

# **IDAHO IMMUNIZATION PROGRAM (IIP)**

## **Policies and Guidelines**

### **Effective October 2012**

#### **Provider Enrollment**

Any health care provider wanting to provide routine childhood vaccines through the federal Vaccines for Children (VFC) program is eligible to enroll with the IIP. The administrative requirements to enroll include:

1. Signing a Provider Enrollment Agreement to follow the IIP Policies and Guidelines,
2. Completing a Provider Profile form, and
3. Completing a new provider training with IIP staff.

#### **Types of Provider Enrollment**

##### **Traditional**

Providers who provide medical services for children 0 through 18 years of age shall administer all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and shall comply with the immunization schedule, dosage, and contraindications established by the ACIP and included in the VFC program unless:

- a. In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate.
- b. The requirement(s) contradict a parent or guardian's religious or personal beliefs.

Examples of Traditional providers include pediatric practices, family practice, etc.

##### **Adolescent**

Providers who provide medical services for children 9 through 18 years of age shall administer all vaccines recommended by the ACIP for the ages seen by the practice. Examples of Adolescent providers include adolescent clinics, juvenile corrections, etc.

##### **Specialty**

Providers who provide specialty medical services for children or adolescents shall administer all vaccines recommended by the ACIP as appropriate for the type of care provided. Examples of a specialty clinic include OB/GYN, emergency clinics, etc.

#### **Patients Eligible for Vaccines Supplied by the IIP**

All children 0 through 18 years of age who are eligible for the federal Vaccines for Children (VFC) program, the Idaho Immunization Assessment, and federal funds for designated targeted populations may receive vaccines supplied by the IIP. Patient eligibility must be screened and documented for every child at each immunization visit.

##### **State-Supplied Eligibility**

All children 0 through 18 years of age whose custodial parent or legal guardian resides in Idaho, and who are not eligible for the federal Vaccines for Children program, are eligible for state-supplied vaccines funded through the Idaho Immunization Assessment.

##### **VFC Eligibility**

All providers must screen every child at each immunization visit for VFC eligibility. VFC eligibility does not have to be verified by the provider, but must be documented. All children 0 through 18 years of age who meet one of the following criteria are considered VFC eligible:

- a. Is a Native American or Alaska Native,
- b. Is enrolled in Medicaid,
- c. Has no health insurance, or
- d. Is underinsured. Underinsured children have private health insurance but the coverage does not include vaccines; the coverage includes only selected vaccines (the child is VFC eligible for non-covered vaccines); or, children whose insurance caps vaccine coverage at a certain amount (once the coverage amount is reached, these children are categorized as underinsured). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or deputized Public Health Department.

Private providers must inform parents of underinsured children that free vaccine may be available at a FQHC, RHC, or Public Health Department.

### **Other Eligibility**

Other populations deemed eligible by the Idaho Department of Health and Welfare's Immunization Program based on available funding and resources.

Patient eligibility status information must be retained and easy to retrieve in the patient's record for three (3) years.

### **Vaccine Funding**

The IIP supplies all vaccines recommended by the ACIP for Idaho children 0 through 18 years of age. The vaccine is purchased with federal and state dollars. The federal dollars, provided through the Centers of Disease Control and Prevention (CDC), fund vaccines for Idaho's VFC-eligible population. State dollars provided by the Idaho Immunization Assessment Board fund vaccines for Idaho children not eligible for the VFC program.

The Idaho Immunization Assessment Board was created in March 2010 after the signing of HB432. The purpose of the Board is to assess insurance carriers for funding a vaccine program. HB432 requires the Board to receive reports generated from the Idaho Immunization Reminder Information System (IRIS) by the Idaho Department of Health & Welfare (IDHW). As a result of this requirement, VFC providers must use IRIS for vaccine accountability.

### **Vaccines Supplied by the IIP**

The following vaccines are available from the IIP at no cost for eligible children:

- **DTaP** (Diphtheria, Tetanus, Acellular Pertussis)
- **DT** (Diphtheria, Tetanus) - pediatric
- **Td** (Tetanus, Diphtheria) - 7 through 18 years of age
- **Hib** (Haemophilus Influenzae type b)
- **MMR** (Measles, Mumps, Rubella) combination vaccine
- **EIPV** (Polio)
- **Hep B** (Hepatitis B)
- **PCV 23** (Pneumococcal Polysaccharide) - high-risk children 2 through 18 years of age
- **PCV 13** (Pneumococcal Conjugate)
- **FLU** (Influenza)
- **Hep A** (Hepatitis A)
- **Varicella** (Varicella)
- **Twinrix** (Hepatitis B, Hepatitis A) combination vaccine - 18 year olds
- **Pediarix®** (Hepatitis B, DTaP, EIPV) combination vaccine
- **Pentacel®** (DTaP, EIPV, HIB) combination vaccine
- **MCV4** (Quadrivalent conjugate meningococcal vaccine)

- **Tdap** (Tetanus, Diphtheria, acellular Pertussis vaccine)
- **Rotavirus** (Rotavirus vaccine, Live, Oral)
- **Kinrix®** (DTaP, EIPV) combination vaccine for children 4-6 years of age
- **HPV** (Human Papillomavirus Vaccine)
- **ProQuad** (Measles, Mumps, Rubella, Varicella combination vaccine)

As new vaccines are added to the federal VFC program, the Idaho Immunization Assessment Board will determine when the vaccine will be supplied universally.

### **Immunization Reminder Information System (IRIS)**

IRIS is a statewide, voluntary immunization registry for people of all ages to record immunization information. All children born in Idaho are entered into IRIS at birth; however, anyone can notify the IIP to have his or her child's immunization information removed/blocked from the registry. All vaccine doses ordered and administered through the IIP must be entered into IRIS.

### **IRIS Information Sharing Access Agreement**

Providers must ensure that computers used by their staff to access IRIS are fully compliant with HIPAA requirements, and that their office staff who have access to IRIS are trained in the application of HIPAA to online data systems containing Personal Health Information.

In addition to any internal remediation measures taken in the event of inappropriate access to or use of IRIS within the provider's practice, the provider must also notify the IIP of the inappropriate use. Acceptable uses of IRIS are outlined within Title 39 Chapter 48 Section 03 of Idaho Code (<http://legislature.idaho.gov/idstat/Title39/T39CH48SECT39-4803.htm>).

### **Vaccine Ordering**

Vaccines can be ordered 24 hours a day, seven days a week through IRIS. Providers must order vaccines in accordance with actual vaccine need within their ordering cycle (see Economic Ordering Quantity below). Current cold storage temperatures and physical on-hand vaccine counts must be submitted before a vaccine order can be created in IRIS.

Providers must be able to distinguish between public and private vaccine stock and develop and maintain complete, accurate, and separate stock records for state-supplied and privately purchased vaccines.

### **Economic Ordering Quantity (EOQ)**

EOQ balances provider order size, order frequency, the timing of orders, and storage and handling to minimize costs and improve efficiencies as orders flow through the system.

Providers will place orders based on an ordering frequency determined by:

- the number of vaccines ordered,
- the number of vaccines administered, and
- the size of the storage unit(s).

Depending on the volume, the ordering frequency may be:

- monthly,
- bi-monthly,
- quarterly, or
- semi-annually.

The IIP will notify providers of their designated ordering frequency.

### **Vaccine Brand Choice**

- Providers will choose which vaccine brands will be used in their office (forms are provided by the IIP).
- Every six months a provider may make changes to the brands previously selected; however, current vaccine stock on-hand is still the responsibility of the provider to use before a different brand is supplied.

Refrigerated vaccines are shipped from McKesson Specialty Distribution, LLC. Freezer vaccines are shipped directly from the manufacturer. After vaccine orders are processed, they may take up to 14 days to ship.

Vaccines must be shipped directly to the offices where the vaccine will be administered. The IIP may grant exceptions for providers with multiple sites. Freezer vaccines must be directly shipped to the office where they will be administered.

Emergency orders will only be placed in response to a disease outbreak or natural disaster.

### **Resources**

The IIP has related forms and educational resources available at no cost to providers. Resources available from the IIP can be ordered online at [www.immunizeidaho.com](http://www.immunizeidaho.com) 24 hours a day, seven days a week. Examples of resources available include:

- Vaccine Information Statements (VIS)
- Temperature Log Sheets
- Vaccine Replenishment Report (for use with VFC-only vaccines)
- Clinic Immunization Record and History/Administration Forms (includes VFC Patient Eligibility Screening Form questions)
- VAERS (Vaccine Adverse Events Reporting System) Report Forms
- Lifetime Immunization Records
- IRIS Brochures

### **Vaccine Administration**

Parents or guardians must be provided a copy of the appropriate Vaccine Information Statement (VIS) prior to each vaccine administered. VISs are available from the IIP at no cost. The National Childhood Vaccine Injury Act requires that the following vaccine and administration information be recorded and maintained in the child's medical record.

The IIP requires the information also be entered into IRIS in order to comply with the reporting requirements:

1. Type of vaccine (DTaP, MMR, etc.),
2. Name of the vaccine manufacturer,
3. Lot number,
4. Name, title, and business address of health care professional administering the vaccine,
5. Date vaccine was administered (month, day, year),
6. Specific site where vaccine was administered (left deltoid, intranasal, etc.), and
7. VIS version date and date it was provided.

The expiration date of vaccine is recommended by the American Academy of Pediatrics (AAP) but is not required to be documented in a patient's medical record.

Vaccines must be administered in accordance with the Recommended Childhood Immunization Schedule, approved by the ACIP, and other Idaho vaccine guidelines and recommendations.

Pre-drawing vaccine into syringes is not an acceptable practice. Providers should draw vaccine only at the time of administration to ensure that the cold chain is maintained and the vaccine is not inappropriately exposed to light.

## Vaccine Inventory and Accountability

The Idaho Immunization Program purchases over **\$30 million dollars** worth of vaccine annually.

Providers must conduct an inventory of vaccines. Providers must use IRIS to account for all vaccines provided by the state.

Providers are required to submit accountability each time a vaccine order is placed. Accountability must be submitted through IRIS. Monthly accountability submission is considered a "best practice" and the IIP encourages all providers to submit accountability on a monthly basis.

Accountability reports must include the following information and be submitted through IRIS:

- Doses received
- Doses expired or wasted
- Doses transferred
- Doses administered
- Vaccine inventory reports (including vaccine replenishment)

The IIP must be notified of expiring vaccine at least 3 months (90 days) prior to the vaccine's expiration date if the vaccine will not be used prior to expiration. To report expiring vaccine, email [IIP@dhw.idaho.gov](mailto:IIP@dhw.idaho.gov) or fax (208) 334-4914. A provider may be required to reimburse the IIP for the cost of expired vaccine, if the IIP was not notified 3 months (90 days) prior to the expiration date (see Vaccine Loss and Replacement).

**Vaccine accountability reports must be current.** Providers that fail to submit vaccine accountability reports will not be shipped vaccine until all accountability reports have been received by the IIP. Accountability includes entering all doses of vaccine supplied by the IIP into IRIS within 45 days of administration. Providers needing assistance with accountability reports should contact the IIP at (208) 334-5931 or (800) 554-2922.

## Vaccine Replenishment

VFC-enrolled providers are expected to maintain an adequate stock for both VFC and non-VFC eligible patients. The provider must ensure that borrowing VFC vaccine will not prevent a VFC eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child. Borrowing may occur only when there is lack of appropriate stock due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory. Providers cannot plan to borrow from either the private stock or the VFC stock. Any instance of vaccine borrowing must be documented on the Idaho Immunization Program Vaccine Replenishment Report, submitted with the Accountability Report, and maintained for a minimum of three years. Examples for when borrowing may occur:

- Private stock vaccine is used for a VFC eligible patient
  - Private stock is administered to a patient who is later determined to have been VFC-eligible (not because of unmet deductibles or co-payment).
  - VFC order was delayed.
  - VFC order was received non-viable.
- VFC-only vaccine used for a non-VFC patient
  - Private stock order was delayed.
  - Private stock was received non-viable.

This is a dose-for-dose replacement of vaccine stock and must be documented on the IIP Vaccine Replenishment Report for state-supplied VFC-only vaccines. Borrowing and replenishment should be infrequent. Providers suspected of abusing the borrowing policy will be investigated.

## **Vaccine Management**

### **Vaccine Personnel**

Providers must 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. The designated vaccine coordinator and backup are responsible for the following vaccine management activities:

- Documenting the temperature, twice a day during normal operating hours, on the temperature logs for each storage unit;
- Adjusting the temperature of a vaccine storage unit, if needed;
- The primary vaccine coordinator reviews temperature logs weekly when daily monitoring is being conducted by a backup person to ensure proper temperature recording. The backup staff will monitor the temperature logs if the primary coordinator is unavailable;
- Training staff that are administering vaccines; and
- Following the office's vaccine storage and handling plan. A simple log sheet with the staff member's name and date of training should be kept as documentation.

Unless otherwise noted, the vaccine coordinator and/or backup will be the immunization contact(s) for the office.

### **Vaccine Storage Practices**

The vaccine storage practices listed below can be the responsibility of the vaccine coordinator or can be delegated to another staff member. If the practices are delegated, then the vaccine coordinator must monitor the activity.

- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine weekly.
- Notify the IIP within 3 months of any vaccine doses that will expire before they can be administered. Only with the approval and direct guidance of the IIP and only if the cold chain can be ensured, redistribute short-dated vaccines to providers who are able to administer them before the vaccines expire.
- Store vaccines requiring 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.
- Space stored vaccine to allow for cold air circulation around the vaccine.
- Do not store vaccines in the door of the storage unit.
- Only store vaccines in the refrigerator and freezer.
- Remove vegetable bins from the refrigerator and replace with cold water bottles.
- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles in the refrigerator and frozen packs in the freezer.
- Store all opened and unopened vials of vaccine in their boxes inside the appropriate storage unit so that their contents and expiration dates are easily visible.
- Store vaccine products that have similar packaging in different locations to avoid confusion and medication errors.
- Mark and/or separate state-supplied vaccine from private purchase vaccine. Suggestions to differentiate between vaccines:
  - Utilize the VFC Only or State-Supplied stickers provided by the IIP
  - Place vaccine on separate, marked shelves
  - Place vaccine in separate storage units

## Storage and Handling Plans

Provider must have written routine and emergency storage and handling plans. Providers may develop their own written routine and emergency storage and handling plans or use the IIP supplied storage and handling templates and customize the templates to reflect office practices. 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.

- Routine vaccine storage and handling plans should include guidance on the following aspects of routine vaccine management:
  - Ordering vaccines
  - Controlling inventory
  - Storing vaccines and monitoring storage conditions
  - Minimizing vaccine wastage
  - Vaccine shipping, including receiving, packing and transporting
- Emergency vaccine storage and handling plans should 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. The emergency plan should include the following:
  - Person(s) responsible for preparing and transporting vaccine, including contact information
  - How this person will be notified that vaccine needs to be moved
  - Location that will receive vaccine
  - How receiving location will be notified of transport
  - How to pack vaccine for transport
  - Worksheet to document vaccine involved in power or equipment failure

At a minimum, both plans must be reviewed and updated annually or as necessary. For example, when there is a change in staff responsibilities specified in the emergency plan.

## Vaccine Storage Equipment

### Storage Units

Providers must have appropriate equipment that can store vaccine and maintain proper conditions.

All VFC providers must have an acceptable storage unit (listed below) prior to receiving vaccine. Providers that do not have an acceptable storage unit will not be shipped vaccine.

Currently two types of storage units are acceptable:

1. Stand-alone refrigerators and freezers, or
2. A combination refrigerator that has a separate freezer compartment with a separate exterior door and dual temperature controls (VFC providers enrolled in the program before October 1, 2012 may use a combination unit until December 31, 2013).

Due to changing vaccine storage and handling guidance from the CDC, combination refrigerators will no longer be acceptable vaccine storage units. Offices with most, if not all, combination refrigerator/freezers will need to replace the units with stand-alone refrigerators and freezers. The exact date of replacement has not been determined but will be no later than December 31, 2013.

Dormitory style and bar-style refrigerators are not acceptable storage units for overnight storage of vaccines. The IIP has allowed the use of dormitory style and bar-style refrigerators for day use storage; however, dormitory style and bar-style units will no longer be acceptable for day use storage of vaccine. VFC providers enrolled in the program before October 1, 2012 may continue to use dormitory style or bar-style refrigerators for day-use-only storage until no later than December 31, 2013.

Refrigerators or freezers used for vaccine storage must comply with the following requirements:

- Be able to maintain required vaccine storage temperatures year-round
- Be large enough to hold the year's largest inventory without crowding
- Be large enough to store water bottles in the refrigerator and frozen coolant packs in the freezer to stabilize the temperature and minimize temperature excursions that can impact vaccine potency
- Be frost-free or automatic defrost cycle units

### Thermometers

Vaccine storage units must be equipped with calibrated, continuous recording temperature monitoring devices that can measure both the minimum and maximum temperatures. Temperature monitoring devices must be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instructions used during calibration of the product are traceable to an ISO/IEC 17025 accreditation testing laboratory or to the National Institute of Standards and Technology. The current certification and calibration information must be on file with the IIP in order to receive vaccines supplied by the IIP.

The IIP supplies a temperature recorder for use in the refrigerator and freezer. For optimal use, place temperature recorder in the center of the refrigerator and inside the freezer next to the frozen vaccine. The IIP will supply one recorder for each 24-hour storage unit that holds vaccine supplied by the IIP. The IIP will maintain the temperature recorders supplied, including calibration. If a temperature recording unit is disposed of or damaged, then the provider will be responsible for replacement of the recorder. In addition, one communicator will be supplied to each provider office. Providers will also be responsible for the replacement of a damaged or disposed of communicator.

Providers are not required to utilize the temperature recorder supplied by the IIP. If a provider's office uses a different temperature monitoring device then the following requirements must be met:

- Use of a calibrated and certified unit to an accuracy of +/- 1° F (0.5°C)
  - Current calibration information must be on file with the IIP
- Use of a continuously recording unit
  - Current temperature displayed outside of unit
  - Memory storage of at least 4,000 readings
  - Temperatures are recorded at a minimum interval of every 15 minutes
  - Hi/Lo alarm for out-of-range temperatures
- Use of a biosafe glycol-encased probe or similar temperature buffered probe

### Vaccine Security and Equipment Maintenance

Providers must post warning notices at both the electrical outlet and the circuit breaker of every storage unit to prevent power from being disconnected. Safeguard vaccines by providing facility security, such as temperature alarms and restricted access, to vaccine storage and handling areas.

### Temperature Ranges for Storing Vaccine

Providers must store vaccines at the appropriate temperatures. The temperature range for refrigerated vaccines is 35-46°F (2°C-8°C). Freezer vaccine must be kept between 5°F-(-58°F) [-15°C-(-50°C)]. ***Failure to store vaccine at the proper temperature can seriously compromise or destroy vaccine efficacy.***

### Temperature Monitoring

Temperature monitoring should be the primary responsibility of the vaccine coordinator and backup. If other staff must monitor temperatures, then they must be trained on how to respond to and document actions taken when temperatures are outside the appropriate range.

- Record refrigerator and freezer temperatures twice each day during normal operating hours (beginning and end) ensuring that refrigerator temperatures are between 35°F and 46°F (2°C and 8°C). The freezer temperature should be between 5°F (-15°C) and -58°F (-50°C). Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used. The actual temperature is required for documentation. An "x" or "✓" is not acceptable.
- 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 or Temperature Recorder spreadsheet.
- Maintain an ongoing file of temperature logs and store completed logs for three years.

### Temperature Incidents (Out of range temperatures)

Immediate corrective action must be taken when vaccine storage temperatures are found to be outside of the acceptable temperature ranges. Providers **must notify the IIP** if a facility has had a temperature incident. After determining the scope of the temperature incident, the program will work with the provider and vaccine manufacturers to assist in determining if the vaccines are still viable. Contact the IIP by calling 208-334-5931 or 800-554-2922.

### Unreported Temperature Incidents

Providers who fail to report a temperature incident when vaccines are stored outside the normal temperature range for more than 2 hours will be placed on probation for 1 year. As a condition of the probation:

- The provider must correct the problem and submit monthly temperature logs along with monthly accountability forms for 1 year.
- In-office training provided by IIP staff on vaccine storage and handling will be offered to the provider's immunization staff.
- The IIP will make recommendations for follow-up action based upon ACIP recommendations.
- Depending on the duration and individual circumstances of the incident, the Department of Health and Welfare may take additional measures as deemed necessary.

**In the event that a provider has a second unreported temperature incident during the probation period or within the two years following the probationary period:**

- The provider, along with their entire immunization and office staff, will be required to attend an in-office training on vaccine storage and handling provided by the IIP.
- The IIP will make recommendations for follow-up action based upon ACIP recommendations.
- The Department of Health and Welfare may take additional measures as deemed necessary.

**In the event of a third unreported temperature incident during the probation period or within the two years following the probationary period:**

- The IIP will terminate the Vaccines for Children agreement with the provider for failure to comply with the Policies and Guidelines.

### Vaccine Shipments

Providers must:

- Immediately check vaccine cold chain monitors<sup>1</sup> and document on the packing slip shipments that arrive with a monitor that was activated.
- Take proper action if cold chain monitor was activated.

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<sup>1</sup> Cold Chain Monitors (CCMs) - These single-use devices come in three basic types: those that indicate whether packages have reached temperatures that are too warm, those that indicate whether packages have reached temperatures that are too cold, and those that continuously record the temperature. These types of monitors are designed to be irreversible indicators of inappropriate temperatures.

- The IIP requires providers to develop a policy, complete with protocols and procedures, for maintaining the vaccine cold chain during transport to off-site clinics or emergency storage locations. See guidelines: [Transporting Refrigerated Vaccines \(http://www.immunize.org/handouts/vaccine-storage-handling.asp\)](http://www.immunize.org/handouts/vaccine-storage-handling.asp).

**To avoid replacing vaccine associated with improper storage and handling, implement proper procedures for vaccine management.**

### **Vaccine Wastage**

- Providers must implement written procedures for reporting and responding to losses resulting from vaccine expiration, wastage, and compromised cold chain.
- Remove wasted/expired vaccine from storage containers with viable vaccine to prevent inadvertent administration.
- Expired or wasted vaccine provided by the IIP must be returned to McKesson for tax credit. A *McKesson Vaccine Return Form* must be faxed to the IIP at (208) 334-4914 or emailed to [IIP@dhw.idaho.gov](mailto:IIP@dhw.idaho.gov), and a copy sent with the expired or wasted vaccine to McKesson.
- A return label will be mailed to the provider as soon as the completed *McKesson Vaccine Return Form* has been submitted to the IIP for processing.

### **Vaccine Loss and Replacement**

As a VFC Provider, you are entrusted with federal and state purchased vaccine to immunize children at *no cost*; however, **providers will be required to replace vaccines lost due to provider negligence.**

### **Situations That Require Vaccine Reimbursement or Replacement**

Below is a list of situations that are considered "provider negligence" and may require financial restitution.

This list is not exhaustive. Failure of a provider or staff to adhere to the current "IIP Policies and Guidelines" will result in a restitution situation. Restitution will be in the form of a dose-for-dose replacement or financial restitution at the provider's discretion. Situations that occur which are not listed here will be considered on an individual basis by the IIP.

- Vaccine wastage and loss of 5% or greater (including unaccounted for vaccine).
- Failure to log temperatures twice daily during normal operating hours and temperatures are found to be out-of-range, resulting in vaccine loss.
- Failure to rotate or request to transfer vaccine that results in expired vaccine (notify the IIP 90 days before the vaccine is to expire).
- Drawing up vaccine prior to patient screening.
- Handling and storage mistakes.
- Vaccine left out of the refrigeration unit that becomes non-viable. Call the IIP first to help determine the stability/viability of vaccine left out of the refrigerator/freezer.
- Freezing vaccine meant to be refrigerated.
- Refrigerating vaccine meant to be frozen.
- Refrigerator left unplugged or electrical breaker switched off.
- Refrigerator door left open or ajar.
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is not provided to the IIP within 30 days from the date of discovery.
- Any power outages in which the provider fails to act according to the posted plan.

**Providers are responsible for the cost of re-vaccination due to negligence.**

## Situations That Do Not Require Financial Restitution

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. Providers may be required to produce a letter from the alarm/alert company or the power company.

- Vaccine shipment is not delivered to the provider in a timely manner or is otherwise damaged or stored improperly during transit. Before making the determination that the vaccine is non-viable, call the IIP.
- A provider who has a current contract with an alert/alarm company has a refrigerator that malfunctions and the alarm/alert company does not notify the provider.
- A provider moves vaccine to a location with a secure power source due to anticipated inclement weather, the location experiences a power failure, and the vaccine is later deemed not viable.
- Power was interrupted or discontinued due to acts of nature, and after consultation with the IIP, it is determined that vaccine is not viable.
- A vial that is accidentally dropped or broken by a provider.
- Vaccine that is drawn up after screening for contraindications and parental education, but not administered due to parental refusal or a change in physician orders.
- Expired vaccine that is not due to provider negligence (including seasonal influenza vaccine).
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the IIP within 30 days from the date of discovery.
- Extraordinary situations not listed above which are deemed by the IIP to be beyond the provider’s control.

## Procedures for Vaccine Replacement

- After the provider supplies the IIP with a copy of the *McKesson Vaccine Return Form* and *Temperature Incident/Wasted Vaccine Report*, the provider must replace each dose of vaccine wasted or provide financial reimbursement for the cost of the vaccine lost.
- The provider will provide a list of replacement vaccine doses with lot numbers to the IIP to be entered into the provider’s inventory or submit payment to the State of Idaho through the IIP.

## Fraud and Abuse

The IIP is required to report suspected VFC fraud and abuse to state and federal authorities.

The following are general examples of fraud and abuse that require corrective action to take place:

- Providing VFC-only vaccine to non-VFC children.
- Selling or otherwise misdirecting VFC vaccine.
- Billing a patient or third party for VFC vaccine.
- Charging more than the established CMS maximum regional charge for administration of a VFC vaccine to a VFC eligible non-Medicaid child.
- Not providing eligible children VFC vaccine because of parents’ inability to pay for the administration fee.
- Not implementing provider enrollment requirements of the VFC program.
- Failing to screen patients for VFC eligibility.
- Failing to maintain VFC records and comply with other requirements of the VFC program.
- Failing to fully account for VFC supplied vaccine.
- Failing to properly store and handle VFC vaccine.
- Ordering VFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC vaccine.
- Wastage of VFC vaccine.

All cases of fraud and/or abuse will be investigated to determine the intent of the provider. If it is found that the intent was to commit fraud and/or abuse, then a formal investigation referral will be made. In the event that the fraud and/or abuse was/is due to oversight in training, an education resolution referral will be made.

The following is a description of the two types of referrals:

**Education Resolution Referral:**

An educational resolution referral will take place on all suspected cases of fraud and/or abuse. The educational visit will be conducted by the IIP and will consist of a targeted training session on the issues as they are related to fraud and abuse. A documented record will be maintained by the IIP of all related fraud and abuse trainings. In the event that after an educational visit the provider is found to be involved in suspected fraud and/or abuse, a referral will be made to the Idaho Medicaid Fraud & Abuse Program Integrity Unit.

**Formal Investigation Referral:**

A formal investigation referral will be made on all suspected cases of fraud and/or abuse where there appears intent to commit fraud and/or abuse as determined by the IIP. The agency that will be responsible for conducting the investigation will be the Idaho Medicaid Fraud & Abuse Program Integrity Unit.

The determination of which type of referral is made will be at the discretion of the IIP. All instances of fraud and/or abuse will result in either an education resolution referral or an investigation by the Idaho Medicaid Fraud & Abuse Program Integrity Unit.

The Centers for Disease Control and Prevention (CDC) and Centers for Medicare and Medicaid Services (CMS) will be notified within 5 working days in the event that a provider commits fraudulent abuse of the VFC program. The entire Fraud and Abuse policy is available from the IIP upon request.

**Quality Assurance**

The IIP will conduct annual quality assurance site reviews at provider offices. These site visits will review compliance with the VFC program requirements including:

- VFC screening and eligibility
- Patient chart review
- Vaccine storage and handling
- Vaccine administration
- Vaccine accountability
- General immunization knowledge
- Assessment of immunization coverage levels

Site visits should take no more than 3-5 hours. A final report, including immunization rates, will be given to all offices following the visit.

**National Vaccine Injury Act**

A Vaccine Adverse Event Reporting System (VAERS) report form must be completed and forwarded to the IIP for the adverse events (following immunization), which are listed in the National Childhood Vaccine Injury Act (NCVIA) Injury Table at <http://www.hrsa.gov/vaccinecompensation/table.htm>. A report of a death following vaccination must be immediately reported to the IIP at (208) 334-5931 or (800) 554-2922.

**Technical Assistance**

Immunization Program staff are available, by calling (208) 334-5931 or (800) 554-2922 Monday thru Friday between 8:00 A.M. and 5:00 P.M. Mountain Time, to answer questions or provide additional immunization information. Additional information and online web education can also be found 24 hours a day, seven days a week at [www.immunizeidaho.com](http://www.immunizeidaho.com).

**Continuing Education**

The IIP strongly encourages all providers to participate in annual continuing education. The IIP offers Shot Smarts, Booster Shots, and immunization meetings annually. The CDC conducts annual courses about Vaccine Preventable Diseases (VPD). Contact your local health department or the IIP at (208) 334-5931 or (800) 554-2922 for additional information.