

ALASKA VACCINE DISTRIBUTION HANDBOOK: 2016

Revised: April 11, 2016



Alaska Department of
Health and Social Services
Division of Public Health



ALASKA
IMMUNIZATION
PROGRAM

Alaska Vaccine Distribution Handbook: 2016

Revised: April 11, 2016

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Alaska Immunization Program

Contact Information

Epidemiology Vaccine Depot (Distribution Center for State-supplied Vaccines)

Phone:	(907) 341-2202
Email:	vaccinedepot@alaska.gov
Fax:	(907) 341-2228
Website:	http://dhss.alaska.gov/dph/Epi/iz/Pages/vaxpacket/default.aspx

Immunization Helpline

Immunization Helpline:	1-888-430-4321 or, in Anchorage, (907) 269-8088
Email:	immune@alaska.gov

VacTrAK (State of Alaska's Immunization Information System)

Phone:	1-866-702-8725 or, in Anchorage, (907) 269-0312
Email:	vactrak@alaska.gov
Fax:	(907) 562-7802
Website:	www.vactrak.alaska.gov

Other Information

Office Phone	(907) 269-8000
Fax	(907) 562-7802
Patient education and provider resources (i.e., free printable materials, posters, etc.)	http://dhss.alaska.gov/dph/Epi/iz/Pages/imrs/default.aspx

Introduction

The Alaska Immunization Program's vision is that all Alaskans are protected against vaccine-preventable diseases. Our mission is to prevent and control vaccine-preventable diseases statewide by:

- Providing vaccines to health care providers at no charge;
- Providing an immunization information system for use by health care providers and schools to maintain consolidated immunization records for Alaskans of all ages;
- Ensuring school and childcare compliance with immunization regulations;
- Providing immunization education and training for health care providers and the general public;
- Coordinating surveillance and control efforts for vaccine preventable diseases; and
- Supporting efforts to increase vaccinations for all Alaskans.

One way of accomplishing our vision is by using federal and state funds to obtain vaccines for distribution to eligible health care providers. These funding sources require both the Alaska Immunization Program and enrolled providers to be accountable for the use and management of these publicly-funded vaccines.

By submitting the Provider Agreement to receive state-supplied vaccines, providers agree that facility staff involved with vaccine management will comply with federal and state requirements. This handbook and associated documents found on the Alaska Immunization Program's website and linked throughout this handbook contain information that is part of each enrolled provider's vaccine management plan. All records related to state-supplied vaccine administration and management must be maintained for a minimum of three years.

If you have any questions or need assistance, please contact the Epidemiology Vaccine Depot.

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Acronyms

ACIP	Advisory Committee on Immunization Practices
AFIX	Assessment, Feedback, Incentives, eXchange
ANP	Advanced Nurse Practitioner
AVAP	Alaska Vaccine Assessment Program
CDC	Centers for Disease Control and Prevention
DO	Doctor of Osteopathy
FQHC	Federally Qualified Health Center
HRSA	Health Resources and Services Administration
MD	Medical Doctor
PA	Physician Assistant
PIN	Provider Identification Number
RHC	Rural Health Center
US DHHS	United States Department of Health and Human Services
VacTrAK	(State of Alaska's Immunization Information System)
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children Program
VIS	Vaccine Information Statement
VOMS	Vaccine Ordering and Management System

Revisions

Revision Date	Detail about Revision
January 1, 2016	First version of 2016
April 11, 2016	Formatting edits made throughout text; calibration certificate checklist updated (Appendix C)

1. Enrollment

1.1 Who May Enroll

Providers enrolling to receive vaccine from the Alaska Immunization Program must hold a license in Alaska, have prescribing authority for vaccines, and be a person (or persons) who will be responsible (and liable) for the conditions outlined in this Handbook for the facility or organization. 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. Providers in remote areas of the state may need to meet additional criteria, including having the ability to receive a vaccine shipment from the Epidemiology Vaccine Depot (“Vaccine Depot”) within 48 hours. Organizations self-identifying as a Federally Qualified Health Center (FQHC) must include a copy of their federal documentation each year with enrollment that validates their FQHC designation. Please contact the Vaccine Depot for additional information.

Providers enrolling in the Alaska Immunization Program to receive state-supplied vaccines must comply with ALL conditions contained in this handbook and the Provider Agreement.

1.2 Enrollment & Re-enrollment Process

Providers are required annually to complete both the VacTrAK Application and the Provider Agreement in order to receive state-supplied vaccine. Filling out the VacTrAK Application gives the provider access to VacTrAK, the State of Alaska Immunization Information System, and designates user authorizations and permissions. The Provider Agreement (located) within VacTrAK allows a provider to enroll to receive state-supplied vaccine.

For detailed instructions on how to complete the VacTrAK Application and Provider Agreement, please refer to the [2016 Vaccine Provider Agreement Instructions](#).

1.2.1 Enrollment Process

1. Complete the VacTrAK New Provider Application	Click here to fill out the VacTrAK New Provider Application. Submit to VacTrAK Support by email at vacktrak@alaska.gov or fax (907) 562-7802. Note that this initial process may take several weeks.
2. Complete the Provider Agreement	Login to VacTrAK and submit the Provider Agreement within VacTrAK. It is not necessary to print and submit the signature page to the Vaccine Depot unless your facility has a new certifying provider who is a PA. In this situation, print the signature page and have both the certifying provider and the collaborating physician sign the signature page. By submitting the Provider Agreement, the certifying provider is agreeing to ensure that all

	<p>program requirements and accountability are met. Print the “PDF Full” for your records.</p> <p>If your facility is a Federally Qualified Health Center (FQHC) or Rural Health Center (RHC), email or fax the Notice of Award from the United States (U.S.) Department of Health and Human Services (DHHS) Health Resources and Services Administration (HRSA) that validates your designation to the Vaccine Depot.</p>
3. Provider Enrollment Visit	Once enrollment has been approved, new providers will be contacted by the Vaccine Depot to arrange a Provider Enrollment site visit.
4. Order Vaccines	New providers will receive the ability to order vaccines after submitting two weeks of approved storage unit temperatures, reviewing the Vaccine Ordering and Management System (VOMS) training resources and completing the Provider Enrollment visit.
5. Education Webinar	The certifying provider, vaccine coordinator and the back-up vaccine coordinator of all facilities receiving state-supplied vaccine are required to complete an education webinar. The Alaska Immunization Program will notify all providers of the annual deadline with a link to the education webinar after enrollment.

1.2.2 Re-enrollment Process

1. Complete Annual VacTrAK Renewal	VacTrAK administrators will be contacted by VacTrAK support to update their information.
2. Complete the Provider Agreement	<p>Login to VacTrAK and submit the Provider Agreement within VacTrAK. Print the “PDF Full” for your records.</p> <p>If your facility is a FQHC or RHC, email or fax the Notice of Award from the U.S. DHHS HRSA that validates your designation.</p>
3. Provider Enrollment Visit	If re-enrolling providers have experienced a lapse of time in between enrollments, an enrollment visit may be required.
4. Order Vaccines	Re-enrolling providers will be able to resume ordering vaccines after the enrollment is approved.
5. Education Webinar	The vaccine coordinator and the back-up vaccine coordinator of all facilities receiving state-supplied vaccine are required to complete an education webinar annually. The Alaska Immunization Program will notify all providers of the annual deadline with a link to the education webinar after enrollment.

1.3 Fee Policies for Vaccines

Providers receiving state-supplied vaccine must comply with the following fee policies:

- Providers **cannot** charge a patient or health plan (i.e., payer) for the cost of a vaccine received from the Alaska Immunization Program.
- For non-Medicaid Vaccine For Children (VFC) eligible children, the administration fee cap is \$27.44 (for more information on the administration fee cap see: <http://dhss.alaska.gov/dph/Epi/iz/Documents/VFCOperationsGuide.pdf>).
- For Medicaid patients, the cap is the State Medicaid fee cap (see the following for more information: manuals.medicaidalaska.com/medicaidalaska/providers/FeeSchedule.asp).
- For privately insured patients, the administration fee is your contracted vaccine administration fee.
- State-supplied vaccine may not be denied to a patient due to the inability of recipient to pay an administration fee.

1.4 Provider Identification Number (PIN)

The Vaccine Depot will issue each facility a unique six-digit Provider Identification Number (PIN). Use this number in **ALL** email, fax, mail and phone interactions with the Vaccine Depot. Referencing the PIN in the subject line of any correspondence with the Alaska Immunization Program will expedite the processing of your information.

1.5 Provider Practice Profile

The Provider Practice Profile is a section within the Provider Agreement in VacTrAK. This section of the agreement defines the number of children and adults who received vaccinations for the full prior year at each facility. The Provider Practice Profile identifies eligibility status by age group. If you are a re-enrolling provider, the Provider Practice Profile will auto-populate with administration data for the prior year. Review carefully and update the numbers accordingly. It is essential to be accurate when describing your patient population in the Provider Practice Profile. Billing staff may be able to help you respond to this section of the Provider Agreement if you are using patient records to help determine your Provider Practice Profile. The Alaska Immunization Program uses the information in the profiles to determine the amount of vaccine each provider will need.

1.6 Changes in Staff/Facility Status

Providers are required to contact the Vaccine Depot within ten days of any change including, but not limited to: the certifying provider, vaccine coordinator, back-up vaccine coordinator, mailing/shipping address, vaccine delivery hours and facility status. Once notified of availability, new certifying providers, vaccine coordinators, and back-up vaccine coordinators must complete an education webinar within 30 days of notification.

1.7 Inactivation

Enrolled facilities may be inactivated due to:

Facility request:	In the event of a facility closure or decision to discontinue receipt of state-supplied vaccine, immediately notify the Vaccine Depot.
Alaska Immunization Program designation:	During enrollment to receive state-supplied vaccines, providers agree to adhere to federal and state requirements. If at any time it is determined that these requirements are not being followed, the Alaska Immunization Program may investigate for fraud and abuse and, if necessary, will inactivate the provider.
Failure to complete the enrollment forms:	If currently enrolled providers do not submit the enrollment forms during the re-enrollment period each year, the Alaska Immunization Program may inactivate the provider.

Inactivated providers will be contacted by the Vaccine Depot for instruction on the proper transfer or return process for all vaccines on hand.

1.8 Fraud and Abuse

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, if necessary, will implement corrective actions or inactivate the provider from the program. Fraud or abuse can occur in many ways. Some examples of potential fraud and abuse are:

- 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 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
- Excessive waste of state-supplied vaccine

2. Vaccine Funding, Eligibility, and Administration Documentation

2.1 State-supplied Vaccine Funding

The Alaska Immunization Program receives various funds to procure child and adult vaccines. These funding sources, which are detailed below, allow enrolled providers to receive state-supplied vaccine. Accurate eligibility screening and documentation are required to ensure accountability and ongoing availability of each funding source.

(A). Vaccines For Children (VFC) Program: This federal entitlement program for children provides funds to purchase all Advisory Committee on Immunization Practices (ACIP) recommended vaccines for administration to children ages 0 through 18 years who meet at least one of the following eligibility criteria:

- Medicaid-eligible/enrolled
- Uninsured
- American Indian or Alaska Native
- Underinsured¹

Providers receiving state-supplied vaccines who serve VFC-eligible children must offer **ALL** age appropriate ACIP recommended vaccines for their patients 0 through 18 years of age. It is the intent of the federal program that all ACIP recommended vaccines are available for any entitled child at all VFC provider locations. The only exceptions to this requirement are: (1) a provider who may not be able to receive varicella vaccine by direct ship from the manufacturer and (2) specialty providers (e.g., OB/GYNs or providers serving only adults) who may limit state-supplied vaccines to those that are relevant for their practice.

Because all pediatric vaccines (i.e., those supplied for persons ages 0 through 18 years) provided by the Alaska Immunization Program are partially supported with VFC funds, vaccine providers enrolled to receive childhood and adolescent state-supplied vaccine are considered VFC providers.

¹ This category may only be used by a Federally Qualified Health Center (FQHC) or a deputized provider. Underinsured means that the child has health insurance, but it (1) doesn't cover vaccines, or (2) doesn't cover certain vaccines, or (3) covers vaccines but has a fixed dollar limit cap for vaccines.

For additional information and answers to frequently asked questions about the VFC Program, visit the Centers for Disease Control and Prevention’s (CDC) VFC website at: www.cdc.gov/vaccines/programs/vfc/index.html.

- (B). **Section 317 of the U.S. Public Health Service Act:** “317” federal funds are available for the purchase of vaccines for children, adolescents, and adults, but are not intended to routinely vaccinate fully insured individuals. Section 317 vaccines are a critical resource for filling gaps in the nation’s immunization services.
- (C). **Alaska Vaccine Assessment Program (AVAP):** To ensure statewide access to vaccines, the State created a vaccine assessment account, which is authorized in AS [18.09.200](#). AVAP is a public-private partnership by which health care insurers and other payers pay an annual assessment based on their proportionate share of the overall vaccine costs. The account funds are then remitted to the Alaska Immunization Program to purchase vaccines and distribute to providers. As part of the statute, there is a three year phase-in period (i.e., from 2015 to 2017) during which payers can opt-out. Providers can also opt-in to cover uninsured adults. The annual assessment rate is approved by an independent eight member council.

A combination of the above mentioned funds are used to procure vaccines for:

- **Children** ages 0 through 18 years for all ACIP recommended vaccines, and
- **Adults** ages 19 and above for the following covered vaccines.

Adult Vaccines	Age Criteria (in years)
9vHPV (Human papillomavirus)	Females 19 through 26; males 19 through 21; high risk* males 22 through 26
Influenza	19+
MCV4 (Meningococcal conjugate)	19 through 20
MenB (Meningococcal B)**	19 through 20
PPSV23 (Pneumococcal polysaccharide)	19+
Td (Tetanus/ Diphtheria)	19+
Tdap (Tetanus/ Diphtheria/ acellular Pertussis)	19+
Zoster (shingles)	60 through 64

*High risk males include either men who have sex with men (MSM) or who have an immunocompromising condition.

** Limited availability for high risk groups, which include those with persistent complement component deficiencies, anatomic or functional asplenia, microbiologist working with serogroup B meningitis, and populations at risk of outbreaks.

Regardless of the funding source, all vaccines distributed through the Alaska Immunization Program are considered “**state-supplied**” vaccines.

2.2 Patient Eligibility: Children (ages 0 through 18 years)

ALL children 0 through 18 years of age are eligible to receive state-supplied vaccines. While patients are not required to provide verification of eligibility status, parents/guardians of children with health insurance should review their policy prior to receiving vaccines since some eligibility criteria is determined by insurance coverage.

2.2.1 Criteria

Children are eligible to receive state-supplied vaccine through one of the following funding mechanisms:

(1) Vaccines For Children (VFC) Program

- Medicaid eligible/enrolled
- Uninsured
- Alaska Native/American Indian
- Underinsured children (available only at Federally Qualified Health Center (FQHC) or deputized provider)
 - A child who has health insurance, but coverage does not include vaccines; or
 - A child whose insurance covers only selected vaccines is eligible to receive only those vaccines that are not covered by the child's insurance through the VFC program; or
 - A child whose insurance caps the cost for vaccine coverage is eligible to receive VFC vaccines only after the insurance cap has been reached

(2) Alaska Vaccine Assessment Program (AVAP)

- All non-VFC children (i.e., children with private insurance)
 - Children with participating payers
 - Children with non-participating payers

For additional information on state-supplied vaccine eligibility for children, click [HERE](#).

2.2.2 Documentation

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

- Child's first and last name and middle initial
- Child's date of birth
- Parent/Guardian/Individual of Record's first and last name and middle initial
- Primary provider's name
- Date of each immunization visit
- One of the following eligibility status:
 - Medicaid eligible/enrolled
 - Uninsured
 - American Indian/Alaska Native
 - Underinsured (served at FQHC, RHC, or a deputized facility)
 - State vaccine (AVAP)
 - Private vaccine

Providers not performing direct data entry into VacTrAK must use a format that meets federal and state requirements for eligibility documentation as described above.

Eligibility documentation must be maintained in the patient's written or electronic medical record for at least three (3) years.

2.3 Patient Eligibility: Adults (ages 19 years and older)

2.3.1 Criteria

Adults are eligible to receive select state-supplied vaccines if they meet one of the following criteria:

- An individual's health plan participates in AVAP (a list of participating payers is posted on http://dhss.alaska.gov/dph/Epi/iz/Documents/ssv/2016AdultEligibility_FINAL.pdf).
 - Medicare is not a participating payer. However, if a provider decides to opt in for their uninsured adult population (which is further described in the below bullet) then a Medicare patient is eligible to receive state-supplied vaccines.
- An uninsured individual's medical provider pays (or opts in) into AVAP for uninsured adults.
 - Opt in providers are able to provide for all adults.
- An individual is covered by Medicaid only.

For additional information on state-supplied vaccine eligibility for adults, click [HERE](#).

2.3.2 Documentation

Eligibility status 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
- One of the following eligibility status:
 - State Vaccine (AVAP)
 - Ineligible (Private Vaccine)

Providers not performing direct data entry into VacTrAK must use a format that meets federal and state requirements for eligibility documentation as described above.

Eligibility documentation must be maintained in the patient's written or electronic medical record for at least three (3) years.

Patients are not required to provide verification of eligibility status.

2.4 Vaccine Administration Documentation

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

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

Per Alaska Administrative Code 7 AAC 27.650 (see text box below for more information):

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 these requirements refer to the Conditions Reportable to Public Health Manual:

dhss.alaska.gov/dph/Epi/Documents/pubs/conditions/ConditionsReportable.pdf

7 AAC 27.650. Health care provider disclosure to the immunization information system

- (a) Not later than 14 days after administering an immunization, a health care provider shall report information concerning the patient and the immunization in accordance with this section to the immunization information system maintained by the department. A health care provider shall disclose participation in the immunization information system to patients.
- (b) A health care provider, public health agent, or designee may report demographic and immunization data, and other pertinent information, permitted under [AS 18.15.360](#) (c), to the immunization information system.
- (c) A health care provider shall submit vaccine information to the immunization information system either through electronic or manual entry in a format approved by the department, and shall include the following data elements:
 - (1) if not already submitted by the state registrar under 7 AAC [05.931](#), the name, address, sex, race, and date of birth of a patient;
 - (2) the date of administration of the vaccine;
 - (3) the lot number of the vaccine;
 - (4) the dose amount and manufacturer of the vaccine;
 - (5) the dose-level vaccine eligibility code;
 - (6) other data elements as specified by the department, if essential for adequate public health response.
- (d) A health care provider who administers state-supplied vaccine shall utilize
 - (1) the ordering module of the immunization information system for ordering state-supplied vaccines; and
 - (2) the inventory module of the immunization information system for tracking public or public and private vaccine supply.
- (e) Data in the immunization information system may be used for the following purposes:
 - (1) any use permitted under 7 AAC [27.892](#) and 7 AAC [27.893](#);
 - (2) to ensure necessary immunizations are provided and over-immunization is avoided;

7 AAC 27.650 (continued). Health care provider disclosure to the immunization information system

- (3) to assess immunization coverage rates and determine areas of under-immunization;
- (4) to assist individuals or entities in the evaluation of immunization data for the purpose of disease management, care management, case management, or quality management programs.
- (f) An immunization record provided by the immunization information system is an official certificate of immunization, as required under [AS 14.30.125](#) and 4 AAC [06.055](#) for attendance at a school, under 7 AAC [50.455](#) for a child in care in a foster home or residential child care facility, and under 7 AAC [57.550](#) for admission to a child care facility.

Providers must distribute a current Vaccine Information Statement (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 Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov/.

3. Vaccine Distribution

3.1 Vaccine Availability

The Alaska Immunization Program makes every effort to maintain consistency in stocking vaccine brands. Typically, when the program does not have a particular brand of vaccine available, it is due to constraints and limitations at a national level.

CDC annually negotiates vaccine contracts with manufacturers. As a result, occasional changes are necessary in the brand of vaccine supplied to the State of Alaska by the CDC. If this occurs, the Alaska Immunization Program may send your facility an alternate vaccine from a different manufacturer to reflect this contract change.

3.2 Accountability Requirements

Providers receiving state-supplied vaccine are required to complete the following accountability measures. Any gaps in data will cause a delay in processing vaccine orders.

Daily:	<p>Document temperatures on the state-specific temperature log.</p> <p>Providers must review and document the temperature status twice a day on all storage units containing state-supplied vaccine on days that the facility is open. The temperature log(s) must be completed in full. You must review and document the alarm status and temperature from the state-supplied calibrated LogTag temperature monitoring device only and not from any other temperature monitoring device or display that may happen to be in the storage unit. Providers are no longer required to submit the log(s) to the Vaccine Depot each month; however, temperature log(s) must be made readily available to the Alaska Immunization Program upon request. See the Inventory Management chapter for more information on monitoring temperatures.</p>
Weekly:	<p>Download and submit the state-supplied LogTag temperature monitoring graphs.</p> <p>Providers must download graph data from state-supplied LogTag temperature monitoring device(s) and submit to the Vaccine Depot weekly. See the Inventory Management chapter for more information on monitoring temperatures.</p>
Monthly:	<p>Perform inventory reconciliation for state-supplied vaccine stock(s) in VacTrAK.</p> <p>Providers must perform a monthly reconciliation for state-supplied vaccine stock(s) regardless of their ordering cycle. This includes processing any returns or adjustments to account for any discrepancies in their state-supplied stock(s).</p>

	Reconciliation must be performed prior to submitting a vaccine order. VacTrAK will not permit a vaccine order to be submitted if reconciliation has not been performed within a 14 day period prior to order submission.
Ongoing:	Providers must enter patient vaccine administration data into VacTrAK within 14 days of service either manually or electronically per 7 AAC 27.650 . This reporting requirement is applicable for any vaccine administered, including state-supplied and privately purchased vaccines. This provides dose-level accountability for all vaccines used in Alaska within VacTrAK. Tracking dose-level accountability in VacTrAK is used to meet federal and state mandates.

3.3 How to Order Vaccines

All state-supplied vaccine requests must be placed through VacTrAK's Vaccine Ordering and Management System (VOMS). Training materials consisting of short videos and/or PDF instructions are available on the VacTrAK homepage under [Vaccines Ordering Management System \(VOMS\) Training Materials](#).

To ensure an accurate order, a provider must take into consideration their ordering cycle schedule, the amount of space available in the storage unit, what stock is on hand and seasonal needs. Choose an individual order set that corresponds to the type of vaccine order being placed (i.e., standard pediatric order set, seasonal flu order set, adult order set, etc.). The Alaska Immunization Program will monitor requests and may adjust order quantities according to administration data, the provider practice profile and current inventory in VacTrAK. If reported administration data and inventory do not support the quantities requested or if specific vaccine(s) are in short supply, the vaccine quantity ordered may be reduced by program staff.

3.4 When to Order Vaccines

The Alaska Immunization Program will assign facilities a standard ordering cycle based on routine rate of vaccine use and/or patient population as identified in the Provider Practice Profile. An order which is placed outside an assigned scheduled ordering cycle will be reviewed to determine the reason for the off-schedule order and the possibility of a formalized change to your ordering cycle. This additional review may cause a delay in receipt of your order.

It normally takes one week to fill an order after verifying that accountability requirements have been met, but may be delayed up to three weeks during periods of high order demand. Please keep in mind that you should NOT place a vaccine order if your facility will be closed for a holiday or an extended vacation. It is your responsibility to notify the Vaccine Depot if your facility is going to be closed or if there has been a change in your business hours or delivery information.

3.5 Direct Ship Vaccines (varicella and zoster)

Varicella and zoster vaccine types require special shipping and storage conditions. They are only available by direct shipment from the manufacturer (Merck) to the provider. This special shipping process usually requires one to three weeks once an order is approved. Once shipped from Merck, the vaccine will typically be in transit for two to three days. Contact the Vaccine Depot and Merck if your shipment was in transit greater than 72 hours so that viability of the vaccine may be determined. Varicella vaccine is funded through two funding sources; therefore, Merck may send your order in two separate shipments. The minimum order of varicella that can be placed is 20 doses to accommodate the two funding sources.

3.6 Shipment and Receipt of Vaccine Orders

Providers can check the status of a submitted order in VacTrAK. Once an order is in the status of “Shipped or Ready for Pick Up” the order is considered “completed” in VacTrAK. This indicates that: (1) Local orders are filled and are awaiting pick up at the Vaccine Depot by the provider or (2) Out of town orders have been shipped to local airports or sent via long distance courier service.

Both local pick up and out of town shipments must be carefully planned by both parties so that the cold chain is maintained. Once the vaccine is picked up from the Vaccine Depot or airport, you must transport vaccine to your facility within one hour. The Vaccine Depot is open for local vaccine pick up only during the days/times shown below:

Vaccine Depot
Hours Open for Vaccine Local Pick Up

Day	Time
Monday	8:00am – 1:00pm
Wednesday	8:00am – 4:30pm
Friday	8:00am – 1:00pm

Note: The Vaccine Depot continues to be available for telephone consultation during business hours Monday – Friday, 8:00am – 5:00pm (excluding State holidays).

3.7 Procedures upon Vaccine Receipt

All facilities must have procedures in place for immediate receipt and storage of vaccine due to its 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:

1. Pick up shipment from the Vaccine Depot or airport and transport it back to your facility within one hour.

2. Review the LogTag included in the shipping container(s) for an alarm notification. Complete this process one box at a time. If multiple boxes are received, each box may experience different temperatures.
3. Unpack each box and verify the contents against the invoice for vaccine quantity, lot number, and expiration date.
4. Immediately and appropriately store all vaccines in your storage unit. (Isolate vaccines with possible temperature issues and label them as “do not use” until the Epidemiology Vaccine Depot is able to determine the viability of the vaccine.)
5. Contact the Vaccine Depot with any discrepancies, possible temperature issues or concerns with an order.
6. Login to VacTrAK and electronically receive in the order in the Orders/Transfer page.
7. Mail the LogTag back to the Vaccine Depot using the small postage-paid box included in your vaccine shipment.

4. State-supplied Vaccine Formularies

4.1 State-supplied Pediatric Vaccines

Pediatric Vaccines	Brand Name®
DT (Diphtheria/ Tetanus)	No trade name
DTaP (Diphtheria/ Tetanus/ acellular Pertussis)	INFANRIX
DTaP/ Hepatitis B/ IPV	PEDIARIX
DTaP/ IPV	KINRIX
Hepatitis A	HAVRIX
Hepatitis B	Recombivax HB
Hib (Haemophilus influenza type b)	PedvaxHIB
9vHPV (Human papillomavirus)	Gardasil 9
Influenza	Varies each season
IPV (Inactivated poliovirus)	IPOL
MCV4 (Meningococcal conjugate)	Menactra
MenB (Meningococcal B)*	Bexsero
MMR (Measles/ Mumps/ Rubella)	M-M-R II
PCV13 (Pneumococcal conjugate)	Prevnar 13
PPSV23 (Pneumococcal polysaccharide)	Pneumovax 23
RV5 (Rotavirus)	RotaTeq
Td (Tetanus/ Diphtheria)	Tenivac
Tdap (Tetanus/ Diphtheria/ acellular Pertussis)	BOOSTRIX
Varicella (chickenpox)	Varivax

* Limited availability for high risk groups, which include those with persistent complement component deficiencies, anatomic or functional asplenia, microbiologist routinely exposed to isolates of *Neisseria meningitidis*, and populations at risk because of a serogroup B meningococcal disease outbreaks.

See [Appendix D](#) for a detailed pediatric formulary, which includes NDC, CPT, and CVX codes.

4.2 State-supplied Adult Vaccines

Adult Vaccines	Brand Name®	Age Criteria (in years)
9vHPV (Human papillomavirus)	Gardasil 9	Females 19 through 26; males 19 through 21; high risk* males 22 through 26
Influenza	Varies each season	19+
MCV4 (Meningococcal conjugate)	Menactra	19 through 20
MenB (Meningococcal B)**	Bexsero	19 through 20
PPSV23 (Pneumococcal polysaccharide)	Pneumovax 23	19+
Td (Tetanus/ Diphtheria)	Tenivac	19+
Tdap (Tetanus/ Diphtheria/ acellular Pertussis)	BOOSTRIX	19+
Zoster (shingles)	Zostavax	60 through 64

*High risk males include either men who have sex with men (MSM) or who have an immunocompromising condition.

** Limited availability for high risk groups, which include those with persistent complement component deficiencies, anatomic or functional asplenia, microbiologist routinely exposed to isolates of *Neisseria meningitidis*, and populations at risk because of a serogroup B meningococcal disease outbreaks.

See [Appendix E](#) for a detailed adult formulary, which includes NDC, CPT, and CVX codes.

5. Inventory Management

5.1 Storage and Handling

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. The vaccine cold chain relies on three main elements:

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

A staff member at each facility must be designated as the vaccine coordinator who will be responsible for ensuring that all vaccines are stored and handled correctly. One back-up vaccine coordinator must also be designated to assume the same responsibilities in the absence of the primary vaccine coordinator.

5.2 Vaccine Storage Units

Providers must have appropriate equipment that is used only for vaccine storage and pharmaceuticals (i.e., no food or drink is in the unit) and maintains proper temperature required conditions for vaccine storage. Information on each permanent, temporary and day use storage unit used within your practice must be submitted in the Provider Agreement at enrollment. Any changes made during the year to storage units used (i.e., purchased a new storage unit, etc.) must be reported to the Vaccine Depot.

5.3 Refrigerators and Freezers

It is highly recommended that providers use pharmaceutical (i.e., "purpose-built" vaccine or laboratory-grade) refrigerators for vaccine storage. Stand-alone separate refrigerator and freezer units provide the next best option. The refrigerator compartment of a combination refrigerator and freezer unit sold for home or commercial use is acceptable for vaccine storage if the refrigerator and freezer compartments each have separate external doors. The freezer compartment of a combination refrigerator and freezer unit sold for home or commercial use can NOT be used to store frozen vaccines. Frozen vaccines must be stored in a stand-alone freezer unit or the freezer compartment of a combination pharmaceutical unit.

Dormitory or bar-style refrigerators are not permitted for **ANY** vaccine storage. A dormitory or bar-style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one external door and has an evaporator plate (cooling coil) which is usually located inside the "freezer" within the refrigerator. Dormitory or bar-style refrigerators place vaccine at a high risk of freezing.

Storage units should be placed in a well-ventilated room and have space around the sides and tops to allow for appropriate heat exchange and cooling functions.

5.4 Vaccine Storage

Placement and organization within the storage unit is vital to maintaining vaccine stability.

- Place the vaccines in the center of the refrigerator, leaving adequate space for air circulation. (Some areas of the refrigerator – e.g., in the door or near the sides – may hold different temperatures than the center of the unit.) Vaccines must be stored on the shelves of the refrigerator or freezer, not in the door or in crisper drawers. (Crisper drawers should be removed from the refrigerator.)
- Small trays may be used to help quickly move stock within a refrigerator, reducing the amount of time the door must remain open, potentially exposing vaccines to warmer air temperatures.
- Store all vaccines in their original box.
- Protect the following vaccines from light: Varivax, Zostavax, MMR, Gardasil and RotaTeq.
- State-supplied vaccines must be segregated and/or marked in such a way that they are easily distinguished from privately purchased vaccines. This does NOT mean that state-supplied and privately purchased vaccines must be stored in separate refrigerator(s) or freezer(s).
- Do not store food or drink in vaccine refrigerators or freezers.
- If using the refrigerator compartment of a combination refrigerator/freezer unit, do not place the vaccine directly under the outlet that blows air from the freezer into the refrigeration area.
- MMR can be stored in the freezer.

5.5 Storage Unit Temperatures

Refrigerator storage units must maintain temperature between 35°F and 46°F at all times. Setting the temperature to achieve an average of 40 degrees will provide the best safety margin.

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

Water bottles should be placed in the refrigerator in the spaces where vaccine is prohibited (i.e., door, drawers and back wall). Water bottles should also be placed in the freezer to help stabilize internal temperatures, including those times in which power outages occur. (Additionally, this practice will provide readily available frozen water bottles for transporting vaccine in the event you need to activate your emergency plan.) Label water bottles with “Do NOT drink.”

5.6 Temperature Monitoring

Temperatures in all vaccine storage units that hold state-supplied vaccine must be monitored. Permanent storage units must be monitored using the calibrated LogTag – the temperature monitoring device – provided by the Alaska Immunization Program.

Instructions on how to install the software and produce required graphs on the LogTag are found at [LogTag Software and Device Initial Setup](#) and [LogTag Instructions for Daily Use](#).

All other vaccine refrigerators/freezers (temporary or day use storage units) must be monitored by using a calibrated temperature monitoring device supplied by your facility. For information on how to recalibrate temperature monitoring devices, contact the monitor manufacturers.

Providers are required to have a back-up calibrated continuous monitoring device on hand in case of emergency or vaccine transport. Providers may calibrate and use the previous state-supplied LogTag as their back-up device.

Temperature monitoring devices used as a back-up or to monitor temporary and secondary storage units must meet the following specs:

- Continuous monitoring and recording
- Alarm for out of range temperatures (that stays on even after temperatures have gone back within range)
- Display of current temp
- Accuracy within 1 degree Fahrenheit/.5 degree Celsius
- Low battery indicator
- Memory stores at least 4,000 readings
- Device is to read and record a temperature at minimum every 15 minutes. A reading of every 5 minutes is preferred.
- Current and valid calibration certificate that meets ISO 17025 standards (required)
 - a. Certificate of calibration testing is issued either by an ILAC MRA-accredited laboratory
OR
 - b. Contains all of the following:
 - i. Name of device (optional)
 - ii. Model number
 - iii. Serial number
 - iv. Date of calibration
 - v. Measurement results indicate unit passed test
 - vi. Documented uncertainty is within suitable limits (recommended uncertainty 1F/.5C)

Certificates of calibration that meet ISO 17025 standards (see [Appendix C](#)) must be maintained for all devices which are used for monitoring state-supplied vaccine at your facility. Documentation must be readily available to the Alaska Immunization Program upon request.

Temperature monitoring devices must be placed in each vaccine storage unit. Place the probe of the device inside the storage unit, in the **middle section** as close to the vaccine stock as possible. This will

allow the device reading to more closely reflect the actual temperature of the vaccine. (Some areas of the refrigerator – e.g., in the door or near the sides – may hold different temperatures than the center where the vaccine is properly stored.) Improper placement of the monitor may result in vaccine wastage.

If using the refrigerator compartment of a combination refrigerator/freezer unit, do **not** place temperature monitoring device directly under the outlet that blows air from the freezer into the refrigeration area.

Each day the facility is staffed, temperatures for all state-supplied vaccine storage units must be recorded at least twice daily on the current version of the Vaccine Temperature Log. It is no longer necessary to submit your completed temperature logs to the Vaccine Depot for review each month. Maintain all completed logs at your facility for a minimum of three years. This documentation must be readily available to the Alaska Immunization Program upon request. It is still a requirement to submit your downloaded temperature LogTag graphs to the Vaccine Depot once a week.

LogTag graphs must be downloaded and reviewed at least once a **week**. When reviewing the LogTag display screen for the twice a day log, view and record the current temperature, ensure the battery life indicator says “ok” and that the word “Alarm” is not displayed. Write down the current temperature on the log, write Y or N for the alarm status and sign your initials. If temperatures are found outside acceptable parameters, take immediate steps to store the vaccine under proper conditions. If the word “Alarm” is displayed on the screen and the current temperature is within acceptable parameters, this means that the device has recorded an out of range temperature since your last review and the graph must be downloaded immediately for your review. If the battery life indicator is low, change the battery.

The [Action Taken Form](#) is a tool available for use by your staff to track temperature adjustments made to the storage unit and other actions taken.

5.7 Temperature Deviations

Each time vaccine storage temperatures fall outside the acceptable range for **any length** of time, complete the following steps.

- Store the vaccine under proper conditions as quickly as possible if the temperatures are currently still outside the acceptable range (i.e. close door left ajar, implement emergency plan, etc).
- Label potentially compromised vaccine(s) as “Do NOT use” until you have determined vaccine viability.
- Download the LogTag graph.
- Complete the Temperature Excursion Report and contact the vaccine manufacturer to obtain stability data for vaccine viability.

- Submit the Temperature Excursion Report and downloaded graphs to the Vaccine Depot every time storage unit temperatures are out of acceptable range.
- Do not waste or return vaccines unless instructed by the manufacturer; in some instances the vaccine may be approved for continued use based on stability data from the manufacturer.

For temperature deviations outside the recommended storage range, the following documentation will be required prior to reinstatement of vaccine deliveries:

- Temperature Excursion Report
- Explained Deviation (e.g., refrigerator door left open, power loss, etc.): 24 hours of stable temperatures shown on the temperature monitoring device graph
- Unexplained Deviation: Two weeks of temperature logs and temperature monitoring device graphs indicating stable temperatures are maintained within acceptable ranges

5.8 Rotating Stock

Rotate stock so that vaccine with the earliest date to expiration is used first. Store so that vaccine with the earliest expiration date is in front of vaccine with a later expiration date.

5.9 Vaccine Returns

All state-supplied vaccines that have expired or are spoiled/wasted must be documented in VacTrAK in the Orders/Transfer menu. For training resources on documenting Vaccine Returns in VacTrAK, please refer to [Vaccine Ordering Management System Training Materials](#). Print the VacTrAK Vaccine Returns page and include this page along with vaccine being returned to the Vaccine Depot within 30 days. 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 Alaska Immunization Program obtains a partial credit on all vaccines returned. **Do not return any privately purchased vaccines or needles to the Vaccine Depot.** Dispose privately purchased vaccines or needles according to facility policies and procedures.

Vaccine inventory must be monitored carefully to keep vaccine wastage to less than five percent of your annual vaccine shipments or you may be subject to corrective actions.

5.10 Emergency Planning

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 a primary vaccine coordinator and at least one back-up vaccine coordinator responsible for vaccine management

An [Emergency/ Power Outage Plan for Vaccines](#) template to assist in the development of this plan is available.

5.11 Vaccine Transfers (State approved between different enrolled facilities)

All state-supplied vaccine transfers must be pre-authorized by the Vaccine Depot prior to transfer and should be a rare occurrence. This authorization allows the Vaccine Depot to ensure that the receiving provider is enrolled to receive state-supplied vaccine and appropriate vaccine accountability has been maintained. In addition, the Vaccine Depot will provide guidance to ensure cold chain management during vaccine transport.

Transfer Procedure:

1. If the cold chain has been maintained, a transferring provider should contact a potential enrolled local provider to obtain their approval to receive the vaccine.
2. The provider requesting the transfer must complete the [Vaccine Transfer Request Form](#) and submit the form to the Vaccine Depot for approval before vaccine is moved.
3. The Vaccine Depot staff will review the request and contact the facilities within 48 hours.
4. If the transfer is approved, the provider can pack and transport the vaccine to the other provider maintaining storage and handling requirements as described in Vaccine Transport Methods.
5. The Vaccine Depot will electronically adjust both providers' inventory in VacTrAK.

5.12 “Borrowing” between State-supplied and Privately Purchased Vaccine within your Facility

“Borrowing” occurs within a single facility and involves temporary sharing between a provider’s privately purchased and state-supplied vaccine stock. This type of practice is no longer permitted.

5.13 Vaccine Ordering Suspension

Vaccine orders may be suspended by the Alaska Immunization Program for providers identified as having an excessive amount of vaccine wastage (i.e., five percent or more of vaccine doses lost/year), insufficient storage capacity, an inadequate storage unit or noncompliance with any program requirements. Providers may be asked to develop and submit a corrective action plan addressing the

problems which led to the suspension. If needed, the Vaccine Depot can provide technical consultation in the development of the plan. The Vaccine Depot will review and approve the plan, as appropriate. After a provider has instituted corrective action(s), the suspension will be lifted and vaccine shipments may be resumed.

6. Quality Assurance (QA) Visits, Assessments and Education

6.1 What are QA Visits, Assessments and Education

Federal and state requirements mandate that the Alaska Immunization Program conduct Quality Assurance (QA) visits, assessments and education with each enrolled provider receiving state-supplied vaccine.

To request additional education and training, please contact the Vaccine Depot.

6.2 Types of QA Visits, Assessments and Education

Provider Enrollment:	This visit is required for new enrolling providers or providers that have had a break between enrollments with the Alaska Immunization Program. The purpose of this appointment is to ensure providers and their staff are provided with education about requirements, and has appropriate resources to implement program requirements.
Annual Education Requirement:	The vaccine coordinator and the back-up vaccine coordinator of all facilities receiving state-supplied vaccine are required to complete an education webinar annually. Providers will be notified when the new education webinar is available.
Compliance:	<p>A compliance site visit consists of an examination of vaccine management and delivery practices to ensure compliance with federal and state guidelines. It involves administration of a questionnaire, evaluating compliance with requirements and providing education. During the visit, there will be a formal review of vaccine management practices as well as a review of patient records and other documentation to assure appropriate vaccine eligibility screening and administration documentation is occurring.</p> <p>The Alaska Immunization Program will contact providers by phone to schedule compliance visits. A visit confirmation letter and a pre-visit questionnaire will be sent prior to the visit. Completion and return of the pre-visit questionnaire prior to the visit provides us with an opportunity to better prepare for your visit.</p>
Unannounced Storage and Handling:	The Alaska Immunization Program is required to perform unannounced storage and handling site visits to serve as “spot checks” on facility vaccine management practices.

When **Compliance and Unannounced Storage and Handling Visits** are completed, providers will receive a report outlining visit findings, and if applicable, identifying areas of noncompliance in need of

correction. Corrective actions for noncompliant practices will be required for continued participation in the Vaccine Distribution Program.

6.3 Assessment, Feedback, Incentives, eXchange (AFIX)

The Alaska Immunization Program is required to perform an AFIX assessment with providers receiving state-supplied vaccines. AFIX is a four part dynamic quality improvement strategy to raise immunization coverage levels and improve standards of practice at the provider level. Additional information regarding the process can be found at: dhss.alaska.gov/dph/Epi/iz/Pages/afix.aspx

Appendix A: Resources

Table A1. List of National Resources

Resource	Further Information about Resource
CDC: Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book: Course Textbook	Includes principles of vaccination, immunization general recommendations and strategies, and information regarding vaccine safety, storage and handling, and details regarding administration of individual vaccines. Website: www.cdc.gov/vaccines/pubs/pinkbook/index.html
CDC: Vaccines and Immunizations	Provides information on immunization schedules, publications about vaccine-preventable diseases, and much more. Website: www.cdc.gov/vaccines Phone: 1-800-CDC-SHOT (1-800-232-4636)
CDC: Vaccine Information Statements (VIS) and Email VIS Update Service	Current VIS and sign up to receive update notices via email. Website: www.cdc.gov/vaccines/hcp/vis/index.html
CDC: Vaccine Storage & Handling Toolkit	Information regarding vaccines and vaccine cold chain. Website: www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf
Immunization Action Coalition (IAC)	Evidence-based vaccine information, VIS in multiple languages, “Ask the Experts”, free print materials, information on vaccine-preventable diseases, and much more Website: www.immunize.org
Medication Errors Reporting Program (MERP)	National voluntary reporting system operated by the Institute for Safe Medication Practices Website: www.ismp.org/orderforms/reporterrortoismp.asp

Table A1 (continued). List of National Resources

Resource	Further Information about Resource
U.S. Licensed Vaccine Information	Includes package inserts. Website: www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm
Vaccine Adverse Event Reporting System (VAERS)	National vaccine safety surveillance program for collection of information about adverse events (possible side effects) occurring after administration of U.S. licensed vaccines Website: www.vaers.hhs.gov/ Phone: 1-800-822-7967

Table A2. List of U.S. Vaccine Manufactures

Vaccine Manufacture	Website (i.e., link to products)
GlaxoSmithKline (GSK)	https://gsksource.com/pharma/content/gsk/source/us/en/brands.html?type=Vaccines
MedImmune	https://www.medimmune.com/medicines
Merck	https://www.merckvaccines.com/Products/Pages/ProductHome
Novartis	https://www.novartis.com/our-work/product-portfolio
Pfizer (Wyeth)	https://www.pfizerpro.com/pfizer-products
Sanofi Pasteur	http://www.sanofipasteur.us/vaccines

Appendix B: Links to Vaccine Management Forms and Resources

1. ["Do Not Unplug" Signs](#)
2. [Emergency/ Power Outage Plan for Vaccines](#)
3. [Excerpts from CDC's Vaccines For Children Operations Guide](#)
4. [Facility Incident Report](#)
5. [LogTag Temperature Monitoring Device Instructions for Daily Use](#)
6. [LogTag Temperature Monitoring Device Software and Device Initial Setup](#)
7. [2016 Vaccine Provider Agreement Instructions](#)
8. [Vaccine Information Statements \(VIS\)](#)
9. [Vaccine Temperature Monitoring Log and Action Taken Form](#)
10. [Vaccine Transfer Request Form](#)
11. [VacTrAK Participant Notice](#)
12. [VacTrAK Participant Notice \(half-page\)](#)

Appendix C: Calibration Certificate Checklist

Certificate of Calibration Testing (Report of Calibration)

VFC Required Elements:

- Model/Device Name or Number
- Serial Number
- Date of Calibration (Report or Issue Date)
- Instrument Passed testing (Instrument In Tolerance)

VFC Optional Element:

- Recommended uncertainty = +/- 0.5°C

Additional information:

If you are looking for ways to determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, you can check to see if the Certificate indicates one or more of the following items below about calibration testing:

- Conforms to ISO 17025
- Was performed by an ILAC/MRA Signatory body accredited Laboratory
List of the ILAC/MRA signatories may be found at: <http://ilac.org/ilac-mra-and-signatories/>
- Is traceable to the standards maintained by NIST
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F (≤ 0.5 °C) or better
- Includes reference to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points.

Note: The CDC recommends that certifications be issued for the entire monitoring unit (detachable probe, data logger, etc.) and not individual certificates for each component.

If you have questions or concerns about particular certificates, please send them to: IZColdChain@cdc.gov

Appendix D: Detailed Pediatric Formulary

Pediatric Vaccines	Brand Name®	Manufacturer	NDC Code	CPT Code	CVX Code	Latex?
DT (Diphtheria/ Tetanus)	No trade name					
DTaP (Diphtheria/ Tetanus/ acellular Pertussis)	INFANRIX	GlaxoSmithKline	58160-0810-11	90700	20	YES – Syringe NO – Vial
DTaP/ Hepatitis B/ IPV	PEDIARIX	GlaxoSmithKline	58160-0811-52	90723	110	YES – Syringe NO – Vial
DTaP/ IPV	KINRIX	GlaxoSmithKline	58160-0812-11	90696	130	YES – Syringe NO – Vial
Hepatitis A	HAVRIX	GlaxoSmithKline	58160-0825-11	90633	83	YES – Syringe NO – Vial
Hepatitis B	Recombivax HB	Merck	00006-4981-00	90744	08	YES – Syringe YES – Vial
Hib (Haemophilus influenza type b)	PedvaxHIB	Merck	00006-4897-00	90647	49	YES – Vial
9vHPV (Human papillomavirus)	Gardasil 9	Merck	00006-4119-03	90651	165	NO
Influenza	Varies each season					
IPV (Inactivated poliovirus)	IPOL	Sanofi Pasteur	49281-0860-10	90713	10	NO
MCV4 (Meningococcal conjugate)	Menactra	Sanofi Pasteur	49281-0589-05	90734	114	NO
MenB (Meningococcal B)*	Bexsero	GlaxoSmithKline	46028-0114-01	90620	163	YES – Syringe Tip Cap
MMR (Measles/ Mumps/ Rubella)	M-M-R II	Merck	00006-4681-00	90707	03	NO
PCV13 (Pneumococcal conjugate)	Prevnar 13	Pfizer	00005-1971-02	90670	133	NO
PPSV23 (Pneumococcal polysaccharide)	Pneumovax 23	Merck	00006-4943-00	90732	33	NO
RV5 (Rotavirus)	RotaTeq	Merck	00006-4047-41	90680	116	NO
Td (Tetanus/ Diphtheria)	Tenivac	Sanofi Pasteur	49281-0215-10	90714	113	NO

Appendix D: Detailed Pediatric Formulary

Pediatric Vaccines	Brand Name®	Manufacturer	NDC Code	CPT Code	CVX Code	Latex?
Tdap (Tetanus/ Diphtheria/ acellular Pertussis)	BOOSTRIX	GlaxoSmithKline	58160-0842-11	90715	115	YES – Syringe NO – Vial
Varicella (chickenpox)	Varivax	Merck	00006-4827-00	90716	21	NO

* Limited availability for high risk groups, which include those with persistent complement component deficiencies, anatomic or functional asplenia, microbiologist routinely exposed to isolates of *Neisseria meningitidis*, and populations at risk because of a serogroup B meningococcal disease outbreaks.

Appendix E: Detailed Adult Formulary

Adult Vaccines	Brand Name®	Age Criteria (in years)	Manufacturer	NDC Code	CPT Code	CVX Code	Latex?
9vHPV (Human papillomavirus)	Gardasil 9	Females 19 through 26; males 19 through 21; high risk* males 22 through 26	Merck	00006-4119-03	90651	165	NO
Influenza	Varies each season	19+					
MCV4 (Meningococcal conjugate)	Menactra	19 through 20	Sanofi Pasteur	49281-0589-05	90734	114	NO
MenB (Meningococcal B)**	Bexsero	19 through 20	GlaxoSmithKline	46028-0114-01	90620	163	YES – Syringe Tip Cap
PPSV23 (Pneumococcal polysaccharide)	Pneumovax 23	19+	Merck	00006-4943-00	90732	33	NO
Td (Tetanus/ Diphtheria)	Tenivac	19+	Sanofi Pasteur	49281-0215-10	90714	113	NO
Tdap (Tetanus/ Diphtheria/ acellular Pertussis)	BOOSTRIX	19+	GlaxoSmithKline	58160-0842-11	90715	115	YES – Syringe NO – Vial
Zoster (shingles)	Zostavax	60 through 64	Merck	00006-4963-41	90736	121	NO

*High risk males include either men who have sex with men (MSM) or who have an immunocompromising condition.

** Limited availability for high risk groups, which include those with persistent complement component deficiencies, anatomic or functional asplenia, microbiologist routinely exposed to isolates of *Neisseria meningitidis*, and populations at risk because of a serogroup B meningococcal disease outbreaks.