AVAP

ALASKA VACCINE ASSESSMENT PROGRAM

MANUAL

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Introduction

The Alaska Vaccine Assessment Program (AVAP) operates to ensure that insured Alaskans and uninsured adults have access to all Advisory Committee on Immunization Practices (ACIP) recommended vaccines.

In 2014, the State of Alaska enacted a statewide funding partnership (Alaska statute 18.09.200) to safeguard universal purchase of childhood and adult vaccines. The program ensures that Alaskans gain improved access to vaccines, health care providers receive state-supplied vaccines at no charge, and payers benefit from cost savings through the state's bulk vaccine purchase and distribution.

Through AVAP, the state serves as the single purchaser of childhood and adult vaccines and receives a more favorable pricing. These savings lower health care costs and, ultimately, help hold down rising premium costs for individuals and benefit costs for employers.

How does the program work?

1. The AVAP Council recommends an annual assessment rate, which is approved by the Alaska Commissioner of Health.
2. Assessment fees are collected from payers including opt-in for uninsured adults.
3. Health care providers order vaccines
4. Health care providers vaccinate eligible Alaskans, only billing payers for administration fees.
5. All vaccines administered are reported to VacTrAK.
6. Vaccine administration data is reviewed annually.

AVAP Program Requirements

Eligible health care providers may enroll to receive state-supplied vaccine from the Alaska Immunization Program. Program enrollment approval and continued participation is contingent upon provider compliance with requirements found on the Alaska Immunization Program website and in the Provider Agreement.

Vaccine Management Plan

This manual and associated documents found on the Alaska Immunization Program's website act as each provider's vaccine management plan. These documents provide current federal and state standard operating procedures (SOPs) for routine program management and participation by providers.

Providers are required to create custom SOPs for vaccine emergency planning.

Provider Agreement and Staff

The AVAP Provider Agreement authenticates that the certifying provider is held responsible for the assurance that all program accountability requirements are met. An updated AVAP Provider Agreement is required annually (unless the certifying provider and/or facility address changes). The agreement is found and completed in VacTrAK.

Each facility is required to have a certifying provider. The "certifying provider" must be a practitioner (NP, ANP, DO and MD) authorized to administer vaccines under state law. A PA cannot be a certifying provider. That individual will be held accountable for the entire facility's compliance with conditions and responsibilities found in the Agreement and the Requirements Manual.

The certifying provider must identify a vaccine coordinator and back-up vaccine coordinator who work onsite and will be responsible for managing the program. The Certifying Provider may serve in one of those positions. Each staff member selected must be knowledgeable about and have the authority to implement policies and procedures to remain compliant with requirements. These staff members will be primary points of contacts for Immunization Program staff members and the certifying provider.

In addition to identifying the staff members above, the agreement must include all licensed health care providers (MD, DO, ANP, NP, PA) at the facility, including the certifying provider, who have prescribing authority.

Provider Agreements must be resubmitted when the certifying provider changes within a clinic/practice or the facility address changes.

Provider Profile

The past 12 months' vaccine administration data will automatically populate in each clinic/practice's Provider Profile within VacTrAK. The data consists of the number of non-VFC eligible children and adults by age cohorts.

The information is used to determine how much vaccine to order for each population served and assists the Alaska Immunization Program with determining statewide vaccine needs. For these reasons, the information in the profile must be reviewed for accuracy annually and updated or corrected as applicable.

Facility/Staff Change Notifications

Changes in staff must be reported to the Alaska Immunization Program by submitting a VacTrAK Add/Modify User Form within 10 days. Changes in a certifying provider or facility information will require a new provider agreement to be submitted in VacTrAK and should be reported within 10 days of the change. Email AVAP@Alaska.gov with questions on how to report other changes.

Program Unenrollment

Unenrolling from the program may be determined by the provider or Alaska Immunization Program. If the provider has not ordered vaccine within a calendar yet, the vaccine provider will be unenrolled.

Advisory Committee on Immunization Practices (ACIP)

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee that provides advice and guidance on effective means to prevent vaccine-preventable diseases. Providers must comply with ACIP immunization recommendations.

You Call The Shots is a CDC interactive, web-based immunization training course. It consists of a series of modules that discuss vaccine-preventable diseases and explain the latest recommendations for vaccine use.

Eligibility

Screening to determine eligibility and documenting the current eligibility status must take place at each immunization visit for all patients. Reference the Immunization Program eligibility charts for both adults and children. Screening results must be documented at each immunization visit even if there is no change in eligibility status.

AVAP-only providers can administer state-supplied vaccine to privately insured children and adults.

Facilities that have opted-in and paid the annual fee for uninsured adults, can also administer state-supplied vaccine to uninsured adults.

Information on documenting patients eligibility criteria can be found on the Adult Vaccine Eligibility and Billing Information form. It is considered fraud and abuse to document a VFC eligibility criteria for an adult.

Fee Policies for Vaccines and Vaccine Administration

Fee information for patients receiving state-supplied vaccines:

- Vaccine: Providers cannot charge for the cost of any vaccine received from the Alaska Immunization Program
- Administration: Providers can bill either the payers or the patients directly for vaccine administration fees, as their current practice.

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.

Storage Units

Facilities are required to have appropriate storage units for the vaccines that they offer.

Storage units must be able to maintain the following CDC required temperature ranges:

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

The following vaccine storage unit types are acceptable for use:

- Pharmaceutical grade stand-alone or combination units
- Household/commercial stand-alone units
- Household/commercial combination units only using the refrigerator section

Appropriate storage units must:

- Have enough space to store the largest inventory a provider might have at the busiest time in the year without crowding the vaccine
- Maintain appropriate temperatures at all times
- Be protected from disconnection from the power source. Label outlets and circuit breakers with "Do Not Unplug" or “Do Not Disconnect” signage

Providers cannot use dormitory-style units for vaccine storage at any time, including temporary vaccine storage. (Dormitory-style units have both refrigerator and freezer compartments behind a single exterior door.)

For more information on storage read The Vaccine Storage and Handling Toolkit. The Toolkit is a comprehensive guide that reflects best practices for vaccine storage and handling from Advisory Committee on Immunization Practices (ACIP) recommendations, product information from vaccine manufacturers, and scientific studies.

Unit Set-up

- Separate and clearly designate privately purchased vaccine from state-supplied, and then pediatric and adult vaccines. This will prevent administering state-supplied vaccine to non-eligible patients (“Borrowing”, which occurs within a single facility and involves temporary sharing between a provider’s privately purchased and state-supplied vaccine is **not** permitted)
- Store shorter-dated vaccines in front of longer-dated vaccines and administer vaccines in expiration date order to prevent wastage
- Store water bottles to assist with temperature stabilization
- Store vaccine in the center of unit with space between vaccines and the unit’s sides and back to allow air circulation
- Store vaccine away from cooling vents
- Use trays for quick movement of stock reducing the amount of time the door is open
- Remove deli, fruit and vegetable drawers
- Do not store food and drink in vaccine storage units
- Store vaccines in their original manufacturer boxes
    - Prevents damage to vials/syringes
    - Protects light sensitive vaccines
    - Easier for managing stock rotation and viewing expiration dates
    - If excursion occurs, easier to mark boxes

Temperature Monitoring Devices

All temperature monitoring devices (including back-up devices) must have the following features:

- Continuous monitoring (provides vaccine temperatures over time)
- Data can be downloaded and reviewed
- A probe (use only the one bundled with the device)
- Active temperature display that can be easily read from the outside of the storage unit
- Display of current, minimum, and maximum temperatures
- Ability to trigger an alarm for temperature recordings outside of acceptable storage temperatures
- Memory stores at least 4,000 readings
- Device reads and records a temperature at minimum of every 30 minutes.
- Calibration testing certificate containing:
    - Name of device (optional)
    - Model number
    - Serial number
    - Date of calibration
    - Measurement results indicate unit passed test

Re-calibration of devices is required within two years of the last calibration date. Providers are responsible for purchasing and re-calibrating their own temperature monitoring devices.

Temperature Monitoring Documentation

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

- Current, minimum, and maximum temperatures
- 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

Additionally, data from monitoring devices must be downloaded and reviewed weekly, as well as when temperatures have gone out of range.

Temperature Excursion

Temperatures outside of CDC determined temperature ranges for any length of time are “excursions” (e.g., 47.0°F). Each time an excursion occurs the following actions are required:

- Immediately mark vaccine “Do Not Use” to prevent administration of potentially nonviable vaccine
- Determine cause of excursion and work to bring unit back into range
- Implement vaccine emergency plan if necessary
- Contact manufacturers to determine vaccine viability
- Submit a temperature excursion report

Emergency Response Plan

Providers are responsible for having appropriate transport equipment and for developing their own

written SOPs for vaccine management in the event of an emergency (e.g., equipment malfunctions, power failures, or natural disasters). An emergency plan template is available to print, fill out and post on your storage units.

The plan must always contain:

- A signature or initials of a staff member who is responsible for its content
- The date of review and when it was updated
- Vaccine coordinator and a back-up coordinator's information (persons responsible for vaccine management)

The plan must be updated annually and whenever there is a change to procedures or contact staff.

Posting the plan with transport instructions in a prominent place (e.g., on storage units) is strongly recommended so any staff member will understand what actions need to be taken and who to contact.

Vaccine Inventory

Borrowing between privately purchased vaccine and that provided through the Immunization Program is not an acceptable practice. To prevent errors and vaccine borrowing, providers:

- Must perform monthly inventory reconciliation
- AVAP providers are not required to order and store all available vaccines and can order based on the needs of the practice
- Must accurately screen and document eligibility
- Must separate privately purchased vaccines from those funded through AVAP
- Must administer vaccines to adults only as indicated on the adult eligibility chart
- Should implement a way to separate pediatric and adult vaccines

Vaccine Orders

Orders for vaccine are placed through VacTrAK (see Vaccine Ordering and Management).

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

- Current inventory
- Recent vaccine usage
- Upcoming expiration dates
- Seasonal need changes (e.g., flu season)
- Provider profile
- Storage capacity

Providers should place smaller, more frequent orders. Over-ordering, stockpiling, or building inventory can put vaccine at risk for waste from an excursion or expiration. Place vaccine orders when you have reached a minimum 4 week supply. Allow up to 3 weeks to receive a shipment. Order vaccine 4 weeks ahead for a vaccine POD or pop-up clinic.

Inventory must be reviewed and submitted in VacTrAK every month and no more than 14 days prior to placing a vaccine order.

Orders will not be approved for providers in an overdue accountability status until they are compliant with requirements.

Once placed, providers should monitor VacTrAK to verify orders have been approved and then shipped.

All staff in your facility should know what to do when vaccine arrives at your clinic. For details regarding vaccine shipments including what to do when shipment issues are identified, see Vaccine Distribution.

Vaccine waste/Loss prevention

In addition to preventing vaccine waste and expiration through appropriate storage and handling, providers must also prevent such by not pulling vaccine from units until just before administration and by ordering appropriately to prevent overstocking. Conducting reminder/recall activities and if necessary, transferring vaccine that will expire within six months will also help reduce waste.

Expired/spoiled vaccine and diluent must:

- Be removed from vaccine storage units to prevent administration
- Be placed in a container or bag and clearly labeled "DO NOT USE"
- Returned as instructed (see Vaccine Ordering and Management)
- Do not mail private vaccine to the Immunization Program

Documentation Requirements

Providers must maintain records related to the program for a minimum of three years and make these records available to the Alaska Immunization Program upon request.

Examples of records include, but are not limited to:

- Eligibility screening documentation
- Vaccine emergency plans
- Billing records
- Patient vaccine administration records
- Provider Agreement copy
- Downloaded temperature graph
- Temperature logs
- Temperature monitoring device calibration certificates
- Temperature excursion documentation
- Education and training records

All vaccines administered, state-supplied or privately purchased, must be documented in VacTrAK within 14 days of administration in accordance with Alaska Administrative code 7 AAC 27.650(a).

Federal Statute 42 US Code 300aa-25 requires the following be documented in the patient's medical record for each vaccine administered:

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

Federal law requires health care staff to provide the appropriate Vaccine Information Statements (VIS) to a patient, parent, or legal representative before administration of each dose of vaccine. Providers who use pre-printed or downloaded VIS must replace them within six months of a new publication date.

Report adverse events that occur after vaccine administration to the Vaccine Adverse Event Reporting System (VAERS).

Fraud and Abuse

When providers enroll to receive state-supplied vaccine they agree to comply with all the program's requirements. Federal fraud and abuse laws apply to the Alaska Immunization Program.

- Fraud: an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to him/herself or some other person. It includes any act that constitutes fraud under applicable federal or state laws
- Abuse: provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program

Examples of potential fraud and abuse of state-supplied vaccine include, but are not limited to:

- Failing to comply with any part of the Provider Agreement and program requirements
- Providing the vaccine to non-eligible people
- Billing a patient or third party for the vaccine
- Selling or misdirecting the vaccine
- Over-ordering the vaccine (e.g., in quantities or patterns that do not match the provider's profile)
- Wasting the vaccine
- Failing to screen for and document eligibility status at each visit
- Failing to maintain records for three years
- Failing to fully account for the vaccine
- Failing to properly store and handle the vaccine

Referrals for investigation into fraud/abuse may be made by immunization program or provider staff, or by the public. Referrals are made by contacting the Alaska Immunization Program and requesting to speak with the Program Manager or Deputy Program Manager.

Quality Assurance

To ensure the quality of state-supplied vaccine and the integrity of program requirements, the Alaska Immunization Program will conduct various types of quality assurance (QA) activities including:

- Education course – All new vaccine coordinators and back-up vaccine coordinators are required to take the course or at the time of provider agreement renewal. The course is available through a link provided by Immunization Program staff
- Compliance visits – to assess vaccine management and immunization practices to ensure providers are compliant with program requirements.
- Other education and training that focus on specific requirement areas of need. May be requested by provider/staff or required by the Immunization Program