# Childhood Vaccine Program



Office of Immunization | (360) 236-2829 | doh.wa.gov/cvp | wachildhoodvaccines@doh.wa.gov

### Provider Agreement: New Enrollment Packet

#### **Enrolling in the Washington State Childhood Vaccine Program**

Thank you for your interest in the Washington State Childhood Vaccine Program (CVP)! This packet includes the steps to begin the enrollment process.

#### 1. Ensure you have the Correct Equipment:

- <u>Vaccine Storage Unit Guide</u>: Enrolling sites must have pharmaceutical grade storage units or commercial/household stand-alone refrigerators and freezers. Pharmaceutical grade units are strongly recommended.
- <u>Thermometer Guide</u> and <u>Temperature Reporting Requirements</u>: All providers must have a digital data logger (DDL) or continuous temperature monitoring system (TMS). Providers are required to have one thermometer per storage unit and at least one back-up thermometer per site.

#### 2. Review Requirements and Submit the Required Documentation:

- <u>Provider Agreement</u> (this packet): The agreement collects facility details and outlines the requirements of
  the program. It must be completed in full and signed (*original or electronic signature*) by a health care
  practitioner authorized by law to prescribe and administer pediatric vaccines in Washington State. This
  provider accepts responsibility for clinic operations and maintaining program requirements under this
  agreement.
- Collaborative Drug Therapy Agreement (CDTA): Pharmacies must have a CDTA in place with a provider who has an active and valid WA State medical license.
- <u>Information Sharing Agreement (ISA)</u>: Facilities use the Washington State Immunization Information
  System (IIS) to order publicly supplied childhood vaccines and complete vaccine accountability. Please
  check the <u>Participating Organizations List</u> to verify whether your organization participates. If not, you
  must complete the digital <u>Exchange of Immunization Data Agreement</u> form.
- <u>Vaccine Management Plan</u>: CDC requires facilities to have plans that address the facility's vaccine management policies and procedures including steps to take during an emergency. The template linked above contains all the required components.
- <u>Temperature Log</u>: Facilities must manually record temperatures using the DOH Temperature Monitoring Log. Clinics must provide downloaded thermometer data and completed temperature logs showing 3-5 days of stable, in-range temperatures <u>before the new enrollment site visit</u>.
- <u>Vaccine Loss Policy</u>: Facilities must review and agree to comply with the policy that outlines processes and repercussions when vaccine is lost or wasted.
- <u>Eligibility for Publicly Funded Vaccines A Guide for Providers</u>: Facilities are required to screen and document patient eligibility status before administering publicly supplied vaccines.
- Washington Vaccine Association (WVA): Must verify ability to submit Dosage-Based Assessments as
  outlined by the WVA for children with private/commercial health insurance. Enrollment of Direct Care
  Practices are currently on hold pending review of state rules related to billing practices.
- <u>DOH New Vaccine Coordinator Training</u>: The Primary and Back-up Vaccine Coordinators are required to complete the <u>DOH New Vaccine Coordinator Training Modules 1-8</u>. Follow the instructions linked above to obtain and print training certificates.

#### 3. Schedule a New Enrollment Visit

 Submit all required paperwork listed above to <u>WAChildhoodVaccines@doh.wa.gov</u> and you will be contacted by a regional program representative to schedule an enrollment visit.

### **PROVIDER INFORMATION**

Facility					
Facility Organization Name:		PIN (is	ssued by pro	gram):	
Facility Name:					
Facility Address:					
City:	County:		State:	: WA	Zip:
Telephone:			Fax:		
Vaccine Shipping Address (if different	rent):				
City:	County:		State:	: WA	Zip:
Medical Director or Equivale	nt				
Instructions: The provider signing administer pediatric vaccines* in the entire facility and its provider individual listed here must sign to *Note: For the purposes of the VF ACIP-recommended product for wards.	Washingt s with the he provid C progran	on State. This practitioner will be responsible conditions outlined er agreement (original or elect on, the term 'vaccine' is defined or	oe held d in the cronic si as any l	accountable provider ignature). FDA-autho	ole for compliance by agreement. <b>The</b>
Last Name, First, MI:		Title:		Specialty	:
License No.:		NPI No.:		EIN (optional):	
Email:					
Provide Information for a second	individual	as needed:			
Last Name, First, MI:		Title:		Specialty:	
License No.:		NPI No.:		EIN (optional):	
Email:					
Clinic Coordinators					
Instructions: There must be sepa completed the required trainings	•	•			
<b>Primary</b> Vaccine Coordinator Nan	ne:				
Telephone:	Email:	Email:			
Completed annual training:  O Yes O No	Type of Training	training received: Date:			
O Yes O No  Back-Up Vaccine Coordinator Nar		,			
Telephone:	Email:				
Completed annual training:	Type of	training received:			

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Training Date:

O Yes O No

Billing Coordinator Name:			
Telephone: E	mail:		
Facility & Provider Type			
Facility Type (select one)		Is this provider site p	part of a hospital/health care system
<ul> <li>Private – privately funded; non-g</li> <li>Public – publicly funded or gover</li> <li>Combo – funded with public and</li> </ul> Provider Type (select only one proving the proving of the provin	rnment entity I private funds	O Yes O No O N/A or Don't Kno	
	1 1		
<ul> <li>Behavioral Health Clinic</li> <li>Birthing Hospital or Birthing Center</li> <li>Community Vaccinator (nonhealth dept)</li> <li>Correctional Facility</li> <li>Direct Care Provider (membership-based practice)</li> <li>Family Planning Clinic (nonhealth dept)</li> <li>Federally Qualified Health Center</li> <li>Hospital</li> </ul>	<ul> <li>Juvenile D</li> <li>Migrant H</li> <li>Mobile Pr</li> <li>Pharmacy</li> <li>Private Pr</li> <li>Public Heach</li> <li>Clinic (state)</li> <li>Refugee H</li> </ul>	actice alth Department te/local) lealth Clinic al/Congregate Care	<ul> <li>Rural Health Clinic</li> <li>School-Based Clinic (permanent clinic location)</li> <li>Student Health Services</li> <li>STD/HIV Clinic (non-health dept)</li> <li>Urgent/Immediate Care Center</li> <li>Women, Infants, and Children (WIC) Clinic</li> <li>Other (specify):</li> </ul>
Is this facility a mobile facility or hat *Answer yes if immunization service unit that provides some immunization of Yes   O No  If applicable, please indicate the specific of Family Medicine	es are offered prion services.  ecialty of the pr	rovider/practice (Selected Medicine	ile clinics or the facility has a mobile t all that apply):
O Internal Medicine O OB/GYN O Pediatrics	O Other (spe	ecify):	

### **Vaccines Offered**

Is this provider a specialty provider?* Please note: the Immunization Program must review and approve any								
-	o identifies as a specialt	y provider.						
_	O Yes							
	O No							
_	ered (Select One):							
	recommended vaccines		, ,					
	* * * * * * * * * * * * * * * * * * * *	-	_	ted as <u>Specialty Providers</u> )				
	alty Provider" is defined	•	•					
	• •			amily planning; naturopathic) ; or				
			ulation of children ages (					
Local hea				. The program has the authority to				
designate	e providers as specialty p	oroviders.						
For Specialty	Providers Only: Select	which vaccine	es will be offered					
O COVID-19	9	O Meningo	ococcal Conjugate	O Rotavirus				
O DTaP		O Meningococcal B		O RSV				
O Hepatitis A		O MMR		О ТО				
O Hepatitis	В	О Мрох		O Tdap				
О нів		O Pneumococcal Conjugate		O Varicella				
O HPV		O Pneumococcal Polysaccharide		O Other:				
O Influenza		O Polio						
Shipping Inf	formation							
<b>Instructions:</b> Facilities are required to be available for vaccine shipments a minimum of four consecutive hours two days a week Monday - Friday. (Example: Tuesday 8:00am to 12:00pm & Wednesday 1:00pm to 5:00pm).								
Monday	From AM	to	AM/PM and	AM/PM to PM				
Tuesday	From AM	to	AM/PM and	AM/PM to PM				
Wednesday	From AM	to	AM/PM and	AM/PM to PM				
Thursday	From AM	to	AM/PM and	AM/PM to PM				
Friday	From AM	to	AM/PM and	AM/PM to PM				
Comments:	L							

#### **PROVIDER VACCINE SELECTION**

#### **Instructions:** Select the vaccine brands your facility prefers.

#### **DTaP Vaccine**

- O SANOFI-PASTEUR DAPTACEL® 5 DOSE
- O GSK INFANRIX® 5 DOSE
- O NO PREFERENCE

#### **DTaP-IPV Vaccine**

- O SANOFI-PASTEUR QUADRACEL® 1 DOSE
- O GSK KINRIX® 1 DOSE
- O NO PREFERENCE

#### **Hepatitis A Vaccine**

- O GSK HAVRIX® 2 DOSE
- O MERCK VAQTA® 2 DOSE
- O NO PREFERENCE

#### **Hepatitis B Vaccine**

- O GSK ENGERIX B® 3 DOSE
- O MERCK RECOMBIVAX HB® 3 DOSE
- O NO PREFERENCE

#### **Hib Vaccine**

- O SANOFI-PASTEUR ACTHIB® 4 DOSE\*
- O MERCK- PEDVAXHIB® 3 DOSE
- O GSK HIBERIX® 4 DOSE\*
- O NO PREFERENCE

#### **Meningococcal Conjugate Vaccine**

- O SANOFI-PASTEUR MENQUADFI™ 2 DOSE
- O GSK MENVEO® one-vial 2 DOSE
- O NO PREFERENCE

- O PFIZER TRUMENBA® 2 OR 3 DOSE
  - \*Penbraya will only be available on order sets with Trumenba.
- O GSK BEXSERO® 2 DOSE
- O NO PREFERENCE

#### **MMR Vaccine**

- O MERCK MMR II® 2 DOSE
- O GSK PRIORIX® 2 DOSE\*
- O NO PREFERENCE

#### **PCV Vaccine**

- O PFIZER PREVNAR 20<sup>TM</sup> 4 DOSE
- O MERCK VAXNEUVANCE™ 4 DOSE
- O NO PREFERENCE

#### **Rotavirus Vaccine**

- O MERCK ROTATEQ® 3 DOSE
- O GSK ROTARIX® 2 DOSE\*
- O NO PREFERENCE

#### **Td Vaccine**

- O SANOFI-PASTEUR TENIVAC® 1 DOSE
- O GRIFOLS TDVAX<sup>™</sup> 1 DOSE
- O NO PREFERENCE

#### **Tdap Vaccine**

- O SANOFI-PASTEUR ADACEL® 1 DOSE
- O GSK BOOSTRIX® 1 DOSE
- O NO PREFERENCE

Meningococcal B Vaccine

<sup>\*</sup>Vaccine requires reconstitution.

### **PRACTICING PROVIDERS**

Practitioner Name	Title	Specialty	License No.	NPI No.

#### **PATIENT POPULATION**

**Instructions:** Report the numbers of patients seen during the previous 12 months for each of the categories, broken out by age group. Count a child once based on the status at the last immunization visit, regardless of the number of visits. \*See note below if you have no data available.

Federal VFC Vaccine	lren who received	en who received VFC Vaccine by Age Category			
Eligibility Categories	<1 year	1-6 years	7-18 years	Total	
American Indian/Alaska Native					
Medicaid/Medicaid Managed Care					
Uninsured					
Underinsured at FQHC/RHC <sup>1</sup>					
Total VFC:					
State Vaccine	# of children who received non-VFC Vaccine by Age Category				
Eligibility Categories	<1 year	1-6 years	7-18 years	Total	
CHIP <sup>2</sup>					
Private Insurance <sup>3</sup>					
Total State:					
Total Patients					

<sup>&</sup>lt;sup>1</sup>Children who have health insurance that does not include vaccines or only covers select vaccine types and are receiving care in a Federally Qualified Health Center (FQHC) or certified Rural Health Clinic (RHC).

Ту	pe of Data Used to Determine Patient Population (Choose all that apply)
0	Provider Billing System
0	IIS (VFC Practice Profile Report)
0	Other (must describe):

<sup>&</sup>lt;sup>2</sup>Children enrolled in the Children's Health Insurance Program (CHIP) or Children's Health Program (CHP).

<sup>&</sup>lt;sup>3</sup>Children who are fully insured receiving care in any facility <u>and</u> underinsured children receiving care in a non-FQHC/RHCs.

<sup>\*</sup>If your clinic has no patient or billing data available to complete this section, please select Other and describe why the clinic can't provide the data in the text field, such as "New clinic."

## **COLD STORAGE EQUIPMENT**

FREEZER 1			
Can freezer maintain an average temperature of 5°F (-15°C) or cooler?			O No
Does the freezer have a separate, insulated door?		O Yes	O No
Name:	Type of Unit (select one):		
	O Commercial Stand-alo	ne O	Pharmaceutical/Medical
Manufacturer:	Model No.:		
In Use Date:	Purchase Date:		
Freezer 1 Thermometer:	Type of Unit (select one):		
	O Digital Data Logger	0	Temperature Monitoring System
Thermometer Brand/Model Name:	Temperature Scale (select	one):	
	O Celsius	0	Fahrenheit
Date of Last Calibration:	Calibration Expiration Dat	e:	
REFRIGERATOR 1			
Name:	Type of Unit (select one):		
	O Commercial Stand-alo	ne O	Pharmaceutical/Medical
Manufacturer:	Model No.:		
In Use Date:	Purchase Date:		
Refrigerator 1 Thermometer:	Type of Unit (select one):		
	O Digital Data Logger	0	Temperature Monitoring System
Thermometer Brand/Model Name:	Temperature Scale (select	one):	
	O Celsius	0	Fahrenheit
Date of Last Calibration:	Calibration Expiration Dat	e:	
By signing this document, I certify appropriate st	orage units are used for va	ccines.	
Full Name of Provider with Signature Authority:			
Signature:		Date:	

On.

To add an electronic signature, select the pen icon in the top tool bar of the Adobe form. Add a signature by typing, drawing or inserting an image of your signature. Then sign where indicated in this document.

#### **PROVIDER AGREEMENT REGULATIONS**

To receive publicly funded federal vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with this health care facility, of which I am the medical director, practice administrator, or equivalent:

- 1. I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if:
  - A. The number of children served changes or;
  - B. The status of the facility changes during the calendar year.
- 2. I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:
  - A. Federally Vaccine-eligible Children (VFC eligible)
    - 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.
  - B. State Vaccine-eligible Children
    - a. In addition, to the extent that my state designates additional categories of children as "state vaccine- eligible", I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 funded doses) to such children.

Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible) are <u>not</u> eligible to receive VFC-purchased vaccine.

- For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:
  - A. In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;
  - B. The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
- I will maintain all records related to the VFC program for a **minimum of three years** and upon request make these records available for review. VFC records include but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
- 5. I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.
- 6. I will not charge a vaccine administration fee to non-Medicaid federal vaccine eligible children that exceeds the administration fee cap of \$23.44 per vaccine dose. For Medicaid 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 publicly 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 current Vaccine Information Statements (VIS) (or Immunization Information Statement for nirsevimab) 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).

Note: If a COVID-19 Vaccine Information Statement (VIS) becomes available, provide information prior to vaccination as follows: EUA Fact Sheet for Recipients, Emergency Use Instructions (EUI), or BLA package insert, as applicable.

For Nirsevimab when not co-administered with other vaccines, report all suspected adverse reactions to MedWatch. Report suspected adverse reactions following co-administration of Nirsevimab with any vaccine to VAERS.

- **9.** I will comply with the requirements for vaccine management including:
  - A. Ordering vaccine and maintaining appropriate vaccine inventories;
  - B. Not storing vaccine in dormitory-style units at any time;
  - C. Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet Washington State Childhood Vaccine Program storage and handling recommendations and requirements;
  - D. Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.
- 10. I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program:

**Fraud** – is 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.

**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 health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

- 11. I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.
- **12.** For specialty providers, such as pharmacies, urgent care, school located vaccine clinics, or birthing hospitals, I agree to:
  - A. Vaccinate all "walk-in" VFC-eligible children and
  - B. Will not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee.

Note: "Walk-in" refers to any VFC eligible child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve VFC patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive vaccinations, then the policy would apply to VFC patients as well. "Walk-in" may also include VFC-eligible newborn infants at a birthing facility.

13. I understand this facility, or the Washington State Childhood Vaccine Program may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the Washington State Childhood Vaccine Program.

By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the federal Vaccines for Children enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.				
Medical Director or Equivalent Name (print):				
Signature:	Date:			
Name (print) Second individual as needed:				
Signature:	Date:			

### PROVIDER AGREEMENT REGULATIONS - WASHINGTON STATE REQUIREMENTS

To receive state funded vaccines at no cost, I agree to the Washington State-specific requirements on behalf of myself and all the practitioners, nurses, and others associated with this health care facility, of which I am the medical director or equivalent:

	or equivalent.
Vaccine Personnel	<ul> <li>A. Designate one staff member to be the primary vaccine coordinator and at least one staff member to be the back-up vaccine coordinator who can perform the same responsibilities in the event the primary coordinator is not available.</li> <li>B. Ensure all staff who administer and handle vaccines are properly trained on best practices in vaccine storage and handling and current immunization recommendations. The primary and back-up vaccine coordinators must take the Centers for Disease Control and Prevention (CDC) You Call the Shots training modules for Vaccines for Children (VFC) and Vaccine Storage and Handling annually.</li> <li>C. Notify the Childhood Vaccine Program (CVP) and update the provider agreement with new staff.</li> <li>D. Ensure no practitioner associated with this medical office is on the Office of the Inspector General's provider exclusion list. All health care providers must be in good standing with the Washington State Department of Health (DOH) throughout the term of this agreement.</li> </ul>
Vaccine Ordering and Inventory Management	<ul> <li>A. Order vaccine according to the assigned ordering schedule in accordance with vaccine need; order enough supply to carry through to the next ordering period; maintain a 30-day safety supply; avoid stockpiling or build-up of excess vaccine inventory.</li> <li>B. Develop and maintain complete, accurate, and separate records for public and private vaccine supplies. Providers must physically distinguish between public and private vaccine supplies is allowed.</li> </ul>
Vaccine Storage and Handling Plans	<ul> <li>A. Every facility receiving publicly supplied vaccine must maintain a current Vaccine Management Plan that is updated annually and includes the following: <ul> <li>a. Designation of primary vaccine coordinator and at least one back-up coordinator</li> <li>b. Vaccine ordering</li> <li>c. Vaccine shipping and receiving</li> <li>d. Vaccine storage and handling</li> <li>e. Vaccine inventory control (e.g. stock rotation)</li> <li>f. Vaccine wastage</li> <li>g. Vaccine transport in the event of a power failure, mechanical difficulty, or emergency (emergency plan)</li> <li>h. Staff training on vaccine management, including storage and handling.</li> </ul> </li></ul>
Vaccine Storage Equipment	<ul> <li>A. Always use appropriate equipment to store and maintain proper vaccine conditions. Vaccine storage unit requirements: <ul> <li>a. Dormitory and combination household units may never be used for storing vaccine.</li> <li>b. Pharmaceutical grade storage units or commercial/household stand-alone refrigerators and freezers are required for all provider sites. Refer to the Vaccine Storage Unit Guide.</li> <li>c. Portable storage units or qualified containers are required to be used during mobile, curbside, or similar off-site vaccination clinics.</li> </ul> </li> <li>B. Refrigerators and freezers used for vaccine storage must comply with the following: <ul> <li>a. Maintain required vaccine storage temperatures at all time.</li> <li>b. Large enough to hold the year's highest inventory without overcrowding.</li> <li>c. Store only vaccines and medical supplies.</li> <li>d. Do not store food and beverages in a vaccine storage unit.</li> </ul> </li> </ul>

## Temperature Monitoring

- A. Use a continuous temperature monitoring device (Digital Data Logger DDL or Temperature Monitoring System TMS) in each unit storing publicly supplied vaccine to monitor vaccine temperature. The device must have the following features:
  - a. A temperature probe in a thermal buffer
  - b. An active current, minimum, and maximum temperature display that can be easily read from outside the unit.
  - c. Alarm for out-of-range temperatures
  - d. Low battery indicator
  - e. Accuracy of  $\pm$  1° F (0.5° C)
  - f. User-programmable logging interval (or reading rate) to measure and record temperatures at least every 30 minutes
- B. Have a current and valid Certificate of Calibration Testing, issued by an appropriate entity, for each temperature monitoring device used to monitor vaccine storage temperatures. Calibration testing should be done every two years or according to the manufacturer's suggested timeline. Certificates must include the following:
  - a. Model/device name or number
  - b. Serial number
  - c. Date of calibration testing (report or issue date)
  - d. Confirmation the instrument passed testing
- C. Have at least one back-up temperature monitoring device readily available in case a device fails, calibration testing is needed, or vaccine must be transported. Back-up devices must include the same features as primary devices. It is recommended they have a different calibration expiration date to avoid all devices requiring recalibration at the same time.
- D. Post a temperature log on vaccine storage units or nearby in a readily accessible place. Please use the CVP's <u>paper temperature log</u>. Download, review and save thermometer data weekly.
- E. Visually review and manually record the refrigerator and freezer temperature twice each day (beginning and end). Once a day, manually record the actual min/max temperatures reached in the unit within the last 24 hours. Ensure the refrigerator temperature is between 36°F and 46°F (2°C and 8°C), freezer temperature is between 5°F and -58°F (-15°C and -50°C)\* and ultra-cold freezer temperature is between -76°F and -130°F (-60°C and -90°C). \*If storing Mpox vaccine, adjust freezer temps to 5°F to -13°F (-15°C to -25°C)
- F. Take immediate action to correct improper vaccine storage conditions, including exposure to light and exposure to temperatures outside the recommended ranges (i.e. excursions). Notify the CVP immediately of any excursions through REDCap or when submitting monthly temperature logs. Refer to the Temperature Excursion Guide.
- G. Submit copies of completed temperature monitoring logs or an approved TMS/DDL report monthly to the CVP via REDCap and maintain an ongoing file of completed temperature logs for three years. Refer to the Temperature Reporting Guide.
- H. Follow the Off-Site Vaccination Clinic Guidelines and obtain prior approval when administering vaccines at an alternate location.
- I. Failure to comply with temperature monitoring requirements could result in further corrective actions according to the Vaccine Loss Policy.

#### Vaccine Storage Practices

- A. Rotate vaccine supply by placing vaccine with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine every week and remove any expired vaccines from the storage units. Do not dispose of expired doses. Return all unopened spoiled or expired publicly purchased vaccines within six months by submitting a vaccine return to request a shipping label to return doses to the vaccine distributor.
- B. Monitor vaccine expiration dates and transfer short-dates vaccines to another enrolled provider (see Provider Map) prior to expiration following the Vaccine Transfer Checklist.

	<ul> <li>C. Providers must receive approval from the program before transferring publicly supplied vaccines to another provider for their use. Refer to the <u>Vaccine Transfer Guide</u> for further guidance.</li> <li>D. Ensure the storage and handling of vaccines are in accordance with the manufacturer's specifications and <u>CDC's vaccine storage and handling guidelines</u>.</li> </ul>
Vaccine Security	A. Post "Do Not Disconnect" signs at both the <u>electrical outlet</u> and the <u>circuit breaker</u> to prevent storage units from losing power. The breaker associated with vaccine storage units should be labeled along with a contact individual's name and phone number.
Vaccine Shipments	<ul> <li>A. Ensure all vaccine shipments are promptly received and stored immediately. Report any problems with vaccine shipments to the CVP immediately.</li> <li>B. Make sure all staff who receive mail know how to handle receipt of vaccine deliveries.</li> <li>C. Receive orders in the IIS to ensure doses are added to inventory.</li> </ul>
Vaccine Preparation	<ul><li>A. Ensure clinic staff does not pre-draw vaccine into syringes.</li><li>B. Draw vaccine only at the time of administration to ensure the cold chain is maintained and vaccine is not inappropriately exposed to light.</li></ul>
Vaccine Wastage	<ul> <li>A. Implement written procedures for reporting and responding to losses resulting from vaccine expiration, wastage, and compromised cold chain.</li> <li>B. Notify the CVP of vaccine incidents where vaccine has been exposed to temperatures above or below the recommended range for vaccine storage. Follow program guidance on how to respond, document and report the incident.</li> <li>C. Bag affected vaccine, mark it do not use, and store it at appropriate temperatures until viability is confirmed by the manufacturer per the Temperature Excursion Guide.</li> <li>D. Create a written report including the reasons for the vaccine loss. Note the measures taken to correct the cause of the loss and to prevent reoccurrence.</li> <li>E. If the vaccine is deemed non-viable, remove spoiled/expired vaccine from storage units to prevent inadvertent administration to patients. Return all unopened spoiled or expired publicly purchased vaccines within six months following the online state returns process and submit a completed Vaccine Loss Log for losses greater than \$2,500.</li> <li>F. Vaccine losses determined to be the result of negligent vaccine storage and handling practices, or failure to comply with storage and handling requirements may result in corrective action in accordance with the Washington State Vaccine Loss Policy.</li> </ul>
Vaccine Accountability	<ul> <li>A. Submit inventory reports monthly using the Washington State Immunization Information System (IIS).</li> <li>B. Submit patient level vaccination data to the IIS or complete a doses administered report monthly in the IIS.</li> <li>C. Participate in a site visit by the regional representative, which may include process improvement work (IQIP).</li> <li>D. Make immunization records available to the regional representative and the CVP as requested.</li> <li>E. Complete provider satisfaction surveys as requested.</li> </ul>
Billing Guidelines	<ul> <li>A. For patients covered by Apple Health Plans (Medicaid and CHIP), bill according to the Washington State Health Care Authority guidelines (see EPSDT billing guide).</li> <li>B. For patients covered by private/commercial health plans, bill according to health plan guidance and complete the Washington Vaccine Association (WVA)'s Dosage Based Assessment process. Refer to the WVA billing guide and assessment grid.</li> <li>a. Follow all billing guidance from the DOH and the WVA.</li> </ul>
	C. For patients paying out of pocket (uninsured, underinsured, deductibles, out-of-network) for vaccine administration fees, bill patients according to the following:

	<ul> <li>a. Cannot bill for cost of vaccine</li> <li>b. Vaccine administration fee cannot exceed \$23.44 per vaccine dose</li> <li>c. May issue only a single bill with 90 days from date of service</li> <li>d. Cannot send bill to collections for unpaid administration fee</li> </ul>
Record Retention	A. Maintain all records related to the CVP for a minimum of three years and upon request make these records available to DOH for review. Records include, but are not limited to, signed provider agreements, eligibility screening documentation, training documentation, vaccine packing slips, temperature logs, vaccine manufacturer reports for out of range temperatures, vaccine incident documentation, vaccine loss logs, borrowing documentation, and vaccine transfer requests/approvals.
Program Guidance	<ul> <li>A. Follow all program requirements, direction, guidance, and corrective actions issued by DOH and the WVA with respect to the CVP.</li> <li>B. Providers are responsible for transferring remaining publicly-supplied vaccines to another enrolled provider prior to disenrolling from the program.</li> </ul>

By initialing this form, I agree on behalf of myself and all immunization providers in this facility, to the Washington State-specific requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.

is individually accountable) for compliance with these requirements.	
Medical Director or Equivalent Name (print):	

Initials:	Date:

#### **APPENDICES**

### **Appendix 1. Additional Practicing Providers**

**Instructions:** List all licensed health care providers (MD, DO, NP, PA, pharmacist, etc.) at your facility who have prescribing authority. **Must list a valid medical license number & NPI number for each practitioner.** 

Provider Name	Title	Specialty	License No.	NPI No.

### **Appendix 2. Additional Cold Storage Equipment - Refrigerators**

REFRIGERATOR #:		
Name:	Type of Unit (select one):	
	O Commercial Stand-alone O Pharmaceutical/Medical	
Manufacturer:	Model No.:	
In Use Date:	Purchase Date:	
Refrigerator Thermometer:	Type of Unit (select one):	
	O Digital Data Logger O Temperature Monitoring System	
Thermometer Brand/Model Name:	Temperature Scale (select one):	
	O Celsius O Fahrenheit	
Date of Last Calibration:	Calibration Expiration Date:	
REFRIGERATOR #:		
Name:	Type of Unit (select one):	
	O Commercial Stand-alone O Pharmaceutical/Medical	
Manufacturer:	Model No.:	
In Use Date:	Purchase Date:	
Refrigerator Thermometer:	Type of Unit (select one):	
	O Digital Data Logger O Temperature Monitoring System	
Thermometer Brand/Model Name:	Temperature Scale (select one):	
	O Celsius O Fahrenheit	
Date of Last Calibration:	Calibration Expiration Date:	
REFRIGERATOR #:		
Name:	Type of Unit (select one):	
	O Commercial Stand-alone O Pharmaceutical/Medical	
Manufacturer:	Model No.:	
In Use Date:	Purchase Date:	
Refrigerator Thermometer:	Type of Unit (select one):	
	O Digital Data Logger O Temperature Monitoring System	
Thermometer Brand/Model Name:	Temperature Scale (select one):	
	O Celsius O Fahrenheit	
Date of Last Calibration:	Calibration Expiration Date:	

### **Appendix 3. Additional Cold Storage Equipment – Freezers**

FREEZER #:			
Name:	Type of Unit (select one):		
	O Commercial Stand-alone O Pharmaceutical/Medical		
Manufacturer:	Model No.:		
In Use Date:	Purchase Date:		
Freezer Thermometer:	Type of Unit (select one):		
	O Digital Data Logger O Temperature Monitoring System		
Thermometer Brand/Model Name:	Temperature Scale(select one):		
	O Celsius O Fahrenheit		
Date of Last Calibration:	Calibration Expiration Date:		
Can freezer maintain an average temperature o	f 5°F (-15°C) or cooler? O Yes O No		
Does the freezer have a separate, insulated doc	or? O Yes O No		
FREEZER #:			
Name:	Type of Unit (select one):		
	O Commercial Stand-alone O Pharmaceutical/Medical		
Manufacturer:	Model No.:		
In Use Date:	Purchase Date:		
Freezer Thermometer:	Type of Unit (select one):		
	O Digital Data Logger O Temperature Monitoring System		
Thermometer Brand/Model Name:	Temperature Scale(select one):		
	O Celsius O Fahrenheit		
Date of Last Calibration:	Calibration Expiration Date:		
Can freezer maintain an average temperature of 5°F (-15°C) or cooler? O Yes O No			
Does the freezer have a separate, insulated doo	or? O Yes O No		
By Signing this document, I certify that appropriate storage is in place for vaccine.			
Full Name of Provider with Prescriptive (Signature) Authority:			
Signature:	Date:		

### **Appendix 4. State Vaccine Eligible**

- 1. Eligibility for Publicly Funded Vaccines: A Guide for Providers
- 2. Patient Eligibility Screening Record

### **Appendix 5. Provider Type & Specialty Definitions**

#### **Behavioral Health Clinic**

Locations that provide counseling, behavioral therapy, medication, case management, and other types of services to persons with behavioral health disorders. This provider type is used for behavioral health treatment centers where on-site vaccination services are provided.

#### **Birthing Hospital or Birthing Center**

Birthing centers or birthing hospitals where on-site vaccination services are provided.

#### **Community Vaccinator**

Community-wide vaccinators that are external to health departments and conduct vaccination clinics in satellite, temporary, or offsite locations exclusively.

#### **Correctional Facility**

Juvenile correctional facilities as well as adult correctional facilities where juveniles are confined, and onsite vaccination services are provided. Unlike juvenile detention centers, correctional facilities are longterm in nature; youths are confined in secure correctional facilities for periods generally ranging from a few months to a year or more.

#### **Direct Care Provider (membership-based practice)**

A practice that typically charges patients a flat monthly or annual fee, under terms of contract, for a defined set of primary care services to replace the traditional system of third party insurance coverage for primary care services.

#### Family Planning Clinic (non-health department)

Clinics that provide contraceptive services for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STD services (including HIV/AIDS), and other preconception health services (e.g., screening for obesity, smoking, and/or mental health). This provider type is used for family planning clinics where vaccination services are provided. NOTE: Non-health department clinics that offer only STD/HIV screening and treatment services should be categorized as "STD/HIV Clinic (non-health department)."

#### **Federally Qualified Health Center**

Community-based health care providers that offer primary care services in underserved areas and meet the criteria for "Federally Qualified Health Center (FQHC)" certification as set by the Centers for Medicare and Medicaid Services (CMS) (Section 1861(aa)(4)(B) and section 1905(I)(2)(B) of the Social Security Act). FQHCs include HRSA Health Center Program award recipients and HRSA Health Center Program look-alikes, which are health centers that meet Health Center Program requirements but do not receive federal award funding. NOTE: Certain tribal organizations are also FQHCs. However, for tribal or urban Indian health clinics enrolled as FQHCs, use the "Indian Health Service, Tribal, or Urban Clinic" designation. The FQHC provider type includes any satellite, temporary, or off-site locations where the provider of record (i.e., FQHC personnel) is administering vaccine.

#### Hospital

All hospitals, with the exception of birthing hospitals, where on-site vaccination services are provided. NOTE: For birthing hospitals, use the "Birthing Hospital or Birthing Center" designation.

#### Indian Health Service, Tribal, or Urban Clinic

Indian Health Service (IHS), Tribal, or Urban Indian Health Program facilities that provide vaccination services. Urban Indian Health Centers are also designated Federally Qualified Health Centers and provide comprehensive primary care and related services to American Indians and Alaska Natives. Alaska Village Clinics should be included in this provider type.

#### **Juvenile Detention Center**

Juvenile detention centers where on-site vaccination services are provided. Juvenile detention is defined as the temporary and safe custody of juveniles who are accused of conduct subject to the jurisdiction of the court who require a restricted environment for their own or the community's protection while pending legal action.

#### **Migrant Health Center**

Centers that provide health services, including on-site vaccination services, to migratory and seasonal agricultural workers and their families.

#### **Mobile Provider**

Providers who exclusively store and administer vaccines out of a mobile facility. This designation should NOT be used for providers who have a mobile unit associated with their facility, but the unit is not the primary site for vaccine administration.

#### **Pharmacy**

Stand-alone retail pharmacies (e.g., CVS, Duane Reade, Walgreens) or retail pharmacies within a hospital or health system where on-site vaccination services are provided. This category also includes retail pharmacies that conduct community vaccination clinics at offsite or mobile locations.

#### Private Practice (e.g., family practice, pediatric, primary care)

Private practice locations, including solo, group, or HMO practitioners, where vaccination services are provided. NOTE: Includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., provider location personnel) is administering vaccine.

#### Public Health Department Clinic (state/local)

State or local public health department clinics that provide vaccination services. This category includes public health department-run STD/HIV clinics, family planning clinics, and teen health centers. NOTE: Includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., public health clinic personnel) is administering vaccine.

#### **Refugee Health Clinic**

Clinics that are designated to improve the health care and monitor medical conditions of refugees who have relocated to the United States. This provider type is used for refugee health clinics that provide vaccination services. NOTE: If vaccination services are provided in a location that is co-located in a physical facility with a refugee health clinic but are not administered by refugee health staff, select the category of the provider with oversight of vaccination services.

#### **Residential/Congregate Care Facility**

Out-of-home settings, including group homes, childcare institutions, congregate foster care facilities, where onsite vaccination services are provided. NOTE: If children in these settings receive vaccinations from a mobile provider or community vaccinator, then that provider type should be used.

#### **Retail Health Clinic**

Health clinics located within grocery, drug, or retail stores that provide onsite vaccination services. Retail health clinics generally provide a focused range of protocol-driven healthcare services, such as the treatment of minor illnesses or injuries and vaccination services (e.g., Minute Clinic, Take Care Clinic).

#### **Rural Health Clinic**

Clinics that are located in a non-urbanized Health Professional Shortage Area, Medically Underserved Area, or governor-designated and secretary-certified shortage area. This provider type is used for rural health clinics that provide vaccination services.

#### School-Based Clinic (permanent clinic location)

Permanent school-based clinics that provide vaccination services through 12th grade. NOTE: For non-permanent school-based clinics, use the "Community Vaccinator" designation. The School-Based Clinic (permanent clinic location) provider type includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., school-based clinic personnel) is administering vaccine.

#### **Specialty Provider**

For purposes of the VFC program, "specialty providers" are defined as providers who offer limited care in a specialized environment or for a specific age group within the general population of children aged 0–18 years (e.g., birthing hospitals, birthing centers). Awardees have the option to allow specialty providers to administer only vaccines recommended for the specific populations the providers serve.

#### STD/HIV Clinic (non-health department)

Clinics that provide timely STD/HIV diagnosis, testing with on-site treatment, and partner services. This provider type is used for STD/HIV clinics NOT located within a health department where on-site vaccination services are provided. NOTE: this category should be used by non-HD clinics that exclusively offer STD/HIV screening and treatment services.

#### **Student Health Services**

Permanent school-based clinics that provide vaccination services for college/university students (e.g., Job Corps).

#### Teen Health Center (non-health department)

Teen health centers that are NOT public health department-sponsored and provide on-site vaccination services.

#### **Urgent/Immediate Care Center**

Locations that provide immediate medical outpatient care for the treatment of acute and chronic illness and injury. This provider type should be used for urgent care centers or walk-in clinics where on-site vaccination services are provided.

#### Women, Infants, and Children (WIC) Clinic

Locations that serve low-income pregnant, postpartum, and breastfeeding women, infants, and children up to age 5 who are at nutritional risk by providing nutritious foods to supplement diets, information on healthy eating including breastfeeding promotion and support, and referrals to health care. This provider type is used for WIC clinics that also provide vaccination services. NOTE: If vaccination services are provided in a location that is co-located in a physical facility with a WIC clinic but are not administered by WIC staff, select the category of the provider with oversight of vaccination services.

#### Other

Any provider type not captured in one of the other provider type options (e.g., CVS Minute Clinic or Walgreens Take-Care Clinic).

#### **Appendix 6: Provider Specialty Definitions**

#### **Family Medicine**

Manages common illnesses and conditions for people of all ages, focusing on overall health and well-being throughout the lifespan.

#### **Internal Medicine**

Deals with the prevention, diagnosis, and nonsurgical treatment of diseases and disorders of the internal organs/structures in adults.

#### **OB/GYN**

Obstetrician-gynecologist. Provides specialized services in women's health.

#### **Pediatrics**

Involves disease/disorder prevention, diagnosis, and treatment associated with the physical and developmental health of children from birth to young adulthood.

#### **Preventive Medicine**

Focuses on the health of individuals and communities with the goal of promoting health and well-being and preventing disease, disability, and death.