



Indiana State  
Department of Health

Immunization Division  
Publicly Funded Vaccine Programs  
Policies and Procedures Manual  
*Updated August 2018*

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## **Executive Summary 2018**

### **Background**

The Indiana State Department of Health (ISDH) Immunization Division Policy and Procedures Manual has been revised, effective July 3, 2018. These revisions reflect the most current practices related to vaccine administration and accountability practices. Policy updates also reflect new programmatic requirements for the Vaccines for Children (VFC) program.

### **Future Changes to the Policy and Procedures Manual**

Policy revisions occur regularly, and the most up to date policies and information are always posted in the CHIRP Document Center. If you have questions about the P&P Manual, please contact the Immunization Division.

### **Policy Changes**

#### Policy 2- Childhood Vaccine Eligibility Statement

Patients who have Medicaid as secondary insurance do not qualify for VFC. If a child has private health insurance covering vaccines and Medicaid as secondary insurance, the child, under these conditions, is considered insured and private health insurance will be the primary payer. VFC provider should administer private stock vaccine and bill the primary insurance carrier for both the cost of the vaccine.

In the rare event the primary insurer denies payment of the vaccine and the administration fee, the provider may replace the privately purchased vaccine with VFC vaccine and bill Medicaid for the administrative fee. This must be documented on the VFC borrowing form and reconciled in CHIRP.

#### Policy 4-New Provider Enrollment

The new enrollment procedures were updated to reflect 2018 changes to the New Provider Enrollment process. This process will help streamline and standardize the New Provider Enrollments. Providers have 60 days from the handoff of the New Enrollment to the Immunization & Registry Educator to complete the first vaccine order in VOMS. Failure to adhere to this timeline will result in a 45 days minimum moratorium period before the enrollment process can be restarted. The restart is initiated by submitting a new Provider Contact form. All documents with current period dates will subsequently need to be submitted as well.

#### Policy 8- Storage and Handling- Storage Unit Requirements

ISDH encourages providers enrolled that still use a combination vaccine storage unit to begin budgeting/planning to replace it with stand-alone units. All providers will be required to have stand-alone units by the submission of the 2019 Provider Recertification in order to continue participating in the Indiana VFC or Adult Vaccine Program starting January 1, 2019.

#### Policy 9 – Storage and Handling- Temperature Requirements

Beginning January 1, 2018, ISDH will no longer supply providers with data logger(s). All enrolled providers must meet the following requirement:

Providers enrolled in any publicly funded vaccine program must have at least one primary and one back-up data logger with a valid and current certificate of calibration readily available to ensure that temperature assessment and recordings can be performed twice a day. The data logger must be maintained on-site.

### Policy 11- Storage and Handling-Cold Chain Failure (NEW)

**After a temperature excursion, proof of at least 5 days of in-range temperatures need to be provided to ISDH to establish that the unit is stable and operating properly. A root-cause analysis (RCA) to find out why the excursion occurred is also required. Additional days-in-range reports may be required depending upon the reason for the temperature excursion.**

### Policy 12- Storage and Handling- Transporting to Off-Site Clinics

Changes have been made to the requirements for transport of vaccines to any off-site clinic beginning on or after January 1, 2018. Providers will no longer follow the procedures for emergency transport of vaccines and they can no longer transport vaccines to/from off-site clinics in hard-side coolers or coolers available at general merchandise stores.

All off site clinics must follow the following requirements:

1. All clinics must use portable vaccine refrigerators/freezers or qualified pack-out units
2. Digital data loggers with a buffered probe and a current and valid Certificate of Calibration Testing must be placed directly with the vaccines and used to monitor vaccine temperature during transport.
3. If vaccines are transferred to a permanent storage unit at the location of the off-site clinic, the storage unit must meet the minimum storage requirements for storage of VFC vaccines and the unit must have been monitored prior to the clinic day with a digital data logger. If vaccines cannot be stored in a permanent storage unit at the clinic location, they can be kept in the portable unit or qualified pack-out.
4. Vaccines must be monitored during the clinic using a digital data logger at least once an hour and documented on the Refrigerator Temperature Log.
5. Within the 24 hours following completion of the off-site clinic and return of all vaccines to the permanent storage unit, the data logger must be downloaded and the report must be reviewed and sent to the respective field representative.

### Policy 16- Publicly Funded Vaccine-Loss Wastage and Reimbursement

As of January 1, 2018, ALL expired, spoiled and wasted doses must be reported on the paper Vaccine Return form. The 5 or more rule no longer applies so in order for vaccine orders to be approved, the provider must submit documentation for any adjustments made to the inventory for these reasons.

### Policy 21- CHIRP-Record Inactivation

CHIRP inactivation policies have been updated to reflect the American Immunization Registry Association's (AIRA) patient active/inactive status guidelines. Inactivation of patients in CHIRP is only allowed for the following reasons:

1. Lost to Follow-up. Three documented failed attempts at contacts over a period of time, using phone, mail, or listed family physician. At least one attempted contact must be by mail.
2. No longer a patient. If the relationship between a provider organization and a patient is terminated because the patient has gone or transferred to another provider organization.
3. No address - no vaccination. CHIRP has never received an address and has never received vaccination information about an individual.
4. Moved out of the area. Verification by school, parents, neighbor or friend that a family has moved out of the providers "practice locale" or county.
5. Deceased-confirmed death of a patient.

<b>Policy &amp; Procedure Title</b>	Provider Eligibility for Vaccines for Publicly Funded Vaccine Programs	<b>Issuing Date</b>	7/17/2012
<b>Policy &amp; Procedure Number</b>	1	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Policy Summary

The purpose of the Vaccines for Children (VFC) program is to increase access to immunizations at providers other than the local health department in order to allow eligible children to remain in their medical home whenever possible. Specific criteria have been established for providers electing to enroll in the VFC program. This policy also applies to any other publicly funded vaccine program enrollment with the Immunization Division.

### Policy Statement

Specific guidelines are described in this policy to use in determining a provider's eligibility to enroll in a publicly funded vaccine program in the state of Indiana.

### Provider Eligibility Criteria

To enroll in a publicly funded vaccine program, the provider must meet the following eligibility criteria:

- Be a licensed medical provider with prescriptive authority in the State of Indiana.
- Providers with prescriptive authority in the State of Indiana include physicians, advanced practice nurses and physicians assistants.
- Pharmacists do not have prescriptive authority in the State of Indiana are not eligible to enroll as a VFC provider.
- Serve individuals who are eligible to receive vaccines through the VFC program, or any publicly funded vaccine program. The population size of eligible individuals must meet the Immunization Division's minimum threshold in accordance with the cost analysis that will be conducted annually.
- Possess a storage unit in compliance with the Storage Unit Certification requirements contained in the Storage and Handling- Storage Unit Requirements policy (Policy 8).
- Ability to receive vaccine shipments and appropriately store each vaccine immediately upon delivery.
- Have no employees or staff reported on the "List of Excluded Individuals and Entities" as administered and published by the Department of Health and Human Services (HHS), Office of Inspector General (OIG).

### Provider Types

Indiana permits both traditional and non-traditional providers to enroll in publicly funded vaccine programs. Traditional providers are providers who have traditionally provided immunization services, such as family practice, general practice and pediatric offices. Traditional providers participating in the VFC program must offer all ACIP recommended vaccines.

Nontraditional providers are providers who serve specific populations, such as adolescents or newborns, and whom have not traditionally provided immunization services to their clients. The Immunization Division has the discretion to allow nontraditional providers to limit their participation in a publicly funded vaccine program to specific vaccines recommended for the specific population served by the provider.



Indiana State Department of Health-Immunization Division

*Examples of Specialty Providers and Appropriate Limitations*

Family Planning Clinics, Long Term Juvenile Correctional facilities, School-based health clinics: Limited to select adolescent vaccinations, such as HPV, Tdap, MCV, Hep A and Hep B

Birthing Hospitals: limited to birth dose of Hep B

Birthing Centers: limited to adult Tdap

**References & Resources**

Immunization Provider Enrollment Request (State Form 54048)

**Revision History**

07/17/2012, Created

11/19/2014, Revised

04/01/2017, Revised

<b>Policy &amp; Procedure Title</b>	Childhood Vaccine Eligibility Statement	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	2	<b>Revision Date</b>	01/01/2018
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Indiana Publicly Funded Vaccine Purchase Policy VFC and Underinsured

Through a combination of VFC, 317 and state funds, the immunization division supplies all routinely recommended pediatric vaccines to all public and private VFC enrolled providers to vaccinate only VFC eligible and underinsured children. (Policy applies to both public and private providers.)

### Eligibility Criteria

**Any immunization provider enrolled in the Vaccines for Children program can provide publicly funded vaccine to the following categories:**

- Birth through 18 years of age
  - Medicaid
  - American Indian/Alaskan Native
  - No Health Insurance

**Any immunization provider enrolled in the Vaccines for Children program can elect to provide publicly funded vaccine to the following category:**

- Birth through 18 years of age
  - Insurance Does Not Cover Vaccines (Underinsured)

### Additional Information

- All ACIP recommended vaccinations are available as publicly funded vaccines.
- All immunization providers are required to adhere to the ACIP recommendations for vaccine administration.
- No additional eligibility requirements may be imposed by providers for the receipt of publicly purchased vaccine by eligible children.
  - This includes but is not limited to requirements pertaining to residency, not having an established primary care physician or the individual requesting data exclusion from the immunization registry.
  - Private providers are not required to provide services to eligible children who are not established patients at their facility.
  - Local health departments are considered by CDC as the safety net providers for the VFC population and they must administer VFC vaccine to any VFC-eligible children who present for immunization services at their facilities.
- A child is considered 18 years of age *up to and until* the date of their 19<sup>th</sup> birthday.
- For eligibility criteria for individuals 19 years of age and older, refer to *Indiana Publicly Funded Adult Vaccine Eligibility Statement*.

### Vaccine Accountability

- All immunization providers are required to account for all publicly funded vaccine. This must be done by documenting all vaccination information in CHIRP as an administered dose.

### Definitions of Eligibility Categories

**Medicaid** A child who has any form of Medicaid insurance.

- CHIRP: Medicaid
- Administration Fee: Bill to Medicaid, Cannot be charged to client as an out of pocket expense. Reimbursement \$8.00 per vaccine from Medicaid.

### Insured and Medicaid as Secondary Insurance

- If a child has private health insurance covering vaccines and Medicaid as secondary insurance, the child, under these conditions, is considered insured and private health insurance will be the primary payer. VFC provider should administer private stock vaccine and bill the primary insurance carrier for both the cost of the vaccine and

administration fee.

- If the primary insurer pays less than Medicaid amount for the vaccine administration fee, the provider can bill Medicaid for the balance of the vaccine fee. As with other Medicaid services, Medicaid is the payer of last resort.
- In the rare event the primary insurer denies payment of the vaccine and the administration fee, the provider may replace the privately purchased vaccine with VFC vaccine and bill Medicaid for the administrative fee. This must be documented on the VFC borrowing form and reconciled in CHIRP.

**American Indian/Alaskan Native** A child who identifies as an American Indian or Alaskan Native, regardless of insurance.

- CHIRP: Am. Indian/Alaskan Native
- Administration Fee: May be charged to client as an out of pocket expense. Not to exceed \$20.32 per vaccine. Vaccination may not be denied for inability to pay administration fee.
- No documentation of ethnicity is required.

**No Health Insurance** A child who does **not** have health insurance.

- CHIRP: No Health Insurance
- Administration Fee: May be charged to client as an out of pocket expense. Not to exceed \$20.32 per vaccine. Vaccination may not be denied for inability to pay administration fee.

**Insurance Does Not Cover Vaccines (Underinsured)** A child who has commercial (private) health insurance but the coverage does not include vaccines, children whose insurance covers only selected vaccines (these children are categorized as underinsured for non-covered vaccines only), or children whose insurance caps vaccine coverage at a certain amount (once that coverage amount is reached, these children are categorized as underinsured). With the implementation of the Affordable Care Act (ACA), it is rare for a child to meet the underinsured eligibility criteria for the VFC Program. Therefore, unless insurance coverage for the vaccines are verified by the provider prior to administration of vaccine, for the purposes of the VFC program, these children are considered insured and NOT eligible to receive VFC vaccines.

- CHIRP: Insurance Does not Cover Vaccines
- Administration Fee: May be charged to client as an out of pocket expense. Not to exceed \$20.32 per vaccine. Vaccination may not be denied for inability to pay administration fee.
- The following are NOT considered underinsured
  - Has a high deductible
  - Has 80/20 or percentage based coverage
  - Has a co-pay
- If the child was vaccinated with private stock vaccine and an insurance denial of payment is later received for that dose, a provider may use the Borrowing Policy to transfer a VFC dose to their private stock. This must be documented on the Borrowing Form and reconciled in CHIRP.

**Fully Insured** A child who has health insurance which provides coverage for vaccines.

- CHIRP: Fully Insured
- Fully Insured children must receive private stock vaccine and their insurance billed.
- All immunization providers are required to carry private stock vaccine. The only exception to this is when a provider is an authorized specialty provider

## Funding Source Definitions

**Publicly Funded Vaccine** Any vaccine supplied through ISDH. ISDH has three primary funding sources to purchase publicly funded vaccine – VFC (Vaccine for Children), 317 and State funds.

### VFC Funds

- Eligibility criteria: Birth through 18 years of age
  - Medicaid
  - American Indian/Native Alaskan
  - No Health Insurance
  - Insurance Does Not Cover Vaccines (Underinsured) – only at FQHC/RHC or providers with a Delegation of Authority (DOA) from an FQHC/RHC
- Funding amount based on population need

### State Funds

- Eligibility criteria: Birth through 18 years of age, per state statute
  - Insurance Does Not Cover Vaccines (Underinsured) – providers who are not an FQHC/RHC or provider with DOA
- Set funding amount that does not change with need

### 317 Funds

- Eligibility criteria: No age requirement
  - Insurance Does Not Cover Vaccines (Underinsured) – providers who are not an FQHC/RHC or provider with DOA
  - Adult Vaccine Program eligible vaccines – See *Indiana Publicly Funded Adult Vaccine Eligibility Statement*
- Set funding amount that does not change with need

**Private Purchase Vaccine** Any vaccine purchased through the manufacturer directly by your facility.

### Outbreaks & Mass Vaccination Campaigns

- **As of January 1, 2011**, there are currently no approved mass vaccination campaigns that permit the administration of publicly funded vaccine to all children and/or adults regardless of eligibility.
- Previously Approved Mass Vaccination Campaigns
  - H1N1 Campaign – Ended in Spring 2010, all vaccine for H1N1 was purchased by the federal government and made available to all children and adults.
  - School Vaccination Campaign – In 2010 the new school required vaccines, Tdap, MCV & Varicella, were purchased using limited ARRA funds, in addition to state and 317 funds. All students 6<sup>th</sup> through 12<sup>th</sup> grade were eligible to receive publicly funded vaccine during mass clinics.
- Mass vaccination campaigns to address specific disease outbreaks may be approved as recommended by the Epidemiology Resource Center (ERC).

### Additional Information

#### Administration Fees

- A child may never be turned away for the inability to pay an administration fee.
- Donations may be accepted, but are voluntary and must have no effect on whether the child will be vaccinated.
- Medicaid Reimbursement is \$8.00 per immunization.
  - No amount of money can be charged to a Medicaid covered child as an out of pocket expense.
  - The vaccine administration fee for a Medicaid covered child must be billed to Medicaid if seeking payment.
- All other eligibility categories have a maximum administration fee per immunization for out of pocket of \$20.32.

### Revision History

07/17/2012, Created

03/03/2015, Revised

04/01/2017, Revised

12/01/2017, Revised



# Indiana Publicly Funded Childhood Vaccine Eligibility Statement

Effective Date: February 1, 2012

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<b>Childhood Vaccine Eligibility Guide</b>					
Birth through 18 years of age					
<b>Eligibility Category</b>	<b>Medicaid</b>	<b>No Health Insurance</b>	<b>American Indian/ Native Alaskan</b>	<b>Insurance Does Not Cover Vaccines (Underinsured)</b>	<b>Fully Insured</b>
<b>Definition</b>	A child who has any form of Medicaid insurance.*	A child who does <b>not</b> have health insurance.	A child who identifies as an American Indian or Alaskan Native, regardless of insurance.	A child who have commercial (private) health insurance but the coverage does not include vaccines, a child whose insurance covers only selected vaccines (eligible for non-covered vaccines only), or a child whose insurance caps vaccine coverage at a certain amount (once that coverage amount is reached, this child is categorized as underinsured).	A child who has health insurance which provides coverage for vaccines.
<b>Can they receive publicly funded vaccine?</b>	Yes	Yes	Yes	<i>FQHC/RHC &amp; Providers w/DOA: VFC Funds All Other Providers: State &amp; 317 Funds (using VFC inventory)</i>	No! Should receive privately purchased vaccine.
<b>CHIRP Marking</b>	Medicaid	No Health Insurance	American Indian/ Native Alaskan	Insurance Does Not Cover Vaccines	Fully Insured
<b>Funding Source</b>	VFC Funds	VFC Funds	VFC Funds	<i>FQHC/RHC &amp; Providers w/DOA: VFC Funds All Other Providers: State &amp; 317 Funds**</i>	Private Purchase by Provider

\*Patients who have Medicaid as secondary insurance do not qualify for VFC. Further explanation and exceptions are listed on page 1-2 of Policy 2.

\*\*When State & 317 Funds Are Exhausted

- Only FQHC/RHC and Providers with a DOA will be able to vaccinate underinsured children with publicly funded vaccine.

#### Administration Fees

- A child may never be turned away for the inability to pay an administration fee.
- Donations may be accepted, but are voluntary and have no effect on whether the child will be vaccinated.
- Medicaid Reimbursement is \$8.00 per immunization. This cannot be charged to the client as an out of pocket expense, it must be billed to Medicaid if seeking payment.
- All other eligibility has a maximum administration fee per immunization for out of pocket is \$20.32.

#### Vaccine Accountability

- All immunization providers are required to account for all publicly funded vaccine. This can be done by documenting all vaccination and eligibility information in CHIRP.

<b>Policy &amp; Procedure Title</b>	Adult Eligibility Statement	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	3	<b>Revision Date</b>	08/15/2018
<b>Policy &amp; Procedure Approval Authority</b>	Dave McConnick		

### Adult Vaccine Program

Publicly funded vaccines for adults are limited to the specific vaccines and provider locations, with the following eligibility criteria. Provider locations electing to participate in the Adult Vaccine Program will be required to enroll in the Adult Vaccine Program. The first step in the process is to complete the *Adult Immunization Provider Profile & Agreement (State Form 54625 (R4 / 3-11))*.

All providers enrolled with the Indiana Adult Vaccine Program must adhere to all other policies and procedures set forth by the Immunization Division, including policies and procedures pertaining to vaccine inventory management, storage and handling and full utilization of the Indiana State Immunization Information System (IIS) called CHIRP.

### Provider Locations Who May Participate in the Adult Vaccine Program

- Local Health Departments (LHD)
  - All vaccines offered through the adult program
- STD Clinics, including STD clinics at LHD
  - All vaccines offered through the adult program
- Birthing Hospitals, Birthing Centers and Prenatal Clinics
  - Tdap only

Primary Care Provider members in the Indiana Primary Health Care Association (IPHCA) are eligible to administer all vaccines offered through the adult program.

The Immunization Division can identify and approve other locations and vaccination needs on a case by case basis.

### Adult Vaccine Program Eligibility Requirements:

To be eligible to receive publicly funded vaccines, adults must be 19 years or older and meet one of the following criteria:

1. Uninsured – Must have no private health insurance coverage. Cannot be Medicaid-eligible, regardless of age.
  - a. If Medicaid-eligible or health program covered, use private stock and bill to appropriate source.
2. Underinsured – Must have private health insurance that does not provide coverage for a specific vaccine or all ACIP recommended vaccines. All individual vaccines should be screened separately.
  - a. High deductible plans do not qualify as underinsured. These individuals are considered fully insured.
  - b. International travelers are excluded from the underinsured category. Even if they have private insurance that will not cover the needed vaccines, he/she is not eligible for publicly funded doses.

### Special Considerations/Populations:

- **Hep B** – Sexual/household contacts of person with chronic hepatitis B are exempt from the financial need criteria for Hep B only.
- **Hep B** – Both Engerix B® and Recombivax HB® are licensed as pediatric and adult formulations. Adults under 20 years of age should receive 3 doses of the pediatric formulation of the Hep B vaccine (.5mL). These pediatric doses to be administered to adult patients can be ordered through the Adult Vaccine Program.
- **Tdap** – There are a few exceptions for Tdap vaccinations:
  - Individuals who are eligible for Medicaid Package E (Emergency Medicaid) are exempt from the financial need criteria. These individuals can be vaccinated with a public dose of Tdap.

- Some patients over 65 years of age who only have Medicare Part A and B may not have coverage for Tdap. These patients would be considered underinsured and would be eligible to receive a public dose of Tdap. All other patients 65 and older, who are Medicare-eligible and who do have any one of the supplemental insurance coverage plans, should be screened each visit for eligibility.
- **Refugees/Immigrants** – Immigration status does not need to be factored in. Screen for financial criteria and if eligible, administer publicly funded vaccine.
- Incarceration** - Federal, state or local correctional facilities are not eligible to participate in the program. Enrolled adult providers **cannot** vaccinate eligible adults in these locations whether in a clinic setting or in conjunction with other medical services.
- **International travelers** – Individuals presenting at the clinic for vaccinations related to any international travel, whether personal or mission related, do not meet the eligibility criteria to receive publicly funded doses through the Adult Vaccine Program. **International travelers are excluded from the underinsured category.** These individuals should be referred to a travel clinic or vaccinated with privately purchased vaccines.

#### Publicly Funded Adult Vaccines Offered:

- Tdap
- Td
- HPV
- MMR\*
- PCV13\*
- PPSV23\*
- Meningococcal\*
- Hepatitis A
- Hepatitis B\*\*
- Varicella\*
- Influenza

\*Unless otherwise noted above, providers enrolled in the Adult Vaccine Program may administer any of the ACIP recommended vaccines listed above.

\*\*Adults under 20 years of age should receive 3 doses of the pediatric formulation of the Hep B vaccine (.5mL). The pediatric formulation can be ordered under 317 funding for this population.

These vaccines should be administered in accordance to the routine recommendations of the CDC's Advisory Council on Immunization Practices (ACIP). Special consideration should be given to adults recommended for certain vaccines based on their medical and/or other risk factors. Please consult CDC's adult immunization schedule for additional information:

<http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>

#### School-Required Vaccinations

Providers enrolled in the Adult Vaccine Program, who are able to administer all publicly funded vaccines offered, are also permitted to vaccinate eligible adults (19-21 years of age) who are enrolled and attending high school full-time. These individuals should be referred to one of these facilities for vaccination. The students must follow the same eligibility criteria as all other adults and must meet the financial criteria to receive publicly funded adult vaccine.

**Outbreaks & Mass Vaccination Campaigns**

- Publicly funded adult vaccines may be provided in the event of a specific disease outbreak or natural disaster.
- The Epidemiology Resource Center (ERC) will identify any specific disease outbreak requiring a mass vaccination campaign.
- During a state of emergency, the Immunization Division in conjunction with the Public Health & Preparedness Division will identify all necessary vaccination response.

**Adult Vaccination Program - Patient Eligibility Screening Form**

1. Initial Screening Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
    M M   D D   YYY Y

2. Patient's Name: \_\_\_\_\_  
                    Last Name                                      First Name                                      MI

3. Patient's Date of Birth: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
                    M M   D D   YYY Y

4. Primary Provider's Name: \_\_\_\_\_  
                                    Last Name                                      First Name                                      MI

5. This patient qualifies for vaccines through the Adult Vaccination Program because s/he (check only one box):  
 The patient does not have insurance  
 The patient is underinsured (has health insurance that does not pay for vaccinations)

Eligibility Status				
Date	Screener initials	Is uninsured	Is underinsured	Does not meet eligibility criteria

Clinic Name: \_\_\_\_\_

Person completing this log: \_\_\_\_\_

Title of the person completing this log: \_\_\_\_\_

Log for: Month \_\_\_\_\_ Year: \_\_\_\_\_

**Revision History**

07/17/2012, Created  
12/02/2013, Revised  
03/01/2014, Revised  
10/01/2014, Revised  
11/19/2014, Revised  
09/30/2015, Revised  
05/02/2016, Revised

<b>Policy &amp; Procedure Title</b>	New Provider Enrollment	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	4	<b>Revision Date</b>	01/01/2018
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Policy & Procedure Summary

All immunization providers electing to enroll in the Vaccines for Children (VFC) or any other publicly funded vaccine program in the State of Indiana must complete the provider enrollment process. This policy summarizes the program requirements for provider enrollment.

### Policy Statement

It is the policy of the Immunization Division that all health care providers electing to enroll in the Vaccines for Children (VFC) or any other publicly funded vaccine program in the State of Indiana must complete the provider enrollment process. The enrollment will be conducted by an Immunization & Registry Educator, and must be completed prior to the provider being permitted to order and receive publicly funded vaccines.

### Phase One: Provider Contact Request

Each provider interested in enrolling in a publicly funded vaccine program must submit State Form 54048, the Immunization Provider Contact Request form (PCR).

- o Completed forms need to be submitted to [Enrollments@ISDH.in.gov](mailto:Enrollments@ISDH.in.gov) (preferred) or fax (317-233-3179)
- o The form is located in the enrollment badge of the CHIRP homepage
- o Once the Immunization Division receives the PCR form, a unique tracking number will be assigned

**Any questions during this phase need to be sent to the Immunization Division at [Enrollments@ISDH.in.gov](mailto:Enrollments@ISDH.in.gov) or 800-701-0704**

### Phase Two: Onboarding & CHIRP

#### Part 1: VFC Enrollment Packet

Once the Immunization Division has processed the PCR form, ISDH staff will email the prospective provider a VFC Onboarding Enrollment Packet containing required enrollment documents. An enrollments checklist is provided in the Onboarding Package for the prospective VFC provider's reference.

- The following onboarding items must be submitted to the Immunization Division via email ([enrollments@isdh.in.gov](mailto:enrollments@isdh.in.gov)) or fax (317-972-8964):
  - o *Advisory Committee on Immunization Practices (ACIP) signatory page, signed by the Medical Director*
  - o *Provider Agreement*
    - *includes list of providers at the facility and VFC program requirements*
    - *The health care providers listed must be authorized to administer pediatric vaccines.*
  - o *Immunization Provider Profile (State Form 50201)*
  - o *Storage Unit Certification form and pictures of each VFC storage unit*
  - o *Temperature Monitoring Certification for primary and backup digital data loggers. Data logger reports are required to be provided to the Enrollments email box twice a month.*
  - o *Certificate of completion of the Vaccines for Children (VFC) and Storage and Handling You Call the Shots Modules for both the primary and back-up coordinator*
- Storage units must be able to maintain in-range temperatures at all times in order to move forward with enrollment.

## Part 2: CHIRP Interface verification

For new CHIRP facilities or facilities with a new EMR:

- o Complete State Form 52306, Provider Site Enrollment Agreement form
- o Write “enrolling” in the VFC PIN field.
- o Personnel from CHIRP will contact facility IT to test interface

For existing CHIRP facilities already sending HL7 messages to CHIRP:

- o Verify IRMS & Facility information. Copy/paste or provide a screenshot of the CHIRP login header
- o Provide SIIS #s for 3-4 recently vaccinated patients to confirm CHIRP/EMR interface.

CHIRP Users:

- o Individual User Agreements for VFC Coordinator and Backup with Full Access & Inventory Management access selected.
- o Individual User Agreements for other personnel, including doctors, at the facility as needed.
- o Forms in CHIRP Document Center>CHIRP User Forms

All Onboarding steps must be complete before enrollment activities can progress. If any activities are not complete or compliance with requirements are not met, enrollment will not proceed.

Central office will contact the provider when documents from Phase 2 (Onboarding & CHIRP) are complete and approved.

A VFC Pin is assigned when all onboarding tasks are completed.

- o A VFC Pin is required for each unique facility in CHIRP as publicly funded vaccine inventory is linked to a each CHIRP facility.
- o Locations that are enrolled in more than 1 publicly funded vaccine program (i.e., Adult Tdap and VFC programs or two VFC Providers using two different EMRs) will have more than 1 PIN number.

**Any questions during this phase need to be sent to the Immunization Division at [Enrollments@ISDH.in.gov](mailto:Enrollments@ISDH.in.gov) or 800-701-0704**

## Phase Three: Enrollment

### Part 1: Enrollment Email

Central office will send an enrollment email to the vaccine coordinator and back-up at the facility. The email contains:

- o New Provider PIN Number
- o VOMS Individual User Access forms
  - Both the VFC Primary and Backup Coordinator need VOMS access
  - Email completed VOMS Individual Access forms to [Enrollments@isdh.IN.gov](mailto:Enrollments@isdh.IN.gov).
  - Allow up to 5 business days for access to be granted.
- o Instructions for completing the online VFC Provider Agreement and Provider Profile in VOMS.
  - The medical director or equivalent in a group practice must sign the form. The practitioner will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the Provider Agreement. All other providers within that practice must be listed on the enrollment form.
  - The provider enrollment form must also include the professional license numbers for listed providers in the practice.

Completed forms must be emailed to [enrollments@isdh.in.gov](mailto:enrollments@isdh.in.gov) or faxed to 317-972-8964

### *Part 2: Handoff to the Immunization & Registry Educator*

The Immunization & Registry Educator will contact the Provider within 10 business days (unless there are extenuating circumstances) of receiving approval to proceed with enrollment and will schedule an Enrollment Visit. If an enrollment visit is not required, the Immunization & Registry Educator will send the required paperwork for completion.

- Providers have 60 days from the handoff of the New Enrollment to the Immunization & Registry Educator to complete the first vaccine order in VOMS.
- Failure to do so will result in providers having to restart the enrollment process from the beginning, and will have to wait at least 45 days before initiating the enrollment process again.
- Each provider who is enrolling in the VFC Program must participate in an initial Enrollment Visit with the assigned Immunization & Registry Educator. Providers who request enrollment in another publicly funded vaccine program must also participate in an enrollment visit if they are not active providers in the VFC program. The Immunization & Registry Educator will notify providers if they are exempt from the enrollment visit requirement.
- During the Enrollment visit, the following activities must be conducted:
  - Complete the Enrollment Site Visit Questionnaire
  - Complete an Education Component
    - Will address all provider education goals established in the VFC Operations Guide, Provider Recruitment & Enrollment (M-2, 2016 ed.).
    - Review Indiana VFC Policies and Procedures
      - A current copy of the Immunization Division's Provider Policies and Procedures Manual is available electronically in the Policies badge on the CHIRP homepage.
    - Verify Provider Will Offer All ACIP Recommended Vaccines including Category A and B vaccines.
  - Review Inventory Accountability Tasks
  - Download data logger reports and check temp logs
  - Complete the First Vaccine Order in VOMS

The vaccine coordinator and back-up are required to attend the initial Enrollment Visit. The vaccine coordinator will hold responsibility for training all other staff who will be handling vaccines or screening patients for VFC program eligibility that do not attend this educational component training. A minimum of 2.5 hours should be scheduled to complete enrollment visit. The visit will be documented in PEAR, which is the Provider Education, Assessment and Reporting System used to monitor VFC provider compliance.

A new enrollments binder will be provided. This binder will include, at a minimum, current ACIP schedule and other immunization work aids, where to find resources in CHIRP, excerpts from the ACIP General Recommendations webpage. It is the responsibility of the VFC provider to update these documents.

***Any questions during this phase need to be sent to the assigned Immunization & Registry Educator***

### **Enrollment Follow-up Visit**

A Field Representative must conduct an Enrollment Follow-up visit 45-60 days following the Enrollment visit. The Enrollment Follow-up visit must consist of a minimum of a Storage & Handling Check. A standard Site Visit must be conducted 4-6 months following the Enrollment Follow-up visit.



## References & Resources

Centers for Disease Control and Prevention. Vaccines for Children Program (VFC).  
<https://www.cdc.gov/vaccines/programs/vfc/index.html>

Centers for Disease Control and Prevention, Vaccines for Children (VFC) Operations Guide. Module 2: Provider Recruitment and Enrollment. Revised January 2017.

Vaccine Order Form

ICPR 54048 Immunization Provider Enrollment Request

ICPR 50201 Immunization Provider Profile

ICPR 52697 Immunization Provider Agreement

ICPR 54615 Immunization Provider Vaccine Storage Unit Certification

Immunization Provider Enrollment Site Visit Questionnaire - Version 4, 1-14

Childhood Vaccine Eligibility Statement

Childhood Vaccine Eligibility Statement FAQs

Adult Vaccine Eligibility Statement

Adult Vaccine Eligibility Statement FAQs

ICPR 48514 R3 3-11 Patient Eligibility Screening Record

## **Revision History**

07/17/2012, Created

03/01/2014, Revised

04/01/2017, Revised

01/01/2018, Revised

<b>Policy &amp; Procedure Title</b>	Provider Agreement Dissolution	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	5	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

**Policy & Procedure Summary**

There may be a number of reasons a provider or the Indiana State Department of Health may choose to dissolve the provider agreement documenting participation in the Indiana State Department of Health’s Publicly Funded Vaccine program. In order to assure a smooth transition the Immunization Division asks that the following steps be taken to discontinue participation and dissolve the provider agreement.

**Policy Statement**

All providers wishing to disenroll from the Indiana State Department of Health’s Publicly Funded Vaccine Program must complete the appropriate paperwork to terminate the provider agreement. If the Indiana State Department of Health’s Immunization Division chooses to terminate the agreement, the provider shall be notified in writing of the reasons for and the effective date of the termination.

**Procedure Details**

The Indiana State Department of Health Immunization Division or the provider may dissolve the provider enrollment agreement at any time. This dissolution can be for personal reasons or failure to comply with the requirements of the program.

*Provider Requested Dissolution*

*If the provider chooses to terminate the agreement, he/she is responsible for all publicly funded vaccine doses in inventory. To protect the vaccine viability, the provider must maintain vaccines properly stored at required refrigerator/freezer temperatures until they are returned or transferred to another provider.*

*Step 1) Disenrollment Request Submitted to the Immunization Division*

- A. Complete the disenrollment form, State Form 54840 Immunization Provider Disenrollment.*
- B. Fax the form to the Director of Vaccine Operations as a notification of the intent to terminate.*

*Step 2) Provide request for VOMS termination for all provider contacts within 24 hours of disenrollment.*

*Step 3) Complete a final inventory and contact the Immunization Division to have the vaccine transferred to a different facility.*

*Indiana State Department of Health Requested Dissolution*

*If the Indiana State Department of Health’s Immunization Division chooses to dissolve the provider enrollment agreement, the provider will receive a letter detailing the reasons for the termination and is entitled to appeal the decision to the Division Director.*

**Appeal Process**

If a provider feels that a termination by the Indiana State Department of Health’s Immunization Division has occurred in error, the provider may request a meeting with the Immunization Division Director to address the issue. The request must be submitted in writing to the Immunization Division within ten (10) business days of receipt of the termination notice. All appeals should be addressed to:

Indiana State Department of Health  
Indiana Immunization Division  
2 N. Meridian Street, 3N-22  
Indianapolis, IN 46204


The Immunization Division Director will schedule the meeting within (5) business days after receiving the request. A written final decision from the Immunization Division Director will be issued within (5) business days of the meeting.

### **References & Resources**

Immunization Provider Disenrollment Form (State Form 54840)

### **Revision History**

07/17/2012, Created  
11/19/2014, Revised  
04/01/2017, Revised

<b>Policy &amp; Procedure Title</b>	Vaccine Coordinator	<b>Issuing Date</b>	7/17/2012
<b>Policy &amp; Procedure Number</b>	6	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>			

### Policy & Procedure Summary

All providers participating in a publicly funded vaccine program are required to identify an individual to serve as the "Vaccine Coordinator" for the facility, handling all duties as listed related to the management of publicly funded vaccine. VFC providers are required to notify the Immunization Division *immediately* when there are changes in key vaccine staff, including termination of all VOMS accounts of former employees within 24 hours.

### Policy Statement

#### *Personnel, Training and Education*

A primary vaccine coordinator who is responsible for ensuring that vaccines are stored and handled correctly should be assigned at each facility. Each facility is required to designate a back-up for the primary vaccine coordinator who can perform these responsibilities in the absence of the primary coordinator. The back-up coordinator must also have access to VOMS (Vaccine Ordering System). These responsibilities include, but are not limited to the following tasks:

- Conducting an annual staff training on your facility's Vaccine Management Plan and keeping a record of the training
- Participating in a compliance site visit review and/or annual educational component training
- Ordering vaccines using VOMS
- Overseeing proper receipt and storage of vaccine shipments
- Organizing vaccines within the storage unit(s)
- Temperature monitoring of the storage unit(s) at least twice daily
- Recording temperature readings
- Daily physical inspection of the storage unit(s)
- Rotating stock so that vaccine closest to its expiration date will be used first
- Monitoring expiration dates and ensuring that expired vaccine is removed from the storage unit(s) and not administered to patients
- Responding to potential temperature excursions
- Overseeing proper vaccine transport
- Maintaining all appropriate vaccine storage and handling documentation, including temperature-excursion responses
- Maintaining storage equipment and records
- Maintaining proper documentation for the Vaccines for Children (VFC) program in participating clinics

- Ensuring that designated staff is adequately trained

All personnel who handle or administer vaccines should be familiar with the routine and emergency vaccine management plans for their facility. This includes not only those who administer vaccines, but also anyone who delivers or accepts vaccine shipments and anyone who has access to the unit(s) where vaccines are stored. These plans as well as the Immunization Division policies and procedures, should be available in writing as a reference for all staff members. Vaccine storage and handling training should be provided to all new personnel who handle or administer vaccines, including temporary staff. Continuing education for staff is essential when new vaccines are stocked and when there are any changes to the storage and handling guidelines for a particular vaccine. Immunization programs often have good resources for staff training.

#### *Annual VFC training requirement for Vaccine Coordinators*

**At minimum, the Vaccine Coordinator and back-up coordinator at each VFC provider office must annually complete the VFC provider educational training requirement.**

- VFC compliance visits include a formal educational component and count as meeting the training requirement for the calendar year.
- Providers not scheduled to receive a VFC compliance visit during the calendar year must receive training online, by webinar, or through an in-person classroom-style presentation. Providers may receive a certificate or other written confirmation at the end of these trainings that can be used as documentation of completion.
- All trainings must be documented on the Vaccine Coordinator training log, which should be maintained in the VFC binder. This training log will be reviewed during the compliance visit.
- The online Annual Provider Recertification Process includes a section to indicate that the vaccine coordinator and back-up coordinator have completed the annual training requirement.

#### **Procedure Details**

*Step 1) The provider should assign at least two staff members to serve as the primary vaccine coordinator and the back-up coordinator to ensure proper storage and handling of all publicly funded vaccine.*

*Step 2) The provider should develop routine and emergency storage and handling plans to provide guidance for daily activities.*

*Step 3) The provider should offer orientation and ongoing training to all staff that handle or administer vaccines.*

#### **References & Resources**


Centers for Disease Control and Prevention (CDC). (2018) Vaccine Storage and Handling Toolkit, Revised January 2018. <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Centers for Disease Control and Prevention (CDC). (13<sup>th</sup> Edition) Epidemiology and Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015.

Refrigerator/Freezer Temperature Log

#### **Revision History**

07/17/2012, Created  
03/01/2014, Revised  
02/01/2016, Revised  
04/01/2017, Revised

<b>Policy &amp; Procedure Title</b>	Storage and Handling-Vaccine Management	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	7	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>			

### Policy & Procedure Summary

All personnel who handle or administer vaccines should be familiar with the routine and emergency vaccine management plans for their facility. Provider vaccine storage and handling plans must include the signature, name, and title of the preparer of the documents. Those trained on these plans include not only those who administer vaccines, but also anyone who delivers or accepts vaccine shipments and anyone who has access to the unit(s) where vaccines are stored. *The vaccine management plan as well as the Immunization Division policies and procedures should be available in writing as a reference for all staff members.*

### Policy Statement

All VFC providers must comply with the program requirements for vaccine management, including the storage of vaccine under proper conditions at all times. Routine and emergency vaccine storage and handling plans should be developed and maintained to provide guidance for daily activities, such as ordering and accepting vaccine deliveries; storing and handling vaccines; managing inventory; and managing potentially compromised vaccines.

Annual training must be conducted for all staff members in each facility enrolled in the VFC program. This training must include a review of the location's routine and emergency vaccine management plans, and the content of these plans. This annual training must be documented with a log of all attendees. VFC providers need to maintain documentation of this training that will be presented during a site visit with an Immunization Field Representative.

In addition, vaccines storage and handling training should be provided to all new personnel who handle or administer vaccines, including temporary staff. Continuing education for staff is essential when new vaccines are stocked and when there are changes to the storage and handling guidelines for a particular vaccine. The Indiana Immunization Division offers training on vaccines specific topics for all facilities.

### Vaccine Ordering and Inventory Control

Vaccine coordinators should order vaccines to maintain an adequate amount to meet the needs of the facility's patients. The amount of vaccine needed can vary throughout the year. Anticipate peak periods such as back-to-school appointments or influenza season and order accordingly. Order the vaccines and presentations that are appropriate for the ages and types of patients the facility serves.

A vaccine inventory should be conducted monthly to ensure adequate supply to meet demand. Vaccine diluents should also be included in the inventory to ensure adequate supplies are available. Determining factors for the amount of vaccine and diluent ordered include projected demand, storage capacity, and current vaccine supply. It is also important to avoid overstocking vaccine supplies which could lead to vaccine wastage or having outdated vaccine on hand.

Vaccine coordinators should request delivery during regular office hours. Vaccine shipments should be delivered when staff is available to unpack and store the vaccine properly. Shipment times should be updated at the time each vaccine order is submitted and should reflect any period of time the office will be closed, such as holidays, scheduled vacation, change in hours of operation and/or lunch hour. Providers must be on site with appropriate staff available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during that day.

### Vaccine Inventory Management

- Vaccine and diluent expiration dates should be closely monitored.
  - Expired vaccine and diluent should never be used and should be promptly removed from the storage unit.

- Rotate stock so that vaccine and diluent with the shortest expiration date are used first to avoid waste from expiration.
- If the date on the label has a specific month, day, and year (mm/dd/yyyy), the vaccine can be used through the end of that day.
- If the expiration date on the label is a month and year (mm/yyyy), the vaccine can be used through the end of that month.
- **Opened vials of multi-dose vaccines should NOT be wasted before the manufacturer's expiration date.** Multi-dose vials of vaccines have different storage and handling requirements than multi-dose vials of medications.
  - **Multi-dose vials should not be discarded 28 or 30 days after opening.** Providers who discard open multi-dose vials after 28 or 30 days may be required to replace the wasted vaccines, according to the Vaccine Loss and Replacement Policy. Some flu vaccines should be disposed after 28 days; information will be provided each flu season.
- Mark reconstituted vaccine with the date and time it is reconstituted. The expiration date or time might change once the vaccine is opened or reconstituted. This information is provided in the manufacturer's product information.
- Keep vaccines in their original packaging with the lids in place until ready for administration and stacked in rows with vaccine of the same type. This prevents exposure to light and prevents mixing of lot numbers and expiration dates.

### **Vaccine Storage Units**

Refrigerator and freezer vaccine storage units must meet all recommendations and requirements. These program requirements are defined in policy "Storage and Handling – Storage Unit Requirements". Please refer to this policy for complete requirements.

### **Vaccine Temperature Monitoring**

Temperature monitoring and equipment must meet program requirements. The temperatures in storage units must be monitored and documented appropriately as defined in the policy "Storage and Handling – Temperature Requirements". Please refer to this policy for complete requirements.

### **Managing Potentially Compromised Vaccines**

If vaccine and/or diluent has expired or has been exposed to a temperature excursion, the Vaccine Coordinator should identify and isolate all potentially compromised vaccines and store separately in an alternate storage unit within the recommended temperature range. Label these as "DO NOT USE".

Contact the Indiana Immunization Division and the vaccine manufacturers for appropriate actions that should be followed for all potentially compromised vaccines and diluents.

Educate staff administering vaccines on correct handling and preparation procedures to decrease the likelihood of vaccines and diluents inadvertently being compromised.

### **Receiving and Unpacking Vaccine Shipments**

Proper vaccine storage and handling is important from the moment the vaccine arrives at the facility. All office staff should be informed of who to notify when a vaccine delivery has arrived. Educate all facility staff about proper vaccine storage.

This is extremely important for receptionists or other front desk staff since they are often the first to know that vaccines have been delivered.

Orders should also be received in VOMS as soon as the shipment arrives to ensure proper inventory management.

**Providers should not manually enter inventory in VOMS when receiving an order.** Failure to follow procedures for receiving vaccine orders may result in providers having large discrepancies in vaccine inventory, and may result in suspension from the program.

Vaccines must be kept in their original packaging with the lids in place until ready for administration to protect them from sunlight and fluorescent light. Storing vaccines outside of their packaging leads to administration errors when staff is confused about vaccines, and makes managing inventory and tracking expiration dates more difficult. Also vaccines not in the original packaging cannot be transferred to another facility.

***Note: NEVER refuse a vaccine shipment of publicly funded vaccine. If there is a problem with the shipment, place the vaccine in the appropriate storage unit and contact the Immunization Division immediately.***

Vaccines should be stored at proper temperatures IMMEDIATELY upon arrival.

- Vaccine shipments should be inspected on arrival.
  - The shipping container and its contents should be examined for any evidence of damage during transport.
  - Both heat and cold temperature monitors/indicators should be checked upon delivery following instructions on the monitors for reading and reporting.
    - If a monitor indicates possible adverse temperature excursion during shipping, the monitor reading should be documented for future reference and reported to the Immunization Division within 2 hours of receipt of the shipment.
    - Shipments sent directly by the vaccine manufacturer are in specially designed boxes and may not contain heat or cold temperature monitors.
  - Determine the length of time the vaccine was in transit by looking at the packing list.
    - If the interval between shipment from the distributor and arrival of the product at the facility was more than 48 hours, this could mean the vaccine has been exposed to excessive heat or cold that might alter its integrity.
  - The contents should be cross checked with the packing slip to be sure they match.
  - Diluents should be stored according to the manufacturers' instructions. Diluents should be clearly labeled, whether they are stored at room temperature or in the refrigerator. Label the packages of corresponding vaccines and diluents from the same manufacturer so that they will be used together. This avoids confusion and helps to ensure that you use only the specific diluent provided by the manufacturer for each type of lyophilized (freeze-dried) vaccine.
  - Immediately store at the appropriate temperatures.

If there are any discrepancies with the packing slip or concerns about the vaccine shipment, the vaccines should be stored in proper conditions, but segregated and marked "DO NOT USE" until the integrity of the vaccines is determined. Any discrepancies or concerns should be reported immediately to the Indiana Immunization Division at (800) 701-0704 within 2 hours of receipt of shipment.



- The contents of each shipment should be received within the Vaccine Ordering Management System (VOMS) immediately upon receipt. Lack of receipt of the vaccines could potentially result in errors in inventory and result in suspension.

### Receiving Direct Ship Vaccines

All varicella-containing vaccines are shipped separately from other vaccines and are shipped directly from the manufacturer, Merck. The vaccine shipping containers are packed according to Merck guidelines that take into account the maximum temperature to which the container will be exposed, the time in transit, and the need to keep the vaccine at the appropriate temperature during shipping.

- Varicella-containing vaccine should be stored at proper temperatures IMMEDIATELY upon arrival.
  - To maintain potency the vaccine must be stored frozen between -58°F and +5°F (-50°C to -15°C).
  - The manufacturer recommends that the vaccine NOT be stored on dry ice. Use of dry ice may subject the product to temperatures colder than -58°F (-50°C).
- Varicella-containing vaccine shipments should be inspected on arrival.
  - The shipping container and its contents should be examined for any evidence of damage during transport.
    - Varicella-containing shipments contain refrigerant packs to protect product on all sides to keep it stable and cold. This practice replaces the use of dry ice during shipment.
  - Determine the length of time the vaccine was in transit by looking at the packing list.
    - Adequate refrigerant (frozen gel packs) are placed to maintain proper temperatures for three days from the shipment date located on the packing slip. If the container is received after this time period, contact Merck Order Management Center immediately for replacement instructions at (800) 637-2579. The Immunization Division should also be contacted in this event.
  - Shipments sent directly by the vaccine manufacturer are in specially designed boxes and may not contain heat or cold temperature monitors.
- Invoice and packing slips are separate from product.
- Diluent is conveniently located in the top compartment of the shipping box underneath the cardboard cap. Store the diluent upon arrival in a refrigerator (2°C to 8°C/36°F to 46°F) or at room temperature (20°C to 25°C/68°F to 77°F).
- Immediately store at frozen temperatures.

### Vaccine Preparation

Vaccine should be drawn from the vial into the syringe at the time of administration. An individual should only administer a vaccine he or she has prepared and drawn up.

Syringes other than those filled by the manufacturer are designed for immediate administration and not for vaccine storage. Do not predraw doses before they are needed. Predrawing vaccine into syringes is a quality control and patient safety issue for many reasons. Filling a syringe before it is needed increases the risk for administration errors. Once in the syringe, vaccines are difficult to tell apart, and there is no stability data available for vaccines stored in plastic syringes. Other problems associated with this practice are wasted vaccine and possible bacterial growth in vaccines that do not contain a preservative, such as vaccines supplied in single-dose vials.

As an alternative to prefilling syringes, CDC recommends use of manufacturer-supplied prefilled syringes for large immunization events, such as community influenza clinics. These syringes are designed for both storage and administration. Once a manufacturer prefilled syringe is activated (i.e., syringe cap removed or needle attached), the sterile seal is broken. The syringe should be used that day or discarded at the end of the clinic day.

Vaccines that must be reconstituted are supplied with diluent specific to that vaccine. Vaccine diluents are not all the same, some contain vaccine antigen. Some are packaged within the same carton and others are packed separately.

For specific information for individual vaccine preparation, see the CDC's Vaccine Storage and Handling Guide found in References & Resources section of this policy.

### Vaccine Disposal

Any wasted or expired vaccine should be reported to the Indiana Immunization Division by creating a Vaccine Return in VOMS, when it is available. In the interim, providers must submit paper Vaccine Return forms (State Form 54052). These vaccines are returned to McKesson Specialty Distribution, the vaccine distributor, for excise tax credits. Program requirements for the completion of vaccine returns are defined in policy "Provider Vaccine Returns".

Contact the Indiana Immunization Division at (800) 701-0704 regarding the disposition of unopened vials, expired vials, unused doses, doses drawn but not administered, and potentially compromised vaccine due to inappropriate storage conditions. **No publicly funded vaccines should be disposed of without first contacting the Immunization Division.** Vaccine that has been prefilled by the provider staff and unused should never be returned to the manufacturer or distribution center. If the Immunization Division advises discarding the vials or syringes, this should be done using the medical waste disposal procedures outlined in individual immunization program guidelines

### Procedure Details

*Step 1) The provider should assign at least two staff members to serve as the primary vaccine coordinator and the back-up coordinator to ensure proper storage and handling of all publicly funded vaccine. See the Vaccine Coordinator policy for detailed responsibilities for these roles.*

*Step 2) The provider should develop routine and emergency storage and handling plans to provide guidance for daily activities.*

*Step 3) The provider should offer orientation and ongoing training to all staff who handle or administer vaccines.*

### References & Resources

Centers for Disease Control and Prevention (CDC). (2018) Vaccine Storage and Handling Toolkit, Revised January 2018. <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Centers for Disease Control and Prevention. (13<sup>th</sup> Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised May 2015. Available at: <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Refrigerator/Freezer Temperature Log

### Revision History

07/17/2012, Created  
03/01/2014, Revised  
11/19/2014, Revised  
02/16/2016, Revised  
04/01/2017, Revised

<b>Policy &amp; Procedure Title</b>	Storage and Handling-Storage Unit Requirements	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	8	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Policy & Procedure Summary

There are few immunization issues more important than the appropriate storage and handling of vaccines. The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines.

Vaccines must be stored properly from the time they are manufactured until they are administered. Proper maintenance of vaccines during transport is known as the cold chain. A proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacturer to administration of the vaccine.

Vaccine storage equipment should be selected carefully, used properly, maintained regularly (including professionally serviced when needed), and monitored consistently to ensure the recommended temperatures are maintained.

All enrolled providers must complete the Cold Storage Unit Certification in Vaccine Ordering Management System (VOMS) during the Annual Provider Recertification Process to document which types of storage units are currently being utilized at their clinic(s).

### Policy Statement

This policy defines the minimum standards that must be met and maintained by each provider enrolled in the Indiana State Department of Health (ISDH), Immunization Division for receipt, storage and proper management and handling of publicly funded vaccine.

This policy supersedes all policies previously issued by the Indiana Immunization Division addressing the storage unit requirements for publicly funded vaccine. It replaces the following policy:

Title of Policy: **Refrigeration/Freezer Standards for Vaccine Storage**  
 Policy Number: II-02  
 Creation Date: Feb 18, 2009

Refrigerators and freezers used to store publicly provided vaccines must be capable of reaching and maintaining the required temperatures established by the vaccine manufactures, the Centers for Disease Control and Prevention (CDC), and the National Institute of Standards and Technology (NIST) standards.

#### *Storage Unit Requirements*

Providers receiving publicly funded vaccine must adhere to all of the following **requirements** for a permanent vaccine storage unit:

- **Beginning January 1, 2015 all newly enrolled providers are required to have Stand-alone units, refrigerators without freezers and/or freezer-only units. This means a self- contained unit that only refrigerates or freezes, is suitable for vaccine storage, and meets all other requirements for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit.**
- **Starting January 1, 2018, all enrolled providers are highly encouraged to use stand-alone units to store publically funded vaccine. However, all providers will be required have stand-alone units by the submission of the 2019 Provider Recertification in order to continue participating in the Indiana VFC or Adult Vaccine Program.**

All providers receiving publicly funded vaccine enrolled prior to January 1<sup>st</sup>, 2015 must adhere to all of the following **requirements** for a permanent vaccine storage unit:

- **As of 3/1/2014, any VFC provider office purchasing or acquiring a new unit which will store VFC vaccines must purchase a stand-alone unit.**
- **ISDH encourages providers enrolled that still use a combination vaccine storage unit to begin budgeting/planning to replace it with stand-alone units. Starting 2019, all VFC and Adult Vaccine providers will be required to have stand-alone storage units to continue participation in the program.**
- Must have separate exterior doors, with separate gaskets, that seal tightly and properly for both the refrigerator and freezer areas.
- Units with a single exterior door and an interior door separating the refrigerator and freezer areas **are not permitted** for vaccine storage at any time.
- Providers with units containing only 1 thermostat control must have a separate stand-alone freezer.
- CDC recommends the use of stand-alone units, refrigerators without freezers and/or freezer-only units. This means a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit.
- While the use of stand-alone units is best practice and highly recommended, an alternative to stand-alone units is using only the refrigerator compartment of a combination household refrigerator/freezer unit to store refrigerated vaccines. In this case, the combination household refrigerator/freezer must have separate exterior doors and thermostat controls. A separate stand-alone freezer should then be used to store frozen vaccines, since studies conducted by the National Institute for Standards and Technology (NIST) have demonstrated that the freezer section of combination units is not capable of reliably maintaining appropriate frozen vaccine storage temperatures.

All providers receiving publicly funded vaccine must adhere to all of the following **requirements** for a permanent vaccine storage unit:

- Must be able to maintain the *Temperature Requirements* at all times.
- Refrigerators **must maintain** temperatures between 36°F and 46°F (2°C to 8°C).
- Freezers **must maintain** temperatures +5°F (-15°C) or colder not to exceed -50°C.
- Must be dedicated to the storage of vaccine.
- Food, beverages (including bottled drinking water) or lab specimens may not be stored in the vaccine storage unit.
- If other biologic products must be stored in the same unit than the vaccines, products should be stored on a lower level shelf than vaccines.
- Must be large enough to hold the year's largest vaccine inventory, while still adhering to the requirements for vaccine storage
- No minimum requirement for unit size.
- Must be located in a well-ventilated room with space around the sides and top and at least 4 inches between the unit and a wall for good air circulation.
- Nothing can block the cover of the motor compartment and the unit should be level and stand firmly with at least 1 to 2 inches between the bottom of the unit and the floor.
- Must be plugged directly into wall outlets; **multi-strip outlets should not be used.**
- Must post a sign with wall outlet to alert all staff, janitors and electricians that the unit must not be unplugged.
- Must label the circuit breakers to alert janitors and electricians not to turn off the power to the storage unit.
- Label must contain the circuit number that controls power to the vaccine storage unit and emergency contact information.
- Keep a calibrated, data logger with a Certificate of Traceability and Calibration in each refrigerator and freezer compartment. (Refer to the Storage and Handling-Temperature Requirements policy 9 for full details)

- Must have temperature monitoring completed twice daily and logs maintained for storage units. These records must be kept on site for a minimum of 3 years. (Refer to the Storage and Handling-Temperature Requirements policy 9 for full details) all

The following are recommendations and not required, but strongly encouraged.

- Storage unit should be frost-free or have an automatic defrost cycle (manual defrost refrigerators are **prohibited**).
- Plug guards or safety-lock plugs should be put in place to prevent someone from inadvertently unplugging the unit.
- A temperature alarm system that will alert staff to after-hour temperature excursions, particularly if large vaccine inventories are maintained, may be helpful in assuring a timely response to storage problems.

#### *Temporary Storage Units*

Dormitory-style refrigerator/freezer units are no longer permissible for vaccine storage at any time. The use of these specific refrigerator/freezers is not allowed at any time for Vaccines for Children (VFC) program providers. Please note that there are compact, purpose built storage units for biologics that are not considered to be dormitory-style or bar-style.

If vaccine must be stored temporarily during a clinic day, the storage unit must meet the same requirements as any long term storage unit.

#### *Storage Unit Organization Requirements*

Providers receiving publicly funded vaccine must adhere to all of the following **requirements** for vaccine storage unit organization:

- All vegetable/fruit bins or drawers must be removed from the refrigerator unit.
- Containers of water, labeled "Do NOT Drink," must be placed in the refrigerator to help stabilize the temperature in the unit. Place these water bottles in the area where there is a greater risk for temperature excursions (for example, top shelf, floor, and in the door racks of refrigerator).
- The water containers may be put in place of the vegetable/fruit bins or drawers, if available.
- Frozen water bottles that are properly conditioned should be stored in the freezer.
- Never store vaccines in the door of the refrigerator or the freezer.
- Water bottles may be placed in the door of the freezer.
- Extra water containers labeled "Do NOT Drink" or similar may be placed in the door of the refrigerator.
- Diluents, that do not contain vaccine antigen, may be placed in the door of the refrigerator.
- Items in door must be placed securely so that they cannot dislodge and prevent the door from closing.
- Caution must be taken to avoid weighing down the doors so much that the seals are compromised when the doors are closed.
- Vaccines or vaccine containers must be placed away from the walls, coils, and vents.
- There must be at least adequate room between the vaccine stacks or containers to provide for good air circulation for even cooling.
- Vaccines must be kept in their original packaging with the lids intact and closed.
- Vaccines must be protected from light at all times.
- Not only live attenuated vaccines, but some inactivated vaccines must be protected from light.
- The vaccine manufacturer's product information indicates if the vaccine must be protected from light.
- Vaccines must be organized within the unit so that they are the stacked in rows with vaccine of the same type.
- Short dated vaccines must be placed in front of vaccines with a later expiration date.
- Each vaccine and diluent stack or container must be clearly labeled.
- Vaccine purchased with public funds must be labeled and easily differentiated from privately purchased vaccines.

The following are *recommendations* and not required.

- Vaccines should be stored in bins, baskets, or some other type of container that allows for air circulation to organize the vaccines within the storage unit.
- Labels differentiating private vs. public stock may be attached directly to the shelves on which vaccines and diluents are sitting or by placing labels on the containers.
- It may be helpful to use color coding (e.g., one color for pediatric and another for adult) or include the age indications for each vaccine type on the labels.
- Having each vaccine and diluent stack or container labeled helps decrease the chance that someone will inadvertently administer the wrong vaccine or use the wrong diluent to reconstitute a vaccine.
- Vaccines that sound or look alike should not be stored next to each other, e.g. DTaP and Tdap.

### *Vaccine Storage Troubleshooting*

To maintain the proper temperature ranges, the freezer and refrigerator must be in good working condition and they must have power at all times.

- While it is important to take measures to prevent problems, equally important is taking immediate corrective action when a problem does exist, for example when the storage unit temperature falls outside the recommended range.
- Every clinic should also have an emergency vaccine retrieval and storage plan. The plan should be easily accessible to staff and identify a backup location where the vaccine can be stored.
- It is very important that staff know whom to contact in case of a malfunction or disaster.
- If the problem is short-term (usually 2 hours or less) and depending on outside ambient temperature, the storage unit temperature can probably be maintained with water bottles in the refrigerator and freezer, and by keeping the unit doors closed.
- If there is an extended period of time before the situation can be corrected and there are no other storage units available on site, the vaccine should be moved to the backup storage facility using the guidelines in the *Vaccine Emergency Management Plan*.
- Potential backup locations might include a local hospital, pharmacy, long-term care facility, or the Red Cross.

### *Diluents*

- Vaccines that must be reconstituted are shipped with diluent specific to that vaccine. Vaccine diluents are not all the same, some contain vaccine antigen.
- As with vaccines, diluents should be stored according to the guidelines in the manufacturer's product information.
- When feasible, diluents that require refrigeration should be stored with their corresponding vaccines.
- Never store any diluent in the freezer because the vials are not designed for freezer storage and could crack.

### **References & Resources**

Centers for Disease Control and Prevention. (2018) Vaccine Storage and Handling Toolkit, Revised January 2018. <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Centers for Disease Control and Prevention. (13<sup>th</sup> Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015. <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Refrigerator/Freezer Temperature Log

### **Revision History**

07/17/2012, Created  
03/01/2014, Revised  
11/19/2014, Revised  
02/16/2016, Revised  
04/01/2017, Revised

<b>Policy &amp; Procedure Title</b>	Storage and Handling-Temperature Requirements	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	9	<b>Revision Date</b>	07/03/2018
<b>Policy &amp; Procedure Approval Authority</b>	Dave McConnick		

### Policy & Procedure Summary

There are few immunization issues more important than the appropriate storage and handling of vaccines. The success of efforts against vaccine-preventable diseases is attributable in part to proper storage and handling of vaccines.

Vaccines must be stored properly from the time they are manufactured until they are administered. Proper maintenance of vaccines during transport is known as the cold chain. A proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacturer to administration of the vaccine.

Vaccine storage equipment should be selected carefully, used properly, maintained regularly (including professionally serviced when needed), and monitored consistently to ensure the recommended temperatures are maintained.

### Policy Statement

This policy supersedes all policies previously issued by the Indiana Immunization Division addressing the storage unit requirements and temperature monitoring for publicly funded vaccine. It replaces the following policy:

Title of Policy: **Refrigeration/Freezer Standards for Vaccine Storage**  
 Policy Number: II-02  
 Creation Date: Feb 18, 2009

Providers must maintain temperatures for all publicly funded vaccine in accordance with the following requirements:

### Temperatures Requirements

Maintaining accurate temperatures are a critical part of ensuring vaccine maintains viability. Vaccines not stored at the proper temperature may not be viable and do not deliver the desired protection from disease. Providers receiving publicly funded vaccine must adhere to all of the following **requirements** for temperatures:

- All inactivated vaccines require refrigerator storage temperatures between 36°F and 46°F (2°C to 8°C), with a desired average temperature of 40°F (5°C).
  - The following live attenuated vaccines must also be kept at refrigerator temperature: influenza (LAIV, FluMist); and rotavirus (RV1, Rotarix and RV5, RotaTeq).
  - Review each manufacturer's instructions in the product information for vaccine specific storage temperatures.
- All varicella-containing vaccines must be stored in a continuously frozen state at the manufacturer recommended freezer temperature (+5°F (-15°C) or colder not to exceed -50°C) until administration. Varicella-containing vaccines (VAR, Varivax; MMRV, ProQuad; ZOS, Zostavax) are sensitive to temperature excursions.
- Varicella-containing vaccines may be transported and stored at refrigerator temperatures, between 36°F and 46°F (2°C to 8°C), for up to 72 continuous hours *prior to reconstitution*. Varicella-containing vaccine stored at refrigerator temperatures must be discarded if it is not used within 72 hours.
  - Discard reconstituted vaccine if it is not used within 30 minutes.
- The use of **dry ice is not allowed**, even for temporary storage. Dry ice may subject varicella-containing vaccine to temperatures colder than -58°F (-50°C).

- If the vaccines must be transported at refrigerated temperatures, follow these steps (Please note: this is considered to be a temperature excursion):
  1. Place a calibrated, glycol-encased, thermometer probe in the container used for transport as close as possible to the vaccines
  2. Place the vaccines in the freezer between -58°F and +5°F (-50°C and -15°C) and label "DO NOT USE" immediately upon arrival at the alternate storage facility. Contact the vaccine manufacturer prior to using varicella vaccine that has experienced the temperature excursion
  3. Document:
    - a. The time the vaccines are removed from the container and placed in the alternate storage unit and the time the vaccines are removed from the storage unit and placed in the container
    - b. The temperature at the beginning, during and end of transport

This policy prohibits providers from refreezing varicella-containing vaccines that are stored at refrigerated temperatures, so please plan accordingly with your vaccine doses.

Do not discard any unused vaccine without first contacting the manufacturer, and the Indiana Immunization Division at (800) 701-0704.

**Please refer to the Storage & Handling Transporting Vaccines & Off-site Clinics (policy number 12) for the procedures for maintaining refrigerated temperatures for the varicella-containing vaccines.**

### Temperature Monitoring Devices

Temperature monitoring devices are a critical part of storage and handling practice. Providers receiving publicly funded vaccine must adhere to all of the following **requirements** for data loggers:

- Must have a certified, calibrated digital data logger in both the refrigerator compartment and the freezer compartment.
  - Must maintain Certificate of Traceability and Calibration for each data logger.
    - This documentation is included with the data logger upon issuance/purchase.
  - Must maintain current certification and calibration of each data logger.
  - Must be a continuous temperature monitoring device such as a data logger
- Pharmaceutical/Purpose Built Storage Units with Built-In Temperature Monitoring OR a dedicated port that dictates placement of the probe.
  - Built in thermometer(s) must be certified and calibrated.
  - Must monitor temperatures in the refrigerator and freezer compartments individually.
  - Must maintain Certificate of Traceability and Calibration for built in thermometer(s).
  - CDC recommends placement of buffered probes in a central location, however placement in other locations may be suitable.

### Primary Temperature Monitoring Devices

As of January 1, 2015, The Indiana State Department of Health, Immunization Division requires the use of data loggers. Data loggers collect vaccine storage unit temperature data 24 hours a day, 7 days a week. **After 2017, the Immunization Division will no longer supply data loggers. Providers are expected to use 2017 to prepare and budget for the purchase of a data logger (both primary and back-up data loggers).**

Data loggers allow for improved temperature accountability and will assist in decreasing the amount of wasted VFC vaccine due to unknown storage unit temperatures. Data loggers will also assist providers and ISDH Immunization Division in assuring the storage units in use have stable temperatures and therefore, that viable vaccine is being administered to children. Data loggers are mandatory for any storage unit that contains publicly funded vaccines. Data loggers/continuous monitoring devices are mandatory for temperature monitoring for all storage units that contain publicly funded vaccines.



Indiana State Department of Health Immunization Division requires data loggers to have the following characteristics:

- Alarm for out-of-range temperatures
- Display current, minimum and maximum temperatures
- Low battery indicator
- Accuracy of +/- 1° F (0.5° C)
- Memo stores at least 4,000 readings; device will not write over old data-stops recording when memory is full
- User programmable logging intervals (or reading rate)
- CDC also requires the use of a detachable, buffered probe.

### Back-up Temperature Monitoring Devices

**Beginning January 1, 2018, providers enrolled in any publicly funded vaccine program must have at least one back-up data logger with a valid and current certificate of calibration readily available to ensure that temperature assessment and recordings can be performed twice a day.** If the data logger is unit specific, a back-up data logger will be required for each unit. The data logger must be maintained on-site, unless approval by ISDH has occurred.

**ISDH will not supply providers with a back-up data logger.** Providers were expected to use 2017 to prepare and budget for the purchase of at least one back-up data logger.

### Temperature Monitoring

- Regular temperature monitoring is vital to proper cold chain management.
- Temperatures in both the freezer and refrigerator units should be read twice each day, once in the morning and once before leaving at the end of the workday\*\*. This documentation must include the initials of the person conducting the reading, and the date/time the temperature reading was taken.
- The minimum/maximum temperatures must be checked and documented once per day, preferably in the morning. Reviewing the minimum/maximum temperatures helps to ensure that temperature excursions will be identified more quickly.
- Data loggers must be downloaded and all data saved bi-weekly. Immunization Field Representatives may require temperature downloads from providers at any time, and require providers to send temperature downloads bi-weekly.
- Data loggers must be downloaded and all data saved any time a high or low temperature alarm is activated. Download the data immediately, even if it is not the scheduled download time.
- A temperature log must be posted on the door of the storage unit where the twice daily temperature readings and the minimum and maximum readings are recorded
- Temperature logs must be kept for at least 3 years. As the storage unit ages, recurring temperature variances or problems can be tracked and documented. This data can be important when evaluating the need for a new storage unit or if there is a potential need to recall and revaccinate patients because of improperly stored vaccine.
- Data logger probes should be placed in central area<sup>1</sup> of storage unit.
- Prior to storing vaccines in a unit, the temperature should be allowed to stabilize and then be measured in various locations within the unit to document that a consistent temperature can be maintained. This can detect if there are any particular cold or hot spots where vaccine should not be placed, as well as determining where the most reliable, consistent thermometer reading can be obtained. New units may need 3-5 days of operation to establish a stable operating temperature prior to storing the vaccine in the new unit.

<sup>1</sup> In a pharmaceutical or purpose-built unit (e.g. designed specifically to store vaccines), CDC recommends thermometer placement in a centralized location, but placement in other locations may be suitable because pharmaceutical units maintain more consistent temperatures throughout the unit.

- If at any time it is discovered that stored vaccines have been exposed to temperatures outside the recommended ranges, these vaccines should remain properly stored, but segregated and marked “Do NOT Use” until guidance can be obtained.
- After a temperature excursion, proof of at least 5 days of in-range temperatures need to be provided to ISDH to establish that the unit is stable and operating properly. A root-cause analysis (RCA) to find out why the excursion occurred is also required. Additional days-in-range reports may be required depending upon the reason for the temperature excursion.
- Contact the immunization program, vaccine manufacturer(s), or both for guidance.
- Providers will need to conduct a recall to revaccinate patients who receive a dose of non-viable vaccine.

\*\*Providers enrolled in the publicly-funded vaccine program have the option of submitting a proposal to the Director of Field Operations to have temperatures recorded and documented twice daily with an electronic temperature monitoring device. Contact the Immunization Division for more instructions on submitting a proposal.

### References & Resources

Centers for Disease Control and Prevention. (2018) Vaccine Storage and Handling Toolkit, Revised January 2018.  
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Centers for Disease Control and Prevention. (13<sup>th</sup> Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015. <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Refrigerator/Freezer Temperature Log

Storage and Handling-Storage Unit Requirement Policy 8

Storage and Handling-Transporting Vaccines & Off-site Clinics Policy 12

### Revision History

07/17/2012, Created  
03/01/2014, Revised  
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04/01/2017, Revised  
01/01/2018, Revised  
07/03/2018, Revised

<b>Policy &amp; Procedure Title</b>	Storage and Handling-Emergency Plans	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	10	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Policy & Procedure Summary

Every clinic that receives publicly funded vaccine should have an Emergency Management Plan in the event of inclement weather, power outages and/or storage unit failures. All clinics must also have a Vaccine Management Storage and Handling Plan. All staff members should be trained on the policies and procedures of the Vaccine Management and Emergency Management plans.

### Policy Statement

#### Storage and Handling Plans

Clinics can be provided with a template on key vaccine management requirements. All provider vaccine storage and handling plans must be reviewed and updated annually, or more frequently if changes to any information within the plan occur, such as new staff members who have responsibilities specified in the plan. A "review date" is required on all plans in order to verify that they are current. The plan must include the signature, name, and title of the preparer of the document. The minimum required components of the Vaccine Storage and Handling Plan include:

- Name of the current primary vaccine coordinator and at least one back-up coordinator
- General operations for the following vaccine storage and handling practices:
  - Proper vaccine storage and handling practices
    - Temperature monitoring
    - Vaccine storage (e.g. equipment, placement)
    - Vaccine shipping and receiving procedures
    - Vaccine ordering procedures
    - Inventory control (e.g. stock rotation)
    - Vaccine expiration, spoilage, and wastage prevention (e.g. protocol for responding to and reporting vaccine loss)
- Staff training (and documentation of training) on VFC requirements, including proper vaccine storage and handling

Written emergency storage and handling plans must be developed and maintained by every facility and/or clinic. A template form should be used and posted on the vaccine storage unit which includes details of the Emergency Management of Vaccines plan, containing instructions and emergency contact information. An Emergency Management Plan is necessary so that vaccine can be transported to another location if situations occur that make it so vaccines can no longer be safely stored at the facility. Such situations may include:

- A power outage that lasts more than 1 hour;
- A malfunction of your vaccine storage unit;
- A natural disaster
- A building maintenance issue such as a burst water pipe that results in standing water, or;
- Even if your facility has a back-up generator, there may be a time when you will not be able to keep your vaccine storage unit plugged in and operational.

**Note: Immediately contact the Indiana Immunization Division in the event of an emergency. NEVER discard vaccine that has been exposed to a temperature excursion unless directed to by the vaccine manufacturer or the Immunization Division.**

Every clinic should also have an emergency vaccine retrieval and storage plan. The plan should be easily accessible to staff and identify a backup location where the vaccine can be stored. Considerations when choosing this site include appropriate storage units, temperature monitoring capability and a backup generator. Potential backup locations might include a local hospital, pharmacy, long-term care facility, or the Red Cross.

Providers should keep an adequate supply of packing materials (i.e. coolers/insulated shipping containers, bubble wrap or packing material and frozen water bottles) and calibrated temperature monitoring device(s) to accommodate the facility's vaccine supply, if transport is needed. Follow the steps **procedure details** and **packing order diagram** to ensure proper vaccine transport.

Power outages or natural disasters are not the only events that can compromise vaccine. Forgotten vials of vaccine left out on the counter or doses of vaccine stored at improper temperatures due to a storage unit failure are other examples of how vaccines can be potentially compromised.

### **Procedure Details**

All providers should follow the following steps in the event of an emergency to ensure the viability of all publicly funded vaccines.

*Step 1) Provider notifies the Emergency contact person for the site*

*Step 2) Provider determines if a generator or alternate power source is available. If so, ensure that all steps are followed to maintain the vaccines within the required temperature range for each storage unit.*

*Step 3) If the power failure will be temporary (less than 1 hour), providers should do the following:*

- a. Ensure that the refrigerator and freezer doors remain closed for the duration of the outage.
- b. Document the time of the power outage and the duration of the outage.
- c. Document the room temperature during the outage.

Under these conditions, it is not necessary to remove the vaccines from the storage unit since the rise in temperature could be only slight or insignificant.

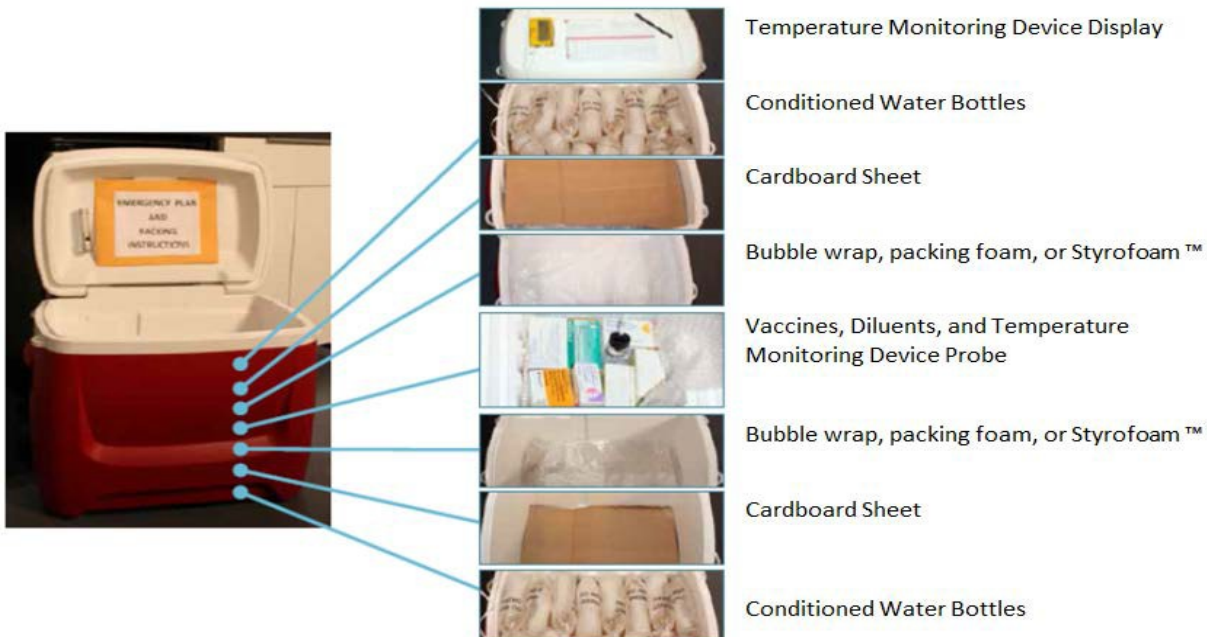
*Step 4) If the power or equipment failure is expected to last longer than 1 hour, follow these steps:*

- a. Maintain use of generator or alternate power source and ensure that vaccines continue to be stored at appropriate temperatures.
- b. If an alternate power source or equipment is not available, the provider should begin making arrangements to transfer the vaccine to a predetermined emergency storage facility.
- c. The provider should begin packing the vaccine for transfer to the alternate location
  - 1) The vaccine should be placed in insulated transport containers or shipping boxes with refrigerator packs, bubble wrap and a continuous temperature monitoring device. Please refer to the **packing order diagram** for further guidance.
    - i. All inactivated or refrigerator vaccines should be transported at 36° to 46°F (2° to 8°C)
    - ii. All varicella-containing or frozen vaccines should be transported at 5°F (-15°C) or colder. Use of dry ice is not recommended, even for temporary storage or emergency transport.

*The CDC and vaccine manufacturer do not recommend transporting varicella-containing vaccines. If these vaccines must be transported, CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). If varicella-containing vaccines must be transported and a portable freezer unit is unavailable, the vaccine MAY be transported at refrigerator temperature 36° to 46°F (2° to 8°C) for up to 72 continuous hours prior to being reconstituted. Please see the Special Instructions for Transport of Varicella-Containing Vaccines located in the References and Resources section of the policy manual.*

- iii. Measles, mumps and rubella vaccine (M-M-R-II) may be transported in a refrigerated or frozen state.
- iv. Diluent does not need refrigeration and cannot be frozen.
- d. If at any time during the power outage or equipment failure, the temperature is recorded **above** or **below** the recommended range, **DO NOT USE** the vaccine until the following steps are taken and the viability of the vaccine has been determined.
  - i. Immediately check the continuous temperature monitoring device for correct placement and operation.
  - ii. Contact the Indiana Immunization Division at (800) 701-0704.
  - iii. Contact the manufacturer of each affected vaccine.
- e. In the event that an outage or equipment failure or if temperatures are **above** or **below** the recommended temperature for an extended period of time **AND** the vaccine was not relocated, immediately contact the manufacturer and the Indiana Immunization Division at (800) 701-0704.

**Packing Order Diagram**



## References & Resources

Centers for Disease Control and Prevention. (2018) Vaccine Storage and Handling Toolkit, Revised January 2018. <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Centers for Disease Control and Prevention. (13<sup>th</sup> Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015. <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Refrigerator/Freezer Temperature Log

Emergency Management of Vaccines Template

Varicella-Containing Vaccines-Special Instructions for Transport (Merck)

Emergency Response Worksheet, Immunization Action Coalition. <http://www.immunize.org/catg.d/p3051.pdf>

## **Revision History**

07/17/2012, Created

11/19/2014, Revised

02/25/2016, Revised

04/01/2017, Revised

<b>Policy &amp; Procedure Title</b>	Storage and Handling-Cold Chain Failure	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	11	<b>Revision Date</b>	07/03/2018
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Policy & Procedure Summary

Vaccines must be stored properly from the time they are manufactured, throughout the delivery process and until the time they are administered. Failure to maintain the cold-chain of vaccines due to shipping delays, power outages, equipment failure and human error may cause vaccines to become ineffective.

### Policy Statement

This policy supersedes all policies previously issued by the Indiana Immunization Division addressing vaccine cold chain failure. It replaces the following policies:

Title of Policy: **Vaccine Cold Chain Failure: Procedures and Corrective Action**  
 Policy Number: III-03  
 Creation Date: February 18, 2009  
 Revision Date: March 2011

If any vaccine is determined to have exceeded the established temperature ranges or storage and handling requirements, steps must be **immediately** taken to ensure the viability of all vaccine. The following procedures and corrective actions should be followed to resolve vaccine cold-chain failures:

- Correct improper storage and handling conditions, including exposure to light and storage temperatures that are outside of the established range.
- Check all digital data loggers for correct placement and operation. Document any temperature fluctuation and the amount of time that vaccines were out of the correct temperature range.
- If vaccine shipping or storage temperatures are recorded **above** or **below** the required range, do not use the vaccine until the viability of the vaccine has been established by the vaccine manufacturer. Place the vaccine in the refrigerator or freezer, depending on the proper storage requirements, and clearly mark the vaccine "Not for Use".
- When receiving vaccine shipments, if any damage, excessive shipping time, cold chain breach has occurred, provider must notify the Indiana Immunization Program within **two hours** of vaccine delivery.
- If the storage unit's ability to maintain the recommended temperatures is in question and the problem persists for over two hours, move vaccines to a pre-established back-up location to maintain the cold-chain.
  - All providers must have written emergency procedures for proper handling of publicly funded vaccines in the event of power or equipment failure. **See the Storage and Handling - Emergency Plans Policy for complete information on emergency procedures.**
- If vaccines are determined to have exceeded designated storage temperatures, providers **MUST** contact the manufacturer and obtain guidance and recommendations for vaccine viability.
  - Providers should report all incidents of vaccine cold-chain failure within 24 hours to the Immunization Division (800)-701-0704.
  - A Vaccine Return transaction should be completed and submitted in VOMS, when available (or submit State Form 54052 in the interim), for all vaccines determined to be non-viable by the Immunization Division.

**After a temperature excursion, proof of at least 5 days of in-range temperatures need to be provided to ISDH to establish that the unit is stable and operating properly. A root-cause analysis (RCA) to find out why the excursion occurred is also required. Additional days-in-range reports may be required depending upon the reason for the temperature excursion.**

**Providers should never discard or return any vaccine unless they are instructed to do so by the Immunization Division.**

The Immunization Division has developed a visual Refrigerator/Freezer Temperature Log to assist providers in tracking storage unit temperatures in order to determine if there has been a temperature excursion. By using this visual temperature log, providers can easily track storage unit temperatures in either Celsius (C°) or Fahrenheit (F°).

**Refrigerator Temperature Log**

Days 16 – 31 Month/Year \_\_\_\_\_

Record temperatures twice (2x) a day.

1. Write your initials and the time of day.
2. Place an "X" next to the current temperature. Aim for 40°F/4°C (Yellow bar)
3. If the temperature is too warm or too cold, follow the actions steps listed on reverse side.
4. At the end of the month, file this log and save for 3 years.

Unit Name/Location \_\_\_\_\_

Thermometer type:  °F (Fahrenheit)  °C (Celsius)

Day of Month	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Staff Initials																
Time																
Min/Max Temp																
<b>Refrigerator Temperatures</b>																
≥49°F	≥10°C															
48°F	9°C															
47°F		Danger! Temperatures above 46°F/8°C are too warm! Immediately follow the action steps listed on reverse side.*														
46°F	8°C															
45°F	7°C															
44°F	6°C															
43°F																
42°F	5°C															
41°F																
40°F	4°C															
39°F																
38°F	3°C															
37°F																
36°F	2°C															
Danger! Temperatures below 36°F/2°C are too cold! Immediately follow the action steps listed on reverse side.*																
35°F																
34°F	1°C															
33°F																
≤32°F	≤0°C															



ISDH Immunization Program Toll Free Number: (800) 701-0704

\*Record problem, Actions taken and Outcome on reverse side.

The temperature log directs providers to record problems on the reverse side of the log. Providers should document all actions taken and outcomes if temperatures are recorded above or below the required temperature range.



**Actions Steps**

1. Store vaccine under proper conditions as quickly as possible.
2. Call the vaccine manufacturer(s) (for Direct Ship Vaccines) to determine if vaccine can still be used.
3. Call your ISDH Field Representative.
4. Record problem, actions taken and outcomes below.

Date/Time & Initials	Problem (Too Warm, Too Cold, Power Failure, etc.)	Actions Taken	Outcome

**Manufacturer Quality Control  
Office Telephone Numbers**

Manufacturer/ Distributor	Telephone Number	Products
<b>GlaxoSmithKline</b>	(Vaccine Service Center) (866) 475-8222  (888) 593-5977	Bexsero® Boostrix® Cervarix® EpiSero-B® Fluarix® FluLaval® Havrix®  Hibemx® Infanrix® Kinrix® MENHIBRIX® Menveo® Pediarix® Rotarix® Twinrix®
<b>MedImmune, Inc.</b>	(877) 358-8478 (LAIV customer support) (877) 633-4411 (General customer support)	Flublist®
<b>Merck</b>	(Health Care Professional) (800) 609-4618 (Adverse Reactions) (800) 672-6372 (Vaccine Customer Care) (877) 829-6372	Gardasil® MMRII® Pedvax-HIB® Pneumovax® ProQuad®  RecombyxHB® RotaTeq® VAQTA® Varivax® Zostavax®
<b>Sanofi Pasteur</b>	(800) 822-2463	ActHIB® Adacel® Daptacel® DT (Generic)  FluZone® IPOL® Menactra® Pentacel® Tenvac®
<b>Pfizer</b>	(800) 879-3477	Prevnar™  TRUMENBA®
<b>Centers for Disease Control &amp; Prevention Drug Service</b>	(770) 488-7100 (404) 639-3717	Distributor for Diphtheria antitoxin
<b>Talecris Biotherapeutics</b>	(919) 553-5011 (800) 520-2807	HBIG, IGIM, RIG, TIG
<b>Biotech Pharmaceuticals</b>	(800) 458-4244	HBIG

The log also provides the Vaccine Manufacturer contact information to assist providers if calls must be made to the manufacturer to determine vaccine viability.

**Procedure Details**

- Step 1) Providers should monitor the storage and handling of all vaccines
- Step 2) If concerns exist regarding the cold-chain of vaccines due to shipping delays, power outages, equipment failure and human error, providers should take the necessary steps to ensure the viability of all vaccines in question.
- Step 3) Providers should document all steps taken on the reverse side of the Refrigerator/Freezer Temperature Log.
- Step 4) If necessary, providers should contact the vaccine manufacturer and the Immunization Division to determine viability.
- Step 5) If necessary, providers should complete and submit the Vaccine Return form to the Immunization Division.

**References & Resources**

- Refrigerator/Freezer Temperature Log
- Storage and Handling-Emergency Plan Policy (17)

**Revision History**

- 07/17/2012, Created
- 03/01/2014, Revised
- 04/01/2017, Revised
- 07/03/2018, Revised

<b>Policy &amp; Procedure Title</b>	Storage and Handling-Transporting to Off-Site Clinics	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	12	<b>Revision Date</b>	01/01/2018
<b>Policy &amp; Procedure Approval Authority</b>	Dave McConnick		

### Policy & Procedure Summary

The number of times vaccines are handled and transported should be minimized. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times.

The Indiana Immunization Division supports the implementation of off-site clinics for the vaccination of children and adults in non-traditional clinic settings. All off-site clinics should be approved by the Immunization Division and should be in conjunction with the respective Local Health Department (LHD.) **Please provide both agencies with advance notification of the clinics. The Immunization Division requests a minimum of 30 days notification**, understanding that outbreak response may be an exception. Each off-site clinic will be required to complete a check-list to ensure they are following proper procedures for holding a clinic off-site.

### Policy Statement

This policy supersedes all policies previously issued by the Indiana Immunization Division addressing the transport of publicly funded vaccine. It replaces the following policy:

Title of Policy: **School Clinics**  
Policy Number: II-05  
Removed from Policy and Procedures Manual March 2011

Title of Policy: **Non-Traditional Sites for Immunization Services**  
Policy Number: II-07  
Removed from Policy and Procedures Manual March 2011

Providers **MUST** receive prior approval from the Indiana Immunization Division before transporting vaccines to another enrolled provider office or to an off-site clinic. This notification is to ensure all vaccine transport practices and procedures are practiced and that proper screening for eligibility will be taking place. Notification of any scheduled off-site clinics must be made *at least 30 days* prior to the scheduled event with the off-site checklist completed at that time. The Immunization Division can be reached at (800)701-0704.

Most often, vaccine transport is conducted by a field representative from the Indiana Immunization Division. All vaccinations administered during an off-site clinic must be entered into CHIRP within seven (7) days.

Providers hosting an off-site clinic are responsible for the return transport and permanent storage of any additional doses of vaccine not administered during the clinic.

Providers are not allowed to transfer vaccines to another provider/facility regardless of their enrollment status in one of Indiana's Publicly Funded Vaccine Programs without prior approval from the Indiana Immunization Division.

Having a patient pick up a dose of vaccine at a pharmacy and transporting it in a bag to a clinic for administration is not an acceptable transport method for varicella-containing or any other vaccine.

## Vaccine Transport and Temperature Monitoring for Off-Site Clinics

Changes have been made to the requirements for transport of vaccines to any off-site clinic beginning on or after January 1, 2018. Providers will no longer follow the procedures for emergency transport of vaccines and they can no longer transport vaccines to/from off-site clinics in hard-side coolers or coolers available at general merchandise stores.

All off site clinics must follow the following requirements:

1. All clinic must use portable vaccine refrigerators/freezers or qualified pack-out units. These types of units are defined in the Centers for Disease Control and Prevention Storage and Handling Toolkit as a type of container and supplies specifically designed for use when packing vaccines for transport. They are qualified through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.
2. Digital data loggers with a buffered probe and a current and valid Certificate of Calibration Testing must be placed directly with the vaccines and used to monitor vaccine temperature during transport.
3. If vaccines are transferred to a permanent storage unit at the location of the off-site clinic, the storage unit must meet the minimum storage requirements for storage of VFC vaccines and the unit must have been monitored prior to the clinic day with a digital data logger. If vaccines cannot be stored in a permanent storage unit at the clinic location, they can be kept in the portable unit or qualified pack-out.
4. Vaccines must be monitored during the clinic using a digital data logger at least once an hour and documented on the Refrigerator Temperature Log. The Indiana Immunization Division has developed an hourly temperature monitoring form located in the References and Resources section of this policy to assist with this process.
5. Within the 24 hours following completion of the off-site clinic and return of all vaccines to the permanent storage unit, the data logger must be downloaded and the report must be reviewed and sent to the respective field representative.

## Use of Multi-dose vials and Diluent at Off-Site Clinics

When a multi-dose vial is used, Food and Drug Administration (FDA) regulations require that it be used only by the provider's office where it was first opened. A partially used vial may be transported to or from off-site clinics operated by the same provider as long as the cold chain is properly maintained. However, such a vial may not be transferred to another provider or transported across state lines. While there is no defined limit to the number of times vaccine may be transported to different clinic sites, each transport increases the risk that vaccine will be exposed to inappropriate storage conditions.

Diluent should travel with its corresponding vaccine to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution. Diluent should be transported at room temperature or inside the same insulated cooled container as the corresponding vaccine, according to manufacturer guidelines for each diluent. If transported inside cooled containers, diluent must not be in direct contact with conditioned water bottles because of the potential for freezing. If any diluents that have been stored at room temperature are going to be carried in the insulated transport container, refrigerate the diluents in advance so they do not raise the temperature of the refrigerated vaccines. Do NOT transport any diluent, including the diluent for varicella-containing vaccines, on dry ice.

## Transporting Varicella-Containing Vaccines to Off-Site Clinics

CDC strongly discourages transport of varicella-containing vaccines to off-site clinics, because Varicella-containing vaccines (VAR, Varivax; MMRV, ProQuad; ZOS, Zostavax) are sensitive to temperature excursions. Portable freezers may be available for rent in some places. Providers who choose to transport these vaccines to an off-site clinic, must follow the appropriate procedures:

- Transporting with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C) is best practice. Any stand-alone freezer that reliably maintains a temperature between -58°F and +5°F (-50°C and -15°C) is acceptable for storage of varicella-containing vaccines for an off-site clinic.
- The use of **dry ice is not allowed**, even for temporary storage. Dry ice may subject varicella-containing vaccine to temperatures colder than -58°F (-50°C).
- Discard reconstituted vaccine if it is not used within 30 minutes.
- Varicella-containing vaccines may be transported and stored at refrigerator temperatures, between 36°F and 46°F (2°C to 8°C), for up to 72 continuous hours prior to reconstitution. Varicella-containing vaccine stored at refrigerator temperatures must be discarded if it is not used within 72 hours. If the vaccines must be transported at refrigerated temperatures, follow these steps (Please note: this is considered to be a temperature excursion):
  1. Place a calibrated, glycol-encased, digital data logger probe in the container used for transport as close as possible to the vaccines
  2. Place the vaccines in the freezer between -58°F and +5°F (-50°C and -15°C) and label “DO NOT USE” immediately upon arrival at the alternate storage facility. Contact the vaccine manufacturer prior to using varicella vaccine that has experienced the temperature excursion
  3. Document:
    - a. The time the vaccines are removed from the container and placed in the alternate storage unit and the time the vaccines are removed from the storage unit and placed in the container
    - b. The temperature at the beginning, during and end of transport

This policy prohibits providers from refreezing varicella-containing vaccines that are stored at refrigerated temperatures, so please plan accordingly with your vaccine doses.

Do not discard any unused vaccine without first contacting the manufacturer, and the Indiana Immunization Division at (800) 701-0704

#### Procedure Details

*Step 1) Providers should contact the Immunization Division to discuss plans for an off-site clinic and complete off-site checklist.*

*Step 2) Providers should keep an adequate supply of packing materials (i.e. coolers/insulated shipping containers, bubble wrap/packing materials and frozen water bottles) to accommodate the facility's clinic supply.*

*Step 3) Providers should conduct routine temperature readings and record on a temperature log throughout the clinic day.*

#### References & Resources

Centers for Disease Control and Prevention. (2018) Vaccine Storage and Handling Toolkit, Revised January 2018.  
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Centers for Disease Control and Prevention. (13<sup>th</sup> Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015. <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations, Updated September 2017. Influenza Work Group of the National Adult and Influenza Immunization Summit.  
[https://www.izsummitpartners.org/content/uploads/2017/02/NAIS-Vaccination-Clinic-Checklist\\_v2.pdf](https://www.izsummitpartners.org/content/uploads/2017/02/NAIS-Vaccination-Clinic-Checklist_v2.pdf)

Additional Resources can be found at the National Adult and Influenza Immunization Summit website at:

<https://www.izsummitpartners.org/nais-workgroups/influenza-workgroup/off-site-clinic-resources/>

Off-Site Clinic Refrigerator & Freezer Temperature Log

Inventory Control Log - Vaccine Going into Cooler

Vaccine Wastage Log

Immunization Clinic Consent Form(s)

#### **Revision History**

07/17/2012, Created

11/19/2014, Revised

02/15/2016, Revised

04/01/2017, Revised

01/01/2018, Revised

<b>Policy &amp; Procedure Title</b>	Vaccine Order Management-Provider Orders	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	13	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>	Dave McConnick		

**Policy & Procedure Summary**

Once enrolled, providers can place vaccine orders with the Immunization Division for any publicly funded vaccine using the Vaccine Ordering Management System, VOMS.

**Policy Statement**

Publicly-funded vaccine is ordered through the Immunization Division using federal and state funds. The Indiana Immunization Division offers providers the option to order any vaccine licensed incorporated into the routine schedules by the Advisory Committee on Immunization Practices (ACIP) and available on the Centers for Disease Control and Prevention (CDC) Vaccine Price List.

All persons who are responsible for ordering publicly-funded vaccines in their facility will need to obtain VOMS access through CHIRP. New providers that do not have access to CHIRP must submit an Individual User Agreement form (State Form 52303) and a VOMS Individual User Access Form to obtain a username and password prior to being granted VOMS access.

Providers are required to notify the Immunization Division *immediately* when there are changes in key vaccine staff, including the need to terminate VOMS accounts for a former employee within 24 hours.

Vaccine coordinators should request delivery during regular office hours. Vaccine shipments should be delivered when staff is available to unpack and store the vaccine properly. Shipment times should be updated at the time each vaccine order is submitted and should reflect any period of time the office will be closed, such as holidays, scheduled vacation, and change in hours of operation and/or lunch hour. Providers must be on site with appropriate staff available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during that day.

**Vaccine Ordering Requirements**

- A. All providers will follow the ordering requirements set by the Immunization Division.
  - 1. All providers will use Vaccine Ordering Management System, VOMS, to place all regular vaccine orders. The VOMS application will help providers order and manage all publicly funded vaccines efficiently.

**Create Order**

<b>Organization (IRMS):</b> NM PEDIATRICS	<b>First Name:</b> SARA
<b>Facility:</b> NM PEDIATRICS	<b>Middle Name:</b>
<b>Phone Number:</b> (569)325-1102	<b>Last Name:</b> ADAMS
<b>Phone Extension:</b>	<b>Address:</b> 1005 SOMEWHERE ST
<b>Email:</b>	<b>City:</b> SANTA FE
	<b>State:</b> NM
	<b>Zip:</b> 87508

<b>Monday:</b>	<input type="checkbox"/> 09:00 <input type="checkbox"/> 12:00 <input type="checkbox"/> 13:00 <input type="checkbox"/> 17:00	<b>Tuesday:</b>	<input type="checkbox"/> 09:00 <input type="checkbox"/> 12:00 <input type="checkbox"/> 13:00 <input type="checkbox"/> 17:00
<b>Wednesday:</b>	<input type="checkbox"/> 09:00 <input type="checkbox"/> 12:00 <input type="checkbox"/> 13:00 <input type="checkbox"/> 17:00	<b>Thursday:</b>	<input type="checkbox"/> 09:00 <input type="checkbox"/> 12:00 <input type="checkbox"/> 13:00 <input type="checkbox"/> 17:00
<b>Friday:</b>	<input type="checkbox"/> 09:00 <input type="checkbox"/> 12:00 <input type="checkbox"/> 13:00 <input type="checkbox"/> 17:00		

**PIN:** 100801      **Instructions:**

**Order Date:** 04/28/2011      **Order Status:** In Progress

**Submitter:** LINDA PURSLEY (LINDA RC)

**Comments:**

**Inventory Last Submitted:** 04/28/2014

**Order Set:** VFC ORDER SET 1 / Distributor

**Order Frequency:** Twice Monthly      **Order Timing:** 15th to End of Month

**Order Schedule:**

Vaccine	Description	Dose Used Last Month	Physical Inventory	Recommended Quantity	Order Quantity	Urgent	Priority Reason	Comments
DTaP	DAPTACEL®	1	9	0	10	<input type="checkbox"/>	--select--	
DTaP	INFANRIX®				0	<input type="checkbox"/>	--select--	

- B. VOMS will maintain the following provider specific information. Providers can change the email address, phone and fax number in VOMS. Providers must contact the Immunization Division for all other changes.
1. Facility Name
  2. Address, City, Zip Code
  3. Phone
  4. Email

*Providers should verify this information each time a vaccine order is submitted. If this information changes at anytime, providers should submit the Provider Change of Contact Information Form. If the delivery days or times have changed, correct it, and once you submit your order, the information will be saved.*

C. Submitting vaccine orders

1. Providers are responsible for providing all required data in VOMS in order for a vaccine order to be successfully submitted and approved. The following items MUST be completed and submitted before the vaccine order will be approved:
  - i. Inventory on Hand
  - ii. Doses Administered
  - iii. Vaccine Order
2. Providers can submit one regular order via VOMS and fax one influenza order at any time during the month.
3. Orders will be reviewed and approved in VOMS on a daily basis by the Immunization Division Vaccine Management staff. Delivery can be expected be delivered within 7 to 10 business days from the time the vaccine order was submitted. Varicella vaccine orders are shipped directly from the manufacturer and may take up to 14 business days for delivery.

*PLEASE NOTE: Any vaccine order may be delayed due to extenuating circumstances.*

4. To avoid vaccine wastage and to keep the most appropriate vaccine inventory on hand, the Immunization Division strongly recommends that providers watch inventory closely and order to maintain a 30-45 day supply (or roughly 5 weeks) of vaccine.

**References and Resources**

Sample Vaccine Order Form (State Form 52775 R4 9-10)

Individual User Agreement (State Form 52303 R4 8-16)

VOMS Individual User Access Form

**Revision History**

07/17/2012, Created

03/01/2014, Revised

04/01/2017, Revised



<b>Policy &amp; Procedure Title</b>	Publicly Funded Vaccine Accountability	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	14	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Policy & Procedure Summary

The Vaccine Accountability Policy is intended to support the strong partnership and collaborative efforts of the Indiana State Department of Health (ISDH) Immunization Division, the Centers for Disease Control and Prevention (CDC) and all providers receiving publicly funded vaccines to promote best practices in vaccine management and helping to ensure an adequate vaccine supply by being good stewards. Together we share a common interest in ensuring that all eligible citizens in the State of Indiana have access to ACIP recommended vaccines and are protected against vaccine preventable diseases.

### Policy Statement

The Indiana Immunization Division provides vaccine free of charge for providers enrolled in publicly funded vaccine programs. These vaccines are purchased through federal and state grants and require high levels of scrutiny for maintenance, administration and storage and handling of each and every dose. This means that providers must be held accountable for all doses ordered to ensure that all Indiana's eligible citizens have access to an adequate supply of vaccine.

All providers participating in Indiana's publicly funded vaccine programs must agree to the following:

### Vaccine Eligibility Screening

The Immunization Division requires that all providers screen and document all children and adults (if applicable) as outlined in the Immunization Provider Agreement and the Indiana Publicly Funded Childhood and Adult Vaccine Eligibility Statements, to determine eligibility for administration of vaccines purchased with VFC, 317, and/or state funds. The screening process determines if a patient is eligible to receive a publicly funded vaccine in Indiana. Accurate and timely screening of all who present for immunizations is an essential accountability activity.

### Vaccine Accountability

All immunization providers are required to account for all publicly funded vaccine. This can be done by documenting all vaccination and eligibility information in CHIRP.

All enrolled providers agree to periodic accountability audits for the evaluation of vaccine ordering patterns, inventory of vaccine, eligibility screening practices, CHIRP data entry, and vaccine management practices. Each month, a predetermined number of enrolled providers will be selected for an accountability audit. The provider(s) will be notified via email and may be required to complete additional documentation. All enrolled providers agree to fulfill all requirements as requested by a representative of the Immunization Division. Once the audit is completed, a member of the Immunization Division will notify the provider and explain the results.

### Records Maintenance

All enrolled providers must maintain records of the authorized representative's responses for a minimum of 3 years.

### Immunization Schedule

All enrolled providers must comply with the appropriate immunization schedule, dosage and contraindications established by the Advisory Committee on Immunization Practices (ACIP).

## Vaccine Information Statements

All enrolled providers must provide the most current Vaccine Information Statements (VIS) to each patient each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA) which includes reporting significant events to the Vaccine Adverse Event Reporting System (VAERS).

## Private Stock Vaccine

All enrolled providers must carry private stock vaccine to ensure that publicly funded vaccine is not administered to a fully insured client. The Indiana Immunization Division strictly enforces the Centers for Disease Control and Prevention's definition of fully insured as an individual with health insurance that covers the cost of vaccines, regardless of a high deductible or co-pay. If the fully insured population is less than 10 children, the provider may request an exemption to this provision. The request must contain the following:

1. One (1) year of data illustrating the number of VFC eligible children and fully insured children
2. A signed agreement with another healthcare provider who maintains private stock stating that they will administer all vaccines as recommended by the ACIP to your fully insured clients
3. A detailed referral plan to track all fully insured children who do not receive their vaccinations in your practice

## Fees

All providers must agree to not impose a charge for the cost of the vaccine and to not charge a vaccine administration fee that exceeds that set forth by the Indiana Office of Medicaid Policy (OMP) or the Department of Health and Human Services (DHHS). Providers agree to not charge a vaccine administration fee directly to a Medicaid VFC-eligible child and will not deny administration of publicly funded vaccine due to inability of the patient to pay an administration fee.

## Site Visits

All enrolled providers agree to periodic site visits for the evaluation of vaccine storage and handling, vaccine ordering patterns, inventory of vaccine, eligibility screening practices documentation, immunization record keeping and/or immunization coverage levels.

## Vaccine Management

All enrolled providers agree to comply with the Indiana Immunization Division requirements for education, vaccine ordering, vaccine accountability, and vaccine management and also agree to operate within the program in a manner to avoid fraud or abuse.

## Required Reporting

There are conditions under which all publicly funded vaccine providers are required to call the Immunization Division. Timely reporting allows staff to assist enrolled providers in protecting publicly funded vaccine.

The following requirements indicate when an Indiana provider should contact the Immunization Division:

### 1. The facility is moving or closing

Contact your field representative or the Immunization Division prior to the move. Facilities that are closing should make arrangements with the Immunization Division to transfer any publicly funded vaccine that will not be used. Providers who choose to disenroll from the program agree to return all unused publicly funded vaccine.

### 2. There is a power failure/storage unit failure

Power outages, equipment failure, natural disasters, or other emergencies can compromise vaccine. Notify the Immunization Division immediately for instructions on handling, transporting, or transferring of publicly funded vaccine, and then implement the Emergency Vaccine Management Plan for the facility.

**3. Temperatures are out of range**

Any temperatures recorded out of acceptable range should immediately be reported to the assigned Field Representative, or call the Immunization Division. Corrective action should be taken immediately and temperature fluctuations documented. Ensure that all questionable vaccines are transferred to a storage unit that can maintain the required temperatures in the interim until the viability of the vaccines can be determined.

**4. There is human error resulting in improper vaccine handling**

Cold chain failure can occur from improper vaccine handling due to human error such as storing vaccines in the door/drawer of the storage unit, or failure to store reconstituted vaccines properly prior to administration. CDC storage and handling guidelines should be followed to assure vaccines remain viable. If a vaccine is exposed to improper storage and handling, the assigned Field Representative should be contacted.

**5. There is a change of primary providers**

The Chief Medical Officer (CMO) of an enrolled facility is defined as the “official VFC program-registered provider” and/or “official publicly funded vaccine program-registered provider” who originally signed the Provider Enrollment Form. When there is a change in the primary practitioner, new enrollment forms must be completed and the new CMO must sign the Immunization Provider Agreement. When new providers/physicians, that are not the CMO, are added to the practice after initial enrollment, the Immunization Division should be contacted and the physicians must be added to the Provider Profile.

**6. There is a change in the VFC Contact/Vaccine Coordinator or Back-up Coordinator**

Staff changes are a common occurrence in provider offices. Any changes in this information could result in information not being received accurately and timely. Providers are required to notify the Immunization Division *immediately* when there are changes in key vaccine staff, including the need to terminate a VOMS access for a former employees within 24 hours.

**7. There is a discrepancy with your publicly funded vaccine shipment**

Always check the shipment against the packing slip and make sure the doses received matches the doses ordered. Also, count the diluent to make sure they match the number of vaccine doses. If discrepancies are found, please contact the Immunization Division **immediately** with any shipping problems. **Contact MUST be made within 2 hours of receiving the order.**

**Vaccine Ordering**

In order to receive publicly funded vaccines, enrolled providers must agree in writing to follow established Immunization Division vaccine usage, inventory management, data collection and reporting requirements. Every vaccine order submitted by a provider is compared to the most recent provider profile. The provider profile is a provider-completed population estimate of the number and type of eligible children that the provider expects to see during a time period of one year.

Providers may submit vaccine orders once each month. Monthly vaccine orders require providers to account for each dose administered and submit a physical inventory in VOMS. Monthly orders are submitted using VOMS (Vaccine Ordering Management System).

The Immunization Division staff will review all submitted orders and supporting documentation to ensure that it has been completed accurately. The Immunization Division staff will contact providers to request changes, as needed, before processing the order.

Once this has been verified, staff will:

1. **Verify the provider has selected the appropriate order intention for each vaccine ordered.**
2. **Compare the current vaccine inventory and the monthly doses used last month column with the requested number of doses for each vaccine.**
3. **Assess whether or not the current provider inventory and doses requested are in alignment with the most recent provider profile population estimate.**
4. **If numbers are not equitable, contact the provider directly.**
5. **Determine if there are special circumstances (i.e. school clinic, influenza clinic, etc) that explain the number of doses requested.**
6. **If no special circumstance exists, reduce vaccine doses.**

Vaccine orders exceeding annual profiled estimated usage are flagged by the Vaccine Management staff and passed on to the Accountability Coordinator or the Director of Vaccine Operations for further review. If necessary, the Accountability Coordinator or Director of Vaccine Operations will contact those providers exceeding profile amounts to determine if distribution of additional vaccine is justified, or if adjustments to the profile are needed. Additionally, Immunization Division staff will validate submitted provider profile data by comparing it to current usage data. Unjustified, excessive and/or repeated discrepancies between provider profile data, vaccine orders, and vaccine usage will be evaluated and referred for further investigation.

### **Annual Recertification**

Every enrolled provider is required to submit an electronic Provider Recertification in VOMS on an annual basis. This is completed for each calendar year during the month of December for the current year. The annual Provider Recertification process affords the Immunization Division the opportunity to reinforce the program requirements and answer any questions providers might have regarding the requirements. Once providers submit the electronic Provider Recertification in VOMS, the following documents must be emailed to [immunize@isdh.in.gov](mailto:immunize@isdh.in.gov) or faxed to 317-972-8964 in order for the recertification process to be complete:

- VFC Provider Agreement
- VFC Provider Profile Report

By signing the Provider Agreement form, providers agree to certain requirements as a condition of participation in the publicly funded vaccine program. Submission of these forms is a requirement for participation.

The Provider Profile should be completed based on actual data and should be updated on an annual basis to accurately reflect the total number of children seen at each provider site. This data is used to evaluate the provider's vaccine orders.

### **Vaccine Wastage and Reimbursement**

The Immunization Division has a policy for management of incidents that result in the loss or wastage of any publicly funded vaccine. The policy applies to all providers who are actively enrolled in Indiana's Vaccines for Children (VFC) Program, or any other publicly funded vaccine program.

The Indiana Immunization Division defines vaccine loss or wastage as any incident or vaccine loss involving 5 or more doses that prevents a vaccine from being properly administered. **This includes all spoiled, expired, or wasted vaccines.** It includes:

**Spoiled** – vaccine that has been spoiled as a result of the following:

- Natural disaster/power outage
- Refrigerator too warm or too cold

- Failure to store properly upon receipt
- Vaccine spoiled in transit
- Mechanical failure of storage unit

**Expired** – non-viable vaccine in its original container (vial or syringe) that was not administered prior to the expiration date. This includes vaccine that was ordered but unable to be administered or transferred prior to the expiration date.

**Wasted** – any vaccine that is unaccounted for which can be due to vaccine ordered but not delivered or loss of vaccine due to poor record keeping

- Vaccine drawn into the syringe but not administered (e.g., the parent refused vaccine after the dose was drawn up or a dose of Varivax could not be administered within 30 minutes of reconstitution).
- Vaccine in open vial but doses not administered
- Compromised vial (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

*Note: All vaccine losses due to expired or non-viable vaccines must be returned to McKesson for proper tax credits, with the exception of opened multi-dose vials or broken or compromised vials/syringes with needles attached. These doses should be appropriately documented as Wastage in VOMS and then discarded in a sharps container.*

**All providers collaborating with the Immunization Division to vaccinate the citizens of Indiana are required to document and report all incidents of vaccine loss and wastage.** Providers must complete the Vaccine Return transaction in VOMS (when available), and submit it to the Immunization Division for review within 30 days of the vaccine loss. In the interim, providers are required to submit a paper form (State Form 54052) and fax to 317-972-8964. In order for inventory in CHIRP to reflect wastage, providers are also required to report vaccine wastage in CHIRP when submitting inventory. Failure to submit returns in a paper return form or in VOMS (when available), will result in vaccine ordering delays or denial. Providers experiencing a storage unit failure or those who fail to adequately monitor temperatures will be placed on a temporary ordering suspension.

Further guidance on vaccine returns and wastage procedures will be given once the Vaccine Return feature in VOMS becomes available.

In accordance with the 2017 Provider Agreement, all providers signed that he/she understands that “ISDH has the right to require dose for dose replacement of all publicly funded vaccine lost due to mismanagement”. The Indiana Immunization Division VFC Program will require providers to replace vaccine that has been wasted due to negligence or failing to correctly store or handle vaccine beginning July 1, 2012, excluding influenza vaccines.

The Immunization Division will review all instances of wasted or expired publicly funded vaccine on a case-by-case basis to determine whether restitution will be required or if extenuating circumstances prevail. This review will help determine whether negligence was involved. If negligence is found, the provider will be asked to make restitution in the form of a dose for dose replacement for any doses that have been lost due to the provider's failure to properly receive, store or appropriately administer vaccines.

## **Fraud and Abuse**

Public and private enrolled providers must ensure that they correctly utilize publicly funded vaccines. Providers must ensure that funded vaccines are given only to children, adolescents and adults who meet established eligibility requirements. The Immunization Division is required by the Centers for Disease Control and Prevention (CDC) to implement VFC fraud and abuse prevention policies and is required to investigate and report suspected cases to the Medicaid Surveillance Utilization Review Unit (SUR) and the Medicaid Fraud Unit (MFCU).

The following definitions, as defined in the Medicaid regulations at 42 § CFR 455.2, apply to all VFC Program Operations and all publicly funded vaccine programs through the Indiana Immunization Division:

- **Fraud** is defined as “an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to him or some other person. It includes any act that constitutes fraud under applicable federal or state law.”
- **Abuse** is defined as “provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to 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.”

Under state law, the Immunization Division is required to take specific action to address situations in which a provider engages in intentional deception or misrepresentation with the intent to achieve some unauthorized benefit for himself or some other person. This could include selling federal or state purchased vaccines or charging clients for the federal or state purchased vaccines over and above the admissible administration fee. The Medicaid Fraud Unit (MFCU) and the Medicaid Surveillance Utilization Review Unit (SUR) investigate these complaints and ensure that the services billed to the Medicaid program by the provider in question fall within the established parameters.

The Indiana Immunization Division will attempt to work collaboratively with providers to address issues of program noncompliance. The Immunization Division will consider previous compliance issues and potential extenuating circumstances in determining remedial action(s). The Immunization Division will develop an appropriate educational training plan for the provider in question to ensure proper administration and management of publicly funded vaccines. The goal is to work with providers in as positive a manner as possible to correct noncompliant behaviors and restore publicly funded vaccine program privileges. Intervention may include, but is not limited to:

- Enrollment training
- Requirement to enroll (if not already) and utilize CHIRP for ordering and managing vaccines
- More frequent reporting of requested data and/or information to the Immunization Division
- Change in ordering cycle
- Limited vaccine ordering

A provider determined to be engaged in fraud and/or abuse will be inactivated (suspended) from participating in any publicly funded vaccine program. Reinstatement in the program will be contingent on the outcome of proceedings conducted by the Attorney General's (AG) office or the Office of the Inspector General (OIG). Final resolution may include, but is not limited to, the following interventions:

- Remedial Education
- Recoupment of funds
- Reimbursement of vaccines
- Reinstatement without penalty
- Referral for criminal prosecution
- Civil resolutions

Suspected fraud or knowledge of fraud and abuse, including but not limited to the fraudulent filings of claims and the acceptance or failure to return money allowed or paid on claims known to be fraudulent must be reported to Indiana Medicaid or other designees. false or

**Please refer to the complete #20 Fraud and Abuse Policy for the complete policy and procedure.**

### **References & Resources**

Immunization Provider Profile (State Form 50201)

Immunization Provider Agreement (CDC Form)

Adult Immunization Provider Profile & Agreement (State Form 54625)

Vaccine Wastage and Reimbursement Policy and Procedure (Policy number 15)

Fraud and Abuse Policy and Procedure (Policy number 19)

Centers for Disease Control and Prevention. VFC Operations Guide, revised 2017. Module 5: Fraud and Abuse.

*Copies of the Ops Guide are posted in the CHIRP Document Center*

### **Revision History**

07/17/2012, Created

11/19/2014, Revised

04/01/2017, Revised

<b>Policy &amp; Procedure Title</b>	Immunization Information System Requirements	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	15	<b>Revision Date</b>	01/01/2018
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Policy & Procedure Summary

All providers enrolled in a publicly-funded and/or Vaccines for Children (VFC) program are required to use the Indiana Immunization Information System (IIS), CHIRP to its fullest capacity. CHIRP stands for Children and Hoosier Immunization Registry Program and is Indiana's designated repository for vaccine inventory and immunization administration. All providers utilizing publicly funded vaccine must provide immunization data to the immunization data registry (CHIRP) for all immunizations no later than 7 business days after providing the immunization.

This program requirement includes full utilization of the Vaccine Lot Inventory Management component of CHIRP.

Effective July 1, 2015 Indiana Code 16-38-5 requires all healthcare providers administering immunizations to persons under 19 years of age and younger to report all administered doses to CHIRP.

### Policy Statement

**IC 16-38-5 specifies that providers must submit the following data to the registry:**

- Patient first and last name.
- Patient date of birth.
- Patient address.
- Patient race.
- Patient gender.
- Vaccine for Children program eligibility. This includes eligibility at the patient level and dose level.
- Vaccination presentation or vaccination code using approved Immunization Information System (IIS) codetype.
- Vaccination date administered.
- Lot number of the administered vaccine.

To ensure the proper funding of vaccine stock, all providers enrolled in the VFC and/or publicly-funded vaccine program must utilize the Vaccine Ordering Management System (VOMS) component of CHIRP to place orders and receive publicly supplied vaccine. Providers are also required to keep the lot inventory up to date, for example expired vaccines should be deactivated, to ensure the most accurate and up to date information is available in the lot inventory component. Providers should follow the steps in the VOMS Accountability Quick Reference Guide to ensure accurate inventory management.

### References & Resources

IC 16-38-5

Accountability policy

AIRA standards

### Revision History

07/17/2012, Created  
 03/01/2014, Revised  
 01/01/2018, Revised



<b>Policy &amp; Procedure Title</b>	Publicly Funded Vaccine: Loss, Wastage and Reimbursement	<b>Issuing Date</b>	7/17/2012
<b>Policy &amp; Procedure Number</b>	16	<b>Revision Date</b>	01/01/2018
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Policy & Procedure Summary

Indiana Immunization Division, the Centers for Disease Control and Prevention (CDC) and all Indiana's providers share a common interest in ensuring that all eligible citizens receive immunizations. Although enrolled providers receive vaccine free of charge through the Immunization Division, these vaccines are purchased through federal and state grants. This means that providers must be held accountable for all doses ordered to ensure that all Indiana's VFC and state-eligible children have access to an adequate supply of vaccine, as well as Indiana's eligible adults. It is important that all providers reimburse for returned or wasted doses so that Indiana can have a sufficient supply of vaccines and funding to continue to ensure the health of the citizens of Indiana.

Nonviable vaccine in its original container (vial or syringe) needs to be returned for excise tax credit following the Vaccine Returns Policy (Policy 17)

#### Policy Statement

##### *Vaccine Loss and Wastage*

The Immunization Division has a policy for management of incidents that result in the loss or wastage of any publicly funded vaccine. The policy applies to all providers who are actively enrolled in any Indiana publicly funded vaccine program. This policy supersedes all policies previously issued by the Indiana Immunization Division addressing wasted vaccine. It replaces the following policies:

Title of Policy: **Recovery of Funds for Spoiled Public Vaccine**  
 Policy Number: II-03  
 Creation Date: April 1, 2006  
 Revision Date: March 2011

Title of Policy: **Vaccine Transfer/Return**  
 Policy Number: II-04  
 Creation Date: April 1, 2006  
 Revision Date: March 2011

The Indiana Immunization Division defines vaccine loss or wastage as any incident or vaccine loss, which prevents a vaccine from being properly administered. **This includes ALL spoiled, expired, or wasted vaccines.** All doses must be documented in the registry under the correct reason code and description. It includes:

**Spoiled** –vaccine that has been spoiled as a result of the following:

- Natural disaster/power outage
- Refrigerator too warm or too cold
- Failure to store properly upon receipt
- Vaccine spoiled in transit
- Mechanical failure of storage unit

**Expired** – non-viable vaccine in its original container (vial or syringe) that was not administered prior to the expiration date. This includes vaccine that was ordered but unable to be administered or transferred prior to the expiration date.

**Wasted**- any vaccine that is unaccounted for which can be due to vaccine ordered but not delivered or loss of vaccine due to poor recordkeeping.

- Vaccine drawn into the syringe but not administered (e.g., the parent refused vaccine after the dose was drawn up or a dose of Varivax could not be administered within 30 minutes of reconstitution).
- Vaccine in open vial but doses not administered
- Compromised vial (e.g., due to a drop causing damage to vial integrity or sterility), broken vial, or lost vial
- Lost or unaccounted doses are required to be reported in the registry. Every effort should be made to reconcile unaccounted for doses of VFC vaccine. In those circumstances where you are unable to reconcile your current vaccine inventory with what is reflected in CHIRP, doses that cannot be accounted for are considered lost doses. These lost and unaccounted doses are a form of wasted vaccine and will count towards the total vaccine loss and wastage amounts.

All providers collaborating with the Immunization Division to vaccinate the citizens of Indiana are responsible for maintaining vaccine quality from the time a shipment arrives until the moment the vaccine is administered. Providers are also required to document and report all incidents of vaccine loss or wastage. All providers experiencing vaccine loss or wastage due to negligent vaccine management are accountable for all the doses and could be required to replace vaccine through private purchase.

The Indiana Immunization Division may withhold vaccine orders until improved accountability is demonstrated by the provider office. If accountability for expired, spoiled and/or wasted public doses does not improve, dose for dose replacement of those lost doses with private stock vaccine will be required. All doses must be recorded in CHIRP and reported to CDC through the Returns/Wastage reporting process.

Vaccine loss or wastage is both costly and preventable, but the Immunization Division understands that some losses (e.g. due to equipment failure and power outages) are unavoidable. The action taken by the Immunization Division will depend on the category of the vaccine loss. For this policy, loss of vaccine is divided into three categories:

Category 1 – Non-preventable Loss

Category 2 – Non-compliance

Category 3 – Negligence

### **Category 1 – Non-preventable Loss**

Vaccine loss or wastage due to non-preventable circumstances is considered to be out of the providers' control and generally do not require financial restitution. The provider is not negligent in his/her handling of the publicly funded doses if the incident is truly non-preventable. This list is not exhaustive, but does include the following:

1. Area power outages due to severe weather or other unavoidable and unanticipated causes in which the provider acts according to the site's emergency response plan
2. Refrigerator/freezer failure – unavoidable or unanticipated
3. Transport company error (i.e. FedEx UPS, etc) when a package is not delivered in a timely manner or is otherwise damaged or stored improperly during transit

*Note: Failure to notify the Immunization Division within two hours of vaccine receipt of any errors, shortages, temperature issues or damage to vaccine shipment from distributor does deem this as negligence. Also, failure of the provider to notify the Immunization Division of a change in office hours or address will not be considered a transport company error.*

4. Single dose spoilage not related to improper storage or vaccine that could not be administered once removed from storage (e.g., the parent refused vaccine after the dose was drawn up or Varivax could not be administered within 30 minutes of reconstitution)
5. Extraordinary situations not listed above which are deemed by the Immunization Division to be beyond the provider's control (when reporting wastage of any kind, providers should provide documentation that demonstrates staff's use of the site's emergency response plan)

### Category 2 – Non-compliance

Vaccine loss due to non-compliance is defined as:

1. Publicly funded vaccine not accounted for in the online ordering system, VOMS. This can be reflected by usage data or inventory discrepancies that reflect lost vaccine supply. Examples include the following:
  - a. Failure to document doses administered;
  - b. Failure to report inventory;
  - c. Inaccurate reporting of inventory;
  - d. Failure to report expired/wasted vaccine within 30 days;
2. Publicly funded vaccine knowingly administered to children and/or adults who do not meet Immunization Division eligibility criteria, including the following:
  - a. Administration of VFC or state funded vaccine to patients who are older than 18 years of age (only approved adult providers are permitted to administer public vaccine to individuals 19 years of age or older);
  - b. Administration of publicly funded vaccine to every patient in the practice whether eligible or not (i.e. a provider discontinues purchasing private stocks of vaccine for administration to patients whose insurance covers immunizations.);
  - c. Administration of publicly funded vaccine in lieu of privately purchased vaccine because the reimbursement rate of the insurance company is low;
  - d. Administration of publicly funded vaccine to a child and/or adult who is fully insured (has private insurance that covers vaccinations), including the administration of publicly funded vaccine to a child who has not met their deductible in order to save the parent the cost of the deductible (a child is considered fully insured even when the deductible has not been met); or
  - e. Administration of publicly funded vaccine to a child even though the insurance company provides a maximum amount of reimbursement for immunizations for the year (upon reaching the maximum amount, the child is then eligible for VFC vaccines in a FQHC/RHC or local health department with a Delegation of Authority (DOA) is then eligible for state-funded vaccine in any other Indiana VFC providers' office.

3. Accepting reimbursement, above and beyond the allowable administration fee, from patients and/or insurance companies for publicly funded vaccines as evidenced by:
  - a. Administering publicly funded vaccine and subsequently billing the insurance for the cost of the vaccine;
  - b. Charging the patient for the cost of the vaccine;
  - c. Directly charging a Medicaid-eligible patient ANY fee.

### Category 3 – Negligence

Negligence is defined as loss of vaccine on the part of the provider/clinic staff. The following situations qualify in this category:

1. Vaccine stored improperly (i.e. refrigerating vaccine that should have been frozen, or freezing vaccine that should have been refrigerated).
2. Using dorm style refrigerators or using improper refrigeration unit to store vaccine.
3. Vaccine left out of refrigerator or freezer and/or failure to store vaccine promptly upon arrival.
4. Refrigerator or freezer unplugged or electrical service interrupted (circuit breaker).
5. Door of refrigerator or freezer left ajar resulting in unit temperature outside the acceptable range.

*Note: Whenever the viability of ANY vaccine is in question due to improper or questionable storage and handling, all providers must first move the vaccine in question to a unit that can maintain temperatures within the required range, quarantine the vaccine and mark "do not use" and then contact the vaccine manufacturers to determine each vaccine's viability. Some vaccines will be simply short-dated and will not require discarding.*

6. Improper maintenance of recommended refrigerator and freezer temperatures resulting in vaccine spoilage, including prolonged storage of vaccines when out of range temperatures are recorded (e.g., failure to respond to temperature alarms)

*Note: Temperatures recorded on temperature logs will be considered official in making vaccine viability decisions. Also, a thermometer's margin of error will not be considered when temperatures are recorded below 36°F or 2°C for refrigerators and at or above 6°F or 15°C for freezers.*

7. Not having correct/certified data loggers and/or placing them incorrectly in each vaccine refrigerator and freezer compartment.
8. Failure to properly read and record refrigerator(s) and freezer(s) temperatures, and/or failure to take immediate corrective actions when temperatures are determined to be out of required range.
9. Pre-drawing or pre-constituting vaccine, then not administering in accordance with the vaccine manufacturers/CDC recommendations.
10. Not requesting prior approval from the Immunization Division for transporting vaccines and/or transferring vaccines inappropriately, thereby potentially not maintaining the cold chain.

11. Failure to notify the Immunization Division within two hours of vaccine receipt of any errors, shortages, temperature issues or damage to vaccine shipment from distributor.
12. Failure to notify the Immunization Division when provider office hours change or the provider moves, resulting in vaccines being undeliverable and consequently becoming non-viable.
13. Situations in which healthcare providers must re-vaccinate due to failure to keep vaccine viable (temperatures out of acceptable range) or an administration error (incorrect vaccine, wrong age, improper administration).

*Note: Provider may be responsible to re-vaccinate the patient with privately purchased vaccine.*

14. Ordering habits resulting in excess inventory or overstock that leads to expiration of vaccines (i.e., maintaining an inventory of more than 90-days inventory)
15. Failure to follow an emergency response plan.
16. Discarding ANY vaccine prior the manufacturer' stated expiration date (e.g., discarding vaccine in a multi-dose vial 30 days after the vial is first used).
17. Vaccine expired due to failure of the provider to notify the Immunization Division three month (90 days) prior to expiration date so that vaccine can potentially be transferred.

*Note: Properly reporting short-dated doses within 90 days prior to expiration does not guarantee transfer out. Also, late reporting of short-dated vaccine (less than 60 days until expiration) can be considered vaccine wastage.*

18. Failure to rotate vaccine stock and administering longer dated vaccine before short-dated doses.
19. Poor accountability processes when vaccines cannot be located or accounted for or are missing from provider inventory. The Immunization program determines the provider did not make every effort to follow required accountability and/or storage and handling procedures resulting in lost or missing vaccine or the provider is repeatedly unable to reconcile the clinic's vaccine inventory with vaccine use.

The Indiana Immunization Division may withhold vaccine orders until improved accountability is demonstrated by the provider office. If accountability for expired, spoiled and/or wasted public doses does not improve, dose for dose replacement of those lost doses with private stock vaccine will be required. All doses must be recorded in CHIRP and reported to CDC through the Returns/Wastage reporting process. Depending on the severity of the issue, the provider's ordering privileges may be suspended until there is an investigation or mandated educational visit by the Immunization Division, and the provider is cleared to receive vaccine again.

### **Vaccine Loss and Wastage Reporting**

**All providers collaborating with the Immunization Division to vaccinate the citizens of Indiana are required to document and report ALL incidents of vaccine loss and wastage.** Providers must complete a Vaccine Return transaction in the Vaccine Ordering Management System (VOMS), when available, or submit a paper form (State Form 54052) within 30 days of the vaccine loss:

*All vaccine losses due to expired or non-viable vaccines must be returned to McKesson for proper tax credits, with the exception of opened multi-dose vials or broken or compromised vials/syringes with needles attached. These doses*

*should be appropriately documented in VOMS as Wastage and then discarded in a container. See Policy 17 Managing Vaccine Returns for special guidance on completing vaccine returns.*

*sharps*

**Providers are no longer able to submit vaccine returns in VTrckS. Return submissions through VOMS or State Form 54052 are the only acceptable methods.**

### **Vaccine Loss and Wastage Reimbursement**

In accordance with the 2017 Provider Agreement, all providers signed that he/she understands that "ISDH has the right to require dose for dose replacement of all publicly funded vaccine lost due to mismanagement". The Indiana Immunization Division will require providers to replace vaccine that has been wasted due to negligence or failing to correctly store or handle vaccine beginning July 1, 2012, excluding influenza vaccines.

The Immunization Division will review all instances of vaccine loss or wastage of publicly funded vaccine on a case-by-case basis to determine whether restitution will be required or if extenuating circumstances prevail. This review will help determine whether negligence was involved. If negligence is found, the provider will be asked to make restitution in the form of a dose for dose replacement for any doses that have been lost due to the provider's failure to properly receive, store or appropriately administer vaccines. Providers must send receipts for the replacement doses they have purchased to the Immunization Division within 90 days of the event occurrence.

The Immunization Division will assess the provider's annual ordering distribution totals for all publicly funded vaccine and will require providers to make restitution for any doses that equal an amount that is over 5% of the total distribution for the previous calendar year.

The following guidelines are followed if a provider is asked to reimburse the Immunization Division for wasted/expired doses of vaccine.

1. If negligence is found and restitution is necessary, the Immunization Division will send the provider a letter and invoice for any vaccine loss or wastage.
2. All provider's who have been required to provide restitution must make arrangements with the appropriate vaccine manufacturers to privately purchase replacement doses of vaccine, as instructed by the Immunization Division. All replacement doses should have at least a 1-year expiration date.
3. Once the replacement doses have been purchased, the provider must submit a copy of the invoice, showing the vaccines purchased, lot number(s), and the number of doses purchased to the Indiana Immunization Division within 90 days of the event occurrence. Proof of payment will also be required.
4. The provider must show that all replacement doses have been transferred appropriately into the provider's publicly funded inventory and that the privately purchased replacement vaccine is used to vaccinate **only eligible patients**. These doses should be entered into the state's immunization registry, CHIRP. The Immunization Division may ask to see records documenting administration of these replacement doses to eligible children.

Depending on the severity of the issue, the provider's ordering privileges may be suspended until there is an investigation or mandated educational visit by the Immunization Division, and the provider is cleared to receive vaccine again.

### **Appeals Policy**

Each provider is entitled to an administrative hearing on this matter. A written request must be filed with Indiana's Immunization Division within ten (10) business days of receipt of this notice.

All requests for an administrative hearing must meet the following criteria:

1. The request must be addressed to:

Director of the Immunization Division  
Indiana State Department of Health  
2 N. Meridian Street 3N-22  
Indianapolis, Indiana 46204

2. The request must outline the reason that the vaccine was wasted.
3. The request must contain a corrective action plan that will ensure that future wastage will not occur.
4. The request must be signed by the medical officer registered with the Indiana Immunization Division.

**Procedure Details**

*Step 1) At the end of each calendar year, the Immunization Division will calculate each provider's annual ordering distribution totals for all publicly funded vaccine, as based on all orders processed in VTrcks. The totals will include the prior calendar year for a period of 12 months.*

<b>For Calendar Year - 1/1/XXXX -12/31/XXXX</b>	
<b>Provider PIN #</b>	<b>Total \$\$</b>
<u><b>MXXLXX</b></u>	<u><b>\$83,030.9000</b></u>

*Step 2) On a monthly basis, all Vaccine Return transactions will be reviewed and approved in VOMS by provider PIN # and total vaccine loss.*

<b>Pin #</b>	<b>Provider Name</b>	<b>Vaccine Returned</b>	<b>Reason</b>	<b># of Doses</b>	<b>\$/per Dose</b>	<b>Loss</b>
<b>MXXLXX</b>	XYZ Medical Center	DTaP - Infanrix	Expired	26	\$14.85	\$386.10
<b>MXXLXX</b>	XYZ Medical Center	IPV - IPOL	Expired	10	\$11.97	\$119.70
<b>MXXLXX</b>	XYZ Medical Center	MCV4 - Menactra	Expired	135	\$82.12	\$11,086.20
<b>MXXLXX</b>	XYZ Medical Center	PCV13 - Prevnar	Expired	40	\$97.21	\$3,888.40
<b>Total</b>						<b>\$15,480.40</b>

*Step 3) On an annual basis, the Accountability Coordinator or Director of Vaccine Operations will review total vaccine wastage, excluding influenza vaccine, by provider PIN # and then compare this with the total distribution totals to determine the wastage rate. This rate, with the corresponding amount owed (if over the wastage threshold for that year), will be communicated via a letter from the Division Director to each provider.*

2016 Total Distribution = \$83,030.90

2016 5% Threshold = \$4,151.55

2016 Vaccine Wastage annually = \$15,480.40

2016 Total Percentage Vaccine Wastage = 19%

*All providers will be assessed on an annual basis as to whether or not he/she has had wastage that reached the total annual wastage allowance of 5%. If the provider exceeds the total maximum annual percentage of wastage, a letter will be sent to inform them of the excessive loss or wastage. If a provider's wastage reaches between 1.25% and 5% of the total distribution for the previous year, a warning letter will be sent to inform the provider that wastage levels last year almost exceed the annual allowance. This will provide an opportunity for the provider to consult with the Immunization Division for assistance in managing vaccine inventory and ordering. If this wastage amount exceeds 5% of the total distribution for the previous year, the Indiana Immunization Division will enforce a dose for dose reimbursement.*

*Any provider exceeding the 5%, at any point throughout the year, will continue to have to reimburse, dose for dose any vaccine loss or wastage in the remainder of that same calendar year.*

## References & Resources

Vaccine Return Form (State Form 54052)

Centers for Disease Control and Prevention. Vaccines for Children Operations Guide. Revised January 2017 2016

Centers for Disease Control and Prevention. (13<sup>th</sup> Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015. <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

## Revision History

07/17/2012, Created

03/01/2014, Revised

11/19/2014, Revised

04/01/2017, Revised

01/01/2018, Revised



<b>Policy &amp; Procedure Title</b>	Provider Vaccine Returns	<b>Issuing Date</b>	7/17/2012
<b>Policy &amp; Procedure Number</b>	17	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McKeonick</i>		

### Policy & Procedure Summary

The Immunization Division has a policy for management of incidents that result in the loss or wastage of any publicly funded vaccine. Providers are also required to document and report all incidents of vaccine loss or wastage. The policy applies to all providers who are actively enrolled in any Indiana publicly funded vaccine program.

### Policy Statement

**All providers collaborating with the Immunization Division to vaccinate the citizens of Indiana are required to document and report all incidents of vaccine loss and wastage.** Providers must complete a Vaccine Return transaction in the Vaccine Ordering Management System, VOMS (when available), within 30 days of the vaccine loss. Currently, all returns are completed via a paper form (State Form 54052) and faxed to 317-972-8964. Providers will also need to mark doses as wasted in CHIRP.

The Indiana Immunization Division defines vaccine loss or wastage as any incident or vaccine loss involving 5 or more doses that prevents a vaccine from being properly administered. **This includes all spoiled, expired, or wasted vaccines.** It includes:

**Spoiled** – vaccine that has been spoiled as a result of the following:

- Natural disaster/power outage
- Refrigerator too warm or too cold
- Failure to store properly upon receipt
- Vaccine spoiled in transit
- Mechanical failure of storage unit

**Expired** – non-viable vaccine in its original container (vial or syringe) that was not administered prior to the expiration date. This includes vaccine that was ordered but unable to be administered or transferred prior to the expiration date.

**Wasted**- any vaccine that is unaccounted for which can be due to vaccine ordered but not delivered or loss of vaccine due to poor record keeping

- Vaccine drawn into the syringe but not administered (e.g., the parent refused vaccine after the dose was drawn up or a dose of Varivax could not be administered within 30 minutes of reconstitution).
- Vaccine in open vial but doses not administered
- Compromised vial (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

The following wasted vaccine products should NEVER be returned to McKesson and should be disposed of properly by the provider. These vaccines should be reported to the Immunization Division but should NEVER be returned to McKesson.

1. Broken vial/syringe
2. Vaccine drawn up into syringe, but not administered
3. Lost or unaccounted vaccine

4. Non-vaccine product (e.g. tuberculosis skin tests, IG, HBIG, diluents)
5. Open multi-dose vial but all dose not administered

**Procedure Details**

The Immunization Division is in the process of converting vaccine returns to VOMS. In the interim, providers with vaccine returns must submit a paper Vaccine Return (State Form 54052) via email to [vaccine@isdh.in.gov](mailto:vaccine@isdh.in.gov) or fax a copy to 317-972-8964.

Once access to the Vaccine Return functionality of VOMS has been granted, providers can electronically submit returns using the following steps:

Step 1) Once a vaccine has expired or has been determined to be a spoiled dose, providers should remove all vaccines from the storage unit and complete a Vaccine Return transaction in the Vaccine Ordering Management System, VOMS. All non-viable vaccine, including influenza, must be documented in the system.

A. Log into CHIRP and using the Navigation Menu, click on **Orders/Transfers Menu** and then the **Vaccine Return** button to open the **Vaccine Return** screen.

Current Order/Transfer List						
Inbound Orders						
Select	Order Number	PIN	Submit Date	Approval Date	Status	
Backordered Orders						
Select	Order Number	PIN	Submit Date	Backorder Date		
Denied Orders						
Select	Order Number	PIN	Submit Date	Denial Date		
Inbound Transfers						
Select	Transfer Number	PIN	Submit Date	Sending Organization (IRMS)/Facility		Status
Outbound Transfers						
Select	Transfer Number	PIN	Submit Date	Receiving Organization (IRMS)/Facility		Status
Rejected Transfers						
Select	Transfer Number	PIN	Submit Date	Receiving Organization (IRMS)/Facility	Reject Date	Rejected By Status

B. The Vaccine Return Page will display all wasted/expired/spoiled vaccine you identified in the Reconciliation screen.

C. Type the **Return Quantity**. Select Receiving Organizing (IRMS) and Facility.

D. Click on the **Submit and Print Vaccine Return** button. A new web page will open showing **Vaccine Return Packing List**.

E. Once you have submitted the vaccine return, ISDH and the State Approvers looks at the return and approve the vaccine return. Once the return is approved, a shipping label will be emailed.

1. If the provider has not received the return label from McKesson within 3 days, contact the Immunization Division so that a 2<sup>nd</sup> request can be made.

Step 2) Once return label is received, ship vaccines back to McKesson via UPS.

A. Providers can simply hand the labeled box of expired vaccine to the UPS driver at the next pick-up.

1. It is not recommended to call UPS for a pick-up as some charges may apply.

**References & Resources**

Centers for Disease Control and Prevention (CDC), Centralized Vaccine Distribution Guide. March 2012

**Revision History**

07/17/2012, Created

03/01/2014, Revised

02/15/2016, Revised

04/01/2017, Revised

<b>Policy &amp; Procedure Title</b>	Borrowing Vaccine	<b>Issuing Date</b>	07/17/2012
<b>Policy &amp; Procedure Number</b>	18	<b>Revision Date</b>	11/19/2014
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Policy & Procedure Summary

The Indiana Immunization Division and the Centers for Disease Control and Prevention's (CDC) expectation is that enrolled providers maintain adequate inventories of vaccine to administer to both publicly funded and privately insured children. The Immunization Division permits the occasional borrowing of vaccine from the appropriate supply, public or private, in order to prevent missed opportunities for vaccinating. This borrowing must meet specific reason requirements and be documented and submitted monthly.

### Policy Statement

Providers that care for publicly funded and privately insured children must maintain two separate inventories of vaccines, one inventory of privately purchased vaccine for the provider's privately insured children and the inventory of publicly funded vaccine supplied to the provider for administration to VFC and state vaccine-eligible children.

- Borrowing between the two inventories of vaccines may occur in specified situations but must be rare.
- Publicly funded vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory.
- The provider must assure that borrowing publicly funded vaccine will not prevent a VFC-eligible child from receiving a needed vaccination.
- Documentation must occur when any vaccine is borrowed regardless of inventory origin.
- The Borrowing Report must be completed in all settings for all vaccine borrowed, and must specify an approved reason for vaccine borrowing:
  - Vaccine may be borrowed due to unforeseen order/shipping delay or circumstance such as delayed vaccine shipment or vaccine spoiled in-transit to provider.
  - Vaccine from the incorrect supply may be administered to a child needing that immunization if the vaccine will expire within one month, such as vaccinating a privately insured patient with a VFC dose that will expire next week. This policy is designed to prevent wastage of both private and publicly purchased vaccine. The dose may then be replaced with a longer-dated dose from the other stock.
  - Vaccine from the incorrect supply may be administered to a child if the dose cannot be used for the intended population prior to expiration, such as administering a short-dated private purchase adult varicella vaccine to a VFC eligible child. The provider could then move a dose of publicly purchased varicella to their private stock.
  - Vaccine from the incorrect supply may be administered to a child if the provider has run out of vaccine from the correct supply between orders. This is meant to be used in rare occasions to prevent a missed vaccination opportunity.
  - A VFC dose can be borrowed to replace a private stock dose if a child was immunized with private stock and the insurance plan refuses to cover the vaccination.

In all circumstances, the provider must document the type of vaccine borrowed, from which stock, the patient's name and DOB, the date the dose was administered, an approved reason for borrowing, and the date the corresponding replacement dose was returned to the appropriate stock.

*Please note: for seasonal influenza vaccine, providers may use private stock seasonal influenza vaccine to vaccinate VFC eligible children if VFC seasonal influenza stock is not yet available. Those private stock doses used on VFC eligible children can later be replaced when VFC stock becomes available. This one-directional borrowing exception is unique to seasonal influenza vaccine. Borrowing from VFC seasonal influenza stock to vaccinate fully insured children is not permissible since there is no guarantee that the influenza vaccine can be replaced within the same season.*

Completed Vaccine Borrowing Reports must be submitted monthly to the Immunization Division, and borrowing activities will be monitored as part of the VFC provider site visit. Follow-up and/ or corrective actions may be taken when excessive or inappropriate borrowing activities are noted.

**Procedure Details**

Step 1) Provider borrows a dose of vaccine from one stock to administer to a child who is eligible to receive vaccine from the other stock.

Step 2) The Borrowing Report MUST be completely filled out for each borrowing occurrence.

A. Each vaccine a child receives must be listed on a separate row.

Step 3) As soon as the borrowed dose of vaccine is replaced in the appropriate vaccine stock, the provider will enter the date on the Borrowing Report.

Step 4) The provider will submit a copy of the Borrowing Report to the Immunization Division monthly and will make the report available to the Immunization Division during the site visit. Reports should be maintained for three years.

Date Range of Vaccine Reporting (date of first dose borrowed to date of last dose borrowed): 11/01/2014 to 11/30/2014

VACCINE BORROWING REPORT TABLE						
A Vaccine Type Borrowed	B Stock Used (VFC or Private)	C Patient Name	D Patient DOB (XX/XX/XXXX)	E Date Dose Administered (XX/XX/XXXX) AND Lot#	F Reason Appropriate Vaccine Stock was not Used (Use legend code on page 1 to mark one reason for each dose borrowed)	G Date Dose Returned to Appropriate Stock (XX/XX/XXXX) AND Lot #
DTap	VFC	Elsa Princess	05/03/2014	11/05/2014 AC14B177AA	1- Private vaccine shipment delay	11/12/2014 C4214BA
MMR	VFC	Anna Princess	11/25/2009	11/05/2014 J003790	1- Private vaccine shipment delay	11/12/2014 J013431
Varicella	Private	Shirley Temple	10/31/2013	11/10/2014 J009004	4- Private dose was short dated	11/12/2014 K002920
I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.						
Provider Name: Dr. Sam Who			Provider Signature: <i>Dr. Sam Who</i>			Date: 11/30/2014

## **References & Resources**

Centers for Disease Control and Prevention (CDC) Borrowing Report

Centers for Disease Control and Prevention. VFC Operations Guide, January 2017.

## **Revision History**

07/17/2012, Created

08/28/2014, Updated

11/19/2014, Revised

<b>Policy &amp; Procedure Title</b>	Vaccine Transfers	<b>Issuing Date</b>	7/17/2012
<b>Policy &amp; Procedure Number</b>	19	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Policy & Procedure Summary

The Indiana Immunization Division holds providers accountable for all publicly funded doses ordered. Providers should order vaccine one time each month and should only maintain a 4-6 week inventory of vaccines. When providers determine that there is an excess of vaccine, providers should first run a reminder recall in CHIRP to determine patient population in need of vaccine. If the provider still has an excess of vaccine they have to make arrangements with the Immunization Division to have vaccines transferred to another enrolled provider. Transfers should only occur in rare situations.

### Policy Statement

This policy supersedes all policies previously issued by the Indiana Immunization Division addressing the transport of publicly funded vaccine. It replaces the following policy:

Title of Policy: **Vaccine Transfers/Return**  
 Policy Number: II-04  
 Creation Date: Apr 1, 2006  
 Revision Date: Mar 1, 2011

Providers should manage their vaccine inventory to determine when there are short-dated doses they may be unable to administer before the expiration date. Vaccine transfers should also be facilitated in the event of a Provider Disenrollment.

When short-dated or excess vaccine needs to be transferred, providers should provide the following information to the Field Representative and/or Accountability Coordinator 90 days prior to the vaccine expiration date:

- Provider's name, PIN number and contact information
- Type of vaccine, vaccine brand name, vaccine National Drug Code (NDC), lot number, expiration date and number of doses.
- Any special circumstances, such as limited hours or dates available, closing date, etc.

The Immunization Division will maintain a list of all available vaccines and the Vaccine Management staff will compare this list to incoming vaccine orders to facilitate vaccine transfers. When appropriate, the Accountability Coordinator will alert the respective Field Representative to complete the vaccine transfer. The appropriate forms and instructions will be forwarded to all parties involved. **All transfer of vaccine between clinics/providers must be authorized by the Immunization Division.**

In the event that a provider is withdrawing from the Publicly Funded Vaccine Program, the Division will assist with the transfer of all applicable vaccine to another enrolled provider, as well.

### Procedure Details

*Step 1) Provider shall notify the Field Representative and/or the Accountability Coordinator of any excess vaccine available for transfer at least 90 days prior to the vaccine expiration date.*

- A. If the provider is withdrawing, the provider should contact the Immunization Division a minimum of 30 days in advance.

*Step 2) Provider will provide all vaccine information to the Immunization Division.*

*Step 3) The Accountability Coordinator will notify the Field Representative of any necessary vaccine transfers.*

*Step 4) All Transfer forms will be provided to the Vaccine Management staff by the Field Representative, once the transfer has been completed. The Transfer transaction will then be processed in VOMS within 7 business days.*

### **References & Resources**

Vaccine Transfer Form (State Form 54658)

### **Revision History**

07/17/2012, Created

03/01/2014, Revised

04/01/2017, Revised



<b>Policy &amp; Procedure Title</b>	Fraud and Abuse	<b>Issuing Date</b>	7/17/2012
<b>Policy &amp; Procedure Number</b>	20	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>	<i>Dave McConnick</i>		

### Policy & Procedure Summary

The purpose of this policy is to provide programmatic direction for the prevention of fraud and abuse of federal and state-funded vaccines. Vaccines supplied through the Indiana State Department of Health (ISDH) Immunization Division are funded through the federal Vaccines for Children (VFC) Program, Section 317 federal program, and state funds.

### Policy Statement

All providers administering publicly funded vaccines must complete and sign the Immunization Provider Profile and Provider Agreement, as well as complete the Cold Storage Unit Certification in VOMS during the Annual Provider Recertification.

### Definitions

Fraud is defined at 42 § CFR 455.2 as “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 is defined at 42 § CFR 455.2 as “provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to 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. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.”

### Procedure Details

#### *Step 1) Compliance Assessment*

In order to receive publicly funded vaccines, enrolled providers must agree in writing to follow established Immunization Division vaccine usage, inventory management, data collection and reporting requirements. Every vaccine order submitted by a provider is compared to information disclosed in the most recent Provider Profile. The Provider Profile is a self-completed population estimate of the number and type of publicly funded vaccine recipients that the provider expects to see during a calendar year. The Provider Profile is completed on an annual basis or as needed when changes occur in the patient population. Annual vaccine usage data are routinely entered into a vaccine management system developed by the Centers for Disease Control and Prevention (CDC).

Vaccine orders exceeding annual profiled estimated usage are flagged by the vaccine management system. Immunization Division staff will contact those providers exceeding profile amounts to determine if distribution of additional vaccine is justified, or if adjustments to the profile are needed. Additionally, Immunization Division staff will validate submitted provider profile data by comparing it to current usage data. Unjustified, excessive and/or repeated discrepancies between provider profile data, vaccine orders, and vaccine usage will be evaluated and referred for further investigation.

#### *Step 2) Fraud and Abuse Investigation*

The following procedure shall be implemented whenever fraudulent use of publicly funded vaccines is suspected. Under Indiana law, fraud and/or abuse is defined as “intentional or unintentional deviation from the signed Provider Agreement with the Immunization Division. Each case will be evaluated and referred to the proper authority or authorities for investigation. In the event that fraudulent use of publicly funded vaccines is suspected, immediately report suspicion of fraud and/or abuse of state supplied vaccines to the Accountability Coordinator or designee by calling the ISDH Immunization Division at 1-800-701-0704 and ask to speak to the Accountability Coordinator.

Upon notification of suspected fraud and/or abuse of publicly funded vaccines, the Accountability Coordinator will:

- A. Immediately collect and prepare written documentation of the suspected fraud and/or abuse of publicly funded vaccines. Documentation will include the provider's name, address, medical license number, PIN number, date(s) of event, manner in which the information was obtained, the name of the individual reporting the suspected fraud/abuse, and a telephone number at which the individual reporting the suspected fraud/abuse can be reached. Gathered information will also include a copy of the Immunization Provider Profile form, Provider Agreement form, provider's vaccine order history, vaccine distribution reports from the vaccine management system, and Doses Administered reports. Documentation should correspond to the time frame that fraud and/or abuse is suspected. The listed forms will be forwarded to the Office of Legal Affairs. Under the guidance of the Office of Legal Affairs, the following steps may be taken:
  - a. The Accountability Coordinator will notify the relevant agencies supported by the finding documentations. This may include but not be limited to Medicaid or Medicaid contractor designee, Medicaid Fraud Unit (MFCU), State Department of Insurance (DOI), and the Office of Inspector General (OIG).
  - b. The Division Director will immediately notify the Centers for Disease Control and Prevention (CDC)
  - c. The Accountability Coordinator will immediately contact the Indiana Professional Licensing Agency to verify the validity of the suspected abuser's medical license.
- B. Remain available during the case review to respond to follow-up questions, provide additional documentation, and/or participate in interviews as requested.
- C. Upon resolution of any formal review or investigation, the Immunization Division will develop an appropriate educational training plan for the provider in question to ensure proper administration and management of publicly funded vaccines. This may include, but is not limited to:
  - a. VFC enrollment training
  - b. Requiring provider to enroll (if not already) and use CHIRP for ordering and managing vaccines.
  - c. More frequent reporting of requested data and/or information to the Immunization Division
  - d. Change in ordering cycle
  - e. Limited vaccine ordering
- D. Upon receipt of the written documentation, Immunization Division Policies and Procedures Committee will review the case. If abuse and/or fraud are suspected, they will refer it to the appropriate agency for investigation, such as the State of Indiana Office of Attorney General and the Medicaid Fraud Unit.

### *Step 3) Resolution*

A provider determined to be engaged in fraud and/or abuse will be inactivated (suspended) from the participating in any publicly funded vaccination program. Reinstatement in the program will be contingent on the outcome of proceedings conducted by the Attorney General's (AG) office or the Office of the Inspector General (OIG). Final resolution may include, but not limited to, the following interventions:

- Remedial Education
- Recoupment of funds
- Reimbursement of vaccines
- Reinstatement without penalty
- Referral for criminal prosecution
- Civil resolutions

If the reported or suspected violator is one of the non-Medicaid providers who are enrolled in the Program, the Immunization Division will evaluate the validity of the report and if it appears to be of a criminal intent, to report all findings to the Office of the State Attorney General.

*Step 4) Medicaid Referral*

Suspected fraud or knowledge of fraud and abuse, including but not limited to the false or fraudulent filings of claims and the acceptance or failure to return money allowed or paid on claims known to be fraudulent must be reported to Indiana Medicaid or other designees.

1. Suspected PROVIDER fraud must be reported to:

- The Office of Medicaid Policy and Planning
- The Indiana Medicaid Fraud Control Unit (MFCU – within the Attorney General's Office)
- Surveillance and Utilization Review Unit (SUR) within the Office of Medicaid Policy and Planning.

2. Suspected MEMBER fraud must be reported to:

- Office of Medicaid Policy and Planning
- The Surveillance Utilization Review Unit,
- The Bureau of Investigation (within the Division of Family Resources)
- The Office of the Inspector General.

*Step 5) Responsibility*

The Immunization Division will develop training modules to educate investigative and enforcement agencies regarding the unique features and structure of the program, including the program integration of public purchased vaccines for Medicaid, the underinsured, Alaskan Natives and American Indians, and the uninsured populations.

The Immunization Division will work in collaboration with internal counsel and will seek input from State investigative and enforcement agencies to develop effective protocols for reporting allegations of fraud; share information and collaborate with all involved parties to determine the best course of action to pursue for suspected cases of fraud; and to educate staff regarding how to properly obtain and document information when an allegation of fraud and/or abuse is reported and how to appropriately gather additional information.

Information about parties who are excluded by the Office of Inspector General is found at their website <http://www.oig.hhs.gov/fraud/exclusions.html> on the List of Excluded Individuals and Entities (LEIE). Information about parties who have been placed in non-payment status by all Executive departments (including OIG's) is found at the General Services Administration website <http://epls.arnet.gov> . The OIG's LEIE contains approximately 17,000 names; the GSA list contains approximately 30,000 names. The OIG also issues monthly reports on its website.

A member of the Immunization Division staff will review these lists each month and cancel the enrollment of any providers identified on the list. Any publicly funded vaccine in the provider's possession should be collected and the provider should be prohibited from receiving future shipments until the exclusion is lifted. If the exclusion is lifted, the individual or entity should be required to reapply for program participation. Any allegations of fraud and abuse in the private sector will require assistance from the State Department of Insurance to determine whether there have been criminal violations of applicable state law including commercial health care fraud and abuse and pursue prosecution or coordinate with the Office of the State Attorney General in pursuant of prosecution.

**References & Resources**

Immunization Fraud and Abuse Program Contacts

Dave McCormick	Immunization Division Director	317.233.7010
Jill King	Immunization Division Deputy Director	317.233.8460
Kevin McCormack	Business Manager	317.233.7758

**Revision History**

07/17/2012, Created  
03/01/2014, Revised  
04/012017, Revised

**Policy & Procedure Title** CHIRP-Record Inactivation  
**Policy & Procedure Number** 21  
**Policy & Procedure Approval Authority** *Dave McConnick*

**Issuing Date** 11/1/2012

**Revision Date** 01/01/2018

### Policy & Procedure Summary

The Children and Hoosiers Immunization Registry Program (CHIRP) is the immunization registry used for the state of Indiana. Many initiatives can be used from the data contained in CHIRP to improve immunization rates throughout the state. Inactivation of a record in CHIRP must be performed consistently among users of CHIRP to ensure the accuracy of the data utilized in these endeavors not only within the state of Indiana, but nationwide. According to guidance set forth by the American Immunization Registry Association (AIRA), patients should be inactivated in immunization registries for specific, defined reasons that should be used consistently by all registry users.

### Policy Statement

Activities such as immunization coverage rates and reminder/recall initiatives are crucial to increasing immunization rates and therefore decreasing the incidence of vaccine-preventable diseases. These activities must be performed using the most accurate information available from immunization registries. The purpose of this policy is to ensure providers are using consistent criteria for the inactivation of a patient's record in order to provide the most accurate information possible from the Children and Hoosiers Immunization Registry Program (CHIRP).

### Procedure Details

Each user must be granted access in CHIRP to perform the activity of inactivation of a record, regardless of the reason for inactivation. If a user has a need for inactivating records, the CHIRP helpdesk (888-227-4439) may be contacted to request this access.

### Examples of when it is appropriate to inactivate a patient in CHIRP

- Lost to Follow-up. Three documented failed attempts at contacts over a period of time, using phone, mail, or listed family physician. At least one attempted contact must be by mail.
- No longer a patient. If the relationship between a provider organization and a patient is terminated because the patient has gone or transferred to another provider organization.
- No address - no vaccination. CHIRP has never received an address and has never received vaccination information about an individual.
- Moved out of the area. Verification by school, parents, neighbor or friend that a family has moved out of the providers "practice locale" or county.
- Deceased-confirmed death of a patient.

Whenever there is a unique situation or assistance in determining the conditions of inactivation of a record, please contact the CHIRP helpdesk for guidance (888-227-4439 or [chirp@isdh.in.gov](mailto:chirp@isdh.in.gov)).

## References & Resources

American Immunization Registry Association (AIRA) (2015). Replacement of 2005 Guidelines. Recommendations of the American Immunization Registry Association (AIRA) Modeling of Immunization Registry Operations Work Group (MIROW) [http://www.immregistries.org/resources/FINAL\\_AIRA\\_PAIS\\_Guide\\_FullFormat.pdf](http://www.immregistries.org/resources/FINAL_AIRA_PAIS_Guide_FullFormat.pdf)

## Revision History

11/01/2012, created  
01/01/2018, updated

<b>Policy &amp; Procedure Title</b>	Administration of Nonviable or Expired Vaccine	<b>Issuing Date</b>	11/19/2014
<b>Policy &amp; Procedure Number</b>	22	<b>Revision Date</b>	04/01/2017
<b>Policy &amp; Procedure Approval Authority</b>	Dave McConnick		

### Policy & Procedure Summary

Refrigerators and freezers used to store publicly provided vaccines must be capable of reaching and maintaining the required temperatures established by the vaccine manufactures, the Centers for Disease Control and Prevention (CDC), and the National Institute of Standards and Technology (NIST) standards. If vaccine shipping or storage temperatures are recorded **above** or **below** the required temperature range, do not use the vaccine until the viability (potency) of the vaccine has been established by the vaccine manufacturer.

Vaccines that have been deemed nonviable (to have lost potency) due to temperature excursions or vaccines beyond the expiration date should never be administered. If these vaccines are administered inadvertently, doses are not counted as valid and should be repeated. All patients, not only those who received publicly-funded doses, should be revaccinated. Serologic testing to confirm a vaccine response may be performed for certain vaccinations. This practice; however, is generally not recommended when the viability is in question due to a temperature excursion.

The Indiana State Department of Health (ISDH) Immunization Division will make every effort to work with the enrolled providers to address the administration of the nonviable vaccines while balancing clinic needs, cost to patients, providers and health plans, the risk of illnesses or outbreaks, and overall effect on public health.

In the event that a large number of patients have received doses of nonviable vaccine, providers will be placed on "suspend" status and will be terminated for failure to comply with any corrective action plans that are issued.

### Policy Statement

All providers enrolled with either the Vaccine(s) for Children (VFC) and/or the Adult Immunization Program must comply with this policy. Providers must also comply with the other ISDH Immunization Division policies for receipt, storage and proper management and handling of publicly funded vaccine.

#### *Determining the Need for Revaccination*

In instances where vaccine potency is lost due to improper storage and handling, the decision to issue a recall notification and/or to revaccinate will be made by the Indiana State Health Commissioner or designee and the Immunization Division Director or designee. All final decisions regarding recall notification and/or revaccination will be sent in writing to the responsible clinician and/or medical director at the facility where the vaccines were administered. Upon receipt of this notification, it will be the responsibility of the provider to determine the identity the names and contact information for all patients in need of revaccination.

In isolated situations where expired doses of vaccine are administered, it will be the responsibility of the responsible clinician and primary vaccine coordinator to revaccinate patients per the vaccine administration guidelines in this policy.

#### *Vaccine Administration*

All patient(s) should be revaccinated during the clinic visit, if there is viable vaccine available and the error is caught during the clinic visit. If the error is not caught during the clinic visit, the vaccine doses should be repeated as soon as possible. If the nonviable or expired dose is a live virus vaccine, providers must wait at least 4 weeks after the previous dose was given to repeat vaccination.

#### *Assistance Provided by ISDH*

The ISDH Immunization Division will offer assistance to enrolled providers to ensure patients are revaccinated in a timely manner. This includes, but is not limited to:

- Technical assistance using CHIRP for recall purposes. This includes marking doses as “subpotent” in the registry.
- On-site assistance to review proper vaccine storage & handling policies and procedures
- Technical assistance with placing additional orders for vaccines
- Technical assistance with developing protocols in conjunction with the clinic, pharmaceutical companies, and Centers for Disease Control & Prevention (CDC)
- Technical assistance with drafting written or verbal patient correspondence

The ISDH field representative will reach-out to the local health department in the county where the enrolled provider site is located to inform them of the incident. The local health department may provide assistance as needed.

The ISDH Immunization Division will document the event in PEAR, including resolution of the issue.

### *Serology Titers to Validate Immunity*

The cost of performing serology testing in lieu of revaccination is the responsibility of the enrolled provider site. The ISDH Immunization Division does not offer any technical assistance to conduct post-vaccination serology testing following known temperature excursions.

The ISDH Immunization Division does not recommend serology testing following known temperature excursions. However, an exception could include vaccines for which a series (more than one dose) is indicated and the potency of all doses in the series is questionable. For instance, if an adolescent or adult received three Hepatitis B vaccines during poor storage times, it could be appropriate to give a first potent dose and draw serology tests at the same time. The additional two doses might be waived depending on the test results.

Serology testing exists for some of the vaccines (many are available through clinical labs, but not all). If the provider opts to choose drawing serology titers instead of revaccinating patients, the provider is required to validate the lab is CLIA certified (test is FDA approved and validated by the lab). Providers also need to consider the following:

- 1) No level of circulating diphtheria or tetanus antibodies confers absolute protection. Diphtheria has been reported in persons with high antibody levels.
- 2) An adequate immune response from one component in a combination vaccine is not an indication of the potency of the other vaccine components.
- 3) No data available on obtaining post-vaccine antibody titers for PCV7, MCV4, HPV or Rotavirus vaccines.

### *Provider Responsibility*

If a provider declines or is otherwise incapable to recall patients who received questionable doses, ISDH will request a list of affected patients and, in conjunction with the local health department, will conduct its own recall of these patients. In these instances the provider will be asked to replace the nonviable/expired publicly-purchased vaccine with privately purchased stock. Failure to do so will result in **permanent** termination from all immunization programs with the Indiana State Department of Health.

If a clinic declines to provide a list of affected patients, ISDH will issue a community notice alerting patients that they have received potentially non-viable vaccine at this clinic, and encouraging patients to contact the local health department to explore revaccination. The ISDH may also send notification to the Indiana Attorney General regarding instances of provider non-compliance to ensure the health and well-being of patients is protected.



## References & Resources

Centers for Disease Control and Prevention. (2018) Vaccine Storage and Handling Toolkit, Revised January 2018. <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

Centers for Disease Control and Prevention. (13<sup>th</sup> Edition) Epidemiology & Prevention of Vaccine-Preventable Diseases, Pink Book. Revised 2015. <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Refrigerator/Freezer Temperature Log

## Revision History

11/19/2014, Created


04/01/2017, Revised

Policy &amp; Procedure Title Vaccine Administration

Issuing Date 11/19/2014

Policy &amp; Procedure Number 23

Revision Date 01/01/2018

Policy & Procedure  
Approval Authority


### Policy & Procedure Summary

The Immunization Division has a policy for the safe administration of vaccines that are included in the routine schedules for children & adults. Providers should follow their own internal policies for the administration of vaccines or medications if such a policy is available, and should follow applicable state and federal regulations pertaining to the administration of vaccines. This policy applies to all providers who are actively enrolled in any Indiana publicly funded vaccine program, but does not cover the administration of vaccines outside the routinely recommended schedules.

### Policy Statement

Administering vaccines correctly promotes optimal vaccine efficacy and reduces the chance of an adverse reaction or injury.

### Rights of Medication Administration

When vaccines are administered, the "Rights of Medication Administration" should be applied. These rights include:

- Right patient
- Right vaccine or diluents
- Right vaccine storage and handling
- Right time (the correct age, correct interval, and before vaccine or diluents expires)
- Right dosage
- Right route, needle gauge and length, and technique
- Right site
- Right documentation

### Staff Training & Education

Prior to administering vaccines, all health care providers should receive competency-based training and education on vaccine administration. This includes a skills check for the administration of vaccines. All staff should be oriented to the vaccine formulary used in their practice. Continuing education for staff should be provided as needed to update staff on the use of new vaccines, new schedules and new or revised recommendations.

### Patient Safety & Education

All patients should be screened for contraindications and precautions prior to administering each dose of every vaccine. The CDC's Pink Book (Appendix A) has several tables detailing known contraindications and precautions to receipt of commonly used vaccinations. Several sample screening questionnaires are available from the Immunization Action Coalition at [www.immunize.org/handouts/screening-vaccines.asp](http://www.immunize.org/handouts/screening-vaccines.asp).

The National Childhood Vaccine Injury Act (NCVIA) of 1986 (Public Law 99-660) requires all health care providers who administer vaccinations to provide a copy of the vaccine information statement (VIS) produced by the Centers for Disease Control and Prevention (CDC) to the parent or legal representative of the child the provider intends to vaccinate. A copy of the VIS should be provided *before* the administration of *every* dose of vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) vaccine. If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines. All available VISs can be downloaded from the Immunization Action Coalition at: [www.immunize.org/vis](http://www.immunize.org/vis) or from the Centers for Disease Control & Prevention website at <https://www.cdc.gov/vaccines/hcp/vis/index.html>.

Upon administration of the vaccine, the provider needs to document in the patient's medical record the edition date of the VIS and the date the materials were provided.

The NCVIA also requires health care providers to report suspected adverse events that occur following vaccination to the Vaccine Adverse Event Reporting System (VAERS). This should be done even if there is uncertainty that the vaccine caused the event. The report should include:

- The type of vaccine received
- Timing of vaccination
- Onset date/time and description of adverse event
- Concurrent illnesses and/or medications
- Past history of adverse events following vaccination
- Demographic information about the patient

VAERS forms can be completed online at: <http://vaers.hhs.gov/index>. A paper form is also available on the website which can be mailed or faxed to VAERS

### Infection Control

Health care providers should follow Standard Precautions to minimize the risk of spreading disease. More information on these standards is available at: <http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-gl-standard-precautions.html>. This includes thoroughly washing hands with soap and water or cleansing with an alcohol-based antiseptic before vaccine preparation, between patients and any time hands become soiled. Occupational Safety and Health Administration (OSHA) regulations do not require gloves to be worn when administering vaccines unless the vaccine is likely to come into contact with potentially infectious body fluids or if the person administering the vaccine has open lesions on his/her hands. Gloves, if worn, should be discarded between patients.

Used needles should not be recapped, cut or detached from the syringe before disposal. All used sharps should be placed in a puncture proof container to prevent accidental injury or reuse.

All needle-stick injuries should be washed thoroughly with soap and water and reported immediately to the site supervisor to obtain necessary medical treatment.

### Medical Reactions to Vaccination

Health care providers should have adequate supplies at their location to effectively manage any medical emergencies following routine vaccination. Each provider of immunizations should have an emergency medical management protocol that is signed by the agency Medical Director or Local Health Officer.

An Emergency Kit of medical supplies should include (at a minimum):

Medical Supplies	Medication
Stethoscope	<b>First-Line Medication</b> <b>Epinephrine</b> 1:1000 (i.e., 1 mg/mL) dilution, in ampules, or vials <b>Epinephrine autoinjectors</b> (EpiPen ®) – multiple 0.30 mg – Adult 0.15 mg – Pediatric (for patients < 15 kg or 33 lbs)
Blood Pressure Cuffs – Consider sizes needed for patient population	
Tongue Depressors	
Pediatric & Adult Oral Airways	<b>Second-Line Medication</b> <b>Diphenhydramine (Benadryl)</b> Injectable (50 mg/mL solution) Oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets)
Flashlight	
Tourniquet	
Alcohol Wipes	
Pediatric & Adult Pocket Masks with one-way valve	

Syringes for Epinephrine & Benadryl	
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## Procedure Details for Administering Vaccine

**Health care providers should always review the manufacturer's package insert for additional guidance and information related to the administration of the vaccine.** Vaccines differ in presentation, packaging and instructions for correct administration. The recommended route of administration is based on clinical trials, practical experience and theoretical considerations. This information is included in the manufacturer's product information for each vaccine. Several vaccines are prepared in a lyophilized (freeze-dried) powder that requires reconstitution with a liquid diluent. Vaccines should be reconstituted according to manufacturer guidelines using only the specific diluent supplied by the manufacturer for that vaccine.

Vaccine should be drawn from the vial into the syringe at the time of administration. An individual should only administer a vaccine he or she has prepared and drawn up. Syringes other than those filled by the manufacturer are designed for immediate administration and not for vaccine storage. Do not pre-draw doses before they are needed. Pre-drawing vaccine into syringes is a quality control and patient safety issue for many reasons. Filling a syringe before it is needed increases the risk for administration errors. Once in the syringe, vaccines are difficult to tell apart, and there is no stability data available for vaccines stored in plastic syringes. Other problems associated with this practice are wasted vaccine and possible bacterial growth in vaccines that do not contain a preservative.

As an alternative to pre-filling syringes, CDC recommends use of manufacturer-supplied prefilled syringes for large immunization events, such as community influenza clinics. These syringes are designed for both storage and administration. Once a manufacturer prefilled syringe is activated (i.e., syringe cap removed or needle attached), the sterile seal is broken. The syringe should be used that day or discarded at the end of the clinic day. For single-dose vials (SDV), the activation occurs when the cap is removed. SDV should also be discarded at the end of the clinic day if the protective cap has been removed. When using pre-filled syringes, it is not necessary to expel the air pocket out of the syringe prior to administering the vaccine.

The type of vaccine, lot number, and date of filling should be labeled on each syringe and the doses should be administered as soon as possible. Some vaccines that are reconstituted must be administered immediately following reconstitution (see section pertaining to vaccines with diluent)

Prior to administering vaccinations, health care professionals should always:

1. Verify the vaccine is stored in the appropriate storage unit (refrigerator vs freezer)
2. Check the expiration date of the vaccine and (if used) diluents on the vial or box. Never use expired vaccine or diluents.
  - a. Vaccine can be used through the last day indicated on the vaccine packaging, for vaccines with only a mm/yy expiration date, this is through the last day of the month
  - b. The expiration date for certain vaccines changes once the vaccine vial is opened or the vaccine is reconstituted.
3. Inspect the vaccine vial or syringe and diluent for signs of damage or contamination.
4. If vaccine is presented in a vial remove the protective vial cap and swab the vial stopper with a new alcohol prep pad prior to drawing up the contents into the syringe.

To reconstitute vaccine:

1. Select a syringe and needle of proper length to be used for both reconstitution and administration of the vaccine
  - a. Exceptions: Rotarix® is an orally administered vaccine, read package insert for instructions for reconstitution. Menomune is administered in a multi-dose vial and will require a new needle and syringe for each dose that is administered (see package insert)
2. Check the labels on both the lyophilized vaccine and diluents to verify they are the two correct products to mix together and that the diluent is the correct volume.
3. Insert the needle of the syringe into the diluents vial and withdrawing the entire contents
4. Inject the diluent into the lyophilized vaccine vial
5. Rotate or gently agitate the contents in the vial to dissolve the powder
6. Check the appearance of the reconstituted vaccine to ensure it matches the description in the package insert. If the appearance does not match the description, do NOT use the vaccine.

7. Administer the vaccine within the timeframes indicated by the manufacturer. Please note that some vaccines must be administered within 30 minutes of reconstitution.
8. If using a multi-dose vial (Menomune) clearly mark the vial with the date and time of reconstitution.

**Procedure Details for Administering Vaccine by Injection (IM or SC)**

1. Cleanse area of injection using a new alcohol swab
2. Stabilize tissue in area of injection to ensure vaccine is administered according to the correct route.
3. Insert the needle at a 90° angle (IM) or 45° angle (SC) to the skin with a quick thrust.
4. Push down on plunger and inject the entire contents of the syringe. Do not aspirate
5. Remove the needle and apply pressure to the injection site with a dry cotton ball or gauze. Hold in place for several seconds.
6. Cover the injection site with a bandage if there is bleeding.
7. Place used syringe in sharps container
8. If administering multiple vaccines in the same extremity, separate the injection sites by 1”.

Intramuscular (IM)	Diphtheria, tetanus, pertussis (DTaP, DT, Tdap, Td) Haemophilus influenza, type b (Hib) Hepatitis A (HepA) Hepatitis B (HepB) Human papillomavirus (HPV) Meningococcal conjugate (MCV4) Meningococcal Group B (Trumemba) Meningococcal Group B (Bexero) Pneumococcal conjugate (PCV13) IIV3/IIV4 Zoster, Recombinant (SHINGRIX)  Combination Vaccines DTaP-HepB-IPV (Pediarix) DTaP-IPV/Hib (Pentacel) DTaP-IPV (Kinrix) Hib-MenCY (Menhibrix)
Subcutaneous (SC)	Measles, mumps, rubella Varicella Meningococcal Polysaccharide (MPSV4) Zoster, Live (ZOSTAVAX)  Combination Vaccines MMRV (ProQuad)
IM or SC	Polio, inactivated (IPV) Pneumococcal polysaccharide (PPSV23)

**Procedure Details for Administering Vaccine by Injection (ID)**

1. Cleanse area of injection using a new alcohol swab
2. Gently shake the microinjection system before administering the vaccine.
3. Hold the system by placing the thumb and middle finger on the finger pads, keeping the index finger free.
4. Insert the needle perpendicular to the skin, in the region of the deltoid, in a short, quick movement.
5. Maintain light pressure on the surface of the skin.
6. Inject the contents using the index finger to push on the plunger. Do not aspirate.

7. Remove the needle from the skin. With the needle directed away from you and others, push very firmly with the thumb on the plunger to activate the needle shield. You will hear a click when the shield extends to cover the needle.
8. Dispose of the applicator in a sharps container

**Procedure Details for Administering Intranasal Influenza Vaccine**

1. Remove rubber tip protector. Do not remove dose-divider clip at the other end of the sprayer.
2. Ask patient to keep head in upright position and breathe normally. Do not tip the head back
3. Place the tip of the applicator slightly inside the nostril
4. Depress plunger rapidly until the dose divider clip prevents further administration of the vaccine
5. Remove applicator from nostril
6. Pinch to remove dose-divider clip from the plunger
7. Place the tip of the applicator slightly inside the other nostril
8. Depress plunger rapidly to deliver remaining vaccine
9. Dispose of applicator in sharps container

**Procedure Details for Administering Rotavirus Vaccine**

1. Follow manufacturer's instructions for vaccine preparation
2. Insert applicator tip inside the infant's mouth. Avoid eliciting the gag reflex
3. Administer the liquid slowly down one side of the inside cheek toward the back of the mouth until fully administered
4. Dispose of applicator in sharps container

Table 1: Route, Needle Size & Injection Site for Commonly Used Vaccines

Route of Administration	Needle Size	Injection Site	Other Considerations
Intradermal  Insert needle at 90 degree angle (a wheal may appear after injection)	Pre-filled micro-injection system  The syringe contains a 30-gauge, 1.5 milliliter micro-needle.	Area of deltoid muscle	Fluzone Intradermal ® is the only U.S. licensed vaccine that is administered by the intradermal route.  Approved for adults 18-64 years only
Subcutaneous (SC)  Pinch up fatty tissue and insert needle at 45 degree angle	5/8" Needle Length 23-25 gauge	<u>Infants (&lt; 12 months)</u> administer injection in fatty tissue of thigh  <u>Children &amp; Adults</u> administer injection into fatty tissue surrounding the tricep muscle	
Intramuscular (IM)  Insert needle at a 90 degree angle Pull skin taut to stabilize injection site	1" Needle Length 22-25 gauge  The needle must be long enough to reach muscle mass.	<u>Young Children &amp; Infants</u> administer injection in vastus lateralis muscle on the anterolateral aspect of thigh.  The deltoid may be used in children >3 years.	A 5/8" needle may be considered when administering IM injections to premature infants and to individuals less than 130 pounds when given in the deltoid muscle

		Teens & Adults administer injection in deltoid muscle of upper arm  Do not administer vaccines in the buttock	
Oral (Rotavirus)	Oral applicator	Inside of Cheek	Administer oral vaccines first
Intranasal	Nasal Spray	Naris	FluMist® is the only U.S. licensed vaccine administered through the intranasal route.*  Administer to individuals 2-49 years.

\*Live attenuated flu vaccine, LAIV, is not recommended by the ACIP for use during the 2017-2018 Influenza season.

### Documenting Vaccination

Following the administration of vaccinations, it is important to document the administration of vaccinations in the patient's medical record. This documentation must include:

- Date (MM/DD/YYYY) the vaccine was administered,
- Manufacturer, lot number, and expiration date
- Vaccination site and route
- Name and title of the person administering the vaccine; address of facility permanent record will reside
- Edition date for VIS & date provided to patient

Document in the patient medical record the reasons for delaying or missing vaccination, including medical contraindications and patient refusal.

It is also advised to document this information on a personal immunization record and in the state immunization registry, CHIRP. Medical providers are required as of July 31, 2015 to document a complete record in the registry for persons 18 years of age and younger.

### Pain and Fever Control

One of the main reasons individuals refuse vaccination is due to the fear of pain from the needle-stick. There are several evidence-based strategies that can be used to decrease pain and fever associated with immunizations including:

- The use of antipyretics (non-aspirin containing) to decrease fever if it occurs after vaccination. Do not administer antipyretics before or at the time of vaccination
- Age appropriate distraction techniques (playing music, reading books, deep breathing, etc.)
- Ingestion of sweet-tasting liquids or breast-feeding in infants up to 12 months of age
- Injecting the most painful vaccines last (MMR, PCV13 or HPV)
- Rubbing the skin near the injection site (demonstrated to be effective in children 4 years and older)
- Do not aspirate IM injections



## References & Resources

Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2016  
<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Centers for Disease Control and Prevention. General Best Practice Guidelines on Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>.

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## Revision History

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