

Vaccine Accountability and Management Business Rules and Guidelines

2010

Washington State Childhood Vaccine Program

Updated November 2010



Vaccine Accountability and Management Business Rules and Guidelines

Washington State Childhood Vaccine Program

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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 participating in the Washington State Childhood Vaccine Program are intended to support the strong partnership and collaborative efforts of the Department of Health (DOH), local health jurisdictions (LHJs) and providers to promote best practices in vaccine management and helping to ensure an adequate vaccine supply by being good stewards of the national Vaccines for Children (VFC) program. Together, we ensure that Washington children have access to ACIP recommended vaccines, and are protected against vaccine preventable diseases.

LHJs manage the state childhood vaccine program at the local level. They are the liaison between DOH and providers regarding vaccine supply and use, and immunization practices of state and national importance. LHJs help assure the quality of immunization services by providing technical assistance and consultation regarding vaccine management and immunization practices. LHJs 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, and support provider and community education and training activities.

These business rules and guidelines are a revision of the 2006 Washington State Third Party Distribution Vaccine Management Business Rules and Guidelines. The original document was created with the assistance of a Public Health Advisory Committee representing 16 local health jurisdictions. Virtually every local health jurisdictions in the state participated in some way by providing sound advice and the insight of practical experience in the development of the guidelines that support and enhance our work in protecting Washington's children against vaccine preventable diseases.

For technical assistance and consultation regarding any element of the Guidelines, please contact the State Department of Health Immunization Program CHILD Profile.

**Vaccine Accountability and Management Business Rules and Guidelines
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Terms and Abbreviations

The Centers for Disease Control and Prevention (CDC): The federal public health agency that manages the VFC program.

CHILD Profile Immunization Registry: A web-based statewide registry of patients' demographic and immunization data.

Department of Health (DOH): The Washington State public health agency.

Local Health Jurisdiction (LHJ): The local public health organization, either a county department or semi-autonomous district. The LHJ manages the WA State Childhood Vaccine Program at the local level and has primary relationship with local health care providers.

Provider: An individual, partnership, private organization, or public organization that is enrolled in the WA State Childhood Vaccine Program. The program is administered by the WA State DOH and is supported by state and federal funds.

Vaccines For Children Program (VFC): The federal portion of the State Childhood Vaccine Program.

Vaccine Management and Ordering System (VOMS): The functions within the CHILD Profile Registry for ordering vaccine, tracking shipments, receiving orders into inventory, and tracking and submitting accountability requirements.

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

**Vaccine Accountability and Management Business Rules and Guidelines
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Business Rule	Principles of Provider Participation
<p align="center">Provider Enrollment and Participation</p>	<ul style="list-style-type: none"> • LHJs are the point of contact for provider enrollment and participation in the state childhood vaccine program. • Providers must have a current, signed VFC Provider Agreement in place to participate in the childhood vaccine program and order vaccine. • LHJs must be contacted by providers in order to establish a VFC Provider Agreement. • LHJs are the point of contact for provider quality assurance and accountability activities. • By signing the VFC Provider Agreement, the provider agrees to adhere to the vaccine accountability and quality assurance requirements of the agreement. • Providers must designate a primary vaccine coordinator and at least one back-up staff. • Providers must ensure accurate shipping information is updated in the VFC Provider Agreement anytime a change occurs. (e.g. correct current ship to address, any special shipping instructions, receiving hours, and contact information). • Availability of vaccine brand(s) will be determined by DOH and identified on the standardized order form. • In the event of a shortage of a specific brand of vaccine; DOH may substitute any available product under the guidance of the Centers for Disease Control and Prevention (CDC).

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

Vaccine Ordering

**Vaccine Accountability and Management Business Rules and Guidelines
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Business Rule	Order Approval: Authority, Process, and Appropriateness
Vaccine Ordering	<ul style="list-style-type: none"> • LHJs have the authority for approving provider orders within their jurisdiction. • When LHJs receive provider orders, the shipping address and instructions should be verified to ensure accurate delivery. • LHJs will review provider orders for appropriateness (timing of ordering, size of order, antigens ordered etc.,). • LHJs may also review provider compliance with submission of accountability reports when determining how to process the order. • The LHJ may approve orders as submitted by providers or hold the order for review. If the LHJ determines that the order is incorrect, or not appropriate, the LHJ will hold for review, discuss the order with the provider, and adjust if necessary. • Once the LHJ approves the order, the LHJ will submit it to DOH for processing. LHJ approval of the order is assumed when the order is submitted to DOH for processing. • Providers are required to have a written plan or procedure for vaccine ordering.

Business Rule	Provider Ordering Forms
Vaccine Ordering	<ul style="list-style-type: none"> • All orders shall be submitted on a hard copy, or electronic version of the standardized vaccine order form provided by DOH, or entered into CHILD Profile Immunization registry • The paper order forms may be customized by LHJs to include LHJ logos and contact information. • LHJs may require copies of paper order forms when providers place orders electronically if needed for quality assurance purposes.

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Business Rule	Frozen Vaccine Eligibility and Ordering
<p align="center">Vaccine Ordering</p>	<ul style="list-style-type: none"> • Frozen vaccines will be ordered on the same order form using the same ordering pattern and frequency of all other vaccines. • LHJs will certify providers for eligibility prior to their ability to order and receive frozen vaccine. • As part of the certification, LHJs will assess freezer equipment; identify a primary and back-up responsible for vaccines, and train provider staff on correct receiving and storing of all vaccines. • The certification form for frozen vaccines will be completed by the LHJ and submitted to DOH prior to placing a frozen vaccine order.

Business Rule	Principles of Vaccine Ordering and Inventory Management
<p align="center">Vaccine Ordering</p>	<ul style="list-style-type: none"> • Providers should order according to their designated regular schedule of frequency and timing. • Order frequency is how often a provider places an order. Ordering frequency options are 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 and yearly. • Order timing is when in the designated month the provider should place their order. Each provider will submit their order to their LHJ based on their scheduled ordering timing between the 1st - 10th or between the 16th – 20th. • LHJs will review, adjust if necessary, approve and submit provider orders by the 15th or 30th of each month, depending on the designated order timing of the provider. • 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 order quantity for each vaccine being ordered. Recommended order quantities will be based on the amount of vaccine the provider has in inventory, and the amount used in a similar time period adjusted for seasonality. • These principles are designed to minimize costs to the national vaccine system and to improve efficiencies as orders flow through the system • For providers and LHJ staff, these principles are designed to reduce questions about when and how much a provider should order. • Exceptions to these principles are emergency orders and seasonal flu orders. • Providers are required to have a written plan or procedure for inventory control.

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Business Rule	Provider Inventory Maintenance
<p align="center">Vaccine Ordering</p>	<ul style="list-style-type: none"> • A physical inventory count of the number of doses of each vaccine in inventory must be submitted at the time a provider submits an order. The inventory on hand is entered into the Immunization Registry Vaccine Management and Ordering Module as part of the order and entered on the vaccine order form. • The physical inventory count helps determine the provider’s vaccine need. • Providers should note any special circumstances (kindergarten round-up, special clinic etc.,) resulting in an increased need for vaccine. • 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: Reserve stock target (30 – 45 days’ inventory) plus (+) doses expected to be administered during the ordering period (e.g., 30 days for a monthly ordering cycle, 60 days for an every other month cycle etc.,) minus (-) current doses in inventory = approximate order amount.

Business Rule	Provider Ordering and Inventory Management: LHJ Role
<p align="center">Vaccine Ordering</p>	<ul style="list-style-type: none"> • In all instances, LHJs shall approve provider ordering frequency, pattern and inventory standards and monitor provider adherence to them. • 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. • DOH will provide consultation to LHJs regarding inventory management upon request of the LHJ.

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 when necessary to prevent the disruption of immunization services. • LHJs will follow-up with providers on all exceptions orders with either a telephone or in-person quality assurance consultation to remediate the conditions which lead to the exception.

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Guidelines	Assessing the Appropriateness of An Order
Vaccine Ordering	<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 (e.g., 1 month for providers ordering monthly, 3 months for providers ordering quarterly etc.). • 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 DOH or available in the CHILD Profile Vaccine Ordering Management System to calculate recommended order amounts. • DOH is available for consultation regarding the appropriateness of provider orders.

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Business Rule	Emergency Orders
Vaccine Ordering	<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 placement with the distributor. • To expedite the order and to assure prompt processing and delivery, providers must contact their LHJ immediately about the emergency need. • Emergency orders are to be limited to specific vaccine products that need to be replaced in an expedited manner. • Emergency orders must have written justification. • LHJs will contact DOH immediately about any emergency order and they will work together to promptly process the order. • 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 quality assurance problems may result in an LHJ site visit for consultation and remedial or corrective action. • DOH is available upon request to support LHJs regarding emergency order follow-up.

Business Rule	Provider Order Placement Methods
Vaccine Ordering	<ul style="list-style-type: none"> • Provider orders will be placed with the LHJ for approval and processing. • Providers will enter vaccine orders into the CHILD Profile Immunization Registry Vaccine Management and Ordering Module. • LHJs may enter orders into the Immunization Registry Vaccine Management and Ordering Module on behalf of the provider. • LHJs will monitor and approve provider orders and provide quality assurance related to order management regardless of whether the provider or the LHJ enters the order into the Immunization Registry Vaccine Management and Ordering Module. • Providers will continue to meet all vaccine quality assurance and accountability requirements as described in the provider agreement.

Business Rule	<p align="center"><i>Granting Provider Access to VOMS</i> (CHILD Profile Immunization Registry Vaccine Management and Ordering Module)</p>
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Vaccine Ordering	<ul style="list-style-type: none"> • LHJ approval is required before a provider can access the CHILD Profile Immunization Registry Vaccine Management and Ordering Module (VOMS). • LHJs are to approve provider use of VOMS on a case by case basis. • LHJs will establish that providers have met the following criteria before approving they be granted ordering permission through VOMS: <ul style="list-style-type: none"> • Minimum of 3 months without a vaccine loss incident. • Consistent timely submission of monthly accountability reports. • Signed provider agreement in place. • Agreement to take responsibility for confirming and updating all shipping information as necessary to ensure correct vaccine delivery. • Adequate technology, including computers and internet access to support the use of VOMS. • Provider completion of training on VOMS. • Current CHILD Profile Immunization Registry Information Sharing Agreement. • LHJs will submit the provider information to DOH confirming that providers have met the participation criteria, and DOH will grant access to VOMS.
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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 Registry Vaccine Ordering and Management Module. • LHJs will review and submit approved orders to DOH within the order timing, frequency and recommended order quantity schedules of 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 DOH as the LHJs receive the orders or the LHJ may batch submit orders to DOH, as long as the orders are submitted within EOQ parameters. • DOH will process orders on a daily basis on regular business days, except recognized holidays or other days that DOH is closed. • DOH will work with LHJs to assure that provider orders are submitted and processed by DOH 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
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Business Rule	Principles of Provider Receiving
<p align="center">Delivery and Receiving</p>	<ul style="list-style-type: none"> • LHJs will monitor the ordering, receipt and quality assurance of providers for all vaccine made available through the state childhood vaccine program for all participating providers. (e.g., routine, emergency, satellite clinic, special clinics etc.). • All vaccines ordered through the LHJ will be distributed directly to the provider office based on the shipping information provided to the LHJ by the provider and contained in the VFC Provider Agreement. • Providers are required to have a written plan or procedure 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 and one back-up staff person fully trained in vaccine storage and handling, including vaccine ordering. • Contact information for the designated vaccine storage and handling staff should be posted with receptionists and/or 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 be in a position 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 or procedure for proper vaccine storage and handling. • Vaccine losses resulting from the failure to appropriately store vaccine upon delivery will result in an LHJ consultation and remedial and possibly corrective action for the provider office.

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Business Rule	Receiving Practices
<p align="center">Delivery and Receiving</p>	<ul style="list-style-type: none"> • Arrange to have the designated vaccine storage and handling person or their back-up notified immediately when vaccine shipments are delivered. • When vaccine arrives, the shipping invoice should be reviewed, and vaccines received in the shipment carefully compared with what is listed on the inventory sheet: <ul style="list-style-type: none"> • Lot numbers should match. • The number of doses and antigen types should match. • Expiration dates should match, and expiration dates should be at least 6 months from the date of receipt. • The package itself should be in good shape without evidence of damage. • Contact the LHJ immediately if: <ul style="list-style-type: none"> • Any of the above criteria are not met (mismatched lot numbers, short expiration dates, etc.). • There are any concerns that the cold chain was not maintained during shipment (e.g., frozen vaccine received with no dry ice). • LHJs will contact DOH 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 most appropriate inventory level to maintain to accommodate the delivery schedule and ensure adequate storage and preparation for receiving the vaccine. • Vaccine delivery will typically occur within 10 -14 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 may want to mark calendars to indicate the importance of closely monitoring UPS and/or FedEx shipments for vaccine deliveries.

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Business Rule	Monitoring the Status of Vaccine Shipments
Delivery and Receiving	<ul style="list-style-type: none"> • DOH will distribute to LHJs information from the CDC on vaccine shipments to providers. • DOH will make provider specific vaccine shipment data available to LHJs via the Immunization Registry Vaccine Management and Ordering Module (VOMS) or via 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 (clinic name, address, contact information) • Number of doses, product name, lot number and expiration date • Value of the vaccine by antigen (cost per dose) • Order tracking numbers for shipments will be available so that individual shipments can be monitored by the LHJ • Providers should contact the LHJ if vaccine orders are not received within 10 days of order placement. • LHJs should use the shipping information supplied by DOH to track the vaccine shipment. • LHJs will contact DOH to follow-up with the distributor regarding problems with vaccine orders.

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Business Rule	Vaccine Transfers
Delivery and Receiving	<p>LHJs may find it necessary on occasion to coordinate a vaccine transfer resulting in the receipt of vaccine by a provider office.</p> <ul style="list-style-type: none"> • LHJs may coordinate transfers of vaccine to providers from an LHJ clinic, or between providers in their community. • Vaccine transfers may be used as needed to: <ul style="list-style-type: none"> • Manage vaccine shortage situations • Support redistribution of influenza vaccine • Redistribute vaccine with short expiration dates • Meet short term, limited emergency dose needs for providers who have run out of vaccine (e.g., provider has patient in injection room, and no vaccine on hand) • If necessary, or appropriate to the situation, the donor clinic can be replenished through the regular vaccine ordering process. • If necessary, or appropriate to the situation, 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 or procedure for transport of vaccine.

Business Rule	Delivery and Receiving of Frozen Vaccines
Delivery and Receiving	<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 vaccines shipments will be made directly from the manufacturer to the provider. • Frozen vaccine orders should be placed with a provider's regular monthly order and will be processed under the same protocols as other vaccines.

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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 exist that create a high potential for vaccine loss due to inability to deliver: <ul style="list-style-type: none"> • clinics with extremely limited hours of operation • remote locations with limited access • other circumstances as determined by the LHJ or DOH • LHJs and DOH will determine the appropriateness of the use of an alternative delivery and/or storage site for any provider or clinic on a case by case basis. • All alternative delivery and storage sites must be approved by DOH. • Any clinic that stores vaccine must have a VFC personal identification number and a current, signed provider site agreement. • Individual site accountability reporting is required (e.g., doses administered reports, temperature monitoring logs, etc.) and must be provided to the LHJ and/or DOH as appropriate. • Individual site quality assurance activities are required by all sites receiving or administering vaccine from the childhood vaccine program.

Business Rule	Emergency Deliveries
Delivery and Receiving	<ul style="list-style-type: none"> • Emergency distribution should be the exception and occur only in the event of an unexpected vaccine loss due to a power-outage or insufficient inventory due to other unforeseeable reasons. • Emergency distribution can be accomplished within 24 hours of submission of an emergency order to the distributor. • Providers must initiate requests for emergency distribution through the LHJ. • LHJs and DOH 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
Delivery and Receiving	<ul style="list-style-type: none"> • Decisions related to participation in the state childhood vaccine program by organizations using a central pharmacy for vaccine management will be considered on a case by case basis. • DOH will work with LHJs and the organization to establish best practices for vaccine ordering, delivery, quality assurance and accountability. • Central pharmacy practices may require approval of CDC. • The Immunization Registry Vaccine Management and Ordering Module must be used by all central pharmacy organizations. • Central pharmacy organizations may continue to order vaccine for satellite clinics and must ensure that satellite clinic site ship to information is up to date. • 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
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**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"> • LHJs are the point of contact for provider reports of vaccine loss. • LHJs will provide follow-up consultation to providers to ensure that remedial action occurs and further incidents are avoided. • LHJs will provide consultation and technical assistance to providers who do not comply with accountability reporting or are in violation of any aspect of vaccine quality assurance. • LHJs will determine the best course of action to ensure provider best practices for vaccine quality assurance and accountability are maintained. • LHJs may hold provider orders until accountability issues have been resolved (e.g., missing reports turned in, doses administered updated, etc.,) or until completion of other follow-up deemed necessary to ensure correct vaccine storage and use. • LHJs may institute remedial or corrective action for vaccine quality assurance violations in accordance with state guidelines. • Providers are required to have a written plan or procedure to reduce and document vaccine wastage • DOH is available for consultation regarding 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. • LHJs will update the information via fax, or submitted electronically via the Immunization Registry Vaccine Management and Ordering Module and submit it to DOH. • At the time of enrollment and renewal of the VFC provider Agreement, all contact information should be verified. • Provider information should also be reviewed and updated as part of routinely scheduled provider site visits.

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Business Rule	Processing Vaccine Returns: Basics
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • In all cases, the LHJ must be notified of a vaccine returns and the reason for the vaccine return. LHJs should be notified immediately if a vaccine return is the result of a storage and handling incident. • In all cases, vaccine return reports must be submitted to the LHJ from the provider returning the vaccine. LHJs will in turn submit vaccine return reports to DOH. • The vaccine return report will include the vaccine type, lot number, expiration date, and number of doses for all returned vaccines. The reason for the vaccine loss and corrective action will also be included on the form. • All vaccine returns (spoiled or expired vaccine) will be returned to the distributor for excise tax processing by either the provider or LHJ as designated by the LHJ.

Business Rule	LHJ Options for Processing Vaccine Returns
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • LHJs should establish one vaccine return policy for the 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. Providers return spoiled or expired vaccines to the LHJ with a vaccine return report. The LHJ in turn will return vaccine to the distributor for processing. 2. Providers return spoiled or expired vaccines directly to the distributor and 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 returns to ensure any necessary remedial action is completed in a timely fashion. • Return labels for shipping will be provided by DOH to the entity designated by the LHJ as responsible for returning spoiled or expired vaccine back to the distributor for excise tax processing.

**Vaccine Accountability and Management Business Rules and Guidelines
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Business Rule	Vaccine Usage Report: Inventory Tracking
<p>Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • The <i>Private Providers' Report of Vaccine Usage</i> form (also known as the monthly accountability form) must be submitted by private providers to LHJ at the time they place their vaccine order. • 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"> ▶ Enter the number of doses of each vaccine from the previous month's form <i>End of Month Inventory Column</i> into the <i>Beginning of Month Inventory</i> column for the current month. ▶ Enter the number of state-supplied doses received during the month from the DOH via the third party distributor into the <i>Vaccine Added This Month</i> column. ▶ Enter the lot number for each antigen received during the month into the column titled <i>Lot #</i>. ▶ Enter the number of doses wasted or expired during the month into the column titled <i>Vaccine Wasted or Expired</i>. ▶ Enter the number of doses transferred out of your inventory in the column titled <i>Viable Transferred</i>. • LHJs must approve all vaccine transfers. (please see section on vaccine transfers for more information). • LHJs will use this form to report their clinic inventory receipts, wasted, spoiled, expired and vaccine transfers. • LHJ summary reports for vaccine administered by public and private providers will now be captured on the "Summary Doses Administered Public and Private," form.

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Business Rule	Vaccine Usage Report: Physical Inventory
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • The physical inventory must also be recorded on the <i>Private Provider's Report of Vaccine Usage</i>. A physical inventory of vaccines, 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, and verify the inventory count. • All state-supplied vaccine in the refrigerator and freezer must be counted. All refrigerator/freezer units, all drawers and boxes, and all containers kept in clinic rooms should be checked and included in the inventory count. • 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! Please note expiration dates. If doses are due to expire within three months and it is anticipated that the doses will not be used, please call your LHJ vaccine coordinator.

Business Rule	Vaccine Usage Report: Doses Administered
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • Completing the lower half of the <i>Provider Report of Vaccine Usage</i> to capture the total number of doses of each vaccine administered throughout the month. • Enter the doses administered by age of vaccine recipient for each antigen specific. • Do not use hash marks for this report • If you actively use CHILD Profile Immunization Registry by manually entering your doses administered, the vaccinations administered report generated from CHILD Profile Immunization Registry will meet the requirements for the doses administered portion of the report. • If you are using batch data processing for doses administered, you may be able to use CHILD Profile Immunization Registry to generate the vaccinations administered report to meet the requirement for the doses administered report. • All accountability forms are available electronically or in hard-copy from the LHJ or DOH.

**Vaccine Accountability and Management Business Rules and Guidelines
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Business Rule	Temperature Logs
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • Temperatures for both the freezer and the refrigerator must be recorded on the temperature log twice per day. • The temperature monitoring logs must be kept at the provider’s office and be available for inspection by the LHJ or DOH staff upon request. • The temperature monitoring must be submitted to the LHJ on a monthly basis as determined by the LHJ. • Frequently checking the temperature throughout the day is the best way to ensure that vaccine remains viable. Frequent temperature checks will allow refrigeration problems to be detected early, and reduce the amount of time vaccine is exposed to inappropriate temperatures. • If temperatures are either too cold or too warm, a storage incident has occurred. Providers should contact your LHJ immediately for instructions about responding to the storage incident.

Guidelines	Records Retention
<p align="center">Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • Providers and LHJs should refer to their own contracts office or legal advisors for the record retention policies for their agency. • The DOH 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
Quality Assurance and Accountability	<p>Proper vaccine storage and handling equipment, well trained staff with designated back-up, and proper planning are critical tools in maintaining vaccine viability and ensuring the intended protection against vaccine preventable diseases. Making sure that staff are trained to properly monitor vaccine temperatures, are oriented to the temperature log, and are familiar with the clinic's emergency back-up procedures and how to respond to a storage incident 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 36 - 46° Fahrenheit (F) [2 - 8° Celsius (C)]. 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>Thermometers: Invest in high quality, certified thermometers, and keep two in each unit and/or compartment to provide a means of confirming the temperature in the unit and/or compartment.</p> <p>Staffing: A primary and back-up staff person fully trained in vaccine storage and handling procedures is the best insurance against unnecessary vaccine losses. Make sure there is always someone in the provider office who is able to play the vital role of ensuring vaccine viability. When there is staff turn-over, make sure that a replacement is trained.</p> <p>Emergency Back-up Procedures: Every organization should have an emergency back-up plan to ensure vaccine is protected in the event there is a failure of the storage unit for any reason. Post the plan on the unit, and train staff to implement the plan well in advance of an actual emergency. More Information on responding to a storage incident is available from your LHJ or DOH.</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 a written plans or procedures for the following:</p> <ul style="list-style-type: none"> • Designation of primary vaccine coordinator & at least one back-up staff • Proper Vaccine Storage & Handling • Vaccine Shipping (includes receiving & transport) • Procedures for vaccine relocation in the event of a power failure, mechanical difficulty or emergency situation (emergency plan) • Review and update the emergency plan annually or since change in responsible staff • Vaccine Ordering • Inventory Control • Vaccine Wastage

Guidelines	General Guidelines for Remediation
Quality Assurance and Accountability	<ul style="list-style-type: none"> • Detailed Guidelines for Remediation are available to LHJs from DOH and may be used to guide LHJ efforts regarding appropriate remedial measures to ensure best practices in vaccine management and immunization practice. These actions may be used to help assure vaccine is used correctly, viable vaccine is always administered to patients and patients are truly protected 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 mishap. The number of incidents, the type of incident, and responsiveness to previous consultation should be considered when determining remediation strategies. • LHJs should ensure that consultation with appropriate individuals within the LHJ (Nursing Director, Health Officer etc.) are consulted prior to instituting remediation requiring restitution. • Thorough information gathering and documentation are key to 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 recommended.

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

Guidelines	General Guidelines for Remediation Documentation
<p>Quality Assurance and Accountability</p>	<ul style="list-style-type: none"> • Information gathering and remediation strategies for incidents may include any of the following separately or in combination of telephone consultation, or site visits either by the LHJ or a joint site visit by the LHJ and DOH. • In all cases, complete documentation by the LHJ of information gathered and action plans is important. • In all cases, written communication must be given to the provider with a copy to DOH, 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 technical assistance provided through an LHJ site visit • A summary of technical assistance provided through a joint LHJ DOH site visit • Consequences for repeated offenses may vary depending on the nature, severity and number of repeat offenses. Remediation may range from scheduled telephone consultation between the LHJ and the provider to check on practices, to requiring providers to replace vaccines losses occurring due to repeat storage incidents resulting from negligence. • DOH is available for consultation regarding remediation. • Refer to the DOH Remediation / Restitution 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).
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