



IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER – Governor
RICHARD M. ARMSTRONG – Director

IDAHO IMMUNIZATION PROGRAM
OFFICE OF EPIDEMIOLOGY, IMMUNIZATION, AND FOOD PROTECTION
DIVISION OF PUBLIC HEALTH
450 West State Street, 4th Floor
PO Box 83720
Boise, ID 83720-0036
PHONE 208-334-5931
FAX 208-334-4914

August 5, 2011

2011 PROVIDER ENROLLMENT PACKET

Dear VFC Provider:

As a Vaccines for Children (VFC) provider, you are required to re-enroll annually. Enclosed is the 2011 Provider Enrollment Packet. The following key updates have been made to the Idaho Immunization Program (IIP) Provider Enrollment Agreement and Policies and Guidelines:

- A decrease in the number of days a provider has to enter a dose of state-supplied vaccine into the Idaho Reminder Information System (IRIS) after administration from 60 to 45.
- The addition of HPV vaccine as a universally supplied vaccine for all Idaho females 0-18 years of age beginning July 1, 2011.

The **2011 Provider Enrollment Agreement (PEA)** must be reviewed, signed, and returned to the IIP no later than **September 12, 2011**. The IIP will process and return a signed copy of the PEA to your office. Also enclosed are the 2011 IIP Policies and Guidelines for your review. Read the policies and guidelines carefully, paying special attention to vaccine ordering, accountability, loss and replacement, and administration of all recommended antigens.

Four additional forms are enclosed for your review and/or completion:

1. Participating Physicians List: a list of all physicians in your clinic – please update
2. Ordering Frequency: a schedule of your clinic's ordering frequency and dates – please review
3. Enrollment Packet Instructions
4. 2011-2012 Influenza Vaccine Survey

Please refer to the Enrollment Packet Instructions (blue paper) to guide you through the forms.

After **September 12, 2011**, the IIP will not process any vaccine orders until the completed 2011 Provider Enrollment Agreement and Provider Profile (both sides) have been submitted. Please mail your completed forms in the enclosed self-addressed, pre-paid envelope or mail the forms to:

IDAHO DEPARTMENT OF HEALTH & WELFARE
IMMUNIZATION PROGRAM 4TH FLOOR
PO BOX 83720
BOISE ID 83720-0036

If you have any questions about the 2011 PEA, Policies and Guidelines, or the additional forms, please contact the IIP at (208) 334-5931 or (800) 544-2922.

Also, enclosed is a copy of the 12th Edition Epidemiology and Prevention of Vaccine-Preventable Diseases (The "Pink" Book). This copy is for your office to keep on-hand for use by your immunization program staff.

The Idaho Immunization Program staff would like to thank you for your continued participation in the Idaho Vaccines for Children Program. We look forward to working with you to protect the health of Idaho's children.

Thank you,

Tamarie Olson
Vaccines for Children Coordinator
Idaho Immunization Program

Enclosures

Packet Instructions
2011 IIP Policies and Guidelines
2011 Provider Enrollment Agreement
2011 Provider Profile
2011 Participating Physicians List
Vaccine Brand Choice Form
EOQ Calendar
Influenza Survey
Self-addressed, pre-paid envelope
12th Edition Epidemiology and Prevention of Vaccine-Preventable Diseases (The "Pink" Book)



IDAHO VACCINES FOR CHILDREN (VFC) ENROLLMENT PACKET INSTRUCTIONS

August 2011

IDAHO IMMUNIZATION PROGRAM (IIP) POLICIES AND GUIDELINES July 1, 2011

Review the 2011 IIP Policies and Guidelines and retain them in your office for reference. This document reviews the requirements (program instructions) for a VFC provider in Idaho. The following office staff must be aware of and understand the policies and guidelines:

Medical Director/Head Physician

Primary Immunization Contact

Secondary (back-up) Immunization Contact

Staff involved with immunizations

IDAHO IMMUNIZATION PROGRAM (IIP) PROVIDER ENROLLMENT AGREEMENT July 2011

Complete the 2011 Provider Enrollment Agreement (PEA) and return the completed form to the IIP. The PEA must be signed by a person authorized to prescribe vaccine in the state of Idaho. Be sure to include the medical license number (vaccine will not be shipped to facilities without a current medical license number), Medicaid provider number (if applicable), and Employer Identification Number (EIN) for your facility (if applicable). ***A current, signed PEA must be submitted to the IIP in order to receive vaccine.***

2011 PROVIDER PROFILE

Complete the Provider Profile. Some providers will have information pre-populated on the form. If so, please review and update the information. All information must be completed. ***Submit the completed form to the IIP.***

For the first table, estimate the number of children, 0 through 18 years of age, to be immunized between January 1, 2011 and December 31, 2011. Count each child once for immunization, regardless of the number of visits or immunizations given.

For Example: *A baby born in April 2011 will receive immunizations at least three different times during 2011.*

Count this patient "once", not three times.

For the second table, use the numbers placed in the first table and list by category the number of children expected to be VFC-eligible by category.

For Example: *According to the first table, your facility will immunize approximately 100 children less than 1 year of age. Of the 100 children, enter the number your facility expects to immunize in 2011 in each VFC category.*

	<1 Year Old
Enrolled in Medicaid	29
No Health Insurance	12
American Indian/Alaska Native	1
Underinsured	11
Total (Note: usually less than the total of children to be immunized)	53

2011 PARTICIPATING PHYSICIANS LIST

Complete the Participating Physicians List. Some providers will have information pre-populated on the form. If so, please review and update the information. ***Submit the completed form to the IIP.***

Please list all practitioners with your facility participating in the VFC program. This list is only for people who administer vaccine and have prescription writing authority. A current medical license number must be listed for varicella vaccine to be shipped to your office.

To remove a physician – draw a line through the name.

To add a physician – write the person's information on the next blank line.

VACCINE BRAND CHOICE

Please complete (by checking the box next to your facility’s brand choice for each vaccine) and **return to the IIP** if you would like to make changes to your current brand choice. You may complete the form with changes to brand choice or you may email your changes to IIP@dhw.idaho.gov.

Some vaccine antigens are available in differing brands. For example, Havrix® and VAQTA® are vaccines for Hepatitis A. Your facility may select which brand to supply in your office. The vaccines selected by your facility are the vaccines you will supply for at least six months.

Below are some examples. These examples are for a visual perspective only. Each facility needs to determine which vaccines brands to supply. The IIP is not recommending one vaccine brand over another.

	Birth	2 months	4 months	6 months	12 months	15 months	18 months
<i>Example 1</i>							
HEP B	RecombivaxHB	RecombivaxHB		RecombivaxHB			
DTAP							
HIB		Pentacel	Pentacel	Pentacel		Pentacel	
IPV							
ROTA		RotaTeq	RotaTeq	RotaTeq			
PCV		Pprevnar13	Pprevnar13	Pprevnar13			
MMR					Pprevnar13		
VAR					MMRII		
HEP A					Varivax		
					VAQTA		
<i>Example 2</i>							
HEP B	Engerix B						
DTAP		Pediarix	Pediarix	Pediarix			
IPV							
HIB		PedvaxHIB	PedvaxHIB		PedvaxHIB		
ROTA		Rotarix	Rotarix				
PCV		Pprevnar13	Pprevnar13	Pprevnar13	Pprevnar13		
MMR					MMRII		
VAR					Varivax		
HEP A					Havrix		

Note: If a vaccine brand chosen by your facility is not available (i.e., a vaccine shortage) when an order is submitted to the IIP, another brand may be substituted.

ECONOMIC ORDER QUANTITY (EOQ) CALENDAR

Please review the 2011 EOQ calendar for your facility, and retain it in your office for a reference. The calendar has yellow highlighted areas indicating your facility’s vaccine ordering period.

2011-2012 INFLUENZA VACCINE SURVEY

Please **review and complete the 2011-2012 seasonal influenza survey and return it to the IIP by August 31, 2011.**

The 2011-2012 seasonal influenza survey will aid in the distribution of influenza vaccine. Supply is expected to be adequate to vaccinate all VFC-eligible children; however, for non-VFC eligible children the vaccine supply is expected to be limited. Depending on the population you serve, your office might be required to maintain separate influenza vaccine stocks for VFC and non-VFC children.

As a reminder, health insurance carriers will be reimbursing for privately purchased influenza vaccine this season.

IDAHO IMMUNIZATION PROGRAM (IIP)

Policies and Guidelines

Effective July 2011

Provider Enrollment

Any health care provider wanting to provide routine childhood vaccines through the 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 (Public Health Departments need to complete the Provider Profile by county), and
3. Completing a new provider training with the IIP.

Types of Provider Enrollment

Traditional

Providers who provide medical services for children 0-18 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 that are 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 particular requirements contradict state law pertaining to religious and other exemptions

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

Adolescent

Providers who provide medical services for children 9-18 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.

Patient 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 0-18 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 other clinic that has a signed Delegation of Authority.

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

Delegation of Authority

The IIP has secured an agreement with the following FQHC's which allows providers to administer VFC vaccines to underinsured children in VFC clinics:

- Benewah Medical Center (District 1 & 2)
- Terry Reilly Health Services (District 3)
- Glenns Ferry Health Center (District 4)
- Family Health Services (District 5)
- Health West (District 6)
- Community Family Clinic (District 7)

Non-FQHC and RHC providers must have a signed agreement, available from the IIP, prior to providing VFC vaccine to underinsured children. Providers who have not signed a Delegation of Authority must inform parents of underinsured children, that free vaccine may be available at a FQHC, RHC, or other provider with a signed Delegation of Authority.

Vaccine Funding

The IIP supplies all vaccines recommended by the ACIP for Idaho children 0 through 18 years of age with the exception of HPV vaccine. 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 universal-select 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.

State Supplied Universal Vaccines

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) - routine for children 2 months of age through 59 months of age
- 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) for all females through 18 years of age

State Supplied VFC-Only Vaccine

The following vaccine is available from the IIP at no cost for male VFC eligible children only:

- HPV [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant vaccine]

As new vaccines are added to the federal VFC program, the Idaho Immunization Assessment Board will determine if the vaccine will be supplied universally or if the vaccine will remain VFC-only.

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 or his/her child's information removed/blocked from the registry. All vaccine doses ordered and administered through the IIP must be entered into IRIS before accountability is submitted.

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). Providers must be able to distinguish between their 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.

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 it 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 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
- Temperature Incident Report Forms
- Wasted Vaccine Reporting Forms
- IRIS Brochures

Vaccine Administration

Parents or guardians must be provided a copy of the appropriate Vaccine Information Statement (VIS) prior to each vaccine administered. VIS's 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 record. The IIP requires the information to be entered into IRIS in order to comply with the Board 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 given (month, day, year),
6. Specific site where vaccine was given (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.

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 **\$22 million dollars** worth of vaccine annually.

Providers must conduct an inventory of vaccines. The IIP must be notified of expiring vaccine at least 3 months prior to the vaccine's expiration date. To report expiring vaccine, email IIP@dhw.idaho.gov or fax (208) 334-4914.

Providers are required to submit accountability based upon a provider's designated EOQ. For example, providers who order vaccines on a monthly basis will be required to submit a monthly accountability report; whereas, providers who order every three months will be required to submit accountability reports every three months. 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 outdated or wasted
- Doses transferred
- Doses administered
- Vaccine inventory reports (including vaccine 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. 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 assure 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 only occur 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. The reason cannot be provider planned borrowing from either the private stock or the VFC stock. This information 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 (e.g. HPV vaccine)
 - 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, 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, the vaccine coordinator must monitor the activity.

- Mark and/or separate state supplied vaccine from private purchase vaccine. Suggestions to differentiate between vaccines:
 - Utilize the VFC Only stickers provided by the IIP (e.g. HPV vaccine)
 - Place vaccine on separate, marked shelves
 - Place vaccine in separate storage units
- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine.
- 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 it before the vaccine expires.
- 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.
- Remove vegetable bins from the refrigerator; replace with cold water bottles.
- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles and frozen packs.
- 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.

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.

Two types of storage units are acceptable:

1. A refrigerator that has a separate freezer compartment with a separate exterior door and dual temperature controls, or
2. Stand-alone refrigerators and freezers.

Dormitory style refrigerators are not acceptable storage units.

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

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 state-supplied vaccines.

The IIP supplies a data logger for use in the refrigerator. For optimal use, place data logger in the center of the refrigerator and ensure the data logger is not positioned directly under the cold air vent that enters from the freezer.

The IIP supplies a minimum/maximum thermometer for use in the freezer. Minimum/maximum thermometers that transmit temperatures to a separate display should have the sensor placed inside the freezer next to the frozen vaccine and the display unit placed outside the refrigerator. The batteries in both the sensor and the display unit must be changed at least once a year.

Minimum/maximum thermometers that are equipped with a sensor should have the sensor placed between two small cool packs. Place rubber bands around the cool packs to hold the sensor in place near the vaccine. Thermometers and temperature log sheets are provided at no cost from the IIP.

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. Freezer vaccine must be kept at 5°F or below. *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, they must be trained on how to respond to and document actions taken when temperatures are outside the appropriate range.

- Post a temperature log on the vaccine storage unit door or nearby in a readily accessible place.
- Record refrigerator and freezer temperatures twice each day (beginning and end) ensuring that refrigerator temperatures are between 35°F and 46°F (2°C and 8°C). The freezer temperature should be 5°F or lower (-15°C or lower). 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 on the temperature log; 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 on the MicroLog 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 where 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 monitors¹ and document on the packing slip shipments that arrive with a monitor that was activated.
- Take proper action if cold chain monitor was activated.
- 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: [Maintaining the Cold Chain During Transport](http://www.immunize.org/catg.d/p3049.pdf) (<http://www.immunize.org/catg.d/p3049.pdf>).

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, and a copy sent with the expired or wasted vaccine to McKesson.

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.

- 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).

¹ 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.

- 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 Wasted Vaccine Return form and Temperature Incident Report form, 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 actions 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, 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 it 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 for 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 2-4 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 at (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.

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.

4. I will permit visits to my facility by authorized representatives of the Idaho Immunization Program or Department of Health & Human Services to review compliance with the Idaho Immunization Program Policies and Guidelines, to include, but not limited to: patient chart review, vaccine handling & storage, administration techniques, and other applicable immunization subjects. Release of such records will be bound by the privacy protection of the federal Medicaid law and falls within the HIPAA Privacy Rules 45 CFR § 164.512(b).
5. I will comply with the immunization schedule, dosage, and contraindications that are 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 particular requirements contradict state law pertaining to religious and other exemptions.
6. I will distribute the most current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA) and will report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
7. I will not charge more than the CMS Regional Fee Cap of \$14.34 per vaccine dose for VFC-eligible non-Medicaid clients. For Medicaid VFC-eligible clients, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
8. I will not impose a charge for state-supplied vaccine.
9. I will not deny administration of any vaccine received from the Idaho Immunization Program to a patient due to the inability of a child's parent, guardian, or individual of record to pay the administration fee.
10. I will complete and submit the Provider Enrollment Agreement and the Provider Profile form within 30 days of receipt.
11. I will comply with the requirements for ordering, vaccine accountability, and vaccine management which include the following:
 - a. complete and submit accountability reports, through the Immunization Reminder Information System (IRIS) with each vaccine order submitted.
 - b. vaccine received from the Idaho Immunization Program will not be distributed to any other health care provider without prior authorization from the Idaho Immunization Program.
 - c. maintain an adequate inventory of Idaho vaccine supply to meet the needs of my eligible patients.
 - d. maintain proper storage and handling procedures for vaccine and reimburse/replace for vaccine loss due to negligence.
12. I agree to operate with the Idaho Immunization Program in a manner intended to avoid fraud and abuse.
13. I will enter and/or update each patient's VFC-eligibility or insurance information into IRIS; and I will enter each dose of state supplied vaccine into IRIS within 45 days of administration.



2011 Provider Profile
Idaho Immunization Program (IIP)

PIN #

Public and Private providers participating in the Idaho Vaccines for Children (VFC) Program **must complete this form annually**, and/or when the clinic information changes. For example: A private provider becomes a Federally Qualified Health Center (FQHC) or a facility contact information changes.

Today's Date _____ Employer's Identification Number: _____
mm/dd/year

Facility Name _____

Immunization Contact: _____ Phone Number: _____

Physician's Email Address: _____ Fax Number: _____

Physician-In-Charge of Immunizations: _____

Vaccine Shipping Address _____
Address City State Zip

Mailing Address _____
Address City State Zip

County: _____ Days and times vaccine may be delivered _____

Type of Facility: Please mark the (square) that correctly defines your facility type

- Public Health Department Public Hospital Private Practice (Individual or Group)
- Rural Health Clinic (RHC) Private Hospital Federally Qualified Health Center (FQHC)
- Other Public Facility Other Private Facility

Provider Type: Please mark the (square) that correctly defines your facility

- Pediatrics Family Practice Other (specify) _____

Children to be immunized for calendar year 2011

Report the number of children to be immunized at your facility during calendar year 2011 by age group (only count a child once even though they may be immunized several times during the year).

Children 0-18 yrs of age	<1 Year Old	1-6 Years	7-18 Years	Total

Children in each VFC eligibility category

Of the total number for each age group above, how many children are expected to be VFC eligible, by category?

	<1 Year Old	1-6 Years	7-18 Years	Total
Enrolled in Medicaid				
No Health Insurance				
American Indian/Alaskan Native				
Underinsured				
Total (Note: usually less than the total of children to be immunized)				

What type of data was used to determine the number of children to be immunized in 2011 for each VFC eligibility category?

- Benchmarking Data Medicaid Claims Data Provider Encounter Data
- Registry Data (IRIS) Vaccine Replacement Data Doses Administered Data
- Prior Ordering Data Other _____

If you have questions about this form please contact Idaho's Vaccines for Children Coordinator at (208) 334-4949.

IDAHO VACCINES FOR CHILDREN (VFC)

VACCINE BRAND CHOICE

Please complete the form below. The vaccine brands chosen by your facility will be in place for a six month timeframe. At the end of six months, if your office would like to make changes to the vaccine brands supplies, please complete a new form. Submit the completed form to the Idaho Immunization Program by fax (208) 334-4914, email IIP@dhw.idaho.gov, or mail – 450 W State St 4th fl, Boise ID 83702

Facility: _____ **Pin:** _____

Completed By: _____ **Date Completed:** _____

Brand Choice: July 1, 2011 **through** December 31, 2011

COMBINATION VACCINE

- Pediarix® (DTaP-Hep B-IPV)
- Pentacel® (DTaP-IPV-Hib)

DTAP (*Diphtheria, tetanus, acellular pertussis*)

- DAPTACEL®
- Infanrix®

HEP A (*Hepatitis A*)

- Harvix®
- VAQTA®

HEP B (*Hepatitis B*)

- Engerix B®
- RecombivaxHB®

HIB (*Haemophilus influenza type b*)

- ActHIB®
- PedvaxHIB®

HPV (*Humanpapilloma-virus*)

- Cervarix®
- Gardasil®

MCV4 (*Meningococcal conjugate*)

- Menactra®
- Menveo®

ROTA (*Rotavirus*)

- Rotarix®
- RotaTeq®

TDAP (*Tetanus Toxioid, Reduced Diphtheria Toxioid and Acellular Pertussis*)

- Adacel®
- Boostrix®



2011-2012 SEASONAL INFLUENZA VACCINE SURVEY

Facility: _____

VFC Pin: _____

Completed By: _____

The Idaho Immunization Program (IIP) expects to supply 2011-2012 Seasonal Influenza for all Vaccines for Children (VFC) eligible patients (children ages 6 months through 18 years). For non-VFC eligible children the supply is expected to be limited.

Your office will need to carefully screen all children in order to determine from which supply you draw in order to immunize them; particularly the practices which use both state-supplied and privately purchased influenza vaccine. Providers can expect to be reimbursed this seasonal year (2011-2012) by health insurance carriers for privately purchased influenza vaccine.

Please help us to better allocate vaccine supplies by completing and returning this survey indicating the total number of doses you expect to order from the IIP. Return the completed survey to the IIP by August 31, 2011.

1. Please complete the table below for influenza vaccine you plan to order from the IIP:

2011-2012 SEASONAL INFLUENZA							
Vaccine	Trade Name	Manufacturer	Presentation	Mercury Content (mcg Hg/0.5 mL dose)	Age Group	Doses VFC-Eligible	Doses Non-VFC Eligible
TIV	FLUZONE®	Sanofi Pasteur	0.25 mL single dose syringe	0	6-35 months		
			0.5 mL single dose syringe	0	≥ 36 months		
			0.5 mL single dose vial	0	≥ 36 months		
			5.0 mL multi-dose vial	25	≥ 6 months		
TIV	FLUVIRIN®	Novartis	0.5 mL single dose syringe	≤1.0	≥ 4 years		
TIV	FLUARIX®	GlaxoSmithKline	0.5 mL single dose pre-filled syringe	0	≥ 3 years		
TIV	AFLURIA®	Merck	0.5 mL single dose syringe	0	≥ 9 years		
LAIV	FLUMIST®	MedImmune	0.2 mL single dose sprayer	0	2-18 yrs		

2. Does your facility plan to privately purchase 2011-2012 seasonal influenza vaccine? Yes No
(please circle one)

3. If yes, please complete the table below:

<i>Presentation</i>	<i>Number of Private Doses</i>
Syringes and/or Vials	
Nasal Spray	

- Flu vaccine arrives from the manufacturers in multiple shipments over several months. Providers who place orders for more than 20 doses of any flu vaccine should expect their orders to be partially filled during the early part of the season until supplies stabilize, which typically occurs around November.
- The IIP encourages providers to order vaccine as needed to avoid over-ordering.
- If there are questions on Flu orders please contact the IIP at 334-6524.

THIS SURVEY DOES NOT CONSTITUTE AN ORDER PLACEMENT

