave) for 30 days or more, an additional person must be identified as a Back-up Coordinator by submitting a VacTrAK modify users form.

## Facility/Staff Information

Providers are required to keep various types of information current with the Immunization Program. The <u>Notification of Staff or Facility Changes</u> chart lists what types of changes must be communicated to the Immunization Program, how to communicate that information, and the deadlines in which the changes must be submitted to the program.

## Childhood Vaccine Eligibility

Eligible children age birth through 18 years may receive state-supplied vaccine that is funded through VFC or <u>AVAP</u>. Eligibility screening and documentation must take place at each immunization visit for each vaccine administered. Information is available to assist with determining the correct eligibility category for children.

Occasionally, children meet more than one eligibility status. When this occurs providers must consult with families to select and document the eligibility category that will require the least amount of out-of-pocket expenses for the child to receive immunizations.

VFC eligibility categories must never be used for people aged 19 years and older. Eligibility determinations are how the Immunization Program accounts for the way in which each dose of state-supplied vaccine is used. Selecting VFC eligibility for persons aged 19 years and older are an indication of misuse of federal funds.

Eligibility documentation (electronic or paper) must include the following:

- Patient's first and last name and middle initial
- Patient's date of birth
- Primary provider's name
- Date of each immunization visit
- Eligibility status

A paper version of an eligibility screening form is available if needed.

## Fees for Vaccines and Vaccine Administration

The <u>eligibility chart for children</u> includes requirements regarding fees for vaccines and vaccine administration, and additional billing and access to care requirements for VFC-eligible children.

Per CDC, providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration. This policy does not apply to vaccine administration fees billed to Medicaid for children who meet VFC program Medicaid eligibility criteria.

Unpaid administration fees for VFC-eligible children may not be sent to collections and providers may not refuse to vaccinate a VFC-eligible child for whom there are unpaid vaccine administration fees.

## Vaccine Administration Documentation

Federal statute 42 US Code 300aa-25 requires the following for each dose of vaccine administered:

- Vaccine name
- · Date administered
- Publication date of VIS/IIS
- Date VIS/IIS provided to patient
- Name of vaccine manufacturer
- Vaccine Lot number
- Name and title of vaccinator
- Clinic address

Alaska Administrative Code <u>7 AAC 27.650</u> requires all healthcare providers document each dose of vaccine administered (including privately purchased vaccine) in <u>VacTrAK</u>, Alaska's immunization information system (IIS), within 14 days of administration. For details on these requirements refer to the <u>Conditions</u> Reportable to <u>Public Health</u> manual.

Each time each vaccine is administered, providers must distribute current Vaccine Information Statements (VIS) and for nirsevimab a current Immunization Information Statement (IIS) to a patient prior to the administration. Both may be found here: https://www.cdc.gov/vaccines/hcp/vis/current-vis.html.

Providers should report suspected adverse reactions following co-administration of nirsevimab with any vaccine to the <u>Vaccine Adverse Event Reporting System</u> (VAERS). For nirsevimab when not co-administered with other vaccines, VFC providers should report all suspected adverse reactions to <u>MedWatch</u>.

## Vaccine Storage and Temperature Monitoring

The vaccine cold chain is a temperature controlled environment used to maintain and distribute vaccines in optimal condition. It begins with the storage unit at the manufacturing plant and does not end until the vaccine is administered to the patient. Appropriate storage and handling conditions must be maintained at every link in the cold chain to maintain vaccine potency. Sound vaccine management practices will minimize vaccine loss and waste and the potential need to revaccinate that could result from administering compromised vaccine.

VFC enrolled providers are responsible for obtaining and maintaining equipment used for the program.

#### Storage Units

Providers must have equipment that meets storage unit requirements, is used only for vaccine storage and

pharmaceuticals, and maintains temperatures required for appropriate vaccine storage.

Each storage unit outlet and circuit breaker must be labeled to avoid intentional or accidental loss of power. (<u>Labels/signage</u> are available.) Note: generators do not prevent manual disconnect from power source; "do not disconnect" signage is still required.

## Storage Unit Temperatures

The following CDC required temperatures must be maintained at all times:

- Refrigerator temperature range: 36.0°F and 46.0°F (2.0°C and 8.0°C)
- Freezer temperature range: -58.0°F and +5.0°F (-50.0°C and -15.0°C)

To facilitate temperature stability:

- Store vaccines in their original box
- Store vaccines in the center of the unit with space between vaccines and the side/back of the unit to allow cold air to circulate
- Do not store food or drink in refrigerators or freezers used for vaccine storage
- Add water bottles to help stabilize temperatures and act as barriers to prevent vaccine and temperature monitoring devices from moving to less than optimal locations in units
- Use small trays for quick movement of stock within a unit reducing the amount of time the door must remain open

## Temperature Monitoring Devices

Temperature monitoring devices (TMDs) must be placed in the center of each vaccine storage unit as close to vaccine stock as possible to more accurately reflect vaccine temperature. Improper placement of the monitor may result in vaccine wastage.

All temperature monitoring devices, including back-up devices, must meet the requirements outlined on the VFC <u>Temperature Monitoring Device Requirements</u> document. This includes keeping devices calibrated (due within two years of last calibration date for each device).

Calibration certificates for each device used, including the back-up device, must be readily available to the Immunization Program upon request.

Monitoring device requirements must be met for all temperature monitoring:

- Routine onsite storage
- Back-up thermometers
- Vaccine transport
- Temporary, Off-site, Satellite, Mobile, & Mass Vaccination Clinics

#### Temperature Monitoring Documentation

Providers must review and document each of the following at the beginning of each workday on a temperature log:

- At least one current/min/max temperature reading per day
- Date and time of each temperature review
- Alarm status ("yes" or "no" the alarm was triggered)
- The name or initials of the person who assessed and recorded each reading

<sup>\*</sup>If using ultra-cold storage unit range: -130°F and -76°F (-90°C and -60°C)

Temperature documentation logs are provided for each type of storage unit (see <u>refrigerator or freezer temperature logs</u>). In addition to documenting daily temperature information noted above, data from monitoring devices must be downloaded and reviewed by provider staff weekly and whenever temperatures have gone out of range.

## Temperature Excursion

Once viable stock is received into a provider's inventory, the provider assumes maintaining cold chain responsibilities. A temperature excursion is *any* out of range temperature (i.e., 46.1°F) for *any* length of time (i.e., even if for less than one minute).

Immediately upon discovering vaccine has been exposed to temperatures outside of CDC's VFC Program acceptable range, follow the required procedures outlined in the <u>VFC Temperature Excursion Report</u>. After contacting manufacturers to determine vaccine viability, submit the report as indicated on the form.

Follow manufacturers' guidance if vaccine is determined to be viable (i.e., mark new expiration date on packaging). If vaccine loss occurs, follow policies and procedures indicated on the <u>Vaccine Distribution</u> website.

For information regarding vaccine shipment related excursions, see Vaccine Distribution.

## Emergency Response Plan

Each facility is required to have a written emergency response plan outlining a methodology to ensure that vaccines are appropriately handled in the event of a power outage or storage unit failure. All staff must be familiar with your facility's plan.

#### The plan must:

- Be posted on or near your vaccine storage unit
- Be updated annually with the staff signature and date of the annual review
- Be updated, signed and dated whenever there is a change to the procedures or emergency contact staff
- Include the contact information for the Vaccine Coordinator and at least one Back-up Coordinator responsible for vaccine management

An <u>emergency plan template</u> is available, as is vaccine <u>transport information</u>.

## **Immunization Standards**

The <u>Advisory Committee on Immunization Practices (ACIP)</u> is legislatively linked to the VFC program. VFC providers must maintain sufficient stock and offer all routine ACIP-recommended vaccines for the VFC population they serve and comply with the immunization schedules, dosages, and contraindications. Policies regarding vaccine availability and usage result from ACIP passing VFC resolutions.

## Vaccine Inventory

The VFC program is an entitlement program for eligible persons birth through 18 years of age. CDC requires VFC providers maintain adequate inventory of vaccine to administer to their patients based on their eligibility status (VFC eligible and non-VFC eligible patients).

By participating in the VFC program, providers agree to make vaccines available to the population they serve. The approved Provider Agreement, provider type and population served indicate which vaccines providers must provide to their VFC patients.

## Borrowing

Borrowing between privately purchased vaccine and that provided through the Immunization Program is not permitted.

To prevent errors and vaccine borrowing, providers must:

- maintain an adequate supply of stock for each vaccine recommended for their patient population (based on ages and eligibility statuses)
- perform physical stock checks (count number of doses available, expiration dates, etc.) at minimum monthly and within 14 days of orders being placed and perform inventory reconciliation tasks within VacTrAK
- accurately screen and document eligibility for each dose of vaccine administered
- label vaccine boxes and store vaccine based on how the vaccine was procured. See <u>Separating and Storing Vaccine Stock</u>.

## Determining vaccine needs

To determine which vaccines and the quantity of each to order, providers must assess their:

- Current pediatric and adult inventory to ensure they have sufficient vaccine for each population
- Recent vaccine usage
- Upcoming expiration dates
- Seasonal needs (i.e., back to school season)
- Provider Profile (which identifies eligibility category by age group)
- Which vaccines they agreed to provide to their pediatric population according to their VFC Provider Agreement

## Combination and single antigen vaccines:

Providers must offer/order routine recommended vaccines for the populations they serve and as noted in their approved VFC provider agreements. If providers have a population that can be served through combination vaccines, they may order the combination vaccines without ordering single antigens as well. The option to order single antigen vaccines does remain if needed.

#### Note the following regarding specific vaccines:

CDC recognizes that stocking the following vaccine at all times may not be a viable option for all providers, however providers must have protocols to ensure access if these vaccines are not maintained in inventory at a provider's facility:

- pneumococcal polysaccharide PPSV23
- meningococcal serogroup B MenB
- maternal respiratory synctial virus
- mpox
- dengue

#### Protocols to ensure access may include:

- ordering when needed
- transferring the vaccine as needed
- referring a patient to a facility which has the vaccine in stock

#### Vaccine orders

- are placed through VacTrAK (if assistance is needed, see <u>Vaccine Distribution</u> website)
- must be placed based on patient population eligibility according to order sets (pediatric, adult, or a combined pediatric and adult order sets). Vaccines ordered from the pediatric order set cannot be administered to an adult and vaccines ordered from the adult order set cannot be administered to a pediatric

- patient. For details see Stock Separation Guide.
- should be placed while providers still have a six-eight week supply of vaccine available to allow for potential delays
- should be placed in smaller quantities and more frequently to minimize the amount of vaccine loss should an incident occur during shipment or in the vaccine storage unit
- <u>accountability statuses</u> are noted on the ordering page and will delay or deny order approval if providers are not in good standing with program requirements

## Receipt of vaccine shipment

Vaccine shipment tracking numbers can be found in VacTrAK's Receive Order page (see <u>Vaccine</u> <u>Distribution</u>).

Facilities must be open/have staff available to recognize and receive vaccine deliveries when they arrive. Immediately upon receipt, ensure vaccine shipment is delivered to the correct facility and follow procedures provided by the vaccine distribution team.

To prevent mismanagement of federally funded vaccines, providers must clearly mark/differentiate vaccines in their units and for administration based on how the vaccines were obtained/ordered:

- pediatric state-supplied order set
- adult state-supplied order set
- blended state-supplied order set
- privately purchased

Vaccine boxes must be clearly marked by funding and vaccines separated in storage units by how they were procured (see <u>Separating and Storing Vaccine Stock</u>).

Appropriately labeling and separating vaccine in this manner will help prevent vaccine administration to ineligible patients, Medicaid VFC related fraud and abuse, and violations of the False Claims Act.

#### Vaccine waste/Loss Prevention

Vaccine loss is costly and often preventable. In addition to improper vaccine storage and handling practices, loss due to expiration is a significant cause of vaccine wastage.

To assist with preventing vaccine wastage, order appropriate quantities and store shorter dated vaccines in front of longer dated vaccines so that they will be administered first.

#### Vaccine Transfers

Vaccine transfers between enrolled VFC provider locations may be approved in limited situations. Transfers may not be used as routine inventory management. CDC permits transfers:

- of short-dated vaccine to avoid wastage
- of vaccine needed to quickly replace loss due to events such as equipment/power failure, disasters
- due to other circumstances determined by the Alaska Immunization Program on a case-by-case basis

Vaccines must not be physically moved to and/or transferred to another provider prior to receiving transfer approval from program staff. This ensures providers involved with the transfer are currently enrolled in, and in good standing with, the VFC Program. (See <u>Vaccine Distribution</u>.)

The sending and receiving providers must ensure temperature documentation validates vaccine efficacy has not been previously compromised, and that the cold chain was maintained during the transport. (See

## Vaccine Transport Methods.)

## Expired/Wasted Vaccine

Vaccines that do expire or those that are spoiled/wasted must be placed in a container or bag clearly labeled "Do Not Use" and removed from storage units to prevent inadvertent use. See <u>Vaccine Distribution</u> website for additional processing and return information.

## Temporary, Off-site, Satellite, Mobile, & Mass Vaccination Clinics

Providers are required to appropriately manage their inventory for these types of clinics.

- Do not plan events until you have physically received vaccine(s) you plan to administer at an event.
- Determine vaccine needs based on planned population to be served and order accordingly (i.e., pediatric COVID-19 vaccine need separately from the adult COVID-19 vaccine need).
- Order vaccines for events four to six weeks in advance of when you'd like clinics to take place. This time frame provides a buffer should there be a barrier to receiving a vaccine order (i.e., vaccine shipment delay). By ordering earlier, providers will be able to address a barrier in a timely manner before the event is to take place.
- Additional logistics will need be considered by providers who conduct these clinics in another community (i.e., how vaccines will arrive in another community).
- Follow additional requirements as indicated on the <u>off-site clinic instruction form</u>.

## VFC Quality Assurance

Federal and state requirements mandate that the Immunization Program conduct various types of quality assurance (QA) activities to monitor and enforce provider compliance. Providers found to be noncompliant during QA activities are required to conduct follow-up activities to remain in good standing with the VFC program. QA activities are conducted as follows:

- VacTrAK is used by the Immunization Program to monitor inventory management (i.e., appropriate
  use of VFC eligibility status, order and reconcile inventory, wastage) and track specific VFC
  accountability requirement needs.
- VFC Enrollment Visits are conducted to ensure newly enrolling providers, and their staff members are provided with education about requirements and have appropriate resources to implement program requirements prior to being approved to participate in VFC. (These visits are also required for providers who did not maintain an active enrollment status and had a break between enrollment periods.)
- Education on VFC requirements through a webinar is required for Vaccine Coordinators and Backup Coordinators. Successful completion of the quiz is required. Training is required:
  - o annually (each year's course is updated),
  - o for newly assigned Vaccine Coordinators and Back-up Coordinators,
  - o prior to newly enrolling provider locations receiving approval to participate in VFC.

Access to the training for required staff is provided after an accurately, completed VacTrAK Add/Modify User Form has been processed and staff have been enrolled into the course. A link to the course is then emailed to the enrollee.

Additional staff (who are not required to take the training) may gain access to the course by emailing a request to vfc@alaska.gov.

• VFC Compliance Visits are conducted to assess vaccine management and immunization practices to ensure providers are compliant with requirements and provide an opportunity for education.

- VFC Vaccine Storage and Handling Visits are conducted to assess vaccine storage and handling
  practices to ensure providers are compliant with requirements and provide an opportunity for
  education. These visits may be planned in advance with providers or may occur without advanced
  notice.
- VFC Contacts are designed to provide additional education that focuses on specific requirement areas of need. VFC Contacts may be requested by provider/staff or may be Immunization Program required.

All QA activities conducted by the Immunization Program are designed to provide education and opportunities for providers to correct noncompliant practices and to ensure VFC providers operate in a manner that prevents fraud and abuse of the federal program.

The Immunization Program is required to investigate potential fraud and abuse if found during QA activities and when reported to the program. Referrals to the Immunization Program for investigation into fraud/abuse of the VFC program may be made by Immunization Program or provider staff, or the public. Referrals may be submitted via email to <a href="mailto:immune@alaska.gov">immune@alaska.gov</a> or <a href="mailto:vfc@alaska.gov">vfc@alaska.gov</a> or by calling the program at 888-430-4321 (toll free) or 269-8088 (Anchorage) and requesting to speak with the Immunization Program or Deputy Program Manager.

Examples of VFC program fraud and abuse include, but are not limited to:

- Failure to comply with any part of the Provider Agreement
- Providing VFC vaccine to non-VFC-eligible persons
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC vaccine
- Charging more than \$27.44 per dose for administration of VFC vaccine to non-Medicaid eligible child(ren)
- Denying VFC-eligible child(ren) VFC-funded vaccine because of person's inability to pay the administration fee or having unpaid vaccine administration fee(s)
- Issuing more than a single bill to a patient for VFC vaccine administration or issuing a bill after 90 days of vaccine administration
- Submitting an unpaid VFC administration fee to collections
- Failure to screen for and document eligibility status at each visit
- Failure to maintain VFC records for a minimum of three years
- Failure to fully account for VFC-funded vaccine
- Failure to properly store and handle VFC vaccine
- Over-ordering VFC vaccine (e.g., quantities or patterns that do not match the provider's profile)
- Wasting VFC vaccine

## Enrollment and Unenrollment

#### Enrollment

Enrollment into the VFC Program is a multistep process that includes tasks that must be completed by provider and Immunization Program staff members. The time it takes to complete the process depends on how quickly each task is successfully completed. To better ensure they will have state-supplied vaccine when they'd like to, providers should begin the enrollment process two to three months in advance.

Providers interested in receiving vaccines through the Immunization program, may contact <a href="mmune@alaska.gov">immune@alaska.gov</a> and specify whether they are interested in receiving pediatric vaccine. Program staff will contact providers to begin the process. Once it begins, the expectation is for providers to remain active

in the enrollment process. Providers who do not complete their tasks within three months may be asked to begin anew to ensure information provided is current.

At the end of the process instructions on how to submit a VFC Provider Agreement in VacTrAK will be emailed. The VFC Provider Agreement is an acknowledgment of providers' understanding of, and agreement to, maintain the requirements of the VFC program. The Immunization Program holds the Certifying Provider responsible for the assurance that requirements for VFC Program participation are met. (For agreement language see pages 14 through 15)

Federally Qualified Health Centers (FQHCs)/Rural Health Centers (RHCs) should identify themselves as such when enrolling to receive vaccines with the following CDC exception: "for tribal or urban Indian health clinics, "Indian Health Service, Tribal, or Urban Clinic" will be the provider type designation. (Only FQHCs/RHCs and deputized providers may use "underinsured" as a VFC eligibility category.)

Providers receiving state-supplied vaccines are assigned a unique six-digit Provider Identification Number (PIN). It is necessary for providers to reference the assigned PIN in all communication with the Immunization Program (i.e., calls, voicemails, emails).

#### Unenrollment

Unenrolling from the VFC program may be provider or Immunization Program determined. Providers who choose to unenroll must email <a href="mailto:vfc@alaska.gov">vfc@alaska.gov</a> within 30 days of planned agreement termination and include the following information to ensure timely contact from Immunization Program staff:

- Organization/facility name
- PIN
- Contact person
- Contact phone
- Date of unenrollment
- Reason for ending VFC Program participation

Program staff will contact provider staff to assist with state-supplied vaccine inventory.

## CDC approved VFC Provider Agreement language

## PROVIDER AGREEMENT

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: I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility 1. changes during the calendar year. 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: A. Federally Vaccine-eligible Children (VFC eligible) 1. Are an American Indian or Alaska Native; 2. Are enrolled in Medicaid: 3. Have no health insurance; 4. 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). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health 2. Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement. B. State Vaccine-eligible Children a) In addition, to the extent that my state designates additional categories of children as "state vaccineeligible," I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 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. 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 3. deems such compliance to be medically inappropriate for the child; b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions. I will maintain all records related to the VFC program for a minimum of three years, or longer if required by state law, and upon request make these records available for review. VFC records include, but are not limited to, VFC 4. screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records. 5. I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine. I will not charge a vaccine administration fee to non-Medicaid federally-vaccine eligible children that exceeds the administration fee cap of \$27.44 per vaccine dose. For Medicaid children, I will accept the reimbursement for 6. immunization administration set by the state Medicaid agency or the contracted Medicaid health plans. I will not deny administration of a publicly purchased vaccine to an established patient because the 7. child's parent/guardian/individual of record is unable to pay the administration fee.

	I will distribute the current Vaccine Information Statement (VIS) (or Immunization Information Statement for nirsevimab) each time a vaccine is administered and maintain records in accordance with the National Vaccine Injury Compensation Program (VICP), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
8.	Note: Untila COVID-19 Vaccine Information Statement (VIS) becomes available, provide information prior to vaccination as follows: EUA Fact Sheet for Recipients, Emergency Use Instructions (EUI), or BLA package insert, as applicable.
	For nirsevimab when not co-administered with other vaccines, report all suspected adverse reactions to MedWatch. Report suspected adverse reactions following co-administration of nirsevimab with any vaccine to the Vaccine Adverse Event Reporting System (VAERS).
	I will comply with the requirements for vaccine management including:
	a) Order vaccine and maintain appropriate vaccine inventories;
	<ul><li>b) Not store vaccine in dormitory-style units at any time;</li><li>c) Store vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage</li></ul>
9.	<ul> <li>Store vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet Alaska Immunization Program storage and handling recommendations and requirements;</li> </ul>
	d) Return all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six
	months of spoilage/expiration
	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:
	<b>Fraud:</b> 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.
10.	<b>Abuse:</b> 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.
11.	I will participate in VFC program compliance site visits, including unannounced visits and other educational opportunities associated with VFC program requirements.
	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.
	Note: "Walk-in" refers to any VFC-eligible child who presents requesting a vaccine, not just established patients.
12.	"Walk-in" does not mean that a provider must serve VFC patients without an appointment. If a provider's office
12.	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.
	For providers with a signed deputization Memorandum of Understanding between a FQHC or RHC and the Alaska
	Immunization Program to serve underinsured VFC-eligible children, I agree to:  a) Include "underinsured" as a VFC eligibility entagery during the screening for VFC eligibility at every
	a) Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit;
	b) Vaccinate "walk-in" VFC-eligible, underinsured children; and
	Submit required deputization reporting data
	Note: "Walk-in" in this context refers to any underinsured child who presents requesting a vaccine, not just
13.	established patients. "Walk-in" does not mean that a provider must serve underinsured patients without an
	commence patients. That in does not mean that a provider mast serve undermistred 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 underinsured patients as well. "Walk-in" may also include VFC-eligible newborn infants at a
	birthing facility.
	Providers must order vaccines and manage inventory within VacTrAK using the Vaccine Ordering and
	Management System (VOMS). In addition, all providers must submit administration data to VacTrAK
14.	within 14 days.
	For providers with Alaska Immunization Program approval to store and distribute publicly funded vaccines, I agree
	to:
	a) Maintain appropriate vaccine inventories to fill provider orders;
	b) Store vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage
	units and temperature monitoring equipment and practices must meet Alaska Immunization
	Program storage and handling requirements; and
15.	c) Transport vaccine under proper storage and handling conditions. Refrigerator and freezer vaccine
	transport units and temperature monitoring equipment must meet Alaska Immunization Program storage and
	handling requirements.
	I understand this facility, or the Alaska Immunization 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 Alaska
16.	Immunization Program.

Note: For information regarding the Alaska Vaccine Assessment Program Provider Agreement, contact <a href="mailto:avap@alaska.gov">avap@alaska.gov</a>.