WYOMING DEPARTMENT OF HEALTH
IMMUNIZATION UNIT

Vaccines for Children/Wyoming Vaccinates Important People (VFC/WyVIP) Program

POLICIES AND PROCEDURES
For Providers

Provider Information	
VFC/WyVIP PIN:	
Facility Name	
Primary Vaccine Coordinator:	
Secondary Vaccine Coordinator:	
WyIR Primary Contact:	
AFIX Contact:	

**All form, reports, and educational materials mentioned in this document can be found on the VFC/WyVIP webpage at www.immunizewyoming.com.*

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ACRONYMS AND DEFINITIONS

ACIP	Advisory Committee for Immunization Practices (p. 4)
AFIX	Assessment, Feedback, Incentives, and eXchange (p. 12)
VAERS	Vaccine Adverse Event Reporting System (p. 32)
VFC	Vaccines for Children (p.3)
WyVIP	Wyoming Vaccinates Important People (p. 3)
WyIR	Wyoming Immunization Registry (p. 29)

Abuse: Provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program

Cold Chain: The system used to maintain and distribute vaccines in optimal condition.

Expired or spoiled vaccine: Nonviable vaccine in its original container (vial or syringe) that is able to be returned for excise tax credit. This includes vaccines not administered prior to expiration or vaccine that has been spoiled as a result of temperature excursions or improper storage.

Fraud: An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Private vaccine: Vaccine purchased by a health care provider to administer to individuals who are not federally or state-vaccine eligible.

Provider: A healthcare provider that is enrolled in the VFC/WyVIP Program. This term is often used to describe the entire office and not just the medical provider.

Public vaccine: Vaccine purchased with 317, VFC or state funds and is provided at no cost to providers to be administered at no cost for the vaccine to eligible persons.

Vaccine Expiration Date: The last date on which the vaccine may be used; expired vaccine includes vaccine that is past the manufacturer expiration date on the vial or expiration date after reconstitution depending on the vaccine and according to manufacturer instructions. Vaccines that only have a months and year for expiration date should be used by the last day of the month.

Wasted vaccine: Nonviable vaccine that is not able to be returned for excise tax credit. This includes vaccine drawn-up into the syringe but not administered, remaining doses in an open vial, compromised vial or syringe (e.g., due to a drop causing damage to vial integrity or sterility), broken vial, or lost vial. Lost or unaccounted for vaccines are also a form of wasted vaccine and required to be reported in the WyIR.

A complete list of acronyms, abbreviations, and definitions can be found at http://www.cdc.gov/vaccines/about/terms.htm.

VFC/WyVIP PROGRAM OVERVIEW

The Vaccines for Children (VFC) Program: At a Glance

"The Vaccines for Children (VFC) program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. The Centers for Disease Control and Prevention (CDC) buys vaccines at a discount and distributes them to grantees—i.e., state health departments and certain local and territorial public health agencies—which in turn distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers. Children who are eligible* for VFC vaccines are entitled to receive those vaccines recommended by the Advisory Committee on Immunization Practices (ACIP)" (CDC, 2012).

*VFC-eligible children are those who are eligible for Medicaid, uninsured, American Indian/Alaska Native, or underinsured at a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC), or any other provider with delegated authority.

Wyoming Vaccinates Important People (WyVIP) Program: At a Glance

The WyVIP program was created after the enactment of the Childhood Immunization Act (2006) to provide an appropriation for purchases for Wyoming children who were not VFC-eligible. Children who are Wyoming residents and do not qualify for VFC vaccine are eligible for WyVIP vaccine regardless of their insurance status.

Provider Enrollment and Annual Recertification

Current VFC/WyVIP providers, as well as healthcare providers wanting to participate in the VFC/WyVIP Program, must complete the following upon initial enrollment or to obtain annual recertification:

1. Provider Profile
2. VFC/WyVIP Enrollment Agreement
3. Vaccine Coordinator Checklists (2)
4. WyIR Enrollment and Access Level Forms
5. Enrollment Site Visit or Annual Compliance Site Visit

Healthcare providers not already enrolled into the VFC/WyVIP Program must contact the Immunization Unit at 307-777-8503 to initiate the enrollment process.

Advisory Committee on Immunization Practices (ACIP)

ACIP's statutory authority includes the authority to determine the vaccines, number of doses, schedule, and contraindications for the VFC program as well as for the general population. ACIP is, therefore, legislatively linked to the VFC Program. The Committee also approves the specific recommendations for inclusion of a vaccine in the VFC Program, which are written in the form of a VFC resolution. After the ACIP recommends a new vaccine or a change in vaccine use, a VFC resolution is voted on for inclusion of the vaccine in the VFC program. VFC resolutions passed by the ACIP form the basis for VFC program policies on vaccine availability and use. CDC contracts for vaccines available through the VFC program are established only after a VFC resolution is in place.

VFC vaccines must be administered according to the guidelines outlined by the ACIP in the VFC resolutions. These consolidated resolutions are placed on the VFC website (http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html) soon after ACIP approval.

VFC/WyVIP Providers must carry all ACIP recommended vaccines for the age cohort seen at the facility. For a list of all current ACIP recommended vaccines visit http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html

PROVIDER GENERAL GUIDELINES

Roles and Responsibilities

There are several different provider roles in the VFC/WyVIP Program. A summary of those roles and corresponding responsibilities is listed below.

Although the same individual may occupy multiple roles, it is not recommended that the Primary Physician or Practitioner serve as a Vaccine Coordinator due to the heavy responsibility and immediate response needed from this role.

***Any change in the roles listed below must be reported to the VFC/WyVIP Program immediately using the "Report New Contact" link on the VFC/WyVIP Program webpage found at www.immunizewyoming.com.**

Primary Physician or Practitioner

- Responsible for the general oversight of the VFC/WyVIP Program within the medical facility and includes but is not limited to:
  - Assigning staff to VFC/WyVIP roles listed below
  - Ensuring program compliance by all facility staff
  - Completing the annual Provider Enrollment Agreement and WyIR Enrollment
  - Communicating with the VFC/WyVIP Program as necessary for compliance and wastage issues.

Primary WyIR Contact

- Responsible for WyIR enrollment, managing WyIR users, and completing the WyIR Access Level Form.
- Must inform the Immunization Unit WyIR Project Coordinator of employee departures by submitting a WyIR Remove User Form within 24 hours of the employee's last day of employment.

Primary and Secondary Vaccine Coordinators

- First and second points of contact for the VFC/WyVIP Program.
- Must be physically located at the facility
- Responsible for:
  - Monthly reports
  - Vaccine Orders, Transfers, and Returns
  - Short-Dated Vaccine Transfer Requests
  - Storage and Handling
  - Program Policies, Procedures, and Compliance
  - Staff Education as applicable
- Responsible for continuous cooperation and communication to ensure awareness of all VFC/WyVIP Program activities among both contacts.

AFIX Contact

- Responsible for communicating with Immunization Unit AFIX Coordinator about immunization rates and areas of improvement.
- Responsible for communicating AFIX information to relevant facility staff.

Provider Office Responsibilities

Providers must meet the following requirements to participate in the VFC/WyVIP Program:

- Designate one staff member to be the primary vaccine coordinator and at least one back-up vaccine coordinator who is able to perform the *same* responsibilities as the primary vaccine coordinator in the event that the primary person is unavailable. These positions will be responsible for key requirements and will provide oversight for all vaccine management within the office;
- Notify the Immunization Unit immediately of any changes in vaccine coordinators;
- The designated vaccine coordinators or their designees must review vaccine storage unit temperatures to ensure they are within the recommended ranges and document the temperature on the VFC/WyVIP Temperature Logs for each storage unit twice a day and respond appropriately to temperature excursions;
- Train other staff who are responsible for administering vaccines or who may be required to transport vaccine in an emergency situation, following the office's vaccine storage and handling plan. A simple log sheet with the staff member's name and date of training must be maintained and provided to program staff when requested.
- The vaccine coordinator and/or back-up will be the VFC/WyVIP contact for the office.
- Develop and follow routine and emergency vaccine storage and handling plans;
- Utilize and maintain proper vaccine storage equipment and temperature monitoring devices;
- Perform vaccine management practices through proper ordering and inventory management, proper temperature monitoring and storage equipment;
- Order vaccine based on actual need of eligible children served by the practice based on the Provider Profile;
- Comply with reporting methods and requirements
- Maintain all VFC/WyVIP related records for no less than three years and be able to provide to Immunization Unit staff for review during site visits.

- Develop and maintain complete, accurate, and separate stock records for both publicly and privately purchased vaccines. The requirement to keep separate records does not necessitate having separate storage units for public and private vaccines. Providers must be able to distinguish between their public and private vaccine stock;
- Post "DO NOT DISCONNECT" notices at both the electrical outlet and the circuit breaker to prevent power from being disconnected to the storage unit; and
- The National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention, strongly recommends that providers draw vaccine only at the time of administration to ensure that the cold chain is maintained and that vaccine is not inappropriately exposed to light. **Do Not** pre-draw doses before they are needed.

VFC/WyVIP Vaccine Eligibility Table

***Subject to change. Visit the VFC/WyVIP Program webpage for the most recent version of this document.**

Vaccine	Brand Type	Manufacturer	Eligibility
DTaP	DAPTACEL®	Sanofi Pasteur	VFC and WyVIP
	Infanrix®	GlaxoSmithKline	VFC and WyVIP
DTaP-Hep B-IPV	Pediarix®	GlaxoSmithKline	VFC and WyVIP
DTaP-HIB-IPV	Pentacel®	Sanofi Pasteur	VFC and WyVIP
DTaP-IPV	Kinrix®	GlaxoSmithKline	VFC and WyVIP
E-IPV	IPOL®	Sanofi Pasteur	VFC and WyVIP
Hepatitis A Peds	VAQTA®	Merck	**VFC ONLY**
	Havrix®	GlaxoSmithKline	**VFC ONLY**
Hepatitis B Ped/Adol	ENGERIX B®	GlaxoSmithKline	VFC and WyVIP
	RECOMBIVAX HB®	Merck	VFC and WyVIP
HIB	PedvaxHIB®	Merck	VFC and WyVIP
	ActHIB®	Sanofi Pasteur	VFC and WyVIP
HPV	Gardasil®	Merck	**VFC ONLY**
	Cervarix®	GlaxoSmithKline	**VFC ONLY**
MCV-4	Menactra®	Sanofi Pasteur	**VFC ONLY**
	Menveo®	Novartis	**VFC ONLY**
MMR	MMRII®	Merck	VFC and WyVIP
MMR/Varicella	ProQuad®	Merck	VFC and WyVIP
PCV-13	Prevnar 13 TM	Wyeth	VFC and WyVIP
PPSV23	Pneumovax®23	Merck	VFC and WyVIP
Rotavirus	RotaTeq®	Merck	VFC and WyVIP
	Rotarix®	GlaxoSmithKline	VFC and WyVIP
Td	DECAVAC®	Sanofi Pasteur	VFC and WyVIP
Tdap	BOOSTRIX®	GlaxoSmithKline	VFC and WyVIP
	Adacel®	Sanofi Pasteur	VFC and WyVIP
Varicella	Varivax®	Merck	VFC and WyVIP

VFC-ELIGIBLE	Medicaid/EqualityCare/Title XIX, American Indian/Alaska Native, Uninsured, Underinsured at FQHC/RHC or at a deputized provider.
WYVIP/NON-VFC-ELIGIBLE	Underinsured at non-FQHC/non-RHC or at an office who has not received a Delegation of Authority, or other insured Wyoming resident

Information About Vaccine Ordering and Distribution

(for providers)

Wyoming Department of Health

Commit to your health.

Universal-Select

What does "Universal-Select" mean?

All children, regardless of insurance status, receive almost all vaccines recommended by the Advisory Committee for Immunization Practices (ACIP) at no cost through the immunization program with the exception of certain vaccines. With Universal-Select states, only VFC-eligible children receive all ACIP-recommended vaccines free-of-charge at any enrolled provider (public and private).

In Wyoming, effective July 1, 2011, the VFC-only vaccines include hepatitis A, human papillomavirus (HPV), influenza, and meningococcal conjugate. Any providers who would like to offer these vaccines to their insured patients may purchase private stock vaccine.

How long will Wyoming have a Universal-Select vaccine supply policy?

It is unknown how long Wyoming will offer a Universal-Select vaccine supply policy. The Immunization Section will continue to communicate information to providers to ensure that providers accurately understand policies for the Wyoming Vaccinates Important People (WyVIP) program.

Underinsured

What does "underinsured" mean?

An underinsured child is one who has commercial (private) health insurance but the coverage does not include vaccines, a child whose insurance covers only selected vaccines (underinsured for non-covered vaccines only), or a child whose insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.

Are children who have high insurance deductibles considered underinsured?

No.

Are underinsured children able to be immunized at any provider office?

Underinsured children are eligible to receive VFC vaccines only through a Federally Qualified Health Center (FQHC), a Rural Health Clinic (RHC), or a provider who has been delegated authority by either an FQHC or an RHC.

How does a provider know whether a child would be categorized as underinsured?

Providers may want to ask the parent or guardian whether his insurance coverage covers "well-child" visits.

What if a parent or guardian doesn't know if her child is underinsured or what vaccines would be covered by her insurance plan?

If a parent or guardian doesn't know if her child is underinsured, the provider has two options:

√ Immunize the child using private stock vaccine and require payment for the immunization at the time of vaccination. The parent or guardian would submit the receipt to her insurance company for reimbursement, if applicable.

√ Ask the parent or guardian to contact her insurance plan to discuss coverage and arrange for vaccination at a later date. If an insurance plan will pay for the vaccine, the parent or guardian can request that the provider bill for the cost of the immunization. (Note: providers may not bill insurance companies for the cost of publicly-supplied vaccines.)

Are children who are enrolled in KidCare CHIP considered underinsured?

Children who are enrolled in KidCare CHIP are considered insured. All children who are enrolled in KidCare CHIP are eligible for immunizations at participating providers. Since these children are considered insured, they would receive private stock vaccine if being immunized for one of the four VFC-only vaccines.

Information About Vaccine Ordering and Distribution

(continued)

Delegation of Authority

What does Delegation of Authority mean?

A Delegation of Authority is an agreement between and FQHC or RHC and another medical provider. A Delegation of Authority agreement allows a medical provider to act on behalf of an FQHC or an RHC to administer VFC vaccines to underinsured children. Without an agreement, underinsured children could only receive VFC vaccines at an FQHC or an RHC.

What are the advantages of Delegation of Authority?

Delegation of Authority ensures that underinsured children have access to vaccines, particularly in locations where no FQHC's or RHC's are located.

Does Delegation of Authority mean that providers can vaccinate all children with publicly-provided vaccine?

Delegation of Authority allows Public Health Nursing offices, private providers, and other non-FQHC or non-RHC providers to offer VFC vaccines to underinsured children. It does not mean that all children are eligible for free vaccines at any provider office.

Are Public Health Nursing (PHN) Offices automatically considered an FQHC or RHC?

No.

Privately-Purchased Vaccines

If a provider purchases vaccine, can the office charge for the cost of the vaccine?

Providers are able to charge insurance plans for the cost of any privately-purchased vaccines.

If a provider administers privately-purchased vaccines, can he charge more than $14.31 for a vaccine administration fee?

Providers are able to charge insurance plans more than $14.31 for the cost of administering privately-purchased vaccines. In addition, providers may charge insurance plans for vaccine toxoids, rather than by dose. For more information about billing insurance plans for vaccines that contain more than one toxoid, visit http://practice.aap.org/content.aspx?aid=2980.

Can providers charge for an office visit when administering privately-purchased vaccines?

Providers may charge for an office visit when administering privately-purchased vaccines. This is established by the provider.

NOTE: If providers have questions about billing insurance plans for privately-purchased vaccines, you may contact Stacie Ross at Northeast Wyoming Pediatric Associates, P.C. at 307-675-5555 for assistance.

Affordable Care Act (ACA)

How will full implementation of the ACA impact immunizations?

Once the ACA has been fully implemented (2014), all insurance plans will be required to pay for all vaccines recommended by the ACIP for all children and adults without any requirements for co-payments or meeting deductibles.

Where can I get more information?

Please call the Wyoming Department of Health's Immunization Section at 307-777-7952.

PATIENT ELIGIBILITY

Provider Responsibility to Screen for VFC Eligibility

Screening and documenting a child's VFC eligibility must take place with **each** immunization visit. Record of this screening must be maintained for at least **3 years** and made available upon request to Immunization Unit staff. **Please remember that screening and documentation must be completed on all patients receiving publicly-supplied vaccine at every immunization visit.**

VFC/WyVIP Eligibility Screening Form

Providers may use the VFC/WyVIP Eligibility Screening form found on the VFC/WyVIP Program webpage as a means of documenting eligibility. The parent, guardian, or provider may complete this form and verification of eligibility is not required.

To maximize efficiency, providers may elect to incorporate these screening questions into an existing form; however, any revision must include the core screening information listed on the CDC-developed form and be approved by the state Immunization Unit.

VFC Eligibility Criteria

Children through 18 years of age, who meet at least one of the following criteria and are eligible to receive VFC vaccine:

- **Medicaid-eligible:** A child who is eligible for the Medicaid program. (For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent.)
- **Uninsured:** A child who has no health insurance coverage.
- **American Indian or Alaska Native:** As defined by the Indian Health Care Improvement Act (**25 U.S.C. 1603)**
- **Underinsured:** A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only).**Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC)** or a deputized provider.

SITE VISITS

VFC/WyVIP Providers will receive site visits for various reasons and at various times during their participation in the program. These visits are used to review and evaluate the practices of the provider's office in regards to the VFC/WyVIP Program guidelines. There are several types of site visits that providers may receive.

Enrollment Site Visit

Prior to the Enrollment Site Visit taking place, the provider must complete the following:

- Provider Profile
- Vaccine Coordinator Checklists (2)
- VFC/WyVIP Enrollment Agreement
- WyIR Enrollment and Access Level Forms

The enrollment site visit will occur upon the provider's initial enrollment into the program and will be a scheduled visit. This visit and the resolution of any concerns identified during the visit must take place prior to receiving VFC/WyVIP vaccines.

The approximate time needed for the Enrollment Site Visit is 2 hours. The Primary Vaccine Coordinator and the Secondary Vaccine Coordinator identified on the Vaccine Coordinator Checklist will need to be available for the visit.

Compliance Site Visit

Almost every provider will receive an annual Compliance Site Visit. This is a scheduled visit that focuses on storage and handling practices. Either the Primary Vaccine Coordinator or Secondary Vaccine Coordinator must be available during this visit.

Upon scheduling the Compliance Site Visit, the provider will receive a Confirmation Letter from the designated Quality and Compliance Specialist reiterating the date and time the visit has been scheduled, a list of accommodations that will be needed during the visit, and individuals who should be available during the visit.

Upon completion of the Compliance Site Visit, the provider will receive a Closure Letter that describes the findings discovered during the visit, resources provided, and goals established during the visit.

AFIX Visit

The AFIX visit is a scheduled visit and may take place in-person or as a conference call. The purpose of the AFIX visit is to review the provider's immunization rates. The AFIX Coordinator will work with the provider to identify areas of improvement and provide resources that may improve immunization rates.

Storage & Handling Unannounced Assessment Site Visit

Per CDC requirement, the Immunization Unit will conduct unannounced site visits. These visits will serve as a "spot check" for proper storage and handling practices. The goal of these visits is to provide guidance and education, to protect the vaccine, and to make certain that all VFC-eligible children receive properly managed vaccines. The following will be considered by the Immunization Unit when selecting which Providers will receive an unannounced site visit:

- Provider's previous history with storage and handling compliance issues
- Time since last Compliance Site Visit
- Geographic distance from those providers who will receive a Compliance Site Visit
- Other criteria set by the Immunization Unit

Non-Compliance Follow-up Visit

The Non-Compliance Follow-up Site Visit may be scheduled or unannounced. These visits are part of a follow-up to a corrective action plan and are a result of a compliance issue. The Primary Vaccine Coordinator <u>or</u> Secondary Vaccine Coordinator must be available during these visits.

VACCINE MANAGEMENT

The management of publicly-supplied vaccine is one of the most important activities for which VFC/WyVIP Providers have responsibility. Vaccines must be maintained properly to protect their viability prior to administration. Adhering to proper storage and handling procedures will minimize vaccine loss, waste and the potential need to revaccinate.

The Cold Chain

Storage and handling practices compromising vaccine viability can be costly in money and time. Vaccines must be stored properly from the time they are manufactured until the time they are administered. Excess heat or cold will reduce their potency and increase the risk that recipients will not be fully protected. The system used to maintain and distribute vaccines in optimal condition is called the "cold chain." The cold chain has three main components to ensure safe vaccine transport and storage:

- Transport and storage equipment
- Trained personnel
- Efficient management procedures

If a cold chain failure is suspected or there is evidence vaccine has been exposed to temperatures outside the recommended temperature range, providers should immediately:

- **Contact the Clinical and Quality Compliance Specialist** with the Immunization Unit for guidance.
- Vaccine should be stored under correct temperature storage conditions and marked "DO NOT USE" so the vaccine is not administered until a response indicating that the vaccine is acceptable for use has been received from a Clinical and Quality Compliance Specialist. Providers should not discard any vaccine unless directed to do so by the Immunization Unit.

Prevention of Vaccine Loss and Waste

VFC/WyVIP Providers are responsible for maintaining vaccine quality from the time a shipment arrives until the moment a dose is administered. **Vaccine waste is both costly and preventable.** There are many reasons for vaccine waste, including heat and/or light exposure, inappropriate freezing, broken vials and syringes, poor reconstitution practices, contamination and suspected contamination, missing inventory, and theft. However, the most significant causes of vaccine waste are attributed to poor vaccine management (i.e., loss due to expiration and loss due to cold chain failures). Vaccine loss due to expiration is frequently a consequence of over ordering and/or poor inventory management.

Inventory Management

Public and private providers enrolled in the VFC/WyVIP program are responsible for the proper maintenance of their vaccine inventories and for ordering vaccine in the appropriate amounts.

Providers are expected to maintain a two to three month inventory and order vaccines in a manner that enables them to support that inventory.

Providers are permitted to place one vaccine order per order set each month during the **Order Window which is the 1st through the 5th of each month.** VFC/WyVIP vaccine inventory must be managed in the WyIR and reconciled prior to submitting the vaccine order.

Provider responsibilities: Cold chain failures and management of vaccine waste

- Immediately notify the Immunization Unit of vaccine cold chain failure incidents involving publicly funded vaccines after discovery of the incident.
- Follow the guidance of the Immunization Unit on how to document and report the incident using a *Vaccine Incident Summary Report*.
- Develop and implement written protocols for reporting and responding to losses resulting from vaccine expiration, spoilage, and waste. Definitions for terms used in this section can be found in Appendix B Definitions and Acronyms.
- Once Immunization staff had determined the vaccine is non-viable or has expired, remove the wasted/expired/spoiled vaccine (this includes wasted/expired/spoiled diluents) from storage containers with viable vaccine to prevent inadvertent administration.
- Publicly purchased vaccines that are expired or spoiled and qualify for return to the distributor for excise tax credit must be reported using the **Vaccine Return Form** found on the Vaccine Program webpage. In addition, the vaccine must be reconciled out of the WyIR inventory appropriately. All returns must be submitted within 3 months of expiration or the date designated as spoiled.
- All wasted, non-returnable vaccine should be disposed of properly and reconciled out of the WyIR inventory.

Summary of Provider Vaccine Storage and Monitoring Recommendations and Requirements

*Required activities:

1. The use of calibrated thermometers with a certificate of Traceability and Calibration that meets the standard of NIST (see www.immunizewyoming.com);
2. Providers are required to assess and document temperature readings twice daily for each refrigerator/freezer unit storing vaccine;
3. Do not store VFC/WyVIP vaccine in a dorm-style refrigerator/freezer at any time;

4. Vaccine storage units must be dedicated to the storage of vaccines. (Food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature);
5. All providers and practices must have written vaccine management plans, updated annually, both for routine storage and handling of vaccines, and for emergency vaccine retrieval and storage; and
6. Active and enrolled providers must participate in awardee training/education on proper storage and handling practices and program requirements.

Recommended activities:

1. The use of digital thermometers with a bio-safe glycol-encased probe rather than measurement of ambient air temperatures;
2. The use of two (2) calibrated thermometers in each unit to ensure temperatures are always being monitored and recorded with a calibrated device;
3. The use of continuous digital data loggers with detachable probes for temperature monitoring;
4. Assessing and documenting minimum/maximum temperatures for each storage unit at the beginning of the workday; and
5. The use of stand-alone refrigerator and freezer units suitable for vaccine storage rather than combination or other units not designed for storing biologics.

Storage and Handling Plans

Providers must have a written Vaccine Management Plan and emergency storage and handling plans. They may develop their own or customize the template provided by the Immunization Unit to reflect their office practice. Both the routine and the emergency plans should be simple, and the processes outlined in the plan should be presented in a clear and concise manner. Both plans should be reviewed and updated annually as necessary.

- The routine vaccine storage and handling plan should include guidance on routine vaccine management processes/practices. Please refer to the "Vaccine Management Plan" template found on the Site Visit Information webpage at www.immunizewyoming.com.
- The emergency vaccine storage and handling plan must include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. Please refer to the "Emergency Plan for Power or Equipment Failure" template found on the Site Visit Information webpage.
- In any type of power outage:
    - Freezers and refrigerators should not be opened until power is restored, except to transport vaccine to an alternate storage location.

  - Temperatures and duration of power outage must be monitored; vaccine should not be discarded or administered until the situation has been discussed with a Clinical and Quality staff member

- At a minimum, the emergency plan must be reviewed and updated annually (or as necessary) or when there is a change in staff that has responsibilities specified in the emergency plan.

Vaccine Storage Practices

The vaccine storage practices listed below are the responsibility of the Vaccine Coordinators. If delegated to the back-up, the designated primary vaccine coordinator must monitor these activities regularly.

- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine at least weekly.
- Notify the Immunization Unit of any vaccine doses that will expire before they can be administered by submitting a Short-Dated Vaccine Transfer Request found on the Vaccine Program webpage. Only with the approval and direct guidance of the Immunization Unit and only if the cold chain can be ensured, short-dated vaccines can be transferred to high-volume providers who are able to administer it before it expires.
- Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent.
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.
- Store vaccine with enough space to allow for cold air circulation around the vaccine.
- Never store vaccines in the door of the storage unit.
- Never store food or drink in the storage unit.
- Keep public vaccine separate from private vaccine and clearly label both.
- Never use a dormitory-style refrigerator/freezer to store vaccine at any time.
- Remove vegetable bins from the refrigerator; replace with cold water bottles.
- Store all opened and unopened vials of vaccine in their original packaging inside the appropriate storage unit to prevent over exposure to light and so that their contents and expiration dates are easily visible.
- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles and frozen packs.
- Keep vaccines organized.
- Open only one vial or box of a particular vaccine at a time to control vaccine use and allow easier inventory control (On each opened vaccine vial, indicate on the label the date and time it was reconstituted or first opened).

- Store vaccine products that have similar packaging in different locations in the storage unit to avoid confusion and medication errors.
- Limit access to the vaccine supply to authorized personnel only.
- Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
- In larger clinics, provide a source of back-up power (generator) and a security system to alert appropriate personnel in the event of a power outage.
- If applicable, test back-up generators quarterly and maintenance back-up generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).

Temperature Monitoring

Temperature monitoring should be the primary responsibility of the Vaccine Coordinators. If other staff must monitor temperatures, those persons must be trained on how to respond to and document actions taken when temperatures are outside the appropriate range.

- Post the **VFC/WyVIP Vaccine Temperature Log** on the vaccine storage unit door or nearby in a readily accessible and visible location.
- Record and assess refrigerator and freezer temperatures twice each day (beginning and end) and recommended to review and record minimum and maximum temperature readings at the beginning of the work day ensuring that refrigerator temperatures are between 2° and 8°C (35° and 46° F) and that freezer temperatures between -50°C and -15°C (-58°F and +5°F). Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used.
- Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges. Document actions taken on the temperature log.
- Maintain an ongoing file of temperature logs, and store completed logs for three years.
- Providers are required to submit Temperature Logs every month during the designated vaccine order window.

VFC/WyVIP Program
Certificate of Calibration Checklist For Thermometers

Providers are encouraged to carefully review their thermometer's **Certificate of Traceability and Calibration Testing** (also known as a Report of Calibration Testing), or speak to the manufacturer PRIOR to purchasing new equipment, to determine if the following requirements are met:

A The certificate identifies one of the Accredited Laboratories below:

The following table lists the **ILAC/MRA Signatory Body Accredited Laboratory** accredited laboratories: *(look for the logo OR name of the laboratory)*

☐ A2LA	L-A-B	ACLASS	IAS	PJLA

And States:

- ☐ Model Number
- ☐ Serial Number
- ☐ Date of Calibration (Report or Issue Date)

If all of the above boxes are checked the device meets the CDC requirements for calibration testing!

B If the Certificate DOES NOT identify an Accredited Laboratory, ALL of the following information must be listed on the certificate:

- ☐ Model Number
- ☐ Serial Number
- ☐ Date of Calibration (Report or Issue Date)
- ☐ Instrument Pass/Fail Testing
- ☐ Measurement results for the device
- ☐ Documented Uncertainty (accurate within, +/-1°F (+/-.5°C))
- ☐ Statement that calibration testing conforms to **ISO 17025**

***** If the Certificate of Traceability and Calibration or the Report of Calibration Testing does not meet the requirements of A or B, it DOES NOT meet CDC requirements!! *****

- The CDC requires thermometer re-calibration every two years, at a minimum.
- If the calibration expiration date listed on the calibration certificate is less than two years from the date of calibration, providers are expected to abide by the manufacturer's recommended calibration expiration date.
- If the calibration expiration date listed on the calibration certificate is more than two years from the date of calibration, providers are required to re-calibrate the device two years from the date of calibration.
- If the certificate does not have an expiration date, providers must write the date the thermometer was put into use on the certificate and re-calibrate the device two years from the in-use date. If the in-use date is not on the certificate when site reviewers inspect the calibration certificate, the calibration expiration date will be defined as two years from the date of calibration.

Don't Be Guilty of These Errors in Vaccine Storage and Handling

The following are frequently reported errors in vaccine storage and handling. Some of these errors are much more serious than others, but none of them should occur. Be sure your clinic or practice is not making errors such as these.

Error #1: Designating only one person, rather than at least two, to be responsible for storage and handling of vaccines

Since vaccines are both expensive and fragile, everyone in the office should know the basics of vaccine handling, including what to do when a shipment arrives and what to do in the event of an equipment failure or power outage. It's very important to train at least one back-up person in all aspects of proper storage and handling of vaccines. The back-up and primary persons should be equally familiar with all aspects of vaccine storage and handling, including knowing how to handle vaccines when they arrive, how to properly record refrigerator and freezer temperatures, and should be prepared to lead the response to an equipment problem or power outage.

Error #2: Refrigerating vaccine in a manner that could jeopardize its quality

The temperature in the vegetable bins, on the floor, next to the walls, in the door, and near the cold air outlet from the freezer may differ significantly from the temperature in the body of the refrigerator: do not store your vaccines or place thermometers in these locations. Always store vaccines in their original packaging in the body of the refrigerator away from these locations, and place your thermometer with the vaccines. Place vaccine packages in such a way that air can circulate around the compartment. Never overpack a refrigerator compartment.

Error #3: Storing food and drinks in the vaccine refrigerator

Frequent opening of the refrigerator door to retrieve food items can adversely affect the internal temperature of the unit and damage vaccines.

Error #4: Inadvertently leaving the refrigerator or freezer door open or having inadequate seals

Remind staff to close the unit doors tightly each time they open them. Also, check the seals on the doors on a regular schedule, and if there is any indication the door seal may be cracked or not sealing properly, have it replaced. Replacing a seal is much less costly than replacing a box of pneumococcal conjugate or varicella vaccine.

Error #5: Storing vaccine in a dorm-style refrigerator

All vaccines should be stored in a refrigerator and/or freezer unit that is designed specifically for the storage of biologics or, alternatively, in a separate free-standing unit. A dorm-style combination refrigerator-freezer unit with just one exterior door has been shown to be unacceptable no matter where the vaccine was placed inside the unit. Small stand-alone refrigerator or freezer units are best for short-term storage needs.

Error #6: Recording temperatures only once per day

Temperatures fluctuate throughout the day. Temperatures in the refrigertor and freezer should be checked at the beginning and end of the day to determine if the unit is getting too cold or too warm. Ideally, you should have continuous thermometers that record temperatures all day and all night; those with alarms can alert you when temperatures go out of range. A less expensive alternative is to purchase maximum/minimum thermometers. Only thermometers with a Current Certificate of Traceability and Calibration* should be used for vaccine storage. It's also a good idea to record the room temperature on your temperature log in case there is a problem with the storage unit. This information may be helpful to the vaccine manufacturer and/or state immunization program in determining whether your vaccine is still usable.

Error #7: Recording temperatures for only the refrigerator or freezer, rather than both

It is essential to monitor and record temperatures in all refrigerators and freezers used to store vaccine. At all times you should have calibrated thermometers in the refrigerators as well as the freezers. Assure that your storage temperature monitoring is accurate by purchasing thermometers that have a Certificate of Traceability and Calibration* and recalibrate them according to the manufacturer's instructions. Your state immunization program may be able to provide more information on calibrated thermometers.

Error #8: Documenting out-of-range temperatures on vaccine temperature logs but not taking action

Documenting temperatures is not enough. Acting on the information is essential! So, what should you do? Notify your supervisor whenever you have an out-of-range temperature. Sometimes the solution is as simple as shutting a door left ajar or re-checking a freezer temperature that is slightly elevated as it goes through a normal, brief defrost cycle. Check the condition of the unit for problems. Are the seals on the door tight? Is there excessive lint or dust on the coils? After you have made any adjustment, document the date, time, temperature, the nature of the problem, the action you took, and the results of your action. Recheck the temperature every two hours. Call maintenance or a repair person if the temperature is still out of range. If the solution is not quick and easy, you will need to safeguard your vaccines by moving them to another storage unit that is functioning at the proper temperature. Label the affected vaccines "Do not use" and contact your state immunization program or vaccine manufacturer to find out if the affected vaccine is still usable. Be sure to notify your state's VFC Program Coordinator if VFC vaccine was involved.

Error #9: Discarding temperature logs at the end of every month

It's important that you keep your temperature logs for at least three years. As your refrigerator or freezer ages, you can track recurring problems. If out-of-range temperatures have been documented, you can determine how long and how often this has been happening and take appropriate action. It's also a great way to demonstrate why you need a new refrigerator or freezer.

Error #10: Discarding multi-dose vials 30 days after they are opened

Don't discard your multi-dose vials of vaccines prematurely. Almost all multi-dose vaccine vials contain a preservative and can be used until the expiration date on the vial unless there is actual contamination or the vials are not stored under appropriate temperatures. However, you must discard multi-dose vials of reconstituted vaccine (e.g., meningococcal polysaccharide, yellow fever) if they are not used within a defined period after reconstitution. Refer to the vaccine package inserts for detailed information.

Error #11: Not having emergency plans for a power outage or natural disaster

Every clinic should have a written Emergency Response Plan that identifies a refrigerator and freezer in another location (ideally, a storage unit with a back-up generator) in which to store vaccine in the event of a power outage or natural disaster. Consider arranging in advance for a local hospital or similar facility to be your back-up location if you should need it. Be sure back-up location staff understand vaccine storage and will allow you to supervise placement and verify storage temperatures so vaccine is not damaged.

*A calibrated thermometer with a Certificate of Traceability and Calibration with calibration measurements traceable to a testing laboratory accredited by the International Organization of Standardization, to the Standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency.

Technical content reviewed by the Centers for Disease Control and Prevention, April 2011.

www.immunize.org/catg.d/p3036.pdf • Item #P3036 (4/11)

VACCINE ORDERS AND TRANSFERS

Vaccine Orders

Vaccine orders will only be accepted under the following terms.

- Vaccine orders must be submitted through the WyIR/VOMS.
- WyIR inventory must be reconciled prior to placing a vaccine order.
- Vaccine orders must be placed within the Order Window which is the 1st through the 5th of each month regardless of holidays and weekends.
    - Orders submitted prior to the 1st and after the 5th will be rejected.
- Providers may place one (1) vaccine order per order set each month.
    - Some providers may have access to multiple order sets such as Influenza Vaccine or Adult Hepatitis. These providers can place one order for each order set they have access to.
    - If an error is identified after the order has been submitted DO NOT place another order. Instead, call the Immunization Unit.
- Orders will not be processed unless Temperature Logs have been received.
    - The most recent version of the VFC/WyVIP Temperature Log must be used.
    - Logs must not have any missing recordings or unexplained temperature excursions.
    - All persons responsible for recording temperatures must be listed on the log.

Appropriate Order Volume

Provider orders must not exceed 2.5 -3 months of their previous months doses administered without justification.

- The general formula for calculating an appropriate vaccine order is:
  $Doses\ Administered\ x\ 2.5 - Current\ Inventory\ = Order\ Quantity$
- *Example*: A provider administered 20 doses last month, they have 10 in inventory.
  $20 \times 2.5 - 10 = 40$

Vaccine orders that exceed the recommended quantity and do not have justification will be cut. Providers holding special clinics must complete the Special Clinic Justification Form.

Vaccine Transfers

- Vaccine Transfers must be created in the WyIR.
- Inventory must be reconciled prior to requesting a vaccine transfer.
- All transfers must be approved by the Immunization Unit.
- Vaccine must NOT be physically moved until the transfer has been approved.
- See the Provider Training Series: Vaccine Transfers for specific guidance on how to properly complete the transfer process.
- See the Storage and Handling Toolkit for guidance on the proper way to transport vaccine.

REPORTING REQUIREMENTS

Vaccine Inventory

Providers are required to manage VFC/WyVIP vaccine inventory in the WyIR. Inventory must be reconciled appropriately each month regardless of whether or not the provider will be requesting vaccine. In addition, providers must reconcile prior to creating a vaccine order or transfer.

Inventory must be accurate as it is reported to the CDC.

Temperature Logs

Providers must submit monthly temperature logs for all storage units that are used to store VFC/WyVIP Vaccine.

- Due between the 1st and the 5th of each month.
- Temperatures must be recorded twice per day, except on weekends and state holidays.
- The most recent version of the log must be used and can be found on the VFC/WyVIP Program webpage.

The following reports must be submitted when applicable.

Vaccine Returns

Publicly supplied vaccines that are expired or spoiled, publicly purchased, and qualify for return to the distributor must be reported to the Immunization Unit using the electronic **Vaccine Return Form** found on the VFC/WyVIP Program webpage.In addition, the vaccine must be reconciled out of the WyIR inventory appropriately. All returns must be submitted within 3 months of expiration or the date it was deemed nonviable.

DO NOT RETURN THE FOLLOWING ITEMS:

- Used syringes, with or without needles
- Needles
- Drawn-up but not used syringe
- Open, multi-dose vials
- IG, HBIG, PPD
- Diluent (expired or not expired)
- Privately purchased vaccine

Short-Dated Vaccine Transfer Request

Short-dated vaccine is vaccine that is within 3-6 months of expiration that a provider feels they will be unable to use prior to expiration. The following conditions apply:

- Submitted using the electronic Short-Dated Vaccine Transfer Request form
- DO NOT report influenza vaccine or open, multi-dose vials.
- Transfers are not guaranteed

- After a transfer is completed the original provider maintains responsibility for any unused vaccine.
- Reporting short-dated vaccine does not absolve the provider of accountability for wasted vaccine. Failure to complete an arranged transfer that results in waste could be subject to the **Vaccine Replacement Policy**.

Non-Returnable Waste

Waste that does not qualify for return to McKesson must be disposed of appropriately and immediately reconciled out of the WyIR inventory by selecting the most appropriate reason. Guidance on reconciling non-returnable waste can be found in the Provider Training Series: Wasted Vaccine found on the Immunization Unit webpage.

Policies and Procedures for Vaccine Wastage
Wyoming Department of Health,
Public Health Division, Community and Public Health, Immunization Section

November 2011

This policy applies to any wasted vaccine reported to the Immunization Section on or after January 1, 2012. **Introduction**

Current state and federal vaccine contracts stipulate that wasted or expired vaccines cannot be returned to the manufacturer for credit or replacement. Such vaccine losses are absorbed directly by the Immunization Section's budget. Because the Vaccines for Children (VFC) and Wyoming Vaccinates Important People (WyVIP) programs are so important to the health and well-being of Wyoming children, it is essential to ensure that every dose of vaccine is not wasted and is used to protect Wyoming residents against vaccine-preventable diseases.

VFC/WyVIP providers must continually monitor vaccine storage and handling practices (also known as "cold chain") to ensure that vaccines are stored safely and prevent vaccine wastage. The Immunization Section offers free education regarding vaccine storage and handling practices at any time to VFC/WyVIP providers to ensure that providers and their staff members understand the significance of effective vaccine storage and handling processes.

All VFC/WyVIP providers are required to report all wasted, expired, spoiled, or lost vaccine to the Immunization Section upon discovery of "cold chain" issues.

This document serves as the Immunization Section's policy for management of incidents that result in the loss of federal- or state-supplied vaccine. In instances where it was determined that vaccine wastage was caused due to a provider's failure to properly store, handle, transfer, or rotate vaccine inventory, providers will be required to purchase private stock vaccine to replace publicly-supplied vaccine that was wasted. Alternative actions may be required at the discretion of the Immunization Section, with input from the State Health Officer and/or Director of the Wyoming Department of Health.

Definitions

- **Wasted vaccine:** Any vaccine that cannot be used. This includes expired, spoiled, and lost vaccines.
- **Expired vaccine:** Any vaccine with an expiration date that has passed.
- **Spoiled vaccine:** Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. Providers should always consult with a clinical staff member of the Immunization Section so that it can be determined whether publicly-provided vaccine is unstable or non-viable.
- **Lost vaccine:** Any vaccine that was delivered to a provider's office but cannot be located within the office. Note: The Immunization Section has the capability of tracking all vaccine shipments from McKesson Specialty to provider's offices.

Vaccine Replacement Policies and Procedures

Vaccine replacement will be required in situations where a VFC/WyVIP provider is determined to be negligent or at fault for wasted vaccine due to improper storage, handling, or rotation of vaccine inventory. Providers will also need to replace their vaccine if they must re-vaccinate due to negligence as a result of a failure to keep vaccine viable (i.e. temperatures out of acceptable range) or improper administration.

- Failure to report wasted vaccine to the Immunization Section upon discovery may result in suspension from the VFC/WyVIP program.
- If it has been determined by the Immunization Section that vaccine wastage could have been prevented, the Immunization Section will formally notify the VFC/WyVIP provider and include what steps must be taken in order to replace the publicly-provided vaccines that were wasted.

Once a provider has been notified about the need to replace wasted vaccines, the provider must take the following steps:

- The VFC/WyVIP provider must order replacement vaccines with private funds.
- The Immunization Section must be notified when the privately-purchased vaccine arrives and a copy of the shipping log must be sent to the Immunization Section.
- A copy of the purchase order or invoice for any replacement vaccines must be submitted to the Immunization Section.
- The replacement vaccine will be labeled as VFC/WyVIP stock and administered to eligible VFC/WyVIP population.

Situations That May Require Vaccine Replacement

Expired Vaccine

- Failure to rotate or transfer vaccine that results in expired vaccine amounting to greater than 10 doses of any one vaccine in a 30 day period

In instances where publicly-provided vaccines may have been compromised, providers must "quarantine" the vaccines in question by placing the vaccines in a paper bag and marking it "do not use" until an investigation has been conducted by a clinical staff member of the Immunization Section. Quarantined vaccines must be stored appropriately during the investigation. **Note: Providers are responsible for conducting stability or viability investigations for privately-purchased vaccines.**

Conditions that may lead to spoiled vaccine

- Pre-drawn vaccine that is not used. Note: the Immunization Section strongly discourages the practice of pre-drawing vaccines.
- Handling, storage, and shipping mishaps by provider staff (e.g. not refrigerating vaccine upon receipt of shipment or not properly shipping transferred vaccine).
- Vaccine that is not stored in a refrigerator or freezer and becomes unstable or nonviable.

- Freezing vaccine that is supposed to be refrigerated.
- Refrigerating vaccine that is supposed to be frozen.
- Refrigerator or freezer was left unplugged.
- Refrigerator or freezer door was left open or ajar.
- Refrigerator or freezer equipment problems where proof of repair or equipment replacement was not provided to the Immunization Section within 30 days of the date the provider became aware of the situation.
- Power outages in which the provider fails to take precautions (e.g. not following an established emergency plan).
- Vaccine that is considered spoiled due to the provider not checking and/or reviewing refrigerator and freezer temperatures twice a day.
- Vaccine that is considered spoiled, because a provider did not take immediate or appropriate action for out-of-range temperatures.

Situations that would not require vaccine replacement

Below is a list of situations that are NOT considered "provider negligence." This list is not exhaustive. In these situations, the provider is deemed not to be at fault.

- A commercial carrier or USPS does not deliver to the provider in a timely manner.
- A provider who has a contract with an alert/alarm company has a refrigerator that malfunctions, and the alarm/alert company does not notify the provider. A provider may be required to produce a letter from the alarm/alert company or the power company.
- A provider moves vaccine to a back-up location due to anticipated inclement weather, the back-up location experiences a power failure, and the Immunization Section determines that the vaccine not viable.
- Power was interrupted or discontinued due to inclement weather, and after consultation with the Immunization Section, it is determined that vaccine is not viable.
- A vial that is accidentally dropped or broken by a provider.
- Vaccine that is drawn at the time of the visit, but not administered, due to parental refusal or a change in physician orders.
- Expired vaccine that is not due to over ordering or provider negligence (including seasonal influenza vaccine).
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Immunization Section within 30 days from the date the provider became aware of the situation.
- Extraordinary situations not listed above which are deemed by the Immunization Section to be beyond the provider's control.

Appeals Process

If a VFC/WyVIP provider disagrees with the determination of provider negligence, the provider may appeal the determination within 10 business days of notification of the necessary action required.

Provider appeals must be signed by a primary practitioner (if the provider is a private practice/facility) or County Health Officer (if the provider is a Public Health Nursing office). Providers who appeal the determination will receive written notification regarding the outcome of the appeal within 10 days of receipt of the appeal request. Each appeal will be considered on an individual basis by the State Health Officer.

Procedures and Policy for Returning Vaccine to McKesson Specialty

In instances where vaccines have been compromised during shipment from the McKesson Specialty vaccine distribution facility, the following procedures should be followed:

- VFC/WyVIP providers should call the Immunization Section as soon as it is suspected that vaccine may be unstable or non-viable when it is received by the provider's office. VFC/WyVIP providers will not be financially accountable for any compromised vaccine that arrives directly from McKesson if they contact the Immunization Section within two hours of delivery.
- VFC/WyVIP providers must return all unopened vials and manufacturer's pre-filled syringes of non-viable vaccine with a completed "Non-Viable Vaccine Return and Wastage Form" to McKesson regardless of any financial restitution status applied to the vaccine. Vaccine provided through the VFC/WyVIP program should never be discarded. All non-viable vaccine must be returned to McKesson Specialty.
- VFC/WyVIP providers should adhere to the following procedures for returning non- viable vaccine to McKesson:
    - Complete a "Non-Viable Vaccine Return and Wastage Form" before returning non-viable vaccine.
    - Make two copies of the form -- one for the provider's records and one for McKesson.
    - Prior to returning non-viable vaccine to McKesson, fax the form to the Immunization Section at 307-777-3615.
    - Ship non-viable vaccine and a copy of the completed return form to McKesson in a shipping container received from a previous vaccine shipment from McKesson.
    - Non-viable vaccine should be shipped via UPS, using a return label provided by the Immunization Section.
    - Providers must not ship viable vaccine to McKesson.
    - Providers must not ship viable or non-viable vaccine received from McKesson to the Immunization Section.
- The Immunization Section is responsible for cold chain investigation and final viability determination on publicly-provided vaccines based upon guidance from vaccine manufacturers.

If you have any questions concerning this policy, please call the Immunization Section at 307-777-7952.

Important Information About the Vaccine Replacement Process

- Providers that are required to replace vaccine must do so within 30 days of the date on the Notification of Vaccine Replacement letter.
- Monetary replacement is not permitted.
- Providers may dispute vaccine replacement by completing a **Vaccine Replacement Dispute Statement.** This statement must be received by the Immunization Unit prior to the due date for replacement listed on the Notification of Vaccine Replacement letter.
    - Upon receipt of a Vaccine Replacement Dispute Statement, a committee will be formed to evaluate all documents and information related to the vaccine replacement. The committee will make a final determination and the provider will be notified within 30 days of the date on the dispute statement.

WYOMING IMMUNIZATION REGISTRY (WYIR)

What is the WyIR?

- The Wyoming Immunization Registry (WyIR) is a secure, confidential, Internet-based immunization database containing the vaccination records of Wyoming residents.
- The WyIR system is administered and maintained by the Immunization Section within the Wyoming Department of Health.
- The WyIR is available free of charge to authorized users, 24 hours a day, seven days a week.

How can the WyIR help me?

- Provides an electronic method of recording and sharing a patient's vaccination history.
- Assists the provider in managing vaccine inventory and placing vaccine orders and transfers.
- Generates Reminder/Recall notifications to alert patients when their immunizations are due or needed.

The WyIR and the VFC/WyVIP Program

All VFC/WyVIP Providers are required to manage VFC/WyVIP vaccine inventory in the WyIR. In addition, the Vaccine Order Management System (VOMS) module in the WyIR must be used to place vaccine orders and create vaccine transfers. VFC/WyVIP vaccine inventory, orders, and other transactions are reported to the CDC.

FRAUD AND ABUSE

Overview

As vaccines become more expensive and immunization programs more complex, the VFC/WyVIP Program becomes more vulnerable to fraud and abuse. The Immunization Unit relies on referrals from Providers and the public to identify potential instances of fraud and abuse.

A working understanding of what constitutes fraud and abuse is critical for all persons working with the VFC/WyVIP Program. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of this *document,* the following definitions will be used:

Fraud: an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse: provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

Examples of Fraud and Abuse

Fraud or abuse can occur in many ways, and some types of fraud and abuse are easier for the VFC/WyVIP Program to prevent or detect than others, depending on how the VFC/WyVIP Program is implemented. The VFC/WyVIP Program should try to differentiate between intentional fraud and abuse and unintentional abuse or error due to excusable lack of knowledge. Some examples of potential fraud and abuse that staff might encounter are:

- Providing VFC/WyVIP vaccine to non- VFC/WyVIP -eligible children.
- Selling or otherwise misdirecting publicly supplied vaccine.
- Billing a patient or third party for publicly-funded vaccine.
- Charging more than the established maximum regional charge for administration of a publicly-funded vaccine to a federally vaccine-eligible child.
- Denying VFC/WyVIP eligible children publicly-funded vaccine because of parents' inability to pay for the administration fee.
- Failing to implement provider enrollment requirements of the VFC/WyVIP Program.
- Failing to screen for and document eligibility status at every visit.
- Failing to maintain VFC/WyVIP records and comply with other requirements of the VFC/WyVIP Program.
- Failing to fully account for publicly-funded vaccine.
- Failing to properly store and handle VFC/WyVIP vaccine.

- Ordering VFC/WyVIP vaccine in quantities or patterns that do not match the provider's profile or otherwise over-ordering of VFC/WyVIP doses of vaccine.
- Waste of VFC/WyVIP vaccine.

Failure to Comply with VFC Requirements

Fraud and abuse by VFC/WyVIP-enrolled providers is a result of the VFC/WyVIP -enrolled provider failing to comply with the VFC/WyVIP Program requirements outlined in each awardee's provider enrollment form. As discussed previously, there are federal requirements that all awardees must include in their VFC/WyVIP -provider enrollment forms. Failure to comply with VFC/WyVIP requirements is defined as any VFC/WyVIP -enrolled provider who is identified as not maintaining any of the federal requirements listed and discussed previously. Failure to comply may be identified by VFC/WyVIP Program staff, the enrolled provider's staff, or a third party. For the purposes of this document, "VFC/WyVIP Program" (unless otherwise noted) is defined as an awardee's VFC/WyVIP Program. An awardee may be a state, urban, territorial, or other political jurisdiction health department that implements the VFC/WyVIP Program.

The Department of Health and Human Services (HHS), Office of Inspector General (OIG), established a program to exclude certain providers from participating in federally-funded health care programs and maintains a list of those excluded on the "*List of Excluded Individuals/Entities (LEIE)*." The basis for exclusion includes program-related fraud, patient abuse, licensing board actions, and default on Health Education Assistance Loans. A VFC/WyVIP -enrolled provider site that has a person employed on the excluded provider list shall be terminated from the VFC/WyVIP Program.

Reporting Suspected Fraud and Abuse

Any individual wishing to make a referral for a Fraud and Abuse investigation may do so by calling the Immunization Unit at 307-77-2413 or by completing the online Fraud and Abuse Referral Form located on the Immunization Unit website. To report a self-discovery of fraud and abuse, providers must complete the Fraud and Abuse Provider Report.

VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the CDC and the Food and Drug Administration (FDA). VAERS is a post-marketing safety surveillance program that collects information about adverse events (possible side effects) that occur after the administration of vaccines licensed for use in the United States.

The National Childhood Vaccine Injury Act (NCVIA) of 1986 requires health professionals and vaccine manufacturers to report to the U.S. Department of Health and Human Services (HHS) specific adverse events that occur after the administration of routinely recommended vaccines. In response to NCVIA, CDC and FDA established VAERS in 1990 (Chen, Vaccine, 1994).

VAERS has demonstrated its public health importance by providing health scientists with signals about possible adverse events following immunization.

The National Childhood Vaccine Injury Act (NCVIA) requires healthcare providers to report:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine; or
- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination, which can be located at http://vaers.hhs.gov that occurs within the specified time period after vaccination.

TRAINING AND EDUCATIONAL RESOURCES

The following training and educational resources are available to providers and vaccine contacts. Additional training is available per provider request.

- **Immunization Unit website (www.immunizewyoming.com)**
  - VFC/WyVIP Program webpage
    - Provider Training Series
    - Storage and Handling Toolkit
- **One-on-One training sessions** (in-person or phone call)
- **Provider Teleconference**
  - Bi-monthly: Dial-In 1-877-278-8686, Participant ID 309491
  - Schedule found at http://www.health.wyo.gov/familyhealth/immunization/CalendarEvents.html
  - Past minutes can be found at http://www.health.wyo.gov/familyhealth/immunization/MeetingMinutes.html
- **Jab N' Gab**
  - Quarterly Newsletter emailed to providers that provides important updates and information.
  - Most recent version can be found on the Immunization Unit home page.
  - Email karoleigh.cassel@wyo.gov for past issues.
- **Regional Training**
  - Training event that occurs annually in multiple locations around the state.