2017 ALASKA VACCINE DISTRIBUTION HANDBOOK

Alaska Immunization Program requirements, policies and procedures

Alaska Immunization Program Operations Manual

Contents

Vaccine Funding and Program Accountability

State-supplied vaccine are purchased with the federally funded Vaccines for Children (VFC) program, Section 317 of the U.S. Public Health Service Act funds, fees assessed on health insurers for covered lives, and fees assessed on opt in health care providers for uninsured adults.

Through these funding sources:

- All vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are supplied at no charge, through a combination of federal and state dollars, for all Alaska children 0 through 18 years of age.
- Select adult vaccines are supplied at no charge.

The multiple funding sources require dose level accountability for each vaccine administered. The Alaska Immunization Program is responsible for ensuring this, and all other accountability requirements are met.

Federal and state requirements mandate that the Alaska Immunization Program conduct quality assurance and education with each provider receiving state-supplied vaccine through the following:

VacTrAK: Per Alaska Administrative Code 7AAC 27.650, ALL immunizations administered (state-supplied and privately purchased) must be entered into VacTrAK, (Alaska's immunization information system) and all patient ages (children and adults).

This statewide central repository of immunization information is used by the Immunization Program to monitor vaccine management and track provider VFC accountability requirements. While providers do not have to physically separate public vaccines by funding source, eligibility **MUST** be documented for each patient for each dose in VacTrAK.

Provider Enrollment Visit (Includes providers who have previously inactivated with Program):
The purpose of this visit is to ensure providers and their staff members are provided with education about all accountability requirements, and have appropriate resources to implement program requirements.

Education Requirement: The purpose is to assist providers in meeting program requirements.
This is required of the vaccine coordinator and the back-up vaccine coordinator and new certifying providers. The Alaska Immunization Program will provide a link to the education course.

Compliance Visit: The purpose of this visit is to assess vaccine management and immunization practices to ensure compliance with federal and state requirements and providing education.

Unannounced Storage and Handling Visit: The purpose of this visit is to assess vaccine inventory and storage practices.

AFIX is a several months' long quality improvement strategy used to raise immunization coverage levels, reduce missed opportunities, and improve standards of practices at the provider level. The process consists of the following:

Assessment: Assessment refers to the quantitative and qualitative evaluation of immunization records to ascertain the immunization level for a defined age cohort of children. Assessment includes:

- Evaluating a provider's vaccination coverage levels and immunization practices
- Identifying opportunities for improvement of vaccination coverage levels and reducing missed vaccination opportunities.

Feedback: Feedback is the presentation and discussion of Assessment findings including service delivery practices. Feedback can give insight on quality improvement (QI) strategies, patient drop-out rates, missed opportunities, and inappropriate use of contraindications. Feedback includes:

- Facilitating discussion among office staff
- Identifying and implementing quality improvement strategies
- Encouraging participation in goal setting
- Supporting the use of continuous Assessments to monitor these goals

Incentives: Incentives are techniques used to encourage individuals or organizations to improve immunization services, recognize and reward improved performance.

eXchange: This is an evaluation of progress toward implementing the quality improvement strategies decided upon during the Feedback process.

Additional information regarding the process can be found at: Assessment, Feedback, Incentives, and eXchange Program (AFIX).

Provider Requirements

Providers are required to participate in and conduct accountability activities in order to receive state-supplied vaccine.

Enrollment to Receive State-supplied Vaccine

For instructions on how to complete the Provider Agreement, see Vaccine Provider Agreement Instructions.

The Provider Agreement is binding and will remain in effect until:

1. Alaska Immunization Program terminates the agreement, at any time, for failure to comply with the program requirements.
2. Facility terminates the agreement for reasons determined by the Certifying Provider.
3. There is a change in the Certifying Provider and/or entity name, or failure to renew annual enrollment.

By agreeing to the Provider Agreement terms and conditions, the Certifying Provider is communicating the willingness to participate in, and abide by, Alaska Immunization Program requirements to receive state-supplied vaccine.

Inactivated providers will be contacted by Immunization Program staff for instruction on the proper transfer or return process for all vaccines on hand.

Provider Identification Number

The Immunization Program will issue each facility a unique six-digit Provider Identification Number (PIN). Referencing the PIN in the subject line of any correspondence with the Immunization Program will expedite the processing of your information or request.

Fraud and Abuse

Federal fraud and abuse laws apply to providers receiving state-supplied vaccine. The following definitions are consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 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. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

If it is determined that providers are not adhering to federal and state requirements, the Alaska Immunization Program may investigate for fraud and abuse and will implement corrective actions or inactivate the provider from the program. Fraud or abuse can occur in many ways; examples include the following:

- Providing state-supplied vaccine to non-eligible patients
- Selling or otherwise misdirecting state-supplied vaccine
- Billing a patient or third party for state-supplied vaccine
- Charging more than the established maximum regional fee cap for administration of a state-supplied vaccine to a VFC non-Medicaid eligible child
- Denying VFC-eligible children state-supplied vaccine because of a parents' inability to pay for the administration fee
- Failing to implement requirements of the Alaska Immunization Program
- Failing to screen and document eligibility status for every vaccine dose administered
- Failing to maintain all program required records for three years
- Failing to fully account for state-supplied vaccine

- Failing to properly store and handle state-supplied vaccine
- Ordering state-supplied vaccine in quantities or patterns that do not match the provider's profile or otherwise over-ordering vaccine
- Negligent waste of state-supplied vaccine

Provider agreement to receive state-supplied vaccines

Submission of the agreement is considered an electronic signature from the certifying provider as acknowledgement of understanding and agreement to maintain the requirements of the VFC Program. By submitting the Provider Agreement, the certifying provider is held responsible for the assurance that all VFC program accountability requirements are met.

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 healthcare facility of which I am the medical director or practice administrator or equivalent:

1) I will screen patients and document eligibility status at each immunization encounter for VFC eligibility and administer VFC-purchased vaccine only to children who are 18 years of age or younger who meet one or more of the following categories:
    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). 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
2) I will comply with immunization schedules, dosages, and contraindications that are established by the
3) 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;
    b. The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
4) I will maintain all records related to the VFC program for a minimum of three years, or longer if required by state law, and make these records available to public health officials, including the state or Department of Health and Human Services, (DHHS) upon request.
5) I will immunize eligible children with VFC-supplied vaccine at no charge to the patient for the vaccine.
6) I will not charge a vaccine administration fee to non-Medicaid VFC-eligible children that exceeds the administration fee cap of $27.44 per vaccine dose For Medicaid VFC-eligible children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.

7) I will not deny administration of a federally purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
8) I will distribute the most current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
9) I will comply with the requirements for vaccine ordering, vaccine accountability, and vaccine management. Agree to operate within the VFC program in a manner intended to avoid fraud and abuse. VFC providers may not store federally purchased vaccine in dormitory style refrigerators at any time. Return all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.
10) I will participate in VFC program compliance site visits, storage and handling unannounced visits, and other educational opportunities associated with VFC program requirements.

I understand this facility or the state/local immunization program may terminate this agreement at any time for personal reasons or failure to comply with these requirements. If I choose to terminate this agreement, I will properly return any unused VFC vaccine.

Additional requirements based on Alaska-specific policies and laws:

State vaccine-eligible

• Underinsured children are considered state vaccine-eligible (e.g., underinsured children not served through an FQHC or RHC) for administration of pediatric vaccines purchased with Section 317 or state funds.

Deputization

For providers with a signed Memorandum of Understanding between a FQHC or RHC and the state/local immunization program to serve underinsured VFC-eligible children, I agree to:

- Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit;
- Vaccinate "walk-in" VFC-eligible underinsured children and
- Report required usage data

Immunization Information System Requirement

Providers must order vaccines and manage inventory within VacTrAK using the Vaccine Ordering and Management System (VOMS). In addition, those receiving state-funded vaccine must submit administration data to VacTrAK within 14 days.

Staffing requirements

Certifying Provider

- Must hold a current license in Alaska
- Must have prescriptive authority for vaccines

- Will be responsible and held accountable for compliance.

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.

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

- Vaccine Coordinator who is responsible for providing oversight for all vaccine management within the facility and ensuring all vaccines are stored and handled correctly. The individual must have the certifying provider's supporting authority to implement and enforce all program requirements.
- Back-up or alternate vaccine coordinator who assumes oversight and vaccine management responsibilities in the absence of the primary vaccine coordinator.

Reporting Changes in Staff/Facility Status

Providers are required to report certain facility and staff changes to the Immunization Program. See Provider Information Change chart for required reporting, including, but not limited to:

- Staff changes (providers, vaccine and/or back up coordinator, AFIX contact, VacTrAK Administrator)
- Mailing/shipping address
- Vaccine delivery hours
- Facility closure/merger

Eligibility/Fees/Documentation Requirements

All facility staff must possess a working knowledge of ALL eligibility criteria and use those criteria to screen for and document eligibility at each immunization visit. Eligibility documentation (electronic or paper) must be retained for three years.

All children 0 through 18 years are eligible to receive state-supplied. Administration fees are determined by eligibility status. See state-supplied eligibility for children.

Adults age 19 years and older meeting specific criteria are eligible to receive select state-supplied vaccines. See state-supplied vaccine eligibility for adults.

Per Alaska Administrative Code 7 AAC 27.650: Within 14 days of administering a vaccine, ALL health care providers must document dose-level eligibility status in VacTrAK. This reporting requirement is applicable for any vaccine administered, including state-supplied and privately purchased vaccines. For details on requirements refer to the Conditions Reportable to Public Health Manual: Conditions Reportable to Public Health.

Vaccine administration documentation (electronic or paper) must include the following:

- Patient information

    - First and last name and middle initial
    - Address
    - Sex
    - Race
    - Date of birth
- If a minor: Parent/Guardian/Individual of Record's first and last name and middle initial
- Primary provider's name
- Vaccine administration date
- Vaccine lot number
- Vaccine dose amount and manufacturer
- VIS version date and date given to patient/guardian
- Dose-level vaccine eligibility status

Providers must distribute a current Vaccine Information Statements (VIS) to a patient each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Adverse Event Reporting System (VAERS).

Vaccine Storage and Handling Practices

Even a small practice is likely to have thousands of dollars' worth of vaccine in the refrigerator at a time. Vaccines must be stored appropriately in order to maintain potency. A temperature controlled environment used to maintain and transport vaccines in optimal condition is called the vaccine cold chain and relies on three main elements:

- Effectively trained personnel
- Appropriate transportation and storage equipment
- Efficient management procedures

Vaccine Storage Units

Providers must have appropriate equipment that is used only for vaccine storage and pharmaceuticals and maintains proper temperature required conditions for vaccine storage. Information about each storage unit used within your practice to store any amount of state-supplied vaccine for any length of time must be submitted in the Provider Agreement.

For additional information on storage units review Vaccine Storage Unit Requirements.

Placement and organization within the storage unit is vital to maintaining vaccine 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 vaccine refrigerators or freezers.
- Segregate and/or mark vaccine inventory to easily distinguish privately purchased vaccines from state-supplied vaccines.

- Rotate stock to ensure vaccine with earliest expiration date is administered first.

Small trays may be used to quickly move stock within a refrigerator, reducing the amount of time the door must remain open, potentially exposing vaccines to warmer air temperatures.

Storage Unit Temperature Monitoring

Refrigerator storage units must maintain temperature between 36°F and 46°F at all times. Setting the temperature to achieve an average of 40°F degrees will provide the best safety margin.

Freezer storage units must maintain temperatures between -58°F and +5°F at all times.

Providers must use currently calibrated, continuous temperature monitoring devices (i.e., data logger) for:

- Routine onsite storage
- During transport
- Mass vaccination clinics
- Back up thermometers

The Immunization Program will no longer require the use of state-supplied LogTags. Providers are responsible for the purchase of their own temperature monitoring devices, however, the Immunization Program will continue to provide LogTags upon request and as grant funding allows.

Temperature monitoring device requirements:

- Capacity for continuous monitoring and recording capabilities where data can be routinely downloaded
- Buffered temperature probe
- Active temperature display that can be easily read from the outside of the storage unit
- Alarm for out-of-range temperatures
- Display of current, minimum, and maximum temperature
- Accuracy ±1° Fahrenheit/.5° Celsius
- Low battery indicator
- Memory stores at least 4,000 readings
- Device reads and records a temperature at minimum of every 15 minutes. A reading of every 5 minutes is preferred.
- Current calibration certificate that contains:
    - Name of device (optional)
    - Model number
    - Serial number
    - Date of calibration
    - Measurement results indicate unit passed test
    - Documented uncertainty is within suitable limits (recommended uncertainty 1F/.5C)

Documentation indicating all temperature monitors are currently calibrated must be readily available to the Alaska Immunization Program upon request.

Temperature monitoring devices 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.

For providers using LogTags, instructions are available at LogTag Software and Device Initial Setup and LogTag Instructions for Daily Use.

Each day the facility is staffed, temperatures for each state-supplied vaccine storage unit must be recorded on the current Vaccine Temperature Log. This documentation must be kept for three years and readily available to the Alaska Immunization Program upon request.

Temperature monitoring device graphs must be downloaded weekly and reviewed for temperature excursions. This documentation must be kept for three years and readily available to the Alaska Immunization Program upon request.

Temperature Excursions

Immediately upon discovering any vaccine storage temperature has fallen outside the acceptable range for **any length** of time (also known as an "excursion"), follow the guidelines and procedures outlined in the Temperature Excursion Instructions and submit the required Temperature Excursion Report.

Inventory

Vaccine inventory must be monitored. **The receipt and acceptance of state-supplied vaccine after the date of the Provider Agreement electronic signature is an additional acknowledgment and acceptance of the terms outlined in the Provider Agreement.**

Because all pediatric vaccines provided by the Immunization Program are partially supported with VFC funds, vaccine providers enrolled to receive childhood and adolescent state-supplied vaccine are considered VFC providers. VFC providers are required to stock all routine ACIP-recommended vaccines based on their Provider Agreement and Profile. VFC Providers are also required to ensure that eligible children have access to non-routine vaccines as needed.

State-supplied vaccine orders are placed and inventory tracked through VacTrAK's Vaccines Ordering Management System (VOMS). VOM training resources are available on the VacTrAK website.

Providers are required to maintain a minimum six-week supply of vaccine. Multiple orders within a month will not be processed.

To determine vaccine order quantity, the following must be considered:

- current inventory
- recent vaccine usage
- upcoming expiration dates
- seasonal need changes (i.e., back to school season)

Direct Ship Vaccines

Due to special shipping and storage conditions, varicella and zoster vaccines are shipped directly from the manufacturer to the provider. This special shipping process requires one to three weeks once an order is approved. Contact Merck if your shipment was in transit greater than 72 hours to determine the viability of the vaccine.

Shipment and Receipt of Vaccine Orders

Providers should check the status of a submitted order in VacTrAK.

- "Approved" indicates that the order has been reviewed by Program staff
- "Shipped or Ready for Pick Up" indicates the order is ready for pickup at the depot or has been shipped to the provider.

Depot hours for local pick up: Wednesday 8:30 a.m. – 4:30 p.m. only.

Procedures for Vaccine Receipt

All facilities must have procedures in place for immediate receipt and storage of vaccine due to temperature sensitivity. All facility staff must be trained to recognize a vaccine shipment when it is delivered and what should be done upon its arrival in your facility. Follow these steps for receiving vaccine:

3. Check the LogTag included in each shipping container(s) for an alarm notification.
4. Verify shipment invoice for vaccine quantity, lot number, and expiration date. Contact the Depot with invoice discrepancies.
5. Immediately place all vaccines in your storage unit(s). (Isolate vaccines with temperature excursions, label them as "do not use" until the viability is determined by Depot staff.)
6. Review expiration date(s) and rotate stock so that vaccine with the earliest expiration date is stored in front of vaccine with a later expiration date.
7. Receive your order in VacTrAK.
   Mail the shipment LogTag to the Depot using the included postage-paid box. Future orders will not be processed until the LogTag is returned.

Vaccine Transfers between Enrolled Facilities

Transferring vaccine should be a rare occurrence. Vaccine transfers must be pre-authorized to ensure the receiving provider is enrolled to receive state-supplied vaccine and appropriate vaccine accountability has been maintained. The cold chain must be maintained during the transfer process following Vaccine Transport Methods.

"Borrowing" between a provider's privately purchased inventory and their state-supplied vaccine stock is not permitted.

Vaccine Returns

Vaccine wastage must be kept to less than five percent of your annual state-supplied vaccine received.

State-supplied vaccines that have expired or are spoiled/wasted must be reconciled in VacTrAK. (See Vaccine Ordering Management System Training Materials.) Within 30 days, send the vaccine and VacTrAK Vaccine Returns page to the Depot. The non-viable vaccines can be hand-delivered or mailed in a box with enough packing material to prevent breakage during transport. Cold packs are not required. The Immunization Program obtains a partial credit on all vaccines returned.

Do not return any privately purchased vaccines or needles to the Depot.

Emergency Response Plan

Each facility is required to have a written emergency response plan outlining your 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 emergency response plan.

The written plan must:

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

An Emergency/ Power Outage Plan for Vaccines template is available.