

Vaccine Accountability Overview

Overview

The Washington State Childhood Vaccine Program places a high priority on vaccine accountability. It is also one of the CDC's highest priorities. We develop and maintain vaccine accountability systems to meet CDC's guidelines. We assure:

1. The vaccines purchased with VFC funds are administered only to VFC eligible children.
2. The amount of vaccine loss and waste is limited and documented.
3. The VFC program is protected against fraud and abuse.
4. Provider vaccine orders are based on his or her VFC-eligible population and state-eligible population.

Background

Washington is a universal vaccine purchase state. We use state, Vaccines for Children Program (VFC) and 317 funds to provide vaccines to every child less than 19 years of age at no cost. Providers agree to meet the state and federal requirements when they sign the Provider Agreement for Receipt of Publicly Supplied Vaccine. Washington has written Vaccine Accountability and Management Guidelines and Business Rules (The Guidelines). We have separate written policies for the more complex requirements. These written policies provide a common understanding of the vaccine accountability requirements. The state staff, LHJ staff and providers use the policies to help assure best practices for vaccine management. We contract with LHJs for provider quality assurance and accountability activities. State and LHJ staff assure accountability through monthly reports and site visits. Resources are available to help providers meet the requirements.

Assuring Providers Administer Vaccines Purchased with VFC Funds only to VFC-eligible Children:

This process begins with the completion of the CDC Population Estimate Survey (PES). The PES determines the number of children in Washington State who are eligible for VFC vaccines. The CDC determines the amount of VFC funded vaccines that will be available for Washington. In addition, the Cost Assessment Tool (CAT), introduced in 2011 assures the State has sufficient funds to meet its obligation for non-VFC eligible children. A third tool, the VPET, introduced in late 2011 assures that vaccines for children eligible for the Childhood Health Insurance Program (CHIP) are funded using state rather than federal funds if the CHIP program is a stand-alone program, rather than a Medicaid expansion program.

Washington monitors the CDC defined VFC budget, and stays within the parameters of the monthly spend plan. If needed, we make adjustments proportionately across all funding sources. This helps assure we support the administration of VFC vaccine only to VFC eligible children. The CDC monitors Washington's spend plan for compliance with the CDC defined budget.

Washington replenishes the state portion of the vaccines used each month. The CDC determines the state replenishment based on the appropriate proportion of funding by fund source. This assures VFC vaccine purchases align with the CDC approved budget.

Screening for Eligibility:

Health care providers enrolled in Washington's State Childhood Vaccine Program must meet federal VFC screening requirements.

Washington's Guidelines for VFC Status Screening:

- <http://www.doh.wa.gov/Portals/1/Documents/Pubs/GuidelinesVFCStatusScreening.pdf>

Resource materials are available on the website.

- <http://www.doh.wa.gov/PublicHealthandHealthcareProviders/PublicHealthSystemResourcesandServices/Immunization/VaccinesforChildren/VFCProgramStatusScreening.aspx>

The Provider Agreement for Receipt of Public Supplied Vaccine (paraphrased):

- 1a) All children less than 19 years of age can receive state supplied vaccine through the State Childhood Vaccine Program. Please see the Guidelines for the Use of State Supplied Vaccine for specific direction.
- 1b) Each provider must document Vaccines for Children Program (VFC) Status for each child receiving state supplied vaccine. Please see the Guidelines for VFC Status Screening for specific direction. Providers use an approved method to ask the child's VFC Status at each immunization visit. The provider documents the child's insurance status in the child's chart. The provider documents whether or not the child is American Indian or Alaska Native.
 - The possible insurance status types include: Medicaid, uninsured, underinsured, or privately insured. The demographic screening criteria includes whether or not the child is American Indian or Alaska Native.
 - If a provider screens every child at every visit for VFC status, he or she may bill private health plans the maximum allowed vaccine administration fee.

Monitoring VFC Status Screening through Compliance Site Visits:

The LHJ staff and state staff verify that providers are completing VFC eligibility screening during Compliance Site Visits. They provide technical assistance at the time of the site visit to assure compliance.

Provider Profiles:

Every provider enrolled in the Program must complete an annual Provider Profile.

The Provider Agreement for Receipt of Publicly Supplied Vaccine:

- Provide data on the number, age and VFC status of children seen in the practice by completing the annual data request for the provider profile.

Managing and monitoring provider vaccine ordering: State and LHJ staff monitor provider vaccine ordering and management.

Provider Agreement for Receipt of Publicly Supplied Vaccine (paraphrased):

- Each provider must order vaccine based on his or her actual vaccine need. They must avoid stockpiling or build-up of excess vaccine inventory.
- Each provider must keep complete, accurate and separate stock records for public and private vaccines. Each provider must be able to distinguish between his or her public and private vaccine stock.

Washington State Vaccine Accountability and Management Guidelines:

- <http://www.doh.wa.gov/portals/1/Documents/Pubs/348-212-VaccineAccountabilityManagementBusinessGuidelines.pdf>
 - The principles of Vaccine Ordering and Inventory Management (page 9)
 - The LHJ reviews provider orders for appropriateness (timing of ordering, size of order, antigens ordered etc.).
 - The LHJ review provider compliance with submission of accountability reports when processing vaccine orders.
 - Each provider must have a written plan for vaccine ordering.
 - The principles of provider Inventory maintenance (page 10)
 - Assessing the Appropriateness of An Order (page 11)

Recommended Order Quantity Guidelines:

- http://www.doh.wa.gov/Portals/1/Documents/Pubs/348-203_RecommendedOrderQuantityCalculationGuidelines.pdf

Recommended Order Quantity Calculator:

- http://www.doh.wa.gov/Portals/1/Documents/Pubs/348-208_RecommendedOrderQuantityCalculator.Xls

Economic Order Quantity FAQ's:

- <http://www.doh.wa.gov/Portals/1/Documents/Pubs/EOQFrequentlyAskedQuestions.pdf>

Inventory Monitoring:

Providers must submit a written monthly accountability report including a detailed inventory report and a report of doses administered each month. They also report their inventory on hand on their vaccine order form when they place their order.

Provider Agreement for Receipt of Publicly Supplied Vaccine:

- Providers must make immunization records available to the LHJ and the department if requested.
- Providers must participate in a site visit by the LHJ or the department. The site visit may include an immunization assessment (AFIX). Provide data on the number, age and VFC status of children seen in the practice by completing the annual data request for the provider profile. Complete a provider satisfaction survey (if requested).

- Providers must complete the Private Provider's Report of Vaccine Usage Form. The report includes the doses of vaccine administered by vaccine type and age group; doses of vaccine wasted, lost or expired; the inventory of vaccine-by-vaccine type and number of doses.

Washington State Vaccine Accountability and Management Guidelines:

- <http://www.doh.wa.gov/portals/1/Documents/Pubs/348-212-VaccineAccountabilityManagementBusinessGuidelines.pdf>
 - Following references:
 - Providers are required to have a written plan for inventory control (page 9).
 - Vaccine Usage Report: Inventory Tracking (page 24)
 - Vaccine Usage Report: Physical Inventory (page 25)

Report forms available on the website:

- http://www.doh.wa.gov/Portals/1/Documents/Pubs/348-025_PrivateProvidersMonthlyReportVaccineUsage.xls
- <http://www.doh.wa.gov/Portals/1/Documents/Pubs/348-025-PrivateProvidersMonthlyReportVaccineUsage.pdf>

Vaccine Returns for Excise Tax Credit.

Providers must report all wasted, lost, spoiled or expired vaccine. The data is captured on the monthly accountability and vaccine incident report forms, whichever is most appropriate.

Provider Agreement for Receipt of Public Supplied Vaccine:

- Implement written procedures for reporting and responding to losses resulting from vaccine expiration, wastage, and compromised cold chain.
- Notify the local health jurisdiction promptly (within 24 hours) of vaccine incidents where vaccine was exposed to temperatures *above or below* the recommended range for vaccine storage. Follow the guidance of the LHI on how to document and report the incident.
- The provider must submit a written report including the reasons for the vaccine loss and measures taken to correct the cause of the loss and to prevent reoccurrence to the LHI in all instances.
- Remove wasted/expired vaccine from storage containers with viable vaccine to prevent inadvertent administration. Return all unopened spoiled or expired publicly purchased vaccines for excise tax credit, as directed by the LHI.
- Vaccine losses determined to be the result of negligent vaccine storage and handling practices, or failure to comply with the storage and handling requirements in this agreement may result in corrective action, including restitution for the value of the vaccine loss resulting from the incident.

Vaccine Incident Report Form and Instructions:

- http://www.doh.wa.gov/Portals/1/Documents/Pubs/348-154_VaccineIncidentForm.doc
- http://www.doh.wa.gov/Portals/1/Documents/Pubs/348-154_VaccineIncidentFormInstructions.doc

Washington's Vaccine Accountability and Management Guidelines:

- <http://www.doh.wa.gov/portals/1/Documents/Pubs/348-212-VaccineAccountabilityManagementBusinessGuidelines.pdf>
 - Processing Vaccine Returns: Basics (page 23)
 - LHJ Options for Processing Vaccine Returns (page 23)
 - General Guidelines for Remediation (pages 28, 29)

Washington's Fraud and Abuse Protocol:

OICP Washington State Childhood Immunization Program:

1. Teaches All Contractors (LHJs) and Internal Reviewers How to:

- c) Educate new and existing providers on their responsibilities to protect the vaccine they are entrusted with
 - all reporting requirements
 - monthly required documentation reports
- d) Conduct proper compliance site visits
 - how to identify non-compliance
 - the importance of correcting provider errors immediately
- e) Make appropriate corrective actions and conduct timely follow-up, including:
 - documentation
 - reporting to the state program
- f) Monitor provider ordering based on patterns and the population that each provider sees
- g) Monitor provider temperatures requiring that temperature logs be submitted on a monthly basis
- h) Use various forms and systems created by the program to support & strengthen their monitoring activities, such as the Level One Education Steps document that outlines the procedures needed to fully correct non-compliance for each **!**High Priority question.

2. Provides and facilitates mentoring and shadowing

- c) for all LHJs and internal reviewers
- d) those that request support
- e) those identified as having needs

3. Tracks all VFC Compliance Site Visit responses

- c) tracks those providers who need corrective actions and follow-up
- d) assure that all non-compliance is resolved appropriately and as soon as possible

4. Refers all practices

- c) those that cannot resolve their non-compliance issues within 30 days are referred to the internal Non-Compliance Review Team
- d) the Team decides next steps on a case-by-case basis, assuring all proper required steps are taken and issues resolved

5. **Monitors all ordering patterns and Provider Profiles** - assuring no discrepancies
6. **Tracks all provider accountability** – with required monthly reporting
7. **Tracks all vaccine incidents** - via specific reporting process and documentation.
8. **Develops and utilizes other systems**
 - a) assist in monitoring/averting possible fraud and abuse
 - b) allegations can come into the LHJ or state health offices
 - c) State Medicaid Program:
 - billing system has edits preventing reimbursement for any vaccine that could have been received through the Washington State Childhood Immunization Program;
 - even if provider purchased vaccine privately and the vaccine was available through the State, s/he cannot get reimbursed for that vaccine;
 - Medicaid Fraud Hotline @ 1-800-562-6906.

OICP Fraud and Abuse Training for All Appropriate State & LHJ Staff

1. **All staff interacting with enrolled providers**
 - a) Receive specialized training (at least annually and for all new employees)
 - b) Assure they understand how to:
 - Prevent situations that involve suspected fraud, abuse or non-compliance;
 - Identify situations that involve suspected fraud, abuse or non-compliance;
 - Initiate the process for all situations that involve suspected fraud, abuse or non-compliance;
 - Track and follow-up on these situations.
 - Use the “Washington State Non-Compliance Steps Outline” (a simpler version of the CDC’s “Non-compliance with VFC Provider Requirements Protocol Algorithm”).
 - c) Assure they understand why the above is important
2. **Training Methods**
 - a) New employee orientation and training packet for OICP staff & for LHJ immunization coordinator staff
 - b) OICP staff will receive annual updates on the Fraud and Abuse Protocols and noted in the annual OICP employee evaluation process.
 - c) Face-to-face and specific topical training available as needed
 - d) Technical assistance always available.
 - e) Teleconferencing
 - f) Developing On-Line Web Training Curriculum with Certificate of Completion
3. **Verification of Training**
 - a) Copies of training documents will be kept in the Fraud & Abuse Training folder
 - b) Verification that staff received training will be kept in their personnel file