

Vaccine Accountability and Management Business Rules and Guidelines

2013

Washington State Childhood Vaccine Program

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Vaccine Accountability and Management Business Rules and Guidelines Washington State Childhood Vaccine Program

Table of Contents

Executive Summary	3
Terms and Abbreviations	4
Provider Enrollment And Participation	5
Principles of Provider Participation.....	6
Vaccine Ordering	7
Order Approval: Authority, Process, and Appropriateness	8
Provider Ordering Forms.....	8
Frozen Vaccine Eligibility and Ordering	8
Principles of Vaccine Ordering and Inventory Management	9
Provider Inventory Maintenance.....	9
Provider Ordering and Inventory Management: LHJ Role.....	10
Exceptions to Established Provider Ordering Frequency	10
Assessing the Appropriateness of An Order	10
Emergency Orders	11
Provider Order Placement Methods	11
Granting Provider Access to VOMS	12
LHJ Processing and Submission of Provider Orders	12
Vaccine Delivery and Receiving	13
Principles of Provider Receiving.....	14
Receiving Practices.....	15
Timeline for Delivery to Providers	15
Monitoring the Status of Vaccine Shipments.....	16
Vaccine Transfers	17
Delivery and Receiving of Frozen Vaccines	17
Use of Alternate Delivery Sites.....	18
Emergency Deliveries	18
Decision Making Regarding Central Pharmacy Practices	19
Quality Assurance and Accountability	20
Promoting Best Practices.....	21
Ensuring Provider Information is Correct	21
Processing Vaccine Returns: Basics.....	22
LHJ Options for Processing Vaccine Returns	22
Vaccine Usage Report: Inventory Tracking.....	23
Vaccine Usage Report: Physical Inventory	24
Vaccine Usage Report: Doses Administered	24
Temperature Logs.....	25
Records Retention	25
Vaccine Storage Basics	26
Vaccine Storage and Handling Plans.....	27
General Guidelines for Remediation	28
General Guidelines for Remediation Documentation	29

Vaccine Accountability and Management Business Rules and Guidelines Washington State Childhood Vaccine Program

Executive Summary

The Vaccine Accountability and Management Business Rules and Guidelines for the Washington State Childhood Vaccine Program promote best practices in vaccine management. The guidelines support the partnership and efforts of the Department of Health (the department), local health jurisdictions (LHJs) and providers. By being good stewards of the national Vaccines for Children (VFC) program, we can ensure an adequate vaccine supply. Together, we help Washington children have access to ACIP recommended vaccines and protect them against vaccine preventable diseases.

LHJs carry out the State Childhood Vaccine Program at the local level. They link the department and providers through immunization practices and vaccine storage and handling. LHJs assure the quality of services by providing technical help and consultation for vaccine management and immunization practices. LHJ responsibilities include:

- Enrolling providers in the State Childhood Vaccine Program
- Monitoring provider participation in the program
- Monitoring and approving provider vaccine orders
- Conducting quality assurance activities
- Overseeing provider accountability
- Supporting provider and community education and training activities

These business rules and guidelines are a revision of the 2010 Vaccine Accountability and Management Business Rules and Guidelines. A Public Health Advisory Committee representing 16 local health jurisdictions helped create the original document. Almost every local health jurisdiction in the state participated by providing advice and insight based on their practical experiences. The department updates these guidelines to reflect current best practices.

If you need assistance or help regarding the Guidelines, please contact the [State Department of Health Office of Immunization and Child Profile](#).

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Terms and Abbreviations

The Centers for Disease Control and Prevention ([CDC](#)):

The federal public health agency that manages the VFC program.

Washington State Immunization Information System ([IIS](#)):

A web-based statewide registry of patients' demographic and immunization data.

Department of Health ([department](#)):

The Washington State public health agency.

Local Health Jurisdiction ([LHJ](#)):

The local public health organization. The LHJ may be a single county department or multi-county district. The LHJ implements the State Childhood Vaccine Program at the local level and is the primary contact for local health care providers.

Provider:

An individual, partnership, private organization, or public organization enrolled in the State Childhood Vaccine Program.

State Childhood Vaccine Program:

The state program that ensures Washington's children get vaccines to help prevent disease. The program is administered by the State Department of Health and is supported by state and federal funds.

Vaccines For Children Program ([VFC](#)):

The federal portion of the State Childhood Vaccine Program.

Vaccine Ordering and Management System ([VOMS](#)):

The functions within the Washington State Immunization Information System that support vaccine management activities (e.g., ordering vaccine, managing inventory, submitting accountability data and others).

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

**Vaccine Management and Accountability
Business Rules and Guidelines:
Provider Enrollment and Participation**

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Principles of Provider Participation
<p align="center">Provider Enrollment and Participation</p>	<ul style="list-style-type: none"> • Local Health Jurisdictions (LHJs) are the point of contact for provider enrollment and participation in the State Childhood Vaccine Program. Refer to the Provider Enrollment Packet on the Immunization website. • Providers must have a current, signed Provider Agreement for Receipt of Publicly Supplied Vaccine to participate in the childhood vaccine program and order vaccine. • Providers must contact LHJs in order to establish a Provider Agreement for Receipt of Publicly Supplied Vaccine. • LHJs are the point of contact for provider quality assurance and accountability activities. • The provider agrees to adhere to the vaccine accountability and quality assurance requirements of the agreement by signing the Provider Agreement for Receipt of Publicly Supplied Vaccine. • Providers must designate a primary vaccine coordinator and at least one back-up staff. • Providers must ensure shipping information is updated in the Provider Agreement for Receipt of Publicly Supplied Vaccine anytime a change occurs (e.g. current ship to address, special shipping instructions, receiving hours, and contact information). • Providers will choose the brand of vaccine they want to use in their practice at enrollment. Providers can change their brand choice twice a year during April and October. Providers use the Immunization Information System to make their brand choices. • In the event of a shortage of a specific brand of vaccine, the department will substitute any available product under the guidance of the Centers for Disease Control and Prevention (CDC).

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

**Vaccine Management and Accountability
Business Rules and Guidelines:
Vaccine Ordering**

Vaccine Accountability and Management Business Rules and Guidelines Washington State Childhood Vaccine Program

Business Rule	Order Approval: Authority, Process, and Appropriateness
Vaccine Ordering	<ul style="list-style-type: none"> • Local Health Jurisdictions (LHJs) have the authority to approve vaccine orders for providers within their jurisdiction. • LHJs review provider orders in the Immunization Information System for appropriateness. • LHJ's should verify the shipping address and instructions when receiving provider orders to ensure accurate delivery. • LHJs will review provider accountability reports when determining how to process the order. • The LHJ may approve orders by providers or hold the order for review. If the LHJ determines that the order is incorrect or not appropriate, the LHJ will hold the order for review, discuss the order with the provider, and adjust the order if necessary. • The LHJ approves the order in the Immunization Information System (IIS) by submitting it for state approval. LHJ submission of the order indicates the LHJ has reviewed and approved the order, the order is accurate and the order is within program requirements. The department will process the order in the IIS for final approval. • Providers are required to have a written plan for vaccine ordering.

Business Rule	Provider Ordering Forms
Vaccine Ordering	<ul style="list-style-type: none"> • Providers should place all vaccine orders using the Immunization Information System.

Business Rule	Frozen Vaccine Eligibility and Ordering
Vaccine Ordering	<ul style="list-style-type: none"> • Providers will order frozen vaccines using the IIS with the same ordering pattern and frequency of all other vaccines. • LHJs must certify providers for eligibility before providers can order and receive frozen vaccine. • As part of the certification, LHJs will assess freezer equipment, identify primary and back up staff responsible for vaccines, and train provider staff on correct receiving and storing of all vaccines. • The provider will complete the certification form for frozen vaccines online in the IIS prior to placing a frozen vaccine order.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Principles of Vaccine Ordering and Inventory Management
<p align="center">Vaccine Ordering</p>	<ul style="list-style-type: none"> • Providers should order vaccines according to their designated schedule for order frequency and timing. • <i>Order frequency</i> is how often a provider places an order. Ordering frequency is based on the volume of immunizations given by the practice. A provider's order frequency may be: twice-monthly, monthly, every other month, once a quarter, twice a year or yearly. • <i>Order timing</i> is when the provider should place their order during the month. Providers will be scheduled to enter their order in the IIS between the 1st - 10th or between the 16th – 20th. • LHJs will review and submit provider orders by the 15th or 30th of each month, depending on each provider's order timing. • Providers should include all needed antigens in the order and limit single-antigen orders. • Providers should use best inventory management practices and recommended order quantities to determine the appropriate vaccine order. Providers determine their recommended order quantities by comparing their current vaccine inventory with their expected doses administered for the next order period. • Exceptions to these principles are emergency orders and seasonal flu orders. • Providers are required to have a written plan for inventory control.

Business Rule	Provider Inventory Maintenance
<p align="center">Vaccine Ordering</p>	<ul style="list-style-type: none"> • A physical inventory of vaccine type and dose count must be submitted at the time a provider submits an order. The inventory on hand is entered into the Immunization Information System Vaccine Ordering and Management System (VOMS) module as part of the order and entered on the vaccine order form. • The physical inventory count is used to determine a provider's vaccine order. • Providers should note any special circumstances resulting in an increased need for vaccine. Such examples might include a kindergarten round-up or special clinic. • Provider orders should be placed when they have a vaccine inventory equivalent to a 30 – 45 day supply. • A brief description of the order determination process is detailed below: Add your reserve stock target with the doses you expect to administer during the next order period. Subtract your current dose inventory from that number to determine your approximate order amount.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Provider Ordering and Inventory Management: LHJ Role
<p align="center">Vaccine Ordering</p>	<ul style="list-style-type: none"> Local Health Jurisdictions (LHJs) shall approve provider ordering frequency, pattern and inventory standards. LHJs shall monitor provider adherence to these standards. The department will make the final decision about requests for changes in ordering frequency or pattern. LHJs will work with providers to determine the best inventory levels to maintain based on storage capacity, recommended ordering frequency, and other factors deemed appropriate by the LHJ. The department will provide consultation to LHJs regarding inventory management upon request.

Business Rule	Exceptions to Established Provider Ordering Frequency
<p align="center">Vaccine Ordering</p>	<ul style="list-style-type: none"> LHJs can allow exceptions to the established order frequency and timing under special circumstances to prevent the disruption of immunization services. LHJs will follow-up with providers on all exceptions orders with a telephone or in-person quality assurance consultation. This follow-up will address the conditions which lead to the exception.

Guidelines	Assessing the Appropriateness of an Order
<p align="center">Vaccine Ordering</p>	<p>To determine whether or not a provider order is within reasonable parameters, LHJs and providers are encouraged to:</p> <ul style="list-style-type: none"> Review provider historical ordering and usage data. Review provider inventory reports when orders are submitted. Compare existing inventory with doses administered data or typical usage data for the order period. Know the number of doses of reserve stock each provider should maintain to have a 30 – 45 day supply on hand. Identify any unusual circumstances warranting an increased order. Review provider success with vaccine storage and handling quality assurance. Utilize tools provided by the department or available in the Immunization Information System to calculate recommended order amounts. The department is available for consultation regarding the appropriateness of provider orders.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Emergency Orders
<p align="center">Vaccine Ordering</p>	<ul style="list-style-type: none"> • Emergency ordering should be the exception (e.g., provider has a vaccine loss due to a power-outage). • Emergency orders can be processed and shipped within 24 hours of approval by the department. • To expedite the order and to assure prompt processing and delivery, providers must contact their Local Health Jurisdiction (LHJ) immediately about the emergency need. • Emergency orders are limited to specific vaccine products that need to be replaced in an expedited manner. • Emergency orders should be limited to the quantity needed for 3 – 5 days while a regular vaccine order is being processed. • Emergency orders must have written justification. • LHJs will contact the department immediately about any emergency order. Both agencies will work together to promptly process the order. • Once approval for the emergency order is given, the provider will place a supplemental vaccine order to assure inventory availability until their next regularly scheduled ordering period. • LHJs will follow-up with providers on all emergency orders with either a telephone or in-person quality assurance consultation to correct the conditions leading to the emergency order. • Repeated emergency orders due to poor order planning, storage and handling issues, or other vaccine management problems may result in an LHJ site visit for consultation and remedial or corrective action. • The department is available upon request to support LHJs regarding emergency order follow-up.

Business Rule	Provider Order Placement Methods
<p align="center">Vaccine Ordering</p>	<ul style="list-style-type: none"> • Providers will enter vaccine orders into the Immunization Information System (IIS) Vaccine Ordering and Management System (VOMS) module. • LHJs will monitor and approve provider orders in the IIS. LHJs will also provide quality assurance for order management and inventory control. • Providers will continue to meet all vaccine quality assurance and accountability requirements described in the provider agreement.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	<i>Granting Provider Access to VOMS</i> (Washington State Immunization Information System Vaccine Ordering and Management System module)
Vaccine Ordering	<ul style="list-style-type: none"> • Local Health Jurisdiction (LHJ) approval is required before a provider can access the Washington Immunization Information System (IIS) Vaccine Ordering and Management System module (VOMS). • All providers should use the IIS for vaccine ordering. • LHJs will establish that providers have met the following criteria before approving vaccine ordering through VOMS: <ul style="list-style-type: none"> • Consistent timely submission of monthly accountability reports • Signed provider agreement • Agreement of responsibility stating all information provided is correct and meets program compliance requirements • Adequate technology, including computers and internet access to support the use of VOMS • Provider completion of training on VOMS • Current Immunization Information System Information Sharing Agreement • LHJs will submit the provider information to the department to initiate account set up and approval of access to VOMS.

Business Rule	LHJ Processing and Submission of Provider Orders
Vaccine Ordering	<ul style="list-style-type: none"> • The LHJ reviews and approves individual provider orders in the Immunization Information System Vaccine Ordering and Management System module. • LHJs will review and submit approved orders to the department within Economic Order Quantity (EOQ) best practice standards and the parameters defined for the provider and LHJ. • The LHJ may review, approve and submit provider orders to the department as the LHJs receive the orders. The LHJ may also schedule their online order approval and submission to the department, as long as the orders are submitted within EOQ parameters. • The department will process orders on a daily basis on regular business days, except on days the department is closed. • The department will work with LHJs to assure that provider orders are submitted and processed as timely as possible.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

**Vaccine Management and Accountability
Business Rules and Guidelines:
Vaccine Delivery and Receiving**

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Principles of Provider Receiving
<p align="center">Delivery and Receiving</p>	<ul style="list-style-type: none"> • Local Health Jurisdictions (LHJs) will monitor the ordering, receipt and quality assurance for all vaccine made available through the State Childhood Vaccine Program to participating providers. • All vaccines ordered through the LHJ will be distributed directly to the provider office based on the shipping information provided in the Provider Agreement for the Receipt of Publicly Supplied Vaccine. • The provider demographics on the Provider Agreement for the Receipt of Publicly Supplied Vaccine must match the demographics in the IIS. • Providers are required to have a written plan for vaccine receiving. • A trained staff person must be available to receive and store vaccines when they are received. • Each provider office shall have at least one primary staff member and one back-up staff member trained in vaccine storage and handling and vaccine ordering. • Contact information for the designated vaccine storage and handling staff should be posted with receptionists and staff who typically receive UPS and FedEx shipments. • Provider offices shall post signage directing UPS and FedEx delivery personnel to assure vaccine or perishable deliveries are not left unattended. • All staff anticipated to monitor UPS and FedEx shipments must be trained to ensure that vaccine deliveries are received by the appropriate person and stored immediately. • Providers are required to have a written plan for proper vaccine storage and handling. • If a provider wastes vaccine by failing to store it appropriately upon delivery, the LHJ will consult with the department to determine remedial and corrective action.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Receiving Practices
<p align="center">Delivery and Receiving</p>	<ul style="list-style-type: none"> • Notify the designated vaccine storage and handling person or their back-up immediately when a distributor delivers vaccine. • Designated staff should review the shipping invoice when it arrives. The staff receiving a shipment should compare the vaccines to the inventory sheet. Staff should check that: <ul style="list-style-type: none"> • Lot numbers match. • The number of doses and antigen types match. • Expiration dates match and expire at least 6 months from the date of receipt. • The package is in good shape without evidence of damage. • The temperature monitoring devices indicate proper temperatures were maintained during transport. • Providers receive the vaccine into inventory by using the receiving functionality in the Immunization Information System. • Contact the Local Health Jurisdiction (LHJ) immediately if: <ul style="list-style-type: none"> • Any of the above criteria are not met. • There are any concerns that the cold chain was not maintained during shipment. For example, a shipment arrives without dry ice. • LHJs will contact the department to follow-up with the distributor regarding problems with vaccine orders.

Business Rule	Timeline for Delivery to Providers
<p align="center">Delivery and Receiving</p>	<ul style="list-style-type: none"> • LHJs will work with providers to determine the appropriate inventory level for their delivery schedule. LHJs will prepare providers to receive and store vaccines. • Vaccine delivery will typically occur within 10 business days of the time providers place their orders with LHJs. Vaccine delivery may occur within 3-5 days of order placement. • Once the pattern of vaccine delivery has been established for the office, office staff should mark calendars so UPS and FedEx shipments can be closely monitored.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Monitoring the Status of Vaccine Shipments
<p align="center">Delivery and Receiving</p>	<ul style="list-style-type: none"> • The department will distribute information about provider vaccine shipments to Local Health Jurisdictions (LHJs). • The department will make provider specific vaccine shipment data available to LHJs via the Immunization Information System Vaccine Ordering and Management System module (VOMS) or in an excel spreadsheet. • Shipping information regarding individual provider shipments may include: <ul style="list-style-type: none"> • Date vaccine was shipped • To whom the vaccine was shipped • Number of doses, product name, lot number and expiration date • Value of the vaccine by antigen (cost per dose) • Order tracking numbers for shipments • Providers can see the status of their order on the Order Status Screen in the IIS. • When the status of an order is “shipped,” the provider can use the receiving functionality in the IIS to enter the vaccine into the inventory management module. • Providers should contact the LHJ to report vaccine orders that are not received within 10 days of order placement. • LHJs may use the shipping information supplied by the department to track the vaccine shipment. • LHJs will contact the department to follow-up with the distributor regarding problems with vaccine orders.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Vaccine Transfers
<p align="center">Delivery and Receiving</p>	<ul style="list-style-type: none"> • Local Health Jurisdictions (LHJs) may need to coordinate a vaccine transfer between providers. • LHJs may coordinate transfers of vaccine to providers from an LHJ clinic, or between providers in their community. Providers should not transfer vaccines without consulting the LHJ. • Vaccine transfers may be approved by the LHJ as needed to: <ul style="list-style-type: none"> • Manage vaccine shortage situations • Redistribute influenza vaccine • Redistribute vaccine with short expiration dates • Meet short term, limited emergency dose needs for providers who have run out of vaccine • If necessary, the donor clinic can be replenished through the regular vaccine ordering process. • LHJs will follow-up with providers to ensure appropriate order placement and inventory management to assure immunization services are not interrupted. • Providers are required to have a written plan for transport of vaccine.

Business Rule	Delivery and Receiving of Frozen Vaccines
<p align="center">Delivery and Receiving</p>	<ul style="list-style-type: none"> • Frozen vaccines will only be shipped to providers who have been certified by their LHJ for the receipt of frozen vaccines. • Frozen vaccine shipments ship directly from the manufacturer to the provider. • Providers add orders for frozen vaccines in their regular monthly order. The frozen vaccine order is processed under the same protocols as other vaccines.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Use of Alternate Delivery Sites
Delivery and Receiving	<ul style="list-style-type: none"> • A designated alternative delivery site may be necessary if circumstances create a high potential for vaccine loss due to the inability to deliver: <ul style="list-style-type: none"> • To clinics with extremely limited hours of operation • To remote locations with limited access • Because of other circumstances as determined by the Local Health Jurisdiction (LHJ) or the department • LHJs and the department will determine if the use of an alternative delivery or storage site is warranted on a case by case basis. • All alternative delivery and storage sites must be approved by the department. • Any clinic that stores vaccine must have a State issued Provider Identification Number (PIN) and a current, signed Provider Agreement for the Receipt of Publicly Purchased Vaccine. • Every site must complete and submit individual accountability reports. The reports must be provided to the LHJ and the department as appropriate. • Every site receiving or administering vaccine from the childhood vaccine program must participate in quality assurance activities.

Business Rule	Emergency Deliveries
Delivery and Receiving	<ul style="list-style-type: none"> • Emergency vaccine distribution should only occur in the event of an unexpected vaccine loss due to a power-outage or other unforeseeable reasons. • The distributor can complete emergency distribution of vaccine within 24 hours once they receive an emergency order. • Providers must initiate requests for emergency distribution through the LHJ. Emergency orders should be limited to a 3 – 5 day supply. • LHJs and department will expedite order processing to ensure 24 hour turn-around. • See Business Rule: Vaccine Ordering Emergency Orders for more information.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Decision Making Regarding Central Pharmacy Practices
<p align="center">Delivery and Receiving</p>	<ul style="list-style-type: none"> • Organizations with a central pharmacy for vaccine management requesting to join the State Childhood Vaccine Program will be considered on a case by case basis. • The department will work with Local Health Jurisdictions (LHJs) and the organization to establish best practices for vaccine ordering, delivery, quality assurance and accountability. • Central pharmacy practices may require approval from the Centers for Disease Control and Prevention (CDC). • The Immunization Information System (IIS) must be used by all central pharmacy organizations. • Central pharmacy organizations may order vaccine for satellite clinics but vaccine will ship directly to the satellite clinic. Satellite clinics need to have up to date shipping information to receive vaccines. • Vaccine that is part of the Washington State Childhood Vaccine Program will not be shipped outside of the state of Washington.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

**Vaccine Management and Accountability
Business Rules and Guidelines:
Quality Assurance and Accountability**

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Guidelines	Promoting Best Practices
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • Local Health Jurisdictions (LHJs) are the point of contact for provider reports of vaccine loss. LHJs will follow-up with providers to ensure that remedial action occurs and further incidents are avoided. • LHJs will provide help and technical assistance to providers who do not comply with accountability reporting or violate of any aspect of vaccine quality assurance. • LHJs will determine the best course of action to maintain provider best practices for vaccine quality assurance and accountability. • LHJs may hold provider orders until accountability issues have been resolved or follow-up has been completed to ensure correct vaccine storage and use. • LHJs may institute remedial or corrective action for vaccine quality assurance violations in accordance with state guidelines. • LHJs must consult with and receive approval from the department before: <ul style="list-style-type: none"> • Suspending provider vaccine ordering privileges • Requiring financial restitution for vaccine loss or misuse • Dis-enrolling a provider from the State Childhood Vaccine Program • Providers are required to have a written plan to reduce and document vaccine wastage. • If you need help, the department is available to answer vaccine quality assurance and accountability issues.

Business Rule	Ensuring Provider Information is Correct
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • Provider shipping information should be reviewed by LHJs to ensure it is correct each time an order is placed. • The provider may update basic shipping information including shipping days and times. • If the provider name or address changes, a new Provider Agreement for Publicly Supplied Vaccine is required. The provider or LHJs should notify the department to initiate a new agreement. • At the time of enrollment and renewal of the Provider Agreement for Publicly Supplied Vaccine, all contact information should be verified. Provider demographics in the agreement should match the information in the IIS. • Site visit staff should review and update provider information as part of the scheduled provider compliance site visits.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Processing Vaccine Returns: Basics
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • Providers must notify their Local Health Jurisdiction (LHJ) about vaccine returns and state the reasons for their vaccine returns. LHJs should be notified immediately if a vaccine return is the result of a storage and handling incident. • Providers must submit Vaccine Incident Reports to the LHJ. LHJs will submit Vaccine Incident Reports to the department. The department must receive reports for every vaccine return. • The Vaccine Incident Report form will be used for all vaccine returns. • The Vaccine Incident Report will include the vaccine type, lot number, expiration date, and number of doses for all returned vaccines. Providers must list the reason for the vaccine loss and any corrective action taken. • The provider or LHJ will return spoiled or expired vaccine to the distributor for excise tax processing. The LHJ will decide who will complete the return.

Business Rule	LHJ Options for Processing Vaccine Returns
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • LHJs should set a uniform vaccine return policy for all providers in their jurisdiction and abide by that policy. • LHJs will determine the most appropriate strategy for managing vaccine returns. LHJ options include: <ol style="list-style-type: none"> 1. Having the providers return spoiled or expired vaccines to the LHJ with a vaccine return report. The LHJ will return vaccine to the distributor for processing. 2. Having the providers return spoiled or expired vaccines directly to the distributor. The provider will submit the vaccine return report to LHJs. • LHJs may consider individual provider storage and handling performance when determining whether the provider should return vaccine directly to the distributor or to the LHJ. • LHJs will provide follow-up consultation on all Vaccine Incident Reports to ensure any necessary remedial action is completed in a timely fashion. • Return labels for shipping will be provided by McKesson after the department enters information from the Vaccine Incident Report into the CDC VTrckS system.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Vaccine Usage Report: Inventory Tracking
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • The Private Providers' Report of Vaccine Usage form must be submitted by private providers to LHJ at the time they place their vaccine order. This form is also referred to as the monthly accountability form. • Complete the following information on the <i>Provider's Report of Vaccine Usage</i> form for all state-supplied vaccine received: <ul style="list-style-type: none"> • Copy the vaccine totals from the previous month's <i>End of Month Inventory Column</i> into the <i>Beginning of Month Inventory Column</i> for the current month. • Enter the number of state-supplied doses received during the month from the distributor into the <i>Doses Added</i> column. • Enter the lot number for each antigen received during the month into the column titled <i>Lot Number</i>. • Enter the number of doses wasted or expired during the month into the column titled <i>Doses Wasted/Expired</i>. • Enter the number of doses transferred out of your inventory in the column titled <i>Doses Transferred Out</i>. • Local Health Jurisdictions (LHJs) must approve all vaccine transfers. Please see the section on vaccine transfers for more information. • LHJs will use this form to report their clinic inventory receipts, their wasted, spoiled, or expired vaccine, and any vaccine transfers. • LHJ summary reports for vaccine administered by public and private providers will be captured on the <i>Summary Doses Administered Public and Private</i> form. • Providers may generate monthly administered doses and inventory reports from the Immunization Information System.

Vaccine Accountability and Management Business Rules and Guidelines Washington State Childhood Vaccine Program

Business Rule	Vaccine Usage Report: Physical Inventory
Quality Assurance and Accountability	<ul style="list-style-type: none"> • The physical inventory must be recorded on the Private Provider's Report of Vaccine Usage. A physical inventory of vaccines listed by antigen must accompany all provider vaccine orders. A physical inventory of vaccines must be completed at least once a month. • Complete the following information on the <i>Private Provider's Report Of Vaccine Usage</i> form for all state-supplied vaccine In inventory: <ul style="list-style-type: none"> • Enter the vaccine count into the column titled <i>End of Month Inventory</i>. • Enter the lot numbers into the column titled <i>Lot #</i>. • Enter the expiration dates into the column titled <i>Expiration Date</i>. • It is recommended that two people complete the inventory count to assure accuracy. • All state-supplied vaccine must be counted. • Estimate the number of doses remaining in open multi-dose vials. <i>Please do not measure by physically removing vaccine from the vial with a syringe.</i> • IMPORTANT! Note expiration dates. Please call your Local Health Jurisdiction (LHJ) vaccine coordinator if you have doses due to expire within three months or if you can't use doses before expiration.

Business Rule	Vaccine Usage Report: Doses Administered
Quality Assurance and Accountability	<ul style="list-style-type: none"> • Complete the Doses Administered Report to capture the total number of doses of each vaccine administered throughout the month. • Enter the doses administered for each antigen by age group. • Do not use hash marks for this report. • If you use the Immunization Information System to enter your doses administered, the vaccinations administered report generated from the Immunization Information System will meet the requirements for the doses administered portion of the report. • If you are using batch data processing for doses administered, you may use the Immunization Information System to generate the vaccinations administered report. This report will meet the requirement for the doses administered report. • All accountability forms are available on the department's website or in hard-copy from the LHJ or the department.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Business Rule	Temperature Logs
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • Temperatures for freezer and refrigerator units must be recorded on temperature logs twice per day. • The temperature monitoring logs must be kept at the provider’s office. The Local Health Jurisdiction (LHJ) or department staff may request to inspect the forms. • Temperature monitoring logs must be submitted to the LHJ on a monthly basis. • Staff should check the temperature throughout the day to ensure vaccine remains viable. Refrigeration problems can be detected early if staff check the temperature frequently. This will reduce the amount of time vaccine is exposed to inappropriate temperatures. • If temperatures are too cold or too warm, a storage incident has occurred. Providers should contact their LHJ immediately for instructions about responding to the storage incident. • Document the temperature of the unit, the amount of time the temperature was out of range, and the temperature of the room. • The manufacturer should be called for consultation about vaccine viability. • For more information on temperature guidelines, refer to the Vaccine Storage Temperature Guidelines.

Guidelines	Records Retention
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • Providers and LHJs should follow record retention policies for their agency. • The department consolidated contract indicates: All books, records, documents, and other material relevant to this Agreement will be retained for six years.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Guidelines	Vaccine Storage Basics
<p align="center">Quality Assurance and Accountability</p>	<p>Providers can maintain vaccine viability and ensure protection against vaccine preventable disease with a few critical tools. Providers should focus on proper vaccine storage and handling equipment, well trained staff, and proper planning.</p> <p>Staff should be properly trained to:</p> <ul style="list-style-type: none"> • Monitor vaccine temperatures • Fill out and understand the temperature log • Understand the clinic’s emergency back-up procedures • Respond to a storage incident <p>Having trained staff will ensure that viable vaccine is always administered to patients and immunized children are protected from vaccine preventable diseases.</p> <p>Refrigerators: Temperatures should be maintained at 35 - 46° Fahrenheit (2 - 8° Celsius). Set the refrigerator control at approximately 40° F (5° C) for the best safety margin.</p> <p>Freezers: Temperatures should be maintained at or below 5° F (-15° C). Set the freezer control at approximately at 0° F for the best safety margin.</p> <p>Dormitory Style Units: Storage of vaccine in a dormitory-style (or bar-style) combined refrigerator/freezer unit is not allowed under any circumstances. Refer to the Dormitory Style Refrigerator Replacement Protocol PDF on the Storage and Handling Page of the department Immunization website for more details.</p> <p>Thermometers: Invest in high quality, certified thermometers, and keep two in each unit to provide a means of confirming the temperature.</p> <p>Staffing: At least two staff should be fully trained in vaccine storage and handling procedures to insure against unnecessary vaccine loss. Make sure there is a trained staff member in the provider office who can ensure vaccine viability. Train replacement staff when there is staff turnover.</p> <p>Staff Training: The primary and back-up vaccine coordinator and the staff responsible for assuring VFC Status Screening must receive annual training. The Provider Compliance Site Visit meets the training requirement. Staff in offices not receiving a site visit must complete an online training. Suggested training modules include:</p> <ul style="list-style-type: none"> • CDC’s You Call the Shots modules <p>Providers must have a Training Plan in place and must document staff training.</p> <p>Emergency Back-up Procedures: Every organization needs an emergency back-up plan to ensure vaccine is protected when a storage unit fails or loses power. Post the plan on the unit and train staff to implement the plan in advance of an actual emergency. More Information on responding to a storage incident is available from your Local Health Jurisdiction (LHJ) or the department.</p>

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Guidelines	Vaccine Storage and Handling Plans
Quality Assurance and Accountability	<p>Providers are required to have written plans or procedures for the following:</p> <ol style="list-style-type: none"> 1. Designation of primary vaccine coordinator & at least one back-up staff 2. Proper Vaccine Storage & Handling 3. Vaccine Shipping (includes receiving & transport) 4. Procedures for vaccine relocation in the event of a power failure, mechanical difficulty or emergency situation (emergency plan) 5. Review and update the emergency plan annually or since change in responsible staff 6. Vaccine Ordering 7. Inventory Control 8. Vaccine Wastage 9. Annual Staff Training Plan on VFC Requirements <p>Templates for each plan can be found on the Site Visit page of the department Immunization website under provider resources.</p>

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Guidelines	General Guidelines for Remediation
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • The department maintains Detailed Guidelines for Remediation for Local Health Jurisdictions (LHJ). These guidelines help the LHJ follow appropriate remedial measures and ensure best practices in vaccine management and immunization practice. These actions help to assure vaccine is used correctly and viable vaccine is administered to protect patients from vaccine preventable diseases. • LHJs should use their judgment in determining the severity and nature of each vaccine storage and handling, quality assurance, or accountability incident. LHJ’s should consider previous provider incidents and their responses when determining remediation strategies. • LHJs must consult with appropriate individuals within their organization and with the department before instituting remediation requiring restitution. • LHJ’s must consult with the department before suspending provider vaccine ordering privileges. • Thorough information gathering and documentation are important in developing the appropriate remediation strategy. • Remedial action should fit the severity and nature of the incident. • A progressive remediation strategy that includes written communication clearly identifying the potential consequences for repeat offenses is required. • LHJs must consult with and receive approval from the department before requesting to withdraw a provider from the State Childhood Vaccine Program. • LHJs must report any suspected cases of fraud or abuse to the department so they may be pursued according to the department’s Fraud and Abuse policy.

**Vaccine Accountability and Management Business Rules and Guidelines
Washington State Childhood Vaccine Program**

Guidelines	General Guidelines for Remediation Documentation
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • Information gathering and remediation strategies for incidents may include telephone consultation and site visits. Local Health Jurisdictions (LHJs) may conduct site visits alone or with the department depending on the situation. • The LHJ must document all information and action plans gathered from the provider. • The provider must be given written communication that clearly describes the following: <ul style="list-style-type: none"> • The current incident • An overview of what actions are needed by the provider to ensure that further incidents do not occur • The timeline during which the corrections must occur • When the LHJ will follow-up to determine if the corrections have been made • The value of the vaccine loss resulting from the incident • A clear assessment of whether or not the incident appears to have been the result of negligence • A clear statement regarding potential consequences should there be a repeat incident of the same or similar type • A summary of the assistance provided through an LHJ site visit • A summary of the assistance provided through a joint site visit from the LHJ and the department. • The LHJ needs to deliver a copy of the written communication to the department. • Consequences for repeated offenses may vary depending on the nature, severity and number of offenses. Remediation may range from scheduled telephone consultation to requiring providers replace vaccine losses due to repeated negligence. • LHJs must consult with the department before suspending provider vaccine ordering privileges or requiring financial restitution for vaccine loss or misuse. • LHJs must consult with and receive approval from the department before requesting to withdraw a provider from the State Childhood Vaccine Program. • LHJs must report any suspected cases of fraud or abuse to the department so they may be pursued according to the department's Fraud and Abuse policy. • The department is available for consultation regarding remediation. • Refer to the DOH Corrective Action Guidelines for more information.

For persons with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-525-0127 (TDD/TTY 1-800-833-6388).