

WASHINGTON STATE

CVP



Childhood Vaccine Program

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

Vaccine Management Plan



To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov. **DOH 348-223, June 2024**



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Provider Information and Contact Page

PIN: _____

Facility Name: _____

Facility Address: _____

Facilities enrolled in the Washington State Childhood Vaccine Program must maintain a vaccine management plan for routine and emergency situations to protect vaccines and minimize loss due to negligence. Each facility must designate a primary and back up vaccine coordinator responsible for implementing the plan and maintaining program compliance.

Primary Vaccine Coordinator Name:

Telephone:

Email:

Back-Up Vaccine Coordinator Name:

Telephone:

Email:

Washington State Department of Health
Childhood Vaccine Program
(360) 236-2829
WAChildhoodVaccines@doh.wa.gov

Annual Review Documentation

Practice/Clinic name: _____

Plan Prepared by: _____
Name, Title

- Review all your vaccine management plans annually or when responsible staff change
- Update as necessary
- Record the review date below

Last reviewed on _____ by _____
Date Signature

Last reviewed on _____ by _____
Date Signature

Last reviewed on _____ by _____
Date Signature

Last reviewed on _____ by _____
Date Signature

Last reviewed on _____ by _____
Date Signature

Last reviewed on _____ by _____
Date Signature

Last reviewed on _____ by _____
Date Signature

Last reviewed on _____ by _____
Date Signature

Definitions

Aggregate Reporters

Providers that do not provide patient specific immunization data in the Immunization Information System.

Beyond-use date (BUD)

The date or time after which a vaccine should not be administered, stored, or transported. The BUD should never exceed the manufacturer's original expiration date.

Buffered Temperature Probe

Temperature probe designed to prevent false readings by protecting the thermometer from sudden changes in temperature that can occur when opening a refrigerator door. A probe is "buffered" by immersing it in a vial filled with liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., Teflon®, aluminum).

Calibration

Professional measurement of the accuracy of a temperature monitoring device's reading against nationally accepted standards.

Certificate of Calibration

The result of calibration testing recorded in a document, sometimes called a calibration report or certificate of calibration. It states the calibration results, one or more property values and their uncertainties, and confirms the necessary procedures were carried out to ensure validity and traceability.

Cold chain monitor (CCM)

Generally, a single-use device that monitors the temperature inside a vaccine shipping container. CCMs should be thrown away after being checked. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer).

Conditioned water bottles

Frozen water bottles that have been submerged under lukewarm water until the ice block inside can spin freely.

Combination Household Storage Unit

A household-grade storage unit that includes both a refrigerator/freezer in the same unit.

Decrementing

When an administered vaccine is successfully added to the Doses Administered Report and is removed from the Reconciliation page in the IIS.

Digital Data Logger (DDL)

An electronic device that records data digitally over time or in relation to location with either a built-in or external instrument or sensor.

Diluent

A diluting agent (e.g., a liquid) added to reconstitute lyophilized vaccine before administration. Manufacturers of these vaccines also supply the matching diluent.

Dormitory-style (bar-style) storage unit

A combination refrigerator/freezer unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

Doses Administered Report (DAR)

Report that accounts for vaccine administrations during a designated period. This report must be submitted monthly by aggregate reporters and prior to the inventory report.

Economic Order Quantity (EOQ)

A facility's vaccine ordering schedule or assigned window of time to place a vaccine order.

Immunization Information System (IIS)

The Washington State Immunization Information System (IIS) is a statewide, lifetime immunization registry that tracks immunization records for people of all ages. The IIS is a secure, web-based tool for healthcare providers that provides a free and user-friendly way to keep immunization records up-to-date and to know which vaccines patients need.

Minimum/Maximum Temperature

A vaccine storage unit's coldest and warmest temperature reached during a set period of time.

Phase change materials (PCMs)

Engineered packing supplies that help control container temperatures during vaccine transport or shipping.

Physical Inventory

The total amount of vaccine that is physically located within a storage unit at the time inventory is being taken.

Portable Vaccine Storage Unit

A type of powered refrigerator/freezer unit specifically designed for use during vaccine transport. These units require a power source to function and come with a power cord for standard outlets and/or a power cord that can be used in vehicles.

Potency

A vaccine's strength or effectiveness; in the context of this plan, potency refers to a vaccine's response to environmental conditions.

Presentation

Type of packaging for a vaccine (e.g., single-dose vial, multi-dose vial, manufacturer-filled syringe, etc.).

Qualified container and pack-out

A type of container and supplies specifically designed for use when packing vaccines for transport. They are "qualified" through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.

Receiving Vaccine

To inspect and appropriately store vaccine deliveries upon arrival to a facility and confirm receipt of the vaccine shipment in the IIS.

Recommended Order Quantity (ROQ)

An equation used to calculate the number of vaccine doses to be order based on EOQ.

Reconciliation (Inventory) Page

A snapshot in the IIS of the amount of vaccine that should physically be in the storage unit. This page is required to be submitted monthly and referred to as your inventory report. This report must be submitted after your DAR.

Temperature Monitoring System (TMS)

A series of thermometers connected to a main computer or hub. Large providers or hospitals use these systems because they have multiple storage units over a wide area. Providers can track the temperatures of all units through one computer. This is the most complex type of thermometer a provider can use.

Temperature excursions

Any temperature reading that is outside the recommended range for vaccine storage as defined by the manufacturer's package insert.

Tolerance

Compliance with nationally accepted standards for the calibration limits of temperature monitoring equipment. The equipment can be considered either "in" or "out of" tolerance.

Vaccine Order

The number of vaccine doses requested and approved by the program. The approved number of doses is the vaccine order to be delivered to the facility.

Vaccine Return

Any Childhood Vaccine Program vaccine that is expired or spoiled must be physically returned to the distributor McKesson. This includes all vaccine incidents that result in unusable vaccine. Once a return is processed within the IIS, a return label will be generated and sent to the provider in order to return the vaccine by mail.

Childhood Vaccine Program Checklist

Staff are responsible for ensuring requirements of the Washington State Childhood Vaccine Program are met. Below is a checklist of routine vaccine management requirements for the Childhood Vaccine Program.

Daily

For Paper Temperature Logs*:

- ☐ Once daily--record the minimum and maximum temperatures of the storage unit(s)
- ☐ Twice daily--record storage unit(s) temperatures on paper Temperature Log
- ☐ Take action for any temperature excursions. Follow the [Vaccine Temperature Excursion Guide](#)

For Temperature Monitoring System (TMS)/Digital Data Logger (DDL) Reporting (with pre-approval)*:

- ☐ Once daily--record the minimum and maximum temperatures of the storage unit(s) and staff name/initials (manual audit)
 - ☐ Take action for any temperature excursions. Follow the [Vaccine Temperature Excursion Guide](#)
- * See [Temperature Reporting Guide](#)

Weekly

- ☐ Check vaccine expiration dates and rotate vaccine inventory based on expiration dates
- ☐ Download and review data logger temperature information
- ☐ Take action for any missed temperature excursions. Follow the [Vaccine Temperature Excursion Guide](#)

Monthly

- ☐ [Submit Doses Administered Report](#), if an aggregate reporter (see definition above)
- ☐ Conduct a physical count of vaccines in inventory and [Submit Inventory Report](#)
- ☐ Submit paper [Temperature Logs](#) (Ultra-Cold Freezer Logs: [Fahrenheit](#) and [Celsius](#)) or TMS/DDL reports
- ☐ Post [Vaccine Loss Log](#) on storage units

As Needed

- ☐ Submit [Online Vaccine Return/Wastage](#) (and [Vaccine Loss Log](#) if needed) and return non-viable vaccines
- ☐ Retain the [Vaccine Loss Log](#) with your [Temperature Logs](#) or TMS/DDL reports
- ☐ Submit and obtain approval prior to [Off-Site Vaccination Clinics](#) and [Vaccine Online Transfers](#)
- ☐ Submit and retain valid thermometer calibration certifications

Yearly and Staff Changes

- ☐ [Renew Provider Agreement](#)
- ☐ Complete CDC – You Call the Shots Training Modules
 - [Vaccine Storage and Handling](#)
 - [Vaccines for Children \(VFC\)](#)
 - [Keys to Storing and Handling Your Vaccine Supply \(optional\)](#)
- ☐ Review and Update [Vaccine Management Plan](#) (this plan) and [Vaccine Loss Policy](#)

Updates

- ☐ [Notify Childhood Vaccine Program](#) when:
- Key Staff Changes: Signatory, Primary Vaccine Coordinator, Back-up Vaccine Coordinator
 - Ownership of the facility changes (e.g. merges)
 - Address or facility name changes
 - Storage Equipment Changes: new cold storage units, new thermometers, updated calibration certificates

Vaccine Management Plan

All components of the Vaccine Management Plan must be reviewed and updated annually (every 12 months), upon new employee hire, when key staff change, and whenever there are updates to best practices. The annual review must be dated and signed on the Annual Review Documentation page by the coordinator responsible for its content.

Every provider enrolled in the Washington State Childhood Vaccine Program is required to have a Vaccine Management Plan that contains the following:

- ☐ A primary vaccine coordinator and at least one back-up coordinator with current information
- ☐ Required and recommended vaccine storage and handling practices
- ☐ Vaccine shipping and receiving procedures
- ☐ Procedures in an emergency
- ☐ Vaccine ordering procedures
- ☐ Procedures for inventory control and maintenance
- ☐ Vaccine wastage procedures
- ☐ Detailed documentation of vaccine management training within the past year

Templates for all the required Vaccine Management Plan components are available in this document.

Complete and keep these templates near the vaccine storage units in a readily available location to meet this requirement.



Is this Vaccine Management Plan near the storage unit?

☐ Yes ☐ No

Training and Annual Review Documentation

All staff who handle and administer vaccines must receive training regarding vaccine management best practices and the Washington State Childhood Vaccine Program’s Vaccine Management Plan. All staff must sign and date this page once their training is complete.

All staff should have awareness of the Vaccine Management Plan in the event of an emergency and review the plan yearly. At a minimum, training must be recorded below for the Primary and Back-up Coordinators. For best practice, have staff administering vaccine or receiving vaccine shipments take the You Call the Shots training yearly and retain training certificates.

Employee Name (Print First and Last Name)	CDC You Call the Shots: Vaccine Storage and Handling (Date Completed)	CDC You Call the Shots: Vaccines for Children (Date Completed)	Vaccine Management Plan (Date Reviewed)	Vaccine Loss Policy (Date Reviewed)

Vaccine Storage and Handling

Requirements

Thermometers

- ☐ [Thermometers](#) must be digital data loggers or temperature monitoring systems. **No other type of thermometer is allowed. The device must have the following features:**
 - ☐ A temperature probe in a thermal buffer*
 - ☐ An active current, minimum, and maximum temperature display that can be easily read from outside the unit
 - ☐ Alarm for out-of-range temperatures and low battery indicator
 - ☐ Accuracy of +/- 1° F (0.5° C)
 - ☐ User-programmable logging interval (or reading rate) to measure and record temperatures at least every 30 minutes
 - ☐ One thermometer is required for each refrigerator and freezer storing vaccine
 - ☐ Thermometers must be placed in a central area of the storage unit
 - ☐ Thermometers must have a current and valid certificate of calibration issued by an appropriate entity †
 - ☐ One back-up battery operated digital data logger with a current certificate of calibration is required for the facility †

* Digital Data Loggers for Ultra-Cold Temperatures (some Pfizer COVID-19): For accurate ultra-cold temperature monitoring, it is essential to use an air probe, or a probe designed specifically for ultra-cold temperatures with the DDL.

Storage Units

- ☐ Place a “[Do Not Unplug](#)” sign by the electrical outlet used by each storage unit
- ☐ Place a “[Do Not Break Circuit](#)” sign on the circuit breaker and include breaker number along with contact name and phone number
- ☐ Do not use power strips unless approved by the Department of Health
- ☐ Food/drinks are not allowed in a storage unit containing publicly-supplied vaccine
- ☐ Do not store vaccine in the door, vegetable bins, floor, or under the cooling vents of a storage unit
- ☐ Dorm-style storage units and combination household units are NOT allowed for vaccine storage

Temperatures

- ☐ Maintain refrigerator temperatures between [36° F and 46° F \(2° C and 8° C\)](#) and set the unit to approximately 40° F (5° C) for the best safety margin.
- ☐ Maintain freezer temperatures between [- 58° F and +5° F \(-50° C and -15° C\)](#) and set the unit to 0° F (-18° C) for the best safety margin.
- ☐ Maintain ultra-cold freezer temperatures between -130° to - 76° F (- 90° to -60° C).

For Paper Temperature Logs:

- ☐ Record temperatures twice a day and post Temperature Logs on the storage unit.
- ☐ Record Min/Max temperatures on [Temperature Logs](#) each day, preferably in the morning; ultra-cold temperature logs, [Fahrenheit](#) | [Celsius](#).
- ☐ Download and review thermometer data weekly.

For Temperature Monitoring System (TMS)/Digital Data Logger (DDL) Reporting (with pre-approval):

- ☐ Once daily--record the minimum and maximum temperatures of the storage unit(s) and staff name/initials (manual audit).
 - ☐ Download and review thermometer data monthly.
-

Recommendations and Best Practices

- ☐ Store vaccine in its original packaging.
- ☐ Store vaccine with similar packaging in different areas of the storage unit to avoid confusion and administration errors.
- ☐ Open only one vial or box of each vaccine type at any one time to prevent waste.
- ☐ Check and rotate vaccine supply every week so vaccine with the longest expiration date is behind vaccine with the shortest expiration date.
- ☐ Store vaccine in the middle of the storage unit compartment, with space between vaccines and the side/back of the unit.
- ☐ Post a sign on the storage unit showing which vaccines are stored in the freezer and refrigerator.
- ☐ Place water bottles and coolant packs in the storage units to help stabilize temperatures, unless otherwise stated by the storage unit manufacturer.
- ☐ Install locks on vaccine storage units, and place covers on electrical outlets to avoid disconnection from power.
- ☐ Allow only authorized personnel access to the vaccine supply.
- ☐ Plug vaccine storage units directly into an outlet, preferably one storage unit per electrical outlet.
- ☐ Avoid using power outlets that can be tripped or switched off, including multi-outlet power strips (unless medical grade), outlets that can be activated by a wall switch, and/or built-in circuit switches (may have a reset button).

†Thermometer Certification of Calibration Testing

Calibration testing is done to ensure the accuracy of a temperature monitoring device's readings against nationally accepted standards. Calibration testing should be done every two years or according to the manufacturer's suggested timeline.

A Digital Data Logger's Certificate of Calibration Testing should include:

- ☐ Model/device name or number
- ☐ Serial number
- ☐ Date of calibration (report or issue date)
- ☐ Confirmation that the instrument passed testing (or instrument is in tolerance)

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.

To determine if a Certificate of Calibration Testing or Report of Calibration was issued by an appropriate entity, check to see if the certificate indicates one or more of the following items about calibration testing:

- ☐ Conforms to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
- ☐ Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
- ☐ Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
- ☐ Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 Tolerance Class F or higher
- ☐ Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Cold Storage Equipment and Thermometers

Refrigerator 1		
Name of Unit (As it appears in your Provider Agreement)	Type of Unit (Select one): <input type="checkbox"/> Standalone <input type="checkbox"/> Combination Unit	Grade of Unit (Select one) <input type="checkbox"/> Pharmaceutical / Medical <input type="checkbox"/> Commercial / Household
Manufacturer:		Serial Number:
Refrigerator 1 Thermometer:		
Make and Model of Thermometer	Type of Thermometer (Select one): <input type="checkbox"/> Digital Data Logger <input type="checkbox"/> Temperature Monitoring System	
Serial Number:	Temperature Scale (Select one): <input type="checkbox"/> Celsius <input type="checkbox"/> Fahrenheit	
Date of Last Calibration:	Calibration Expiration Date:	
Freezer 1		
Name of Unit (As it appears in your Provider Agreement)	Type of Unit (Select one): <input type="checkbox"/> Standalone <input type="checkbox"/> Combination Unit	Grade of Unit (Select one) <input type="checkbox"/> Pharmaceutical / Medical <input type="checkbox"/> Commercial / Household
Manufacturer:		Serial Number:
Freezer 1 Thermometer:		
Make and Model of Thermometer	Type of Thermometer (Select one): <input type="checkbox"/> Digital Data Logger <input type="checkbox"/> Temperature Monitoring System	
Serial Number:	Temperature Scale (Select one): <input type="checkbox"/> Celsius <input type="checkbox"/> Fahrenheit	
Date of Last Calibration:	Calibration Expiration Date:	

*Copy and paste for more units if necessary

Vaccine Receiving



ALL Childhood Vaccine Program shipments must be accepted by the facility.

NEVER reject or return a vaccine shipment.

Staff Responsible for Vaccine Receiving	
Primary	
Back up	
Other	

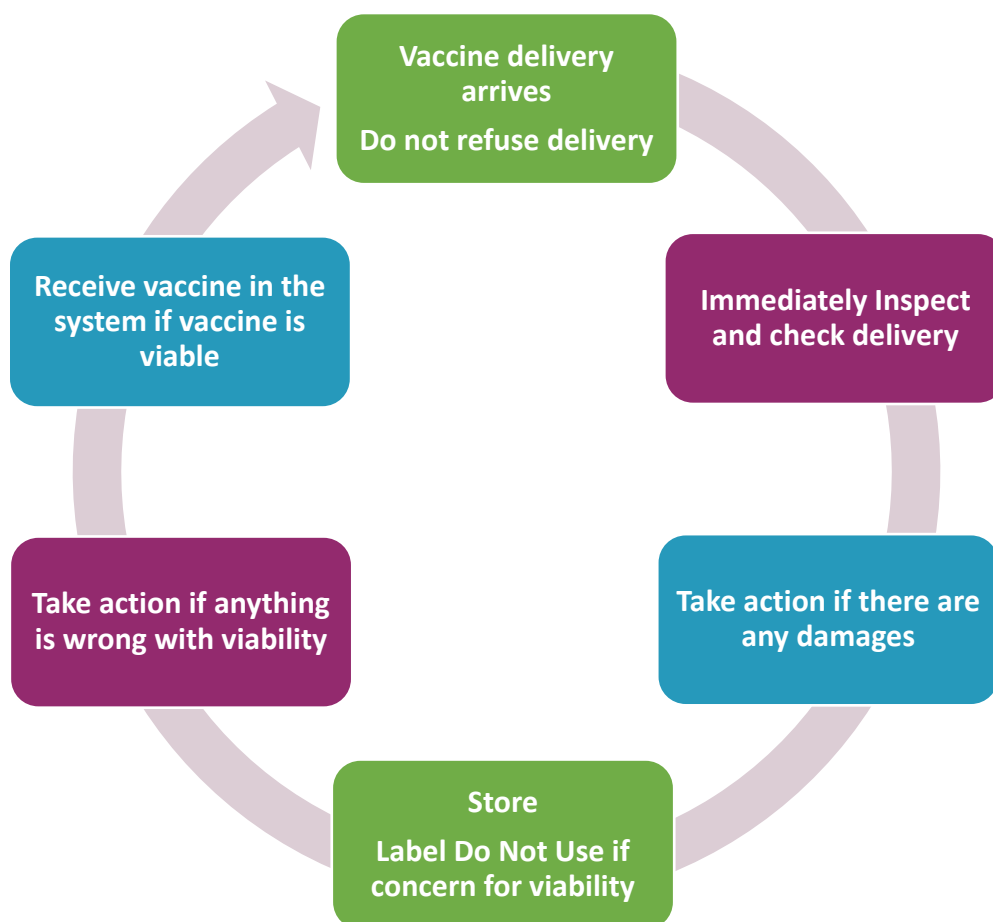
Vaccine Delivery

- ☐ Contact the primary coordinator, back-up coordinator, or other persons to receive the vaccine shipment.
- ☐ Inspect the container and contents for damage.
 - If the package and contents **ARE NOT** damaged – continue unpacking.
 - If the package or contents **ARE** damaged – ***immediately*** contact the Childhood Vaccine Program for McKesson orders, fill out the web-based form **CDC/VFC Vaccine Inquiry Tool** <https://cdcshipping.merck.com/> for Merck orders, or for Pfizer orders call the customer service line at 1-800-666-7248 Option 2.
 - ✓ Label the vaccine **Do Not Use** and store under proper conditions.
 - ✓ **Do not receive the vaccines into the IIS or placed a new order** until the distributor or manufacturer makes a determination.
 - ✓ **Do not reject the order in the IIS** until the distributor or manufacturer makes a determination.
- ☐ Open the package immediately and check the temperature indicators or shipping insert.
 - Refrigerated vaccines ship with temperature indicators. Read the indicators to determine if vaccines were exposed to out-of-range temperatures.
 - Varicella-containing vaccines come with a shipping insert indicating the allowable shipping time. Check the packing slip's shipment date to determine how long the vaccines were in transit.
 - Pfizer direct ship COVID-19 vaccine may come with a digital data logger (DDL) or cold chain monitor (CCM) that needs to be returned. Return instructions are located in the shipping container.
 - If the indicators or shipping insert **ARE** within range/time – continue unpacking and store under proper conditions.
 - If the indicators or shipping insert **ARE NOT** within range/time – ***immediately*** contact the manufacturer/distributor on the chart on the next page **AND**:
 - ✓ Note the date, time, and temperature monitor reading
 - ✓ Label the vaccine **Do Not Use** and store under proper conditions in your storage unit

- ✓ **Do not receive the vaccines or reject the order in the IIS** until the distributor or manufacturer makes a determination.
 - ✓ Do not place a new order in the IIS as a replacement until McKesson, Merck or Pfizer makes a determination.
- Crosscheck package contents and expiration dates with the packing slip. If shipment does not match what was ordered, contact the Childhood Vaccine Program. Report any identified issues **immediately**. **The vaccine distributor and Childhood Vaccine Program must be contacted the same day the vaccine arrived from the carrier.**

For delivery issues, contact the vaccine distributor, manufacturer, or the Childhood Vaccine Program immediately (same day notification is required):	
McKesson Specialty	877-836-7123 (only for viability issues during shipment)
Merck Frozen Vaccines & Diluent	https://cdcshipping.merck.com/
Pfizer COVID-19	800-666-7248 Option 2
Childhood Vaccine Program	360-236-2829 or wachildhoodvaccines@doh.wa.gov (for all shipping issues with McKesson)

- [Receive vaccine](#) using the Washington State Immunization Information System (IIS) so the inventory is up-to-date and ready for online reporting.



Vaccine Emergency Plan

Do not risk staff safety during an emergency. Use common sense when attempting to protect vaccines. Use the following guidance for safeguarding vaccines in the event of an emergency, such as mechanical failure, power outage, natural disaster, or human error.

In an emergency, contact the following people in the order listed:

Name	Role/Responsibility	Phone #	Alt Phone #	E-mail Address
1.				
2.				
3.				
4.				

Does the facility have a generator? ☐ Yes ☐ No
If so, where is it located?

It may be necessary to transport vaccines to an alternate storage location (e.g., a local hospital or another provider). Identify alternate location(s) that has vaccine storage units. The alternate location cannot be a provider or staff member's personal residence.

Alternate Facility	Address & City	Contact Name	Contact Information



Do you have a written agreement between you and your back-up facility? ☐ Yes ☐ No

Location of Back-up Digital Data Logger:

Location of Emergency Packing Supplies:

Useful Emergency Numbers

Service	Name	Phone #	Alt Phone #	E-mail
Utility Company				
Building Maintenance				
Building Alarm Company				
Refrigerator/Freezer Alarm Company				
Refrigerator/Freezer Repair				

During an Emergency

Due to the risk to vaccines from improper packing and transporting, follow these instructions during an emergency to determine whether vaccines should be transported or sheltered in place.

Step	Description
------	-------------

- | | |
|----|---|
| 1. | Do not open the unit. |
| 2. | Place a “DO NOT OPEN” sign on vaccine storage unit(s) and leave door(s) shut to conserve cold air. |
| 3. | Notify the emergency contacts. |
| 4. | Note the time the outage started and document storage unit temperatures (CURRENT, MIN and MAX). |
| 5. | Assess the cause of the power failure and estimate the time it will take to restore power. |
| 6. | Take appropriate action.
In the event of appliance failure: <ul style="list-style-type: none">Place vaccines in an approved backup storage unit with a program compliant data logger, or transport vaccines to the designated alternate storage facility. (Refer to Vaccine Transport section for instructions.) In the event of thermometer failure: <ul style="list-style-type: none">Place back up thermometer in storage unit.Monitor and continually document temperatures until thermometer is reading temperatures within required ranges. For power outages: <ul style="list-style-type: none">Monitor storage unit temperatures.If temperatures near out-of-range conditions, or for outages that extend beyond the current business day, transport vaccines to the alternate storage facility. (Refer to Vaccine Transport section for instructions.)Monitor temperatures throughout transport and report any excursions. (Refer to Vaccine Temperature Excursion Guide) |
| 7. | Once power has been restored, follow the steps listed in After an Emergency section. |
-

After an Emergency

Follow these instructions after vaccine-related emergencies.

Step	Description
1.	Verify power is restored and storage units are functioning properly.
2.	Once vaccine storage unit temperatures have stabilized, notify the emergency contacts identified on the vaccine management plan.
3.	If vaccines were transported due to an emergency: <ul style="list-style-type: none">• Follow the same transportation procedures and transfer vaccine back to original storage unit.• If vaccines were kept within proper temperature during the power outage, notify supervisor that the vaccines may be used.
4.	If vaccines were maintained within required temperatures: <ul style="list-style-type: none">• Remove the “DO NOT OPEN” sign from storage unit(s).• Notify supervisor that vaccines may be used.
5.	If vaccines were exposed to out-of-range temperatures: <ul style="list-style-type: none">• Store vaccine under proper conditions as quickly as possible.• Label affected vaccines “Do Not Use.”• Follow the Vaccine Temperature Excursion Guide and contact vaccine manufacturers to determine whether the vaccines are viable. Be prepared to provide documentation and data logger information. Follow manufacturer guidance based on viability of vaccines.• If manufacturer guidance is unclear, contact the Childhood Vaccine Program at WACHildhoodVaccines@doh.wa.gov with the manufacturer results to determine next steps.

In case of a temperature excursion, call the manufacturers to determine vaccine viability		
AstraZeneca (Medimmune) 800-236-9933	Merck 800-672-6372	Pfizer 800-438-1985
GlaxoSmithKline 888-825-5249	Moderna 866-663-3762	Sanofi Pasteur 800-822-2463
MassBiologics (Grifols) 800-520-2807	Novavax 855-239-9174	Seqirus 855-358-8966

Facility Closure Policy

The policy for temperature monitoring of publicly supplied vaccines during both short-term and extended facility closures are as follows:

For Closures 10 Days or Less:

- ☐ Vaccine temperatures (min/max and current) must be checked every 5 days at a minimum.
- ☐ A staff member must physically go to the facility to do this temperature check or staff can check temperatures remotely if DDLs have that functionality. Temperatures must be recorded on temperature logs for submission in REDCap.
- ☐ If your system has a remote alert option, which sends out a message if temperatures move out of acceptable range, please ensure this feature is enabled.
- ☐ A staff member must be available during the closure to respond to emergencies (power outages, out-of-range temperatures, etc.) and be ready to follow the Vaccine Emergency Plan.

For Closures 11 -30 Days:

- ☐ Vaccines can be left on-site if the building is accessible or temperatures from vaccine storage units can be monitored remotely if DDLs have that functionality. Staff must be available to check temperatures every 5 days and temperatures must be recorded on temperature logs for submission in REDCap.
- ☐ If your system has a remote alert option, which sends out a message if temperatures move out of acceptable range, please ensure this feature is enabled.
- ☐ A staff member must be available during the closure to respond to emergencies (power outages, out-of-range temperatures, etc.) and be ready to follow the Vaccine Emergency Plan.
- ☐ Download and thoroughly review all temperature data before resuming vaccinations to ensure no temperature excursions happened while the facility was closed.

OR, if this is not possible,

- ☐ Vaccine must be transported to another Childhood Vaccine Program enrolled provider who can store and monitor it during the closure. An online vaccine transfer request does not need to be completed for this, however, please notify WACHildhoodVaccines@doh.wa.gov with where the vaccines are temporarily being stored.
- ☐ Once facility operation resumes, vaccines can be transported back to the facility of origin. Review temperature data to ensure the storage unit is working properly before transporting and placing vaccine back inside the unit.
- ☐ Documentation on the Temperature Log during transport and while stored at the alternate location is important to verify all vaccine temperatures stayed within range.

For Closures Greater Than 30 Days:

- ☐ Notify WACHildhoodVaccines@doh.wa.gov of facility closure and estimated re-opening date.
- ☐ Transfer all vaccine to another enrolled provider who can use the vaccine before expiration.
- ☐ Please follow the [Vaccine Online Transfer Guide](#) to receive pre-approval.
- ☐ Adjust inventory in the IIS to reflect the transferred vaccine, if needed.
- ☐ Once facility operation resumes, submit DDL temperature data in REDCap for approval to ensure the storage unit is working properly (3-5 days minimum). If unit is working properly, place a new vaccine order.

Reminder: As long as all publicly supplied vaccine is transferred out, monthly Temperature Logs or TMS/DDL reports are not required to be submitted. Temperature Logs or TMS/DDL reports will be required once storage of vaccine received through the Childhood Vaccine Program resumes.

Vaccine Transport

It is critical vaccine potency is always protected by maintaining the cold chain during transport of vaccines. Program guidelines for transporting vaccine and use of proper equipment must be followed. Refer to the [Vaccine Transport Guidelines](#) document found on the [Vaccine Storage and Handling](#) webpage for more details.

Vaccine Transfer/Transport Equipment				
Type of Unit	Emergency Transport	Routine Transfer	Off-site Clinic	Clinic Move
Portable Vaccine Refrigerator or Freezer	Yes	Yes	Yes	Yes
Qualified Container and Packout	Yes	Yes	Yes	Yes
Conditioned Water Bottle Transport System	Yes	Yes	No	Yes
Hard-sided cooler	Yes	Yes	No	Yes
Manufacturer's Original Shipping Container	Yes (Last resort only)	No	No	Yes (Last resort only)
Pre-approval Required	No*	Yes	Yes	Yes

*Transporting vaccine during an emergency (i.e., power outage) does not require pre-approval

Vaccine Transport Requirements

- ☐ Use proper vaccine transport equipment (see table).
- ☐ Place the buffered thermometer probe inside the transport container with the vaccine.
- ☐ Monitor vaccine temperatures during transport with a certified digital data logger.
- ☐ Always stay with the vaccine during transport. Promptly place the vaccine into appropriate storage units upon arrival.
- ☐ When transporting vaccines in vehicles, use the passenger compartment and not the trunk.
- ☐ Frozen varicella-containing vaccine can only be transported with a qualified container and pack-out and/or portable freezer.
- ☐ Considerations for COVID-19 vaccine (see [COVID Vaccines at-a-Glance](#) for more information):
 - Ultra-cold presentations of Pfizer COVID-19 vaccine (multi-dose and single dose vials) can be transported at ultra-cold temperatures (-90°C to -60°C or -130°F to -76°F) or at refrigerated temperatures (2°C to 8°C or 36°F to 46°F). The vaccine can be stored for 10 weeks at refrigerated temperatures and up to the expiration date at ultra cold temperatures. This vaccine should not be stored at regular freezer temperatures.
 - Moderna COVID-19 vaccine can be transported at regular freezer temperatures (-50°C to -15°C or -58°F to 5°F) or at refrigerated temperatures (2°C to 8°C or 36°F to 46°F). The vaccine can be stored for 30-days at refrigerated temperatures and up to the expiration date at freezer temperatures.
 - For both Moderna and ultra-cold presentations of Pfizer COVID-19 vaccines: If vaccine is thawed and transported at 2°C to 8°C (36°F to 46°F), vials should not be refrozen and should be stored at 2°C to 8°C (36°F to 46°F) until use. The refrigerated beyond use date should be recorded on the carton after the transport.

Vaccine Transfers

- ☐ Transferring vaccine is highly discouraged. Providers should only transfer vaccine that is within 90 days of expiration or for clinic closures of more than 30 days.
- ☐ Please follow the [Vaccine Online Transfer Guide](#) to receive pre-approval unless it is an emergency transfer due to power outage or storage unit failure.
- ☐ Follow vaccine transport guidelines (see above).

Off-Site Vaccination Clinics

- ☐ Contact the Childhood Vaccine Program well in advance of the scheduled off-site clinic to receive approval. Please use the [Off-Site Vaccination Clinic](#) form to receive pre-approval.
- ☐ Follow vaccine transport guidelines (see above).
- ☐ Monitor vaccine temperatures during transport and throughout the clinic with a certified digital data logger and record temperatures hourly using a paper Temperature Log.
- ☐ After the clinic, download and review the digital data logger's temperature data.
- ☐ Assure the total time for vaccine transport and clinic workday does not exceed 8 hours.

Clinic Moves

- ☐ Contact the Childhood Vaccine Program well in advance of the scheduled move to receive approval. Please use the [Clinic Move Checklist](#) form to receive pre-approval.
- ☐ Follow vaccine transport guidelines (see above).

EOQ and ROQ

Economic Order Quantity (EOQ)

EOQ is the facility's assigned vaccine ordering schedule and is displayed on the orders page in the Immunization Information System (IIS). It encompasses:

- Frequency - how often an order may be placed
- Timing - time of the month an order may be placed
- Schedule - the months an order may be placed

All providers enrolled in the Childhood Vaccine Program are assigned to a monthly ordering frequency with a time period of either the 1st through the 15th of the month or 16th through the end of the month. Providers are required to order according to their assigned EOQ but are not required to place an order every month. If you would like a review of the assigned EOQ for your facility, please contact us at

WACHildhoodVaccines@doh.wa.gov.

Recommended Order Quantity (ROQ)

ROQ is an equation used to calculate the appropriate number of doses to be ordered according to the assigned EOQ including a 30-day vaccine safety supply. The [ROQ Calculator](#) is intended to ensure enough vaccine is ordered to avoid running out of vaccine between orders, while also reducing over ordering or stockpiling vaccine supplies.

If your facility is in danger of running out of publicly supplied childhood vaccine, an order may be place outside the assigned EOQ. Please review the ordering and doses administered patterns for your facility and make necessary adjustments to your ROQ if frequently running low on vaccine between orders. Additionally, it is recommended a 30-day safety stock of publicly supplied vaccine be maintained in case of emergencies or delays in vaccine deliveries.

For more information regarding EOQ and ROQ, please see the [Economic Order Quantity \(EOQ\)/Recommended Order Quantity \(ROQ\)](#) guide and [Vaccine Order Schedule Information](#) guide.

Ordering Vaccine

- ☐ Order using the Washington State Immunization Information System (IIS)
- ☐ Place orders according to EOQ schedule
- ☐ [Calculate a Recommended Order Quantity](#) (ROQ) that includes a back-up safety supply. Order enough vaccine to avoid running out, but do not order too much or stockpile inventory.
- ☐ EOQ does not apply to seasonal influenza vaccines, COVID-19 vaccine, or vaccines with limited availability.
- ☐ Influenza vaccine and COVID-19 vaccine can be ordered as needed for a 30-day supply.
- ☐ The *Holiday Shipping Schedule* runs November through January. This schedule restricts vaccine shipping to prevent orders from being delivered on certain dates.
 - ☐ Order outside your Economic Order Quantity schedule before the Holiday Shipping Schedule delivery hold dates to ensure adequate stock November through January.
- ☐ In addition to holiday shipping schedules, vaccine orders may not be delivered due to weather delays. It is important to ensure adequate stock is maintained and ordered appropriately.

Circle or highlight your facility's Economic Order Schedule:

Frequency:	Monthly	
Timing:	1st-15th	16th-last day of the month

For more information regarding ordering, see the [Vaccine Ordering & Receiving](#) guide.

Vaccines available in single doses: Td, PPSV23

Td and PPSV23 are available for ordering in single dose quantities in the Immunization Information System for the Childhood Vaccine Program. Because of the limited use of these vaccines please order a dose or doses for your patients only when needed. It is not required for your facility to have these vaccines routinely on hand.

Inventory Management

Accurate inventory management assures vaccine is available for patients when needed and prevents vaccine waste.

Managing and Tracking Inventory

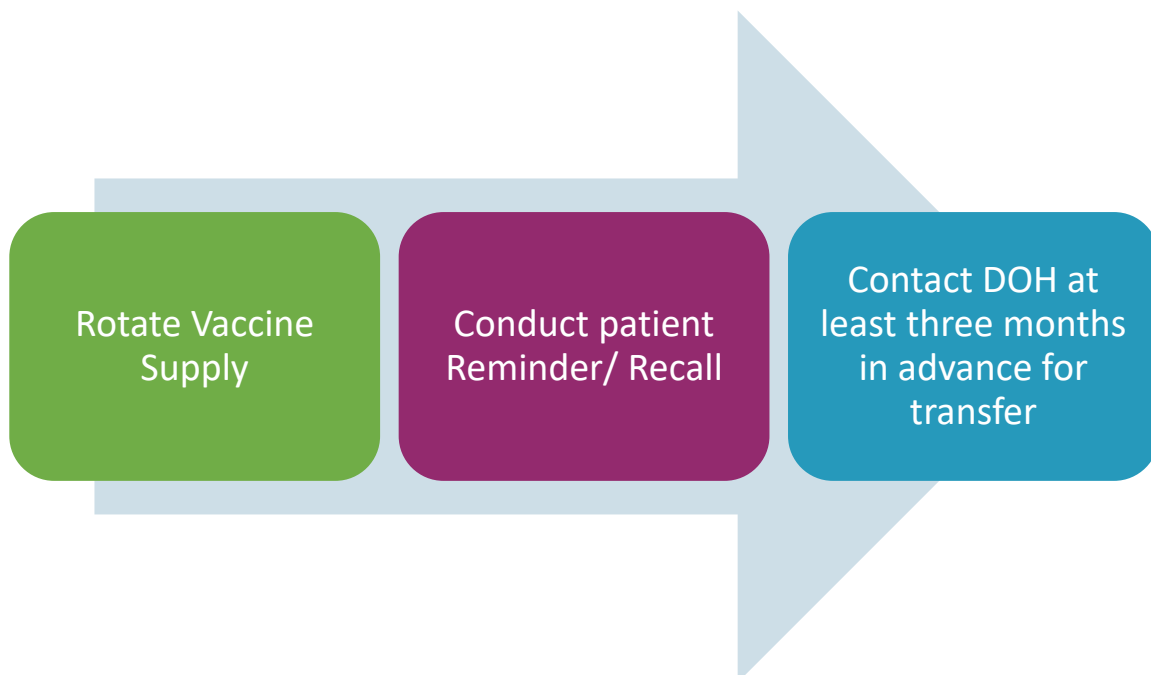
Reporting Vaccine	<ul style="list-style-type: none"><input type="checkbox"/> Complete monthly inventory report* using the Immunization Information System (IIS).<input type="checkbox"/> If significant adjustments are occurring on the inventory report troubleshoot using the patient detail report. If using an interface use the guide on Managing Inventory.<input type="checkbox"/> If an aggregate reporter, account for doses used from inventory each month by submitting the Doses Administered Report* using the IIS<input type="checkbox"/> If immunization data is provided in the Immunization Information System, ensure that the information is accurate for patient records.
Ordering Vaccine	<ul style="list-style-type: none"><input type="checkbox"/> Order vaccine during the assigned EOQ timeframe and/or when there is only a 30-day supply remaining in inventory.<input type="checkbox"/> Conduct a physical count of vaccines in inventory before placing an order.<input type="checkbox"/> Account for any special circumstances (back to school, special clinics, etc.) resulting in an increased need for vaccine when determining the number of doses to order.<input type="checkbox"/> Maintain enough inventory to meet patient needs while avoiding stockpiling vaccine inventory. Not having enough vaccine increases the chance of missing vaccination opportunities. Stockpiling vaccine increases the risk of wasting vaccine due to expiration or during a storage incident.<input type="checkbox"/> Follow EOQ and ROQ recommendations.
Receiving Vaccine	<ul style="list-style-type: none"><input type="checkbox"/> Enter all vaccine inventory into the IIS by receiving vaccine shipments through the Inbound Order Screen.<input type="checkbox"/> Rotate stock every time an inventory is conducted so vaccine doses closest to expiration are used first.
Returning Vaccine	<ul style="list-style-type: none"><input type="checkbox"/> Adjust vaccine inventory using the Reconciliation screen when vaccine is wasted, expired, spoiled, or transferred.<input type="checkbox"/> Follow the online vaccine return process in order to receive a UPS shipping label to return non-viable (expired, spoiled, etc.) vaccine to McKesson.

*Clinics are required to submit their Reconciliation Report in the IIS prior to placing a vaccine order in addition to submitting paper Temperature Logs or TMS/DDL reports. If you are one of the few clinics that are aggregate reporters, then the Doses Administered Report is also required. *For more information refer to the Accountability & Reporting section in this plan.*

Short Dated Vaccine

Every effort should be made to avoid large amounts of short dated vaccine. Below are best practices for getting the vaccine used:

- ☐ Ensure proper stock rotation so vaccine doses closest to expiration are used first.
- ☐ Run a [Reminder/Recall report](#) to locate patients who are due or past due for the vaccine. Contact them for an immunization appointment.
- ☐ Contact the Childhood Vaccine Program to arrange a possible transfer of vaccine to another participating clinic who can administer the vaccine before expiration.
 - Due to the increased risk of a temperature excursion occurring during transport, vaccine transfers should only be used as the option of last resort to reduce waste.
 - If you have vaccine expiring within three months and do not expect it will be used, notify the program at WACHildhoodVaccines@doh.wa.gov.
 - Use the [provider map](#) to help locate another Childhood Vaccine Program enrolled clinic within close proximity who may administer the vaccine before expiration.
 - The Vaccine Advertisement feature in the IIS under Orders/Transfers can also be used to help transfer short dated vaccine. Advertising can be one strategy, but it shouldn't be the only strategy as this feature is not widely utilized by Childhood Vaccine Program providers. You still need to actively contact providers using the provider map to transfer the soon to expire vaccine.
 - All vaccine transfers need prior approval from the program, providers must follow the [Vaccine Online Transfer Guide](#) to submit an online transfer request in the IIS.



Accountability and Reporting

Providers enrolled in the Childhood Vaccine Program are required to complete monthly reports and be accountable for all publicly supplied vaccine received by the facility. For assistance with report submission, please contact the Childhood Vaccine Program at 360-236-2829 or WAChildhoodVaccines@doh.wa.gov or the IIS Help Desk at 1-800-325-5599 or WAIISHelpDesk@doh.wa.gov.

Monthly Accountability Checklist

- Submit the Doses Administered Report if facility is an aggregate reporter
- Submit the Reconciliation (Inventory) Report
- Submit paper Temperature Logs or TMS/DDL reports
- Respond to any email inquiries regarding submitted reports

Inventory (Reconciliation) Report

- The Inventory report is a reconciliation or accounting of the current vaccine inventory. In other words, it is a snapshot of what is in your vaccine storage unit at that exact point in time. Please see the [Inventory Report Guide](#) for instructions.
- To submit the inventory report on the reconciliation screen, vaccine must be received in the Immunization Information System (IIS). Please see the [Vaccine Ordering & Receiving Guide](#) to learn how to receive vaccine in the IIS.

Tips and Things to Remember

- Post the [Vaccine Coordinator Quick Start Guide](#) on your storage unit as a reminder of the basic duties to ensure proper temperature monitoring and accountability reporting.
- Post the [Vaccine Loss Log](#) on your storage unit to track and record vaccine waste. This will help with monthly inventory adjustments and properly accounting for vaccine.
- Sometimes vaccine doses may not appear in the IIS until the next day.
- Use the lot number on the box and only open one box of vaccine at a time.
- Conduct inventory counts first thing in the morning or at the end of the day.
- When using the Online Return functionality, do not inactivate the vaccine lot number until the online return is created under the Create/View Orders screen. The return will not generate correctly if the lot number is inactivated prior to submitting the return. Please see the [Online Return Guide](#) for instructions.

Vaccine Wastage

Providers enrolled in the Childhood Vaccine Program are required to report all instances of expired, spoiled, wasted, or transferred vaccines to the program by using the [online returns/waste](#) module in the Immunization Information System (IIS).

Vaccine Wastage Type

Expired	Any vaccine with an expiration date that has passed.
Spoiled	Any vaccine exposed to temperature exceeding the required range for appropriate vaccine storage and is deemed non-viable or spoiled due to the temperature excursion. Providers should contact vaccine manufacturer for guidance on determining if vaccine is spoiled based on the parameters of the incident.
Wasted	Any vaccine that cannot be used due to spillage, vial breakage, drawn but not administered, etc.
Lost or Missing	Any vaccine that cannot be accounted for or is missing.
Borrowing	Intentional use of incorrect vaccine supply (public or private) for use in a patient not eligible for that supply type with plans to replace the vaccine when proper inventory becomes available. Borrowing vaccine between public and private stock is not allowed.

Requirements and Reporting

- Remove wasted, expired, and spoiled vaccine from vaccine storage units to prevent inadvertent administration to patients.
- Bag and label all expired/spoiled/wasted vaccine as “DO NOT USE”.
- Return all expired or spoiled vaccine **within six months** to the distributor for excise tax credit. Wasted vaccine should be disposed of properly.
 - All unopened expired and spoiled vaccines must be returned to McKesson Distribution. To return the vaccine, complete the online return process with the IIS. This process will generate a label that will be emailed to the address on file to return the vaccine.
 - For instructions, please see the [Online Vaccine Return Quick Reference Guide](#).
- Contact the appropriate vaccine manufacturer for guidance on determining if vaccine is spoiled based on the parameters of the storage and handling incident. Follow the [Vaccine Temperature Excursion Guide](#) for assistance.
- Notify the program **immediately** and submit the [Vaccine Loss Log](#) outlining the wastage incident if vaccine is unusable due to a storage and handling incident.

Eligibility Screening

Requirements

All providers participating in the Childhood Vaccine Program must document patient age and eligibility status at every immunization visit, prior to vaccine administration. The patient, parent, or legal guardian may be asked the screening questions or be asked to fill out a form to collect the information. In Washington State, children under the age of 19 will meet one of the categories listed below.

Federal Eligibility Categories:

- Medicaid
- Uninsured
- Underinsured at a Federally Qualified Health Center/Rural Health Center (FQHC/RHC)
- Alaska Native/American Indian

State Eligibility Categories:

- Private/Commercial Insurance
- Children's Health Insurance Program (CHIP) or Children's Health Plan (CHP)

Documentation

Patient eligibility documentation must be standardized at the provider site regardless of the method (paper or electronic) used. Screening documentation may be completed using:

- [The Patient Eligibility Status Screening Record](#)
- [The Washington State Immunization Information System \(IIS\)](#)
- An electronic health record (EHR)
- A provider developed form

Billing



UNPAID VACCINE ADMINISTRATION FEES CANNOT BE SENT TO COLLECTIONS

Requirements

The Childhood Vaccine Program uses a combination of federal and state funds to provide over \$170 million in vaccines to enrolled providers each year for children under the age of 19. In accordance with state and federal requirements, participating facilities are required to bill for publicly supplied vaccines according to program requirements outlined in the [Eligibility for Publicly Funded Vaccines – A Guide for Providers](#). The billing guidelines for publicly supplied vaccine depends upon the patient's eligibility category.

- Patients screened as federally eligible cannot be billed for the cost of publicly supplied vaccines.
- Patients screened as state eligible with Private Insurance must be billed for the cost of publicly supplied vaccines in accordance with the [Washington Vaccine Association's](#) process and policy.
- Administration fee cap established by the Centers for Medicare and Medicaid Services (CMS) is set at \$23.44 for Washington State.
 - Patients paying the vaccine administration fee may not be charged more than \$23.44 per vaccine dose.
 - Health plans paying the vaccine administration fee may be billed in accordance with current contracted health plan rates.
- Providers may issue one bill within 90 days of immunization service to the patient.
- Established patients cannot be refused immunization services for an inability to pay vaccine administration fee(s).
- Unpaid vaccine administration fees cannot be sent to collections.

Billing Contact Information		
Contact Name:	Phone Number:	Email
Contact Name:	Phone Number	Email

Helpful Training Links

[Washington State Childhood Vaccine Program](#)

[Washington State Childhood Vaccine Program Training](#)

[IIS Training Portal](#)

[Washington State's Vaccine Storage and Handling](#)

[Vaccine Coordinator Quick Start Guide](#)

[CDC's Vaccine Storage and Handling Resources](#)

[CDC's General Best Practice Guidelines for Immunization \(ACIP\)](#)

[CDC's You Call the Shots Trainings \(*Vaccines for Children \(VFC\) & Vaccine Storage and Handling*\)](#)