450 W State Street 4th FL
Boise, Idaho 83702
(208) 334-5931

2020-2021 VACCINES FOR CHILDREN PROGRAM PROVIDER AGREEMENT

FACILITY INFORMATION

Facility Name:			VFC Pin#:
Facility Address:			
City:	County:	State:	Zip:
Telephone:		Fax:	
Shipping Address (*if different than facility address):*			
City:	County:	State:	Zip:

MEDICAL DIRECTOR OR EQUIVALENT

Instructions: *The official Vaccines for Children (VFC) registered healthcare provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law who will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the provider enrollment agreement. The individual listed here must sign the provider agreement.*

Last Name, First, MI:			
Title:	Specialty:	Email:	
License No.:		Medicaid or NPI No.:	Employer Identification No. *(optional):*

VFC VACCINE COORDINATOR

Primary Vaccine Coordinator Name:	
Telephone:	Email:
Completed annual training: ○ Yes ○ No	Type of training received:
Back-Up Vaccine Coordinator Name:	
Telephone:	Email:
Completed annual training: ○ Yes ○ No	Type of training received:

IDAHO DEPARTMENT OF HEALTH & WELFARE
DIVISION OF PUBLIC HEALTH

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Boise, Idaho 83702
(208) 334-5931

PROVIDERS PRACTICING AT THIS FACILITY *(additional spaces for providers at end of form)*

Instructions: *List below all licensed healthcare providers (MD, DO, NP, PA, pharmacist) at your facility who have prescribing authority.*

Provider Name	Title	License No.	Medicaid or NPI No.	EIN *(Optional)*

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PROVIDER AGREEMENT

To receive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the healthcare facility of which I am the medical director or equivalent:

1.	I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.
2.	I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories: A. Federally Vaccine-eligible Children (VFC eligible) 1. Are an American Indian or Alaska Native; 2. Are enrolled in Medicaid; 3. Have no health insurance; 4. Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement. B. State Vaccine-eligible Children 1. In addition, to the extent that my state designates additional categories of children as "state vaccine-eligible", I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 funded doses) to such children. Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are **not** eligible to receive VFC-purchased vaccine.
3.	For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless: a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child; b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
4.	I will maintain all records related to the VFC program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
5.	I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.

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6.	I will not charge a vaccine administration fee to non-Medicaid federal vaccine eligible children that exceeds the administration fee cap of $20.13 per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
7.	I will not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
8.	I will distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
9.	I will comply with the requirements for vaccine management including: a) Ordering vaccine and maintaining appropriate vaccine inventories; b) Not storing vaccine in dormitory-style units at any time; c) Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet Idaho Immunization Program storage and handling requirements; d) Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.
10.	I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program: **Fraud:** is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law. **Abuse:** provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.
11.	I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.
12.	For providers with a signed deputization Memorandum of Understanding between a FQHC or RHC and the Idaho Immunization Program to serve underinsured VFC-eligible children, I agree to: a) Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit; b) Vaccinate "walk-in" VFC-eligible underinsured children; and c) Report required usage data

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	Note: *"Walk-in" in this context refers to any underinsured child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve underinsured patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations, then the policy would apply to underinsured patients as well.*
13.	I agree to replace vaccine purchased with state or federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a dose-for-dose basis.
14.	I will enter and/or update each patient's VFC-eligibility or insurance information into Idaho's Immunization Reminder Information System (IRIS); and I will enter each dose of vaccine supplied through the Idaho Immunization Program into IRIS within 28 days of administration.
15.	I understand this facility, or the Idaho Immunization Program may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the Idaho Immunization Program.

By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.	
Medical Director or Equivalent Name (print):	
Signature:	Date:

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2020-2021 VACCINES FOR CHILDREN PROGRAM PROVIDER AGREEMENT-IDAHO IMMUNIZATION PROGRAM ADDENDUM

STATE VACCINE-ELIGIBLE CHILDREN

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

The Idaho Immunization Assessment Board was created in March 2010 after the signing of HB432. The purpose of the Board is to assess insurance carriers for funding a dedicated vaccine program. State dollars provided by the Idaho Immunization Assessment Board fund vaccines for Idaho children not eligible for the VFC program.

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

BIRTH DOSE OF HEPATITIS B VACCINE

The Idaho Immunization Program supplies the birth dose of hepatitis B vaccine to all children born in Idaho regardless of state of residence or insurance status. The birth dose must be administered at the birthing facility.

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ADDITIONAL PROVIDERS (if needed)

PROVIDERS PRACTICING AT THIS FACILITY *(attach additional pages as necessary)*				
Instructions: *List below all licensed health care providers (MD, DO, NP, PA, pharmacist) at your facility who have prescribing authority.*				
Provider Name	**Title**	**License No.**	**Medicaid or NPI No.**	**EIN *(Optional)***

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2020-2021 PROVIDER POLICIES AND GUIDELINES

PROGRAM OVERVIEW

Idaho Immunization Program

The Idaho Immunization Program (IIP) administers the federal Vaccines for Children (VFC) program in Idaho. All vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are supplied at no cost, through a combination of federal and state dollars, for Idaho children 0 through 18 years of age. Providers must be enrolled and active with the IIP to receive the vaccine.

The federal dollars, provided through the Centers for Disease Control and Prevention (CDC), fund vaccines for children eligible for the VFC program. The State dollars, provided by the Idaho Immunization Assessment Board and the Idaho Department of Health and Welfare, fund vaccines for Idaho children who are not eligible for the VFC program.

Vaccines for Children Program

The federal VFC program provides vaccines at no cost to children who might not be vaccinated because of an inability to pay. The program is administered by the CDC and was created by the Omnibus Budget Reconciliation Act of 1993 as a new entitlement program to be a required part of each state's Medicaid plan.

Idaho Immunization Assessment Board

The Idaho Immunization Assessment Board was created in March 2010 after the signing of HB432. The purpose of the Board is to assess fees from health insurance carriers to fund a dedicated vaccine program which provides free vaccine for insured children (see Patient Eligibility section below).

Immunization Reminder Information System (IRIS)

IRIS is a secure, statewide immunization registry which can track, forecast, and help enrolled providers remind patients when immunizations are needed. IRIS also provides patients with a permanent immunization record to help reduce unnecessary immunizations and save providers time when requesting patient records. IRIS is a voluntary immunization registry for people of all ages. All children born in Idaho are entered in to IRIS at birth; however, anyone can notify the IIP to have some or all of his or her child's information removed from the registry.

Prior to immunization, providers must notify patients that IRIS is voluntary, as outlined within Title 39 Chapter 48 Section 04 of Idaho Code (https://legislature.idaho.gov/statutesrules/idstat/Title39/T39CH48/SECT39-4804/).

Providers should ensure that computers used by their staff to access IRIS are fully compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements, and that their office staff who have access to IRIS are trained in the application of HIPAA to online data systems containing personal health information.

In addition to any internal remediation measures taken in the event of inappropriate access to or use of IRIS within the provider's practice, the provider must also notify the IIP of the inappropriate use. Acceptable uses of IRIS are outlined within Title 39 Chapter 48 Section 03 of Idaho Code (https://legislature.idaho.gov/statutesrules/idstat/Title39/T39CH48/SECT39-4803/).

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Advisory Committee on Immunization Practices

The ACIP is a federal advisory panel that provides advice and guidance on the most effective means to prevent vaccine-preventable disease. Congress gave the ACIP unique legal authority to determine recommendations for the routine administration of vaccine to children and practices for children and adults in the United States.
The major functions of the ACIP are to:

- Develop technical recommendations on vaccine use and immunization practices;
- Harmonize immunization schedules with those of other advisory groups such as the American Academy of Pediatrics and the American Academy of Family Physicians; and
- Approve vaccines for use in the VFC program.

After approval, ACIP recommendations are published in *Morbidity and Mortality Weekly Report* (MMWR), a scientific periodical prepared by the CDC (http://www.cdc.gov/mmwr/), and become the standard of practice for administering the applicable vaccines.

Once a new or amended recommendation is published, the ACIP approves it for inclusion in the VFC program by passing a VFC resolution. VFC resolutions determine what vaccines are available through the VFC program, including dosage, schedule, and contraindications. VFC resolutions are the rules that providers must follow when administering vaccines under the VFC program.

The CDC publishes current VFC resolutions on their website at
https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html
Please note the following information about VFC resolutions:

- An ACIP recommendation does not apply to the VFC program until the VFC resolution is approved.
- For newly recommended vaccines, a VFC resolution must be approved before the CDC can negotiate a purchase contract with the manufacturer. Therefore, there may be a delay between when the resolution is approved and when the vaccine is available.

All providers agree to comply with immunization schedules, dosages, and contraindications established by the ACIP and included in the VFC program unless:

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

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PROVIDER ENROLLMENT

Any healthcare provider who serves children 0 through 18 years of age, wants to provide childhood vaccines through the federal VFC program, has a current medical license in good standing, and has independent prescription writing authority to administer vaccines in Idaho, may enroll with the IIP.

New Providers

Healthcare providers wishing to enroll can begin by contacting the IIP by phone (208-334-5931) or email (IIP@dhw.idaho.gov). New provider enrollment involves the following steps:

- Signing the Provider Agreement to follow the current Provider Policies and Guidelines;
- Acquiring the required vaccine storage and handling equipment;
- Assigning staff (primary and back-up vaccine coordinators) to be responsible for vaccine management and training; and
- Completing an enrollment site visit with IIP staff.

Once the completed paperwork has been received and processed by the IIP, a VFC pin number will be assigned and the facility will be enrolled in IRIS. Please note that the sequence and timing of new provider enrollment activities may vary depending on the clinic's location and the availability of IIP staff. Prior to the enrollment visit, providers must have appropriate vaccine storage equipment (appropriate equipment is determined by submitting make and model information to the IIP) in place. Vaccine orders can be processed after the training has been completed and three days of current, stable, in-range temperature data from a continuous recording device for all vaccine storage units have been submitted to the IIP (see Temperature Monitoring Devices section below for additional details).

Re-Enrollment

Each year all vaccine providers must re-enroll with the IIP through IRIS by electronically:

- Signing the Provider Agreement to follow the current Provider Policies and Guidelines,
- Completing the Provider Profile, and
- Verifying the primary and back-up vaccine coordinators have completed the required annual education (see Required Provider Education section below).

Providers must complete an updated Provider Agreement through IRIS any time during the year if:

- The medical director (or equivalent) changes (this is the person who signed/signs the Provider Agreement); or
- The clinic ownership changes.

Providers must notify the IIP through IRIS when:

- The primary or back-up vaccine coordinator changes;
- Staff needs to be added, changed, or deleted from IRIS;
- The clinic contact information changes (i.e. address, email, phone number);
- The vaccine shipping hours or instructions change; or
- The facility type changes.

Providers must notify the IIP through an email to IIP@dhw.idaho.gov when:

- The facility adds or removes a vaccine storage unit
    - The unit's make and model information needs to be included in the email
    - Three days of stable temperatures must be documented before vaccine may be stored in new equipment or equipment that has been moved, and those temperatures must be available for review.

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Termination

At any time, a provider may choose to terminate enrollment with the IIP. If a provider chooses to leave the program and no longer receive vaccine, then the IIP must be notified as soon as possible. In addition, the IIP may choose to terminate a provider from the program due to repeat non-compliance issues that have not been appropriately addressed or a permanent condition such as being listed on the Office of Inspector General List of Excluded Providers or the Idaho Medicaid Provider Exclusion List.

Terminated providers are required to account for all vaccine supplied by the IIP. All vaccine supplied by the IIP that is in the provider's office must be stored appropriately until arrangements can be made to have the vaccine transferred to another location, if needed. In addition, all equipment and materials supplied by the IIP must be returned. Failure to return viable vaccine and equipment to the IIP may result in vaccine replacement and/or reimbursement costs to the provider office. After all vaccine and equipment have been accounted for, the IIP will issue a letter to the provider finalizing the termination.

SPECIALTY PROVIDERS

Specialty providers are providers that offer limited care in a specialized environment or provide health care in a focused specialty area. A "specialty provider" is defined as a provider that only serves:

- A population defined by the practice specialty (e.g. OB/GYN, STD clinic, family planning); or
- A specific age group within the general population of children 0 through 18 years of age.

Specialty providers only need to supply and administer the specific vaccines recommended for the population they serve. A birthing hospital that supplies only the birth dose of hepatitis B vaccine is an example of a specialty provider.

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PATIENT ELIGIBILITY

All children 0 through 18 years of age who are eligible for the federal Vaccines for Children (VFC) program, the Idaho Immunization Assessment, and federal funds for designated targeted populations may receive vaccines supplied by the IIP. **Patient eligibility must be screened and documented for every child at each immunization visit**. Patient eligibility status information must be retained and easy to retrieve in the patient's medical record for at least three (3) years.

VFC Eligibility

All providers must screen every child for VFC eligibility at each immunization visit. VFC eligibility must be documented for each dose of vaccine administered. All children who are 0 through 18 years of age, and meet one of the following criteria, are considered VFC eligible:

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

Private providers must inform parents of underinsured children that free vaccine may be available at an FQHC, RHC, or Public Health District. If a child qualifies for more than one category, then the provider must select the eligibility category that will require the least out-of-pocket expense to the parent or guardian for the child to receive immunizations.

Children whose health insurance covers the cost of vaccinations are not eligible for federal VFC vaccines. This applies even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible has not been met.

State Eligibility

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

*Washington participates in Idaho's Immunization Assessment

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BILLING

The main premise of the VFC program is to supply vaccine at no cost to eligible children. There are two costs associated with vaccine— the cost of the vaccine and the administration fee. Providers must select and document the eligibility category that will require the least amount of out-of-pocket expense to the parent/guardian for the child to receive necessary immunizations and bill the administration fee in accordance with that category.

Vaccine

- Providers may not charge patients and may not receive reimbursement for any IIP-supplied vaccines.

Administration Fee

- The reimbursement rate set by the Centers for Medicare & Medicaid Services (CMS) of $20.13 per dose (not per antigen) may be charged for the administration of vaccine to Idaho VFC-eligible, non-Medicaid children.
    - Providers may not exceed the CMS reimbursement rate when determining administration fees for VFC-eligible, non-Medicaid children.
    - VFC-eligible, non-Medicaid includes Native American, Alaska native, children with no insurance, or children who are underinsured.
    - Healthcare providers who bill for the vaccine administration fee for a non-Medicaid, VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration.
- The reimbursement rates set by Idaho Medicaid may be charged for the administration of vaccine to children enrolled in Medicaid (per dose or per antigen).
- The reimbursement rates set by contracted medical health plans may be charged for the administration of vaccine to children with private health insurance coverage for immunizations (per dose or per antigen).

Providers may not deny administration of IIP-supplied vaccine to an established patient because of the child's parent's or guardian's inability to pay the administration fee. In addition, unclaimed vaccine administration fees cannot be sent for collections. Therefore, healthcare providers must establish a process to waive unpaid vaccine administration fees.

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NATIONAL CHILDHOOD VACCINE INJURY ACT REQUIREMENTS

The National Childhood Vaccine Injury Act (NCVIA) of 1986 was enacted to provide a cost-effective arbitration and compensation system for vaccine injury claims and reduce the potential liability of vaccine manufacturers. It also created a system for reporting and tracking adverse events related to vaccinations. Healthcare professionals must adhere to the following NCVIA requirements when administering vaccinations. Please note that these requirements apply to all vaccinations administered at your facility, not just those supplied by the IIP.

Vaccine Information Statements (VISs)

VISs are published by the CDC and provide information to vaccine recipients about the risks and benefits of each vaccine. **Federal and State laws require providers to supply a current, vaccine-specific VIS to each patient or each patient's legal guardian at every immunization visit, prior to the administration of the vaccine.**

VISs are updated periodically, and the CDC maintains current print, audio, and foreign language versions on their website at http://www.cdc.gov/vaccines/hcp/vis/index.html. Whether managed as electronic or paper documents, clinics must provide *current* VISs to patients for all vaccine antigens being administered. Offices using EHRs must be sure the date of the VIS being distributed is the same as the date documented in the patient's medical record.

Ways to Give a VIS

With the evolution of electronic media, there are many ways to appropriately distribute VISs.

- A practice may produce permanent, laminated, office copies of each VIS, which may be read by recipients prior to vaccination.
- VISs may be reviewed on a computer monitor (or any video display).
- VISs may be downloaded by the recipient to a smartphone or other electronic device to read at his or her convenience.
- VISs may be made available to be read before the immunization visit (e.g. by giving the patient or parent a copy to take home during a prior visit or telling them how to download or view a copy from the Internet). These patients must still be offered a copy in one of the formats previously described to read during the immunization visit, as a reminder.
- Providers must still offer a copy (which can be an electronic copy) of each appropriate VIS to take away following the vaccination; however, the recipient may decline.

Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national vaccine safety surveillance program created through the NCVIA and co-sponsored by the CDC and the Food and Drug Administration (FDA). VAERS provides a nationwide system for reporting, analyzing, and publishing information on adverse events related to vaccines. The VAERS website is https://vaers.hhs.gov/professionals/index. VAERS reporting may be conducted online and VAERS reporting forms may be ordered on the VAERS website.

Reportable Events – Required

The NCVIA requires healthcare providers to report:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine; or
- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination (https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) that occurs within the specified time period after vaccination.

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Vaccine Charting Requirements

The NCVIA requires that vaccination records be included in a patient's permanent medical record and that the following information is included:

- Type of vaccine (DTaP, MMR, etc.);
- Vaccine lot number;
- Date of administration (month, day, year);
- Name of the vaccine manufacturer;
- Name and title of the person who administered the vaccine;
- Name and address of the clinic where the vaccine was given;
- Edition date of the VIS; and
- Date the VIS was provided to the patient.

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

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SITE VISITS

The CDC requires the IIP to periodically visit providers, who receive vaccine from the IIP, to assess compliance with program requirements. One of the IIP's goals is to ensure provider compliance through effective communication, and site visits provide an educational opportunity rather than an audit. Most program compliance issues are addressed through training and follow-up. Only cases of repeated and intentional non-compliance progress to corrective actions.

VFC Visit

Providers can expect a VFC visit from the IIP at least every other year. VFC visits help determine a provider's compliance with program requirements. This includes identifying potential issues with VFC documentation, accountability, and determining whether vaccines are being handled, stored, and administered in accordance with the laws and policies governing the VFC program.

IQIP (Immunization Quality Improvement for Providers) Visit

The IIP will conduct IQIP visits with at least 25% of enrolled providers each year. The IQIP visits are used to improve immunization rates and practices. The IQIP component, once understood and implemented, can assist practices with increasing immunization coverage levels and decreasing missed vaccination opportunities.

After the IIP schedules a VFC or IQIP visit with a provider's office, communication is sent to the primary vaccine coordinator confirming the date and time. VFC and IQIP visits are normally 2 to 4 hours in length. Duration may vary depending on the size of the clinic, whether both visits are conducted the same day, and any compliance issues that may arise. During the visit, the primary and back-up vaccine coordinators must be available, and any key staff involved in immunizations should also be available.

Storage and Handling Visit

Providers may receive an unannounced storage and handling visit from the IIP at any time. Storage and handling visits focus on vaccine management in a provider's office, specifically vaccine storage practices and equipment. Storage and handling visits are approximately 30 minutes in duration, unless concerns are discovered.

Educational Visits

Educational visits may be conducted by the IIP or local public health district staff. The purpose of educational visits is to provide guidance and direction and not to assess compliance. Educational visits are typically conducted with any organization not receiving a VFC visit during the calendar year. In addition, a needs-focused educational visit may be conducted for non-compliance. Finally, providers may request additional training online at www.immunizeidaho.com. Educational visits vary in length depending on the topic covered, the number of attendees, and any non-compliance issues that are addressed.

At the end of some site visits, clinics will receive feedback and a list of any required corrective action plans with deadlines for completion. If follow-up action is required, then provider staff must carry out corrective action(s) by the deadline(s). IIP staff will follow-up by telephone, email, mail, or in-person.

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FRAUD AND ABUSE

Fraud

Fraud is an intentional deception or misrepresentation made by a person with 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

Abuse is provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the IIP (and/or including actions that result in an unnecessary cost to Medicaid, a health insurance company, or patients) or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.

The IIP is required to report any suspected fraud and abuse to state and federal authorities for further investigation.

Examples of Fraud and Abuse

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

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RESOURCES

The IIP has related forms and educational resources available at no cost to providers. Resources available from the IIP can be ordered online at www.immunizeidaho.com or printed 24 hours a day, seven days a week. Resource orders will be shipped within 7 – 10 business days.

Examples of orderable resources include:

- Vaccine Bins and Labels
- Do Not Unplug Stickers for vaccine storage units
- Lifetime Immunization Records
- Childhood and Adolescent Brochures

Printable resources include:

- IIP Provider Resource Binder
- Vaccine Storage and Handling Toolkit
- Clinic Immunization Record

TECHNICAL ASSISTANCE

IIP staff are available to answer questions or provide additional immunization information. The IIP may be reached by phone (208) 334-5931 or by email IIP@dhw.idaho.gov Monday through Friday between 8:00 A.M. and 5:00 P.M. Mountain Time.

For questions about IRIS, please contact the IRIS Help Desk by phone (208) 334-5995 or by email IRIS@dhw.idaho.gov. Requests for IRIS usernames must be submitted online at www.immunizeidaho.com.

Additional information and online education can be found 24 hours a day, seven days a week at www.immunizeidaho.com.

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VACCINE MANAGEMENT

PERSONNEL

Providers must designate one staff member to be the primary vaccine coordinator and at least one back-up vaccine coordinator. The back-up vaccine coordinator must be able to perform the same responsibilities as the primary vaccine coordinator in the absence of the primary. These positions will be responsible for key requirements and will provide oversight for all vaccine management within the office. The responsibilities of the designated primary and back-up vaccine coordinators include the following vaccine management activities:

- Temperature documentation during normal operating hours for each vaccine storage unit, including date, time and name/initials of reviewer;
    - Once daily minimum and maximum temperature documentation at the start of each clinic day is required.
- Download temperatures monthly, save a copy of the file at the clinic for review, and submit the file, to the IIP, by email at IIP@dhw.idaho.gov, by the 7th of each month for the previous month's temperatures;
- Adjust the temperature of a vaccine storage unit, if needed;
- Weekly review of temperature logs by the primary vaccine coordinator when daily monitoring is being conducted by a back-up person to ensure proper documentation and temperature recording. The back-up vaccine coordinator will monitor the temperature logs if the primary coordinator is unavailable;
- Train all staff involved with vaccines at least annually;
- Document all staff training, include the date(s) of training(s), topics covered, and staff in attendance;
- Follow the office's routine vaccine operating procedures and emergency storage and handling plans. Review the plans annually and make changes as needed throughout the year;
- Document all updates and reviews of the routine vaccine operating procedures and emergency storage and handling plans; and
- Notify the IIP, through IRIS, when changes have been made to the primary or back-up vaccine coordinators.

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REQUIRED PROVIDER EDUCATION

All primary and back-up vaccine coordinators must complete VFC compliance and storage and handling training annually. All trainings must be documented.

How to Meet the Annual Training Requirement

Vaccine coordinators can meet the annual training requirement by completing one or more items below:

- Participate in an Enrollment Visit.
- Participate in a VFC Visit.
- Participate in an Educational Visit conducted by local public health district staff.
- Complete two web-based training modules. *CDC's You Call the Shots*: Vaccine Storage and Handling, and Vaccines for Children (VFC), located at https://www.cdc.gov/vaccines/ed/youcalltheshots.html.
    - After the training is complete, print the certificate of completion. Document the coordinator's name and the date of the training and keep a copy on file for review by the IIP.

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REQUIRED WRITTEN PLANS

Providers must have written routine vaccine operating procedures and emergency storage and handling plans. Providers may develop their own written routine and emergency storage and handling plans or use the IIP supplied Vaccine Management Plan template (which can be found online at www.immunizeidaho.com). Both the routine and the emergency plans should be presented in a clear and concise manner and must be reviewed at least annually.

Routine Vaccine Operating Procedures

Routine vaccine operating procedures must include the following guidance:

- Names of the clinic's current primary and back-up vaccine coordinators;
- Proper storage and handling practices;
- Vaccine shipping and receiving procedures;
- Vaccine ordering, inventory control (e.g. stock rotation), and wastage and return processes;
- Documentation of staff training on IIP requirements, including proper vaccine storage and handling; and
- Signature of document reviewer and date of annual review and/or plan updates.

Emergency Storage & Handling Plan

Emergency storage and handling plans must include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. The emergency plan should include the following:

- Person(s) responsible for preparing and transporting vaccine, including contact information;
- How this person will be notified that vaccine needs to be moved;
- Alternative storage unit or facility(s);
    - Must be a storage unit where temperatures have been and will continue to be monitored by a temperature monitoring device that meets IIP requirements, as described further below in the Temperature Monitoring Devices section
    - Must maintain appropriate temperatures for vaccine storage
    - May not be a personal refrigerator or freezer at home
- How the receiving location will be notified of transport;
- How to pack vaccine for transport; and
- Up-to-date list of vaccine manufacturer phone numbers.

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VACCINE STORAGE UNITS

Providers must have appropriate equipment that can store vaccine and maintain proper conditions. All VFC providers must have appropriate storage units (requirements are listed below) prior to the enrollment visit and receiving vaccine. Any time a provider's office does not have appropriate vaccine storage equipment, vaccine will not be shipped.

Current appropriate storage units are:

- A stand-alone refrigerator and stand-alone freezer; or
- A stacked unit with separate doors, dual temperature controls, a separate freezer condenser and compressor, and a separate refrigerator condenser and compressor, with no air vents connecting the two.
  Note: Providers enrolled in the program before October 1, 2012 may continue to use the refrigerated portion only of a single–condenser combination unit (must have separate doors and temperature controls); storage units purchased after July 1, 2017 must be stand-alone units.

The use of dormitory style or bar-style refrigerators is **not allowed at any time** in any circumstance for storage of vaccine. A dormitory style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

Cooling or evaporator plates, located inside the unit, are not allowed for the storage of vaccine received by the IIP.

Note: Providers enrolled in the program before October 1, 2012 and who purchased a storage unit prior to March 14, 2014 may continue to use a storage unit with a cooling/evaporator plate until further notice; however, any storage units purchased after March 15, 2014 with cooling/evaporator plates will not be approved by the IIP for vaccine storage.

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

- Be able to maintain required vaccine storage temperatures year-round.

Refrigerator	36° to 46° F	2° to 8° C
Freezer	-58° to +5° F	-50° to -15° C

- Be large enough to hold the year's largest inventory, which includes influenza vaccine, without crowding.
- Be large enough to store water bottles in the refrigerator and frozen water bottles in the freezer to stabilize the temperature.
- Be frost-free or have an automatic defrost cycle (recommended).
- Be dedicated to vaccine storage.
  - Food and beverages are not to be stored in a vaccine storage unit.
  - If biologicals must be stored in the same unit, then they must be stored below the vaccine. In addition, the vaccine is the priority in the storage unit. If the biologicals inhibit vaccines from being stored appropriately, then the biologicals must be removed from the vaccine storage unit.

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TEMPERATURE MONITORING DEVICES

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

The IIP supplies a temperature monitoring device for use in the refrigerator and freezer. The IIP will supply one recorder for each 24-hour storage unit that holds vaccine supplied by the IIP. If a temperature monitoring device is disposed of or damaged, then the provider will be responsible for replacement of the device and the equipment provided to use the device. The buffered probe must be placed in the center of the refrigerator or inside the freezer next to the frozen vaccine.

Providers are not required to utilize temperature recorders supplied by the IIP. If a provider's office uses a different temperature monitoring device, then the following requirements must be met, in addition to the requirements above, and the device approved for use by the IIP:

- Use of a calibrated and certified device to an accuracy of +/- 1° F (0.5°C)
    - Current calibration information must be on file with the IIP. Vaccine cannot be shipped to an office if a current calibration certificate is not on file.
- Use of a continuous recording device with capability to download data routinely (data logger)
    - Current temperature displayed outside of unit
    - Minimum and maximum temperature display
    - Memory storage of at least 4,000 readings
    - User programmable logging interval (or reading rate) set at a maximum time interval of every 30 minutes
    - Alarm for out-of-range temperatures
    - Low battery indicator
- Use of a temperature probe with buffered material that best reflects the temperature of the vaccine

Providers must have at least one back-up temperature monitoring device readily available. Back-up thermometers must meet the data logger requirements listed above. If a back-up thermometer is not physically located in the provider's office, then a plan must be in place for how the back-up thermometer will be accessed within a timeframe that complies with the requirement to check and record temperatures. Information about the back-up temperature monitoring device must be included in the clinic's Routine Vaccine Operating Procedures.

Note: Back-up vaccine temperature monitoring devices should not be stored in the storage unit. This can result in conflicting temperature readings between the back-up and main device, which can lead to potential confusion. For acclimation purposes, back-up probes may be stored in the unit as long as they are not connected to the back-up device.

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ROUTINE VACCINE STORAGE AND HANDLING REQUIREMENTS

The vaccine storage practices listed below are the responsibility of the primary vaccine coordinator and can be delegated to the back-up vaccine coordinator. If the practices are delegated, then the primary vaccine coordinator must monitor the activity.

- Store refrigerated vaccine at 2° to 8° C (36° to 46° F)
- Store frozen vaccine at -50° to -15° C (-58° to +5° F)
- Store vaccines requiring refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas
- Space stored vaccine to allow for cold air circulation around the vaccine
- Only vaccines are to be stored in the refrigerator and freezer
    - If biologicals must be stored in the same unit, then they must be stored below the vaccine. In addition, the vaccine is the priority in the storage unit. If the biologicals inhibit vaccines from being stored appropriately, then the biologicals must be removed from the vaccine storage unit.
- Do not store vaccines in the door or in the drawers of the storage unit
- Remove vegetable bins from the refrigerator and replace with cold water bottles
- Stabilize refrigerator and freezer temperatures with use and proper placement of water bottles
- Store vaccines in their original packaging, with the lids closed and in place, until ready to administer to protect them from sunlight and fluorescent light
- Store vaccine products that have similar packaging in different locations to avoid confusion and medication errors
- Store MMR vaccine in the freezer
- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine weekly
    - Notify the IIP, in writing, within 3 months (90 days) of any vaccine doses that will *expire before they can be administered*. Only with the approval and direct guidance of the IIP, and only if the cold chain can be ensured, can short-dated vaccines be redistributed to providers that are able to administer them before the vaccines expire.
- Immediately remove expired vaccine from the storage unit
- Prepare vaccines immediately prior to administration; pre-drawing vaccine into syringes is <u>not</u> an acceptable practice
- "Do not unplug" stickers must clearly mark all electrical outlets and circuit breakers of every vaccine storage unit
- Vaccine storage units cannot be plugged into GFI outlets (with a reset button), outlets that can be activated by a wall switch, or multi-outlet power strips

If a provider has privately purchased vaccine, then the vaccine must be marked and/or separated from the vaccine supplied by the IIP. Suggestions to differentiate between private and public vaccines:

- Utilize State-Supplied stickers (blue) provided by the IIP
- Place vaccine on separate, marked shelves
- Place vaccine in separate storage units

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VACCINE ORDERING

Vaccines can be ordered 24 hours a day, seven days a week through IRIS. Providers must order vaccines in accordance with actual vaccine need within their ordering cycle (see Economic Ordering Quantity section below). A physical on-hand vaccine count must be submitted in IRIS before a vaccine order can be created. In addition, vaccine orders may not be processed if a provider has an unresolved temperature incident, has not submitted monthly temperature files to the IIP, and/or has not submitted requested information after a site visit. Emergency orders will be placed only in response to a disease outbreak or natural disaster.

Providers are expected to monitor vaccine orders after they have been submitted. If a vaccine order, with a status of shipped, has not been received within 4 days of the ship date, then contact the IIP at (208) 334-5931.

For additional details about vaccine ordering, please see the Placing Vaccine Orders in IRIS guidance located at www.immunizeidaho.com.

Economic Ordering Quantity (EOQ)

EOQ balances provider order size, order frequency, the timing of orders, and storage and handling to minimize costs and improve efficiencies as orders flow through the system. The IIP will notify providers of their designated ordering frequency. Providers are asked to place orders and plan inventory supply based on the assigned EOQ; however, EOQ is not intended to keep providers from ordering vaccine anytime there is a need. In addition, providers may contact the IIP to request a change to the assigned EOQ.

Providers will place orders based on an ordering frequency determined by the number of vaccines ordered, the number of vaccines administered, and the size of the storage unit(s). Depending on the volume, the ordering frequency may be monthly (once a month), bi-monthly (every other month), quarterly (every third month), or semi-annually (twice a year).

Vaccine Brand Choice

Providers are required to choose which vaccine brands to supply when competing vaccines are available. For example, there are two manufacturers for hepatitis A vaccine. Each clinic will determine which hepatitis A vaccine to supply. Brand choice must be submitted through IRIS, by completing the Brand Choice screen.

Vaccine brand choice changes may be submitted anytime; however, changes become effective either the first of January or July, whichever month follows the change. Providers that decide to change vaccine brands are still responsible to use the vaccine stock currently on-hand. Additionally, brand choice is used by the IIP to help determine statewide vaccine need and helps decrease administration errors when two brands of the same vaccine type are not interchangeable.

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RECEIVING VACCINE SHIPMENTS

Refrigerated vaccines are shipped from McKesson Specialty Distribution, LLC. Varicella-containing vaccines, which are frozen, are shipped directly from the manufacturer (Merck). After vaccine orders are processed, they may take up to 14 days to ship and may arrive in multiple shipments.

Vaccines must be shipped directly to the offices where the vaccine will be administered. The IIP may grant exceptions for providers with multiple sites; however, the office must submit a vaccine transport plan to the IIP if vaccines will not be directly shipped to an office. If the plan is approved, a memorandum of understanding must be issued by the IIP. Vaccine transport plans must be updated annually during the re-enrollment period. Frozen vaccines must be directly shipped to the office where they will be administered. Appropriate staff must be available to receive vaccine at least one day per week, other than Monday, for at least four consecutive business hours during that day.

Upon receipt of a vaccine shipment, providers must:

- Open the vaccine shipment immediately;
  - Check the temperature monitor reading;
  - Inspect the vaccine and packaging for damage;
  - Determine the length of time the vaccine was in transit by looking at the packing list;
    - Varivax® orders of 50 doses or more will be shipped in the large 4-day box (vaccine is viable for 4 days from shipping date). Varivax® orders of 40 doses or fewer will be shipped in the small 2-day box (vaccine is viable for 2 days from shipping date), unless those 40 doses or fewer are shipped on a Thursday or Friday in the large 4-day box for delivery on Monday.
    - ProQuad® orders are viable for 1 day regardless of shipping container size.
  - Compare the vaccine received with the vaccine products that appear on the packing list;
    - Contact the Idaho Immunization Program at (208) 334-5931 with any discrepancy/damage immediately after receiving a vaccine shipment.
    - If vaccines are deemed non-viable and replacement doses shipped, then a copy of the packing list for the replacement doses must be provided to the IIP so the doses may be added to the clinic's IRIS Public inventory.
    - Contact McKesson Specialty at 1-877-822-7746 with any discrepancy/damage within 2 hours of receiving the vaccine shipment.
    - Contact Merck at 1-800-637-2579 regarding varicella-containing vaccines.
- Immediately store the vaccine at the appropriate temperatures (place in the vaccine storage units); and
- If no discrepancies/damage, then accept the vaccine into the provider's IRIS Public inventory.

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VACCINE INVENTORY

The IIP purchases an average of $38 million dollars of pediatric vaccine annually and distributes an average of 720,000 doses of pediatric vaccine each year.

Providers are responsible to account for all doses of vaccine supplied by the IIP. Accountability is completed in IRIS. A physical, on-hand count of the vaccine is required each time vaccine is ordered. The count must be submitted through IRIS. Monthly inventory counts are considered a best practice and the IIP encourages providers to count inventory monthly.

Providers that fail to report accurate on-hand counts may not be shipped vaccine. All vaccine shipments must be accepted into the organization's IRIS Public inventory and all doses of wasted or expired vaccine must be accounted for in IRIS. In addition, all doses of vaccine supplied by the IIP must be entered in to IRIS within 28 days of administration. If the inventory counts become too far off (difference between IRIS inventory and provider's physical inventory), then provider orders may be reduced or may not be approved until counts can be reconciled. Unaccounted for or lost vaccine may be subject to replacement by the provider office (see Vaccine Loss and Replacement section below).

Vaccine Borrowing

Borrowing a vaccine supplied by the IIP to administer to a patient who is not eligible for the vaccine is not allowed. If providers plan to vaccinate patients who are not eligible for the vaccines supplied by the IIP, then they are expected to maintain adequate stock of privately purchased vaccines for those patients.

On rare occasions, a provider's private vaccine stock may be administered to a child eligible for the vaccine supplied by the IIP or a provider may inadvertently administer a vaccine supplied by the IIP to an ineligible patient. When either of these scenarios occur, dose-for-dose replacement of vaccine stock must be made. The IIP does not accept or give financial reimbursement. Moreover, vaccines may not be available for purchase in single dose quantities; units of five or more doses may have to be purchased by clinics to replace vaccine supplied by the IIP. The provider must document the instance by submitting a Vaccine Replacement Form, found online through IRIS (on the related links tab). The form will be processed by the IIP (see Vaccine Replacement Guidelines). IIP-supplied vaccines must be replaced as soon as possible. Privately purchased vaccines must be replaced within 12 months of administration. Each dose replaced must be replaced with the same vaccine type.

Expired, Spoiled, Wasted Vaccine

The IIP must be notified of expiring vaccine at least 3 months (90 days) prior to the vaccine's expiration date *if the vaccine will not be administered*. To report expiring vaccine, email IIP@dhw.idaho.gov, with the vaccine type, brand, lot number, expiration date, and the number of doses that will not be administered. A provider may be required to replace expired vaccine supplied by the IIP if the IIP was not notified 3 months (90 days) prior to the expiration date (see Vaccine Loss and Replacement section below).

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Expired or Spoiled Vaccine is nonviable vaccine in its original container (vial or syringe) that is returned to McKesson Specialty Distribution, LLC for federal excise tax credit. The expired or spoiled vaccine must be reported to the IIP and returned to McKesson within six months of loss. Returnable vaccine includes expired vaccine or 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 vaccine storage unit)
- Spoiled (vaccine in its original packaging that has been destroyed by another means not listed here)
- Recall (vaccine that has been recalled)

Wasted Vaccine is nonviable vaccine that cannot be returned for federal excise tax credit. Wasted vaccine must be reported to the IIP at least with each vaccine order and disposed of per the provider's business practices. Wasted vaccine includes the following:

- Broken vial/syringe
- Vaccine drawn up into syringe but not administered
- Lost or unaccounted for vaccine
- Non-vaccine products (e.g. IG, HBIG, diluent)
- Open vial that all the doses have not been administered

For instructions about how to report vaccine wastage and returns, please see the Manage Vaccine Wastage and Returns guidance located at www.immunizeidaho.com.

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TEMPERATURE MONITORING

Providers must store vaccines at the appropriate temperatures. The temperature range for refrigerated vaccines is **2° to 8° C** (36° to 46° F). Frozen vaccines must be kept between **-50° to -15° C** (-58° to +5° F). ***Failure to store vaccine at the proper temperature can seriously compromise or destroy vaccine efficacy***.

Providers must record the refrigerator and freezer minimum and maximum (min/max) temperatures at the start of each clinic day since the last clinic day min/max temperatures were recorded.

Temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used. The actual temperature is required for documentation. An "x" or "✓" is not acceptable. In addition, the date, the time of the temperature, and the reviewer's name/initials are required. The IIP supplies a temperature log, which may be found on the IIP website, for providers to use; however, providers may use a different method to document the required information. Temperature logs must be complete and stored for three years.

Providers must download temperatures monthly, save a copy of the file at the clinic for review, and submit the file, to the IIP, by email at IIP@dhw.idaho.gov, by the 7th of each month for the previous month's temperatures.

Vaccine Transport

On rare occasions vaccine must be moved over a short time and distance between providers. For example, when one provider has expiring vaccine that will not be used and another provider can administer the vaccine before expiration. The transport is usually performed by providers or IIP staff using a private vehicle or courier service. The expected length of transport is less than eight (8) hours or a regular business day.

Vaccine should be packed for transport following the CDC's Packing Vaccines for Transport during Emergencies resource, located at www.immunizeidaho.com. The use of a digital data logger with buffered probe is required for vaccine transport.

Temperature Incidents (Out of range temperatures)

Immediate corrective action must be taken when vaccine storage temperatures are found to be outside of the acceptable temperature ranges. Providers **must notify the IIP** any time temperatures are outside of the appropriate range by submitting a Vaccine Temperature Incident or Alarm Report, found online through IRIS (on the related links tab). After determining the scope of the temperature incident, the IIP will work with the provider and vaccine manufacturers to assist in determining if the vaccines are still viable.

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Unreported Temperature Incidents

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

- In-office training provided by IIP staff on vaccine storage and handling will be offered to the provider's immunization staff;
- The IIP will make recommendations for follow-up action based upon ACIP recommendations; and
- Depending on the duration and individual circumstances of the incident, the Department of Health and Welfare may take additional measures as deemed necessary.

If a provider has a second unreported temperature incident within two years following the unreported temperature incident:

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

In the event of a third unreported temperature incident within two years following the previous unreported temperature incident:

- The IIP may terminate the Provider Agreement with the provider for failure to comply with program requirements.

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VACCINE LOSS AND REPLACEMENT

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

Situations That Require Vaccine Replacement

Below is a list of situations that are considered provider negligence and may require a provider to replace lost or wasted vaccines dose-for-dose. This list is not exhaustive. Failure of a provider or staff to adhere to the current IIP Provider Agreement and Policies and Guidelines may result in a restitution situation. Restitution will be in the form of dose-for-dose replacement. Situations that occur which are not listed below will be considered on an individual basis by the IIP.

- Vaccine inventory wastage (loss) of 5% or greater (including unaccounted for vaccine).
- Provider fails to log temperatures appropriately during normal operating hours and temperatures are found to be out-of-range, resulting in vaccine loss.
- Provider fails to rotate or request to transfer vaccine that results in expired vaccine (the IIP was not notified, in writing, 90 days before the vaccine expired).
- Vaccines are drawn up prior to patient screening (pre-drawing vaccine) resulting in vaccine loss.
- Provider storage and handling mistakes resulting in vaccine loss.
- Vaccine that is left out of the vaccine storage unit and becomes non-viable.
- Freezing vaccine meant to be refrigerated.
- Refrigerating vaccine meant to be frozen.
- A refrigerator or freezer left unplugged or electrical breaker switched off.
- A refrigerator or freezer door left open or ajar.
- Refrigerator/freezer equipment problems when proof of repair or equipment replacement is not provided to the IIP within 30 days from the date of discovery.
- Any power outages for which the provider fails to act according to the provider's Emergency Storage and Handling plan.
- IIP-supplied vaccine is routinely administered to non-eligible patients (see Vaccine Borrowing).
- Failure to use appropriate vaccine storage and handling equipment that results in vaccine loss.
- Failed vaccine delivery attempt during a clinic's vaccine delivery hours that results in vaccine loss.

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

Procedures for Vaccine Replacement

- After the provider supplies the IIP with the vaccines that were lost/wasted and a Vaccine Temperature Incident or Alarm Report, if needed, the provider must replace each dose of vaccine wasted/lost.
- The provider will submit a list of replacement vaccine doses that includes Trade Name, lot number, National Drug Code (NDC), and expiration date to the IIP to be entered in to the provider's IRIS Public inventory.

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Situations That Do NOT Require Vaccine Replacement

Below is a list of situations that are not considered provider negligence. This list is not exhaustive. In these situations, the provider is deemed to not be at fault. Providers may be required to produce a letter from the alarm/alert company or the power company.

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

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2020-2021 PROVIDER POLICIES AND GUIDELINES ACKNOWLEDGMENT FORM

FACILITY INFORMATION	
Facility Name:	VFC Pin#:

By signing this form, I certify on behalf of myself and all immunization providers and staff at this facility, I have read and agree to comply with the current Idaho Immunization Program (IIP) Provider Policies and Guidelines.

In addition, I understand the current Provider Policies and Guidelines supersedes any prior IIP policies and guidelines. I further understand that content and forms referenced may be updated or modified at any time. Updates and revisions will be communicated to my office through announcements in Idaho's Immunization Reminder Information System (IRIS); and/or Provider Updates published by the IIP; and/or direct mail, email, and/or fax.

Medical Director or Equivalent	
Name (please print):	
Signature:	Date:

Primary Vaccine Coordinator	
Name (please print):	
Signature:	Date:

Back-up Vaccine Coordinator	
Name (please print):	
Signature:	Date:

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2020-2021 VACCINES FOR CHILDREN PROGRAM PROVIDER PROFILE

FACILITY INFORMATION

All health care providers participating in the Vaccines for Children (VFC) program must complete this form annually or more frequently if the number of children served changes or the status of the facility changes during the enrollment period.

Facility Name: VFC Pin#:

Vaccine Delivery Address:

City: County: State: Zip:

Telephone: Fax:

Email:

Days and Times Vaccine May Be Delivered:

FACILITY TYPE (select only one facility type)

Private Facilities	Public Facilities	
☐ Private Hospital	☐ Public Health District Clinic	☐ STD/HIV
☐ Private Practice (solo/group/HMO)	☐ Public Health District Clinic as agent for FQHC/RHC-deputized	☐ Family Planning
☐ Private Practice (solo/groups as agent for FQHC/RHC-deputized)	☐ Public Hospital	☐ Juvenile Detention Center
☐ Community Health Center	☐ FQHC/RHC (Community/Migrant/Rural)	☐ Correctional Facility
☐ Pharmacy	☐ Community Health Center	☐ Drug Treatment Facility
☐ Birthing Hospital	☐ Tribal/Indian Health Services Clinic	☐ Migrant Health Facility
☐ School-Based Clinic	☐ Woman, Infants and Children	☐ Refugee Health Facility
☐ Teen Health Center	☐ Other_____	☐ School-Based Clinic
☐ Adolescent Only Provider		☐ Teen Health Center
☐ Other_____		☐ Adolescent Only

VACCINES OFFERED (select only one box)

☐ All ACIP Recommended Vaccines

☐ Offers Select Vaccines (**This option is only available for facilities designated as Specialty Providers by the VFC Program)**

A "Specialty Provider" is defined as a provider that only serves (1) a defined population due to the practice specialty (e.g. OB/GYN; STD clinic; family planning) or (2) a specific age group within the general population of children ages 0-18. Local health departments and pediatricians are not considered specialty providers. The Idaho Immunization Program (IIP) has the authority to designate VFC providers as specialty providers.

Select Vaccines Offered by Specialty Provider:

○ DTaP	○ Meningococcal Conjugate	○ Rotavirus
○ Hepatitis A	○ Meningococcal B	○ TD
○ Hepatitis B	○ MMR	○ Tdap
○ HIB	○ Pneumococcal Conjugate	○ Varicella
○ HPV	○ Pneumococcal Polysaccharide	○ Other, specify:
○ Influenza	○ Polio	

IDAHO DEPARTMENT OF HEALTH & WELFARE
DIVISION OF PUBLIC HEALTH

450 W State Street 4th FL
Boise, Idaho 83702
(208) 334-5931

PROVIDER POPULATION

Report the estimated number of children your facility may vaccinate in the next 12 months, by age group. Only count a child once based on the anticipated eligibility status, regardless of the number of visits each child may have. The following table documents how many children may receive VFC vaccine, by category, and how many may receive non-VFC vaccine.

VFC Vaccine Eligibility Categories	# of children who received VFC Vaccine by Age Category			
	<1 Year	1-6 Years	7-18 Years	Total
Enrolled in Medicaid				
No Health Insurance				
American Indian/Alaska Native				
Underinsured in FQHC/RHC or deputized facility[1]				
Total VFC:				

Non-VFC Vaccine Eligibility Categories	# of children who received non-VFC Vaccine by Age Category			
	<1 Year	1-6 Years	7-18 Years	Total
Have Health Insurance (that covers vaccines)				
Other Underinsured[2] (non-Idaho resident)				
Birth Dose (Hep B) – Other Insured at Birthing Hospitals Only[3]		← Birthing Hospitals ONLY		
Total Non-VFC:				
Total Patients (must equal sum of Total VFC + Total Non-VFC)				

[1]Underinsured includes children with health insurance that does not include vaccines or only covers specific vaccine types. Children are only eligible for vaccines that are not covered by insurance.

In addition, to receive VFC vaccine, underinsured children must be vaccinated through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or under an approved deputized provider. In Idaho only the Public Health Districts have a written agreement with an FQHC/RHC and the IIP in order to vaccinate these underinsured children.

[2]Other underinsured are children that are underinsured but are not eligible to receive federal vaccine through the VFC program because the provider or facility is not a FQHC/RHC or a deputized provider (Public Health Districts). These children may be served if vaccines are privately purchased and provided to cover these non-VFC eligible children.

[3]Birth Dose of hepatitis B administered at the birthing facility to infants that are non-Idaho, non-Washington residents who have a health insurance benefit.

TYPE OF DATA USED TO DETERMINE PROVIDER POPULATION (choose all that apply)

- ○ Benchmarking
- ○ Medicaid Claims
- ○ IIS (IRIS)
- ○ Other (must describe):
- ○ Doses Administered
- ○ Provider Encounter Data
- ○ Billing System

IDAHO IMMUNIZATION PROGRAM

2020 PROVIDER VACCINE BRAND CHOICE

FACILITY INFORMATION			
Facility Name:			**VFC Pin#:**
Brand Choice:	July 1, 2020 or date of enrollment	**through**	December 31, 2020 (unless a change is not requested)

COMBINATION VACCINE (select only one)

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

DTAP *(diphtheria, tetanus, acellular pertussis)*

☐ DAPTACEL® ☐ Infanrix®

DTAP-IPV *(diphtheria, tetanus, acellular pertussis, polio)*

☐ Kinrix® ☐ Quadracel™

Hep A *(hepatitis A)*

☐ Havrix® ☐ VAQTA®

Hep B *(hepatitis B)*

☐ Engerix B® ☐ RecombivaxHB®

HIB *(haemophilus influenza* type b)

☐ ActHIB® ☐ Hiberix® ☐ PedvaxHIB®

MCV4 *(meningococcal conjugate)*

☐ Menactra® ☐ Menveo®

Men B *(meningococcal group b)*

☐ Bexsero® ☐ Trumenba® ☐ None

ROTA *(Rotavirus)*

☐ Rotarix® ☐ RotaTeq®

TDAP *(tetanus toxoid, reduced diphtheria toxoid and acellular pertussis)*

☐ Adacel® ☐ Boostrix®

COMPLETED AND SUBMITTED BY	
Name (please print):	Title:
Signature:	Date: