Iowa's
Vaccines for Children Program
Operations Guide

Iowa Department of Public Health
Immunization Program

Revised January 2018

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Overview

January 2018

Welcome to the Iowa Vaccines for Children Program

The Vaccines for Children (VFC) program is a federally funded program providing vaccines at no cost to eligible children from birth through 18 years of age. Eligible children include those who are: enrolled in Medicaid, uninsured, American Indian or Alaskan Native or underinsured. The VFC Program was created by the Omnibus Budget Reconciliation Act of 1993 and was implemented in October 1994 as part of the President's Childhood Immunization Initiative. Funding for the VFC Program is approved by the Office of Management and Budget and allocated through the Centers for Medicare and Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC). Children eligible for VFC vaccines are entitled to receive vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).

The VFC Program is a unique component of the federal Medicaid Program. The VFC Program represents an unprecedented approach to improving vaccine availability nationwide by making federally purchased vaccine available to both public and private immunization providers. With the program in its third decade, it has been recognized for its success in raising immunization coverage rates among high-risk children and reducing disparities in access to health care.

VFC Program Highlights

The VFC Program:

- Provides public-purchased vaccine for eligible children at no charge to VFC-enrolled public and private providers
- Covers vaccines recommended by the ACIP
- Saves parents and enrolled providers out-of-pocket expenses for vaccine
- Eliminates or reduces vaccine cost as a barrier to vaccinate eligible children
- Reduces the practice of referring children for vaccination

VFC Operations Guide/Resources

The VFC Operations Guide and other noted resources are intended for the management and operation of the VFC Program. The requirements and procedures are applicable to all providers receiving VFC vaccines.

As changes to this guide occur, an individual module or section will be revised and the date of the latest revision will appear in the module or section header. New information will be posted on the Immunization Program website (https://idph.iowa.gov/immtb/immunization), and VFC Program providers will be notified.

VFC Program Email List

The Iowa VFC Program has an email list serve available to update VFC providers with important and timely program information. Providers can join the VFC list serve and receive updates directly to their inbox. Visit the Iowa VFC Program webpage (http://idph.iowa.gov/immtb/immunization/vfc) to submit an email address.

Enrollment

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Enrollment Process

All providers wanting to participate in the VFC program must complete the following as part of the enrollment process. All providers who administer and store VFC vaccine are required to enroll in the VFC Program.

- Submit the Provider Enrollment Form; Provider Profile; and Immunization Registry Information System (IRIS) Enrollment Form
- Submit a Vaccine Storage and Handling Plan
- Record and submit refrigerator and freezer temperatures for five days for each unit which will store VFC vaccine
- Receive a VFC Enrollment Site Visit

Medical providers may have a main facility and satellite sites where immunization services are provided. Any satellite site storing VFC vaccine must also enroll in the VFC Program as a separate facility.

Provider Enrollment Requirements

Each provider must agree to the following requirements of the Iowa VFC Program:

- Properly screen patients for VFC eligibility and document the eligibility status at each immunization encounter.
- Comply with the appropriate immunization schedule, dosage, and contraindications established by the Advisory Committee on Immunization Practices (ACIP), and are 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 for the child, or
    - The particular requirement contradicts Iowa law, including laws relating to religious or medical exemptions.
- Maintain all records related to the VFC Program for a minimum of three years and upon request make these records available to public health officials or the Department of Health and Human Services (DHHS). VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records verifying receipt of vaccine, vaccine ordering records and vaccine purchase and accountability records.
- Immunize eligible children with VFC vaccine at no charge to the patient for the vaccine.
- Do not charge a vaccine administration fee to non-Medicaid VFC-eligible children exceeding the administration fee cap of $19.68 per vaccine dose. For Medicaid VFC-eligible children, accept the reimbursement for immunization administration set by the Iowa Medicaid agency or contracted Medicaid health plans.
- Do not deny administration of VFC vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
- Provide current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Compensation Act

(NCVIA) which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

- Comply with following Iowa requirements for vaccine management:
  - Order vaccine and maintain appropriate vaccine inventories.
  - Do not store vaccine in dormitory-style units at any time.
  - Store vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet Iowa Immunization Program storage and handling requirements.
  - Return all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.
- Operate the VFC Program in a manner intended to avoid fraud and abuse.
- Participate in VFC program compliance site visits including unannounced visits and other educational opportunities associated with VFC program requirements.
- Local public health agencies with a signed deputization Memorandum of Understanding between a RHC to serve underinsured VFC-eligible children must:
  - Include "underinsured" as a VFC-eligibility category during the screening for VFC eligibility at every visit.
  - Vaccinate "walk-in" VFC-eligible underinsured children.
  - Report required usage data.
  - 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 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.*
- Pharmacy/pharmacists, urgent care facilities and school-located vaccine clinics must:
  - Vaccinate all "walk-in" VFC-eligible children.
  - Not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee.
- Replace vaccine purchased with state and federal funds deemed non-viable due to provider negligence on a dose-for-dose basis.

Provider Enrollment Form (Appendix 1)

The Provider Enrollment Form is used to document all health care providers practicing at the facility and their agreement to comply with program requirements. It is necessary to include the NPI (National Provider Identifier) number, medical license number and e-mail address for each provider listed. If the facility does not have a physician or nurse practitioner on staff, or does not have an individual NPI number, include the facility's NPI number if applicable.

VFC providers shall re-enroll into the VFC Program annually using the Immunization Registry Information System (IRIS). If health care providers practicing at the facility change during the year, the medical facility is responsible for updating the physician list in IRIS.

Provider Profile (Appendix 2)

The Provider Profile Form, completed either as an individual physician or provider group, is used to establish the number of VFC-eligible children served by the facility for a one-year period. The provider profile allows the Iowa VFC Program to determine how much vaccine a facility is eligible to receive and ensures VFC-funded vaccine is being administered only to VFC-eligible children.

IRIS Enrollment Form (Appendix 3)

IRIS is a confidential, computerized repository of individual immunization records from participating public and private health care providers. VFC providers are required to use IRIS to submit VFC vaccine orders and complete annual VFC Program Re-enrollment. If the facility is an enrolled IRIS user, an IRIS Enrollment Form is not required to enroll in the VFC program. New VFC providers using electronic health records may submit immunizations electronically to IRIS. To establish procedures for electronic data exchange with IRIS, contact the IRIS Help Desk at 1-800-374-3958. All enrolled IRIS users shall review and abide by the IRIS Security and Confidentiality Policy (https://idph.iowa.gov/portals/1/userfiles/39/iowa security and confidentiality policy january 2017.pdf).

Vaccine Storage and Handling Plan (Appendix 4)

New VFC providers must complete the Vaccine Storage and Handling Plan Template to document procedures on vaccine management requirements, safeguarding vaccine supplies and responding to improper vaccine storage and handling events. The routine and emergency storage and handling plan is required for program enrollment and receiving VFC vaccine shipments and should be submitted with the Provider Enrollment and Provider Profile forms.

Refrigerator and Freezer Temperatures (Appendix 5)

Before providers may order and receive VFC vaccine shipments, storage unit temperatures must be evaluated to determine if the units can maintain appropriate temperatures. Providers are required to submit temperature logs demonstrating a minimum of five days of in-range temperatures documented two times each day.

Enrollment Site Visit

Once enrollment forms are submitted and approved, a VFC staff person will contact the facility to set up an enrollment site visit. The enrollment site visit ensures the provider and office staff receive education regarding VFC Program requirements and have appropriate resources to implement the VFC Program.

Facility Types

The VFC Program classifies facilities in the following groups:

- Public Health/County Health Department
- Public Health/County Health Department as agent for FQHC/RHC-delegated authority
- Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC)
- Tribal/Indian Health Services Clinic
- Woman, Infants and Children Clinic
- Family Planning Clinic
- Juvenile Detention Center
- Correctional Facility
- Drug Treatment Facility
- School-Based Clinic
- Private Hospital
- Private Practice (solo/group/HMO)
- Pharmacy

Federally Qualified Health Center (FQHC)

Federally Qualified Health Centers are public and private non-profit health care organizations meeting certain criteria under the Medicare and Medicaid Programs (Sections 1861(aa)(4) and 1905(l)(2)(B), respectively of the Social Security Act) and receive funds under the Health Center Program (Section 330 of the Public Health Service Act). Health centers are community-based and patient-directed organizations serving populations with limited access to health care.

To inquire about FQHC status, contact HRSA, Bureau of Primary Health Care at (301) 594-4300. A look-up tool is also available at http://bphc.hrsa.gov/.

Rural Health Clinic (RHC)

The Rural Health Clinic Program was established in 1977. Its two-fold purpose is to increase access to health care for rural, underserved communities, and expand the use of nurse practitioners, physician assistants, and certified nurse midwives in rural communities.

Currently, RHCs make up one of the largest outpatient primary care programs for rural underserved communities. RHCs provide comprehensive, family-oriented primary health service to medically underserved and disadvantaged populations experiencing financial, geographical, or cultural barriers to care.

To enquire about RHC status, contact the Iowa Department of Public Health (IDPH), State Office of Rural Health at (515) 499-4467.

VFC Delegated Authority

As part of the VFC Program, FQHCs and RHCs have the ability to grant FQHC/RHC status to local public health agencies (LPHA) to immunize underinsured children on their behalf. Delegation of this authority requires a written agreement between the FQHC/RHC and the LPHA. To inquire about delegated authority, contact the VFC Program at 1-800-831-6293.

Provider Identification Number (PIN)

A Provider Identification Number (PIN) is assigned to each enrolled VFC provider site. Using the assigned PIN on all correspondence allows the VFC Program to quickly and accurately respond to providers. It is important to notify the VFC Program and update information in IRIS if there is a change in the facility enrollment information. This includes changes in the contact person, mailing address, shipping address, practice hours, e-mail address and medical providers. Updating facility information ensures accurate provider data and allows for the successful delivery and receipt of vaccine orders in a timely and efficient manner. PINs are assigned to a particular site and do not transfer with a health care provider.

Eligibility

January 2018

VFC Eligibility Criteria
Screening Documentation
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VFC Eligibility Criteria

VFC Program providers may only administer VFC vaccine to eligible patients. Children, 18 years of age and younger, who meet at least one of the following criteria are eligible to receive VFC vaccine:

- Medicaid enrolled
  - Children enrolled in Medicaid/IA Health Link as primary or secondary coverage are eligible for the VFC Program. This includes individuals who have a primary health insurance company and Medicaid as secondary coverage. These children are eligible for the VFC Program and should be immunized using VFC vaccine.
  - Children enrolled in Medicaid/IA Health Link must present a Managed Care Organization (MCO) member ID card to verify enrollment **(Appendix 6)**. MCO's in Iowa include:
    - Amerigroup Iowa, Inc.
    - UnitedHealthcare Community Plan
- Uninsured
- American Indian or Alaskan Native
- Underinsured
  - Underinsured children include those with health insurance but the benefit plan does not include immunizations, covers only select vaccines, or caps the vaccine cost at an established limit. Underinsured children are eligible to receive VFC vaccine only if they are served by a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or Local Public Health Agency (LPHA).
  - The child's parent or guardian must present an insurance card or name and policy number to verify insurance coverage for vaccines.
  - 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, these children are considered insured and not eligible to receive VFC vaccines at the immunization encounter.

Underinsured Circumstances-VFC Eligible

- Some insurance plans limit coverage to a specific number of provider visits annually. If a child's insurance will not cover the cost of vaccine after the child has exceeded the number of provider visits, the child can be considered underinsured for the purposes of the VFC Program because the insurance would not cover the vaccine. The child would be VFC eligible and can only be seen at a FQHC/RHC/LPHA.
- Persons 18 years of age and younger who do not know their insurance status and who present at family planning clinics for contraceptive services or STD treatment can be considered uninsured for the purposes of the VFC Program. Persons 18 years of age and younger who may have insurance but because of the confidential circumstances for seeking services in a family

planning clinic does not have access to insurance coverage is considered uninsured for the purposes of the VFC Program.
- If a person 18 years of age and younger loses access to health insurance because of incarceration, the minor is considered uninsured and VFC eligible.

Insured Circumstances-Not VFC Eligible

- Children whose health insurance covers the cost of vaccinations are NOT eligible for VFC Program benefits even when a claim for the cost of the vaccine and its administration would be denied if submitted to the insurance carrier for payment because the plan's deductible (high deductible plan) had not been met.
- Some insurance plans may cover all ACIP-recommended childhood vaccines but exclude certain combination vaccines or certain products. A child with this type of coverage would be considered insured and NOT eligible for VFC because all recommended vaccines are covered. Some insurance plans may cover a portion of the cost of the vaccine, even though it may be only a small portion of the cost of the vaccine, this child is considered insured for the purpose of the VFC Program and is NOT eligible for the program.

hawk-i Program

- Children enrolled in *hawk-i* are not eligible under the VFC Program since the *hawk-i* Program is a full coverage insurance plan. Children enrolled in *hawk-i* must be vaccinated with private purchased vaccine.
- Children enrolled in *hawk-i* are members of the MCO's serving Medicaid patients. MCO member ID cards for *hawk-i* patients appear similar to Medicaid with the exception of the *hawk-i* name and or logo which replaces the IA Health Link logo **(Appendix 7)**. Children presenting a *hawk-i* MCO member ID card are NOT eligible for VFC vaccine.

In general, the location where vaccine services are delivered is not a factor in determining VFC eligibility (e.g., LPHA). Children receiving vaccines at a local public health agency cannot automatically be considered VFC eligible. Children must be screened for eligibility, and VFC vaccine can be administered only to VFC-eligible children.

VFC-eligible children, regardless of their state of residence, may be seen at Iowa VFC enrolled provider sites and receive vaccine provided by the Iowa VFC Program. Providers vaccinating Medicaid-enrolled children from another state must enroll as a Medicaid provider in that state to bill for a vaccine administration fee and/or office visit fee.

Refugees, immigrants, foreign-exchange students, and undocumented immigrants must be screened for VFC eligibility. If the individual does not have insurance or are Medicaid enrolled they should be vaccinated with VFC vaccine.

Screening Documentation

In order for children to receive immunizations through the VFC program, eligibility screening and documentation must take place at each immunization visit. Providers must properly and accurately document eligibility status, including eligibility category, at each immunization encounter prior to vaccine administration. To be considered accurate, patient records must include the following:

- If Medicaid enrolled, have documentation of Medicaid/IA Health Link status (e.g., copy of MCO member ID card) **(Appendix 6)**
- If Uninsured, have no documentation of insurance or Medicaid enrollment
- If AI/AN, proof of eligibility is not required
- If Underinsured, have documentation of insurance (e.g., copy of card or name/policy #)

To be considered properly documented, the date of the last screening must correspond to the date of the last immunization visit and be different from the date of the previous screening result. VFC providers must use the Patient Eligibility Screening Record **(Appendix 8)** or incorporate screening questions into an existing form or electronic medical record. For each child enrolled, a Patient Eligibility Screening Record or equivalent information must be completed and kept on file for at least three (3) years regardless of VFC eligibility.

Providers using an electronic health record (EHR) or the Immunization Registry Information System (IRIS) to document patient eligibility must have the patient review the Patient Eligibility Screening Record to determine eligibility status. Providers then select the child's current eligibility status to add the new immunizations to the patient record in the EHR or IRIS.

Administration Fee

The federal VFC Program requires the Secretary, Department of Health and Human Services (HHS), to establish a limit on the dollar amount providers can charge and be reimbursed for administration of vaccine to VFC- eligible children.

The maximum administration fee established by HHS per injection for Iowa is $19.68. The maximum administration fee is applicable to VFC-eligible patients who have no health insurance, are American Indian/Alaskan Native, or are underinsured (seen only at Federally Qualified Health Centers, Rural Health Clinics, and Local Public Health Agencies). The vaccine administration fee should be charged to the patient. Providers may not deny immunization services for a patient's inability to pay the administration fee.

Office Visit Fee

The VFC Program allows providers to charge an office visit fee established by the facility. Discretion should be used to ensure the office visit fee does not create barriers for patients to receive immunizations. Participating in the VFC Program requires health care providers to not deny administration of VFC vaccine due to inability of the child's parent/guardian/individual of record to pay.

Vaccine Ordering

September 2017

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VFC resolutions passed by the Advisory Committee on Immunization Practices (ACIP) form the basis for VFC program policies on vaccine availability and usage. Resolutions may not necessarily match the general usage recommendations of the ACIP, but rather represent the rules providers must follow for administering each specific vaccine under the VFC program. The CDC and Centers for Medicare and Medicaid Services (CMS) communicate VFC resolutions to state Immunization and Medicaid programs for dissemination to local providers. VFC vaccine must be administered according to the guidelines outlined by the ACIP in the VFC resolutions.

Vaccine Availability

Iowa VFC Program Vaccine Brand and Presentation Policy

The Iowa VFC Program offers all vaccines listed on the CDC/VFC vaccine contract, unless noted in the Exceptions (see below). In addition, the Program allows provider choice between manufacturer and brand and offers vial and syringe presentations when available.

Vaccine Brand and Presentation Exceptions

- PPSV 23 is available only on a case-by-case basis. Cases shall be identified as high-risk as defined by the VFC provider and in consultation with the Iowa VFC Program.
- The Iowa VFC Program will limit or restrict vaccine products or quantities due to constraints and limitations imposed by CDC or vaccine manufacturers.

The VFC Program shall substitute ordered vaccine with an equivalent vaccine if a provider places an order and the vaccine is unavailable. If a vaccine is unavailable, the IRIS order form shall be updated to show only available products. VFC covered vaccines are listed in **(Appendix 9)**.

Vaccine Ordering

Providers are responsible for ordering and maintaining an adequate vaccine supply at their facility. Providers shall submit VFC vaccine orders in IRIS for processing based upon the facility's assigned ordering frequency (monthly, bi-monthly, quarterly). The goal of ordering frequency is to balance shipping costs with inventory and vaccine wastage costs. Each VFC provider is assigned a vaccine order frequency based on the number of doses distributed annually. VFC providers shall place vaccine orders for adequate doses of vaccine to immunize children for the period of time determined by the assigned ordering frequency.

Vaccine Ordering Process

The order processing and delivery schedule is subject to change during holidays and extreme weather conditions. Facilities shall allow up to 30 days to receive vaccine orders.
Providers:

- Select the day(s) and delivery hours on the Create Order screen in IRIS which the provider is accepting orders. The hours entered will carry over with each subsequent vaccine order. Update day(s) and delivery hours in IRIS as needed when submitting vaccine orders. Do not place orders if the facility is going to be closed for an extended period of time.
- Order vaccine quantities consistent with the facility's established provider profile (doses administered reports) and the number of VFC eligible children served.
- Review all vaccine needs prior to ordering. Providers should consider the following:
    - Vaccines which may expire before the next ordering frequency
    - Current vaccine inventory (consider historical doses administered data to ensure the facility does not run out of vaccine before the next order frequency), single antigens and combination vaccines in inventory
    - Seasonality (school physicals, kindergarten round-up)
    - Planned specialty clinics (school based clinics)
- Doses on hand data automatically display on vaccine order form for IRIS inventory users. Enter current vaccine inventory (doses on hand) for each vaccine if the provider is a non-inventory IRIS user.
- Determine the proper quantity for an order based upon the recommended order quantity displayed on the Create Order screen in IRIS. The recommended order quantity is calculated based on VFC doses administered during the same period the previous year, doses on hand and package size. The recommended order includes additional doses of vaccine to account for packaging quantity, unexpected need or potential delays.
- Enter the vaccines needed and submit the vaccine order in IRIS.

VFC Program:

- Process vaccine orders in the order they are received.
- Review each vaccine order to verify need for quantity of vaccine ordered. The amount of vaccine ordered is compared to:
    - Recommended vaccine order quantity
    - Number of doses on hand
    - Vaccine expiration dates
    - Single antigens and combination vaccines in inventory
    - Doses administered for similar time period 12 months earlier
    - Doses distributed during last quarter
    - Provider profile
- Contact providers as necessary if order quantities require follow up:
    - Review vaccine needs with the provider to verify and approve the vaccine order.
    - Adjust vaccine order if the need is not supported.
    - Discuss vaccine needs when a product is in limited supply and to accommodate a decreased allocation quantity.
- Approve vaccine order in IRIS when review is completed and order is verified.
- Make changes to the vaccine order if needed and process the order in IRIS.
- Submit order to McKesson for distribution.

Distribution of Varicella Containing Vaccine

All VFC varicella-containing vaccine orders will be shipped directly from the manufacturer (Merck). The maximum time required for vaccine orders to be processed and shipped is 30 days.

Receiving and Unpacking Vaccine Shipments

In order to receive vaccine shipments, the facility must be available to receive vaccine shipments at least one day a week other than Monday, and be available for at least four consecutive hours during the day.

VFC providers must develop and post a protocol for accepting vaccine deliveries that indicates who may accept vaccine shipments to ensure vaccines are stored appropriately and **IMMEDIATELY** after arrival.

All facility staff involved in accepting deliveries shall be trained and complete the following with each vaccine shipment:

- Immediately notify the vaccine coordinator or alternate (back-up) coordinator when deliveries arrive.
- Unpack vaccine shipment immediately.
- Inspect the vaccine and packaging for damage.
- Cross check the vaccine received with the shipping invoice to match the number of doses, lot number and expiration dates. If there is a discrepancy with the vaccine order, immediately contact the VFC Program at 1-800-831-6293, ext. 5.
- Verify shipments which include lyophilized (freeze-dried) vaccines come with the correct type and quantity of diluents. Diluents for varicella-containing vaccines are stored in a separate compartment in the lid of the shipping container and should be stored separately in the refrigerator.
- Check the cold chain monitor (CCM) for indication of a temperature excursion during transit. CCMs are stored in a separate compartment of the shipping container. Document warm or cold monitor readings if indicative of out-of-range temperature exposure, and immediately contact the VFC Program at 1-800-831-6293, ext. 5 for further guidance. Store the vaccine at appropriate temperatures. Mark the vaccine "Do Not Use" so the potentially compromised vaccines can be easily identified and not used until viability of vaccine is determined. Document action taken based on VFC Program instructions.
- For VFC direct shipments of frozen vaccine (varicella-containing), the packing list will show the maximum time vaccines can be in transit based on the shipment date. Providers should contact the VFC Program immediately at 1-800-831-6293, ext. 5 if vaccines were received after the acceptable transit time.
- Document on the invoice the date vaccine was received. Maintain vaccine shipping invoices for both public and private inventory for a minimum of three years.
- Store vaccine immediately at appropriate temperatures according to manufacturers' product specifications.
- "Receive" VFC vaccine orders electronically using 'Manage Transfer' into the organization's IRIS inventory. Failure to receive vaccine orders in IRIS may result in inaccurate vaccine inventory, unaccounted for vaccines and errors in VFC vaccine doses administered reporting.

Vaccine Management

January 2018

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Proper Vaccine Storage Temperatures
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Vaccine Accountability
Management of Expired, Spoiled and Wasted Vaccine
Vaccine Restitution Policy

Proper management of vaccine is one of the most important activities conducted by a VFC provider. Implementing proper inventory maintenance and storage and handling procedures will ensure the vaccine cold chain is maintained at the clinic. Sound vaccine management practices will minimize vaccine loss and waste. Providers should consult CDC's Vaccine Storage and Handling Toolkit available at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html for the most current guidance and best practices regarding vaccine storage and handling. This should be the primary resource for vaccine storage and handling information.

Staffing and Training Requirements

Each VFC provider must designate one staff member as the primary vaccine coordinator and at least one back-up coordinator who is able to perform the same responsibilities as the primary vaccine coordinator. These positions shall be responsible for oversight of vaccine management within the facility and serve as the VFC contact for the office. Providers are required to update contact information in IRIS when there is a change in vaccine coordinators. Instructions to make changes for all organization contacts in IRIS can be found in the IRIS Administrative User Training Handout, Section XI, pages 24-26 available on the IRIS website..

The primary and back-up vaccine coordinators are required to complete the CDC's web-based modules, "You Call the Shots" each year. The training is available at https://www.cdc.gov/vaccines/ed/youcalltheshots.html. The two modules listed below are required prior to completing the re-enrollment process:

1. *Vaccine Storage and Handling*
2. *Vaccines for Children (VFC)*

VFC providers must annually train ALL staff with vaccine management responsibilities on proper vaccine storage and handling procedures. Staff training must be documented and included as part of the facility's Vaccine Storage and Handling Plan **(Appendix 4)**.

Vaccine Storage and Handling Plan

VFC Program providers must develop and maintain a written routine and emergency Vaccine Storage and Handling Plan. The Immunization Program developed a Vaccine Storage and Handling Plan template **(Appendix 4)** to assist providers. The plan should be posted on or near the vaccine storage unit so it is easily accessible. At a minimum, the plan must be reviewed and updated annually, or any time there is a change in staff with responsibilities specified in the plan. A log with staff member's name and date of training should be kept as documentation.

Storage Unit Requirements

Refrigerators and freezers used for vaccine storage must:

- Maintain appropriate temperature range at all times.
- Provide sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer to stabilize the temperature.
- Be large enough to hold the year's largest inventory without crowding.

Vaccine Storage Unit Recommendations

The following list provides guidance on types of storage units, in order of preference, offering greater assurance of proper temperatures based on equipment testing by the National Institute of Standards and Technology (NIST).

- Purpose built or pharmaceutical grade unit
  - Medical grade (pharmacy or blood bank) purpose built refrigerator or freezer units provide a stable, uniform controlled cabinet temperature with minimal temperature fluctuation.
- Separate stand-alone refrigerator or freezer units
  - A stand-alone refrigerator or freezer unit is a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage.
  - Frost-free or automatic defrost cycle units are preferred.
- Refrigerator compartment only of a combination household refrigerator/freezer unit
  - Typical household single-condenser combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures in refrigerator and freezer compartments.
  - Use only the refrigerator compartment for refrigerated vaccines.
  - Keep the freezer compartment on to maintain proper temperatures in the refrigerator. Place water bottles on top shelf, floor, and in door racks of refrigerator to maintain stable temperatures and serve as a physical barrier to placing vaccines in an area where there is greater risk for temperature excursions.
  - Use a stand-alone freezer for frozen vaccines.

Use of Dorm-Style Refrigerators

The use of dormitory or bar-style refrigerator/freezer units for storage of federally purchased vaccines is not allowed under any circumstances, including temporary storage. Performance testing indicates dorm-style units cannot reliably maintain appropriate vaccine storage temperatures. A dorm-style refrigerator is defined as a small combination refrigerator/freezer unit with one external door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator. A dorm-style unit should never be used for storing vaccine.

Equipment Safeguards

- Plug in only one storage unit per electrical outlet to avoid creating a fire hazard or triggering a safety switch that would turn off power.
- Use a safety-lock plug or an outlet cover to prevent the unit from being unplugged.
- Post "DO NOT UNPLUG" warning signs at outlets and on storage units to alert staff, custodians, electricians, and other workers not to unplug units.
- Label fuses and circuit breakers to alert people not to turn off power to storage units. Labels should include immediate steps to take if power is interrupted. If the building is owned by a third party, work with the building manager to ensure access to circuit breakers.
- Ensure doors are shut tightly.

Temperature Monitoring Devices

Iowa VFC providers must use continuous temperature monitoring devices (digital data loggers) with a valid and up to date certificate of calibration to monitor VFC vaccine temperatures during routine clinic storage, transport of vaccine between providers and during offsite vaccination clinics. The use of digital data loggers is required as they provide more accurate and comprehensive documentation of storage unit temperatures.

To meet VFC program requirements, the device must be equipped with:

- A temperature probe
  - A buffered probe is recommended
- An active temperature display which can be easily read from the outside of the unit
- Continuous monitoring and recording capabilities where the data can be routinely downloaded
- A current and valid Certificate of Calibration Testing issued by an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) accredited laboratory or, if not ILAC MRA-accredited, the certificate must contain the measurement results and a statement indicating it meets ISO 17025 standards

The following are additional recommended features for digital data loggers:

- Alarm for out-of-range temperatures
- Current temperature, as well as minimum and maximum temperature display
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings (device will not rewrite over old data and stops recording when memory is full)
- User programmable logging interval (or reading rate) recommended to measure and record temperatures at a maximum time interval of every 30 minutes

Back-up Temperature Monitoring Device

Iowa VFC providers shall have at least one back-up digital data logger with a valid and current certificate of calibration from an ILAC/MRA accredited laboratory or that complies with ISO 17025 specifications readily available in case a temperature monitoring device in a storage unit unexpectedly stops working or needs to be replaced during calibration testing. **T**he back-up device must meet the CDC data logger requirements.

If the back-up device is not physically on-site, a plan must be in place documenting how the back-up device will be accessed within a timeframe to comply with the requirement to assess and record temperatures as required.

Certificate of Calibration Testing

VFC providers must maintain a Certificate of Calibration (also known as Report of Calibration Testing) for each temperature monitoring device. Calibration testing and traceability must be performed by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body **OR as an alternative** by a laboratory or manufacturer that provides documentation demonstrating calibration testing performed meets ISO/IEC 17025 international standards for calibration testing and traceability.

All Certificates of Calibration Testing must include:

- Model/device name or number
- Serial number
- Date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or instrument in tolerance)
- Recommended uncertainty of +/-0.5° C (+/-1° F) or less

Placement of Temperature Monitoring Devices

In a household combination unit or commercial unit, the device must be placed in a central area of the storage unit directly with the vaccines. Temperature monitoring devices must not be placed in unit's doors, near or against walls, or close to the floor, ceiling, or vents. In a pharmaceutical or purpose-built unit, placement in other locations may be suitable based upon manufacturer recommendations.

Proper Vaccine Storage Temperatures

Vaccines must be maintained properly to protect viability. Storage and handling errors compromising vaccines are costly. Vaccines must be stored properly from the time they are manufactured until they are administered. Exposure to temperatures outside recommended ranges will reduce potency and increase the risk recipients are not protected. Adhering to proper storage and handling procedures will minimize the potential for vaccine loss and wastage.

Refrigerated vaccines must be stored at 36.0° F through 46.0° F or 2.0° C through 8.0° C.
Store all varicella-containing vaccine (Varivax and ProQuad) at -58.0° through +5.0°F or -50.0° through -15.0°C.

Temperature Alarm Settings

Using temperature alarm settings safeguards vaccine viability by alerting staff of out of range storage temperatures. Data loggers provide more accurate and detailed temperature readings than the previously used min/max thermometers. Data loggers are able to record temperatures to a tenth of a degree, VFC providers can assure viability of vaccines by utilizing appropriate parameters to evaluate storage unit temperatures.

The temperature alarm settings are as follows. Instructions to reconfigure temperature alarm settings for the state supplied LogTag TRED30 are available on the Immunization Program, Vaccine Storage and Handling webpage.

Refrigerator	**Freezer**
35.9°F and 46.1°F	5.1°F
1.9°C and 8.1°C	-14.9°C

Best Practices for Storing Vaccine in Storage Units

- Store MMR vaccine in the freezer. Storing MMR vaccine in the freezer with MMRV may help prevent inadvertent storage of MMRV in the refrigerator. Diluent should NOT be stored in the freezer.
- Store all opened and unopened vaccines and diluents in their original packaging with lids closed to protect them from light until administration.
- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles and frozen packs.
- Place water bottles on the top shelf and floor and in the door racks. Do not store vaccine in the door of the unit, crisper, or in the bottom of the unit. Remove vegetable bins from the refrigerator.
- Store vaccines requiring refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent.
- Store vaccines requiring freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.
- Store vaccine products with similar packaging in different locations in the storage unit to avoid confusion and medication errors.
- Store vaccine with enough space to allow cold air to circulate around the vaccine.
- Do not store food or drink in the storage unit.
- Open only one box of a particular vaccine at a time to control vaccine use and allow easier inventory control.
- Keep VFC vaccine organized and separate from private vaccine; clearly label both.
- Limit access to the vaccine supply to authorized personnel only.

Back-up Supplies/Facility

- It is important to have a back-up plan to appropriately store vaccine if vaccine storage equipment malfunctions or there is a power outage.
- Make formal arrangements (memorandum of understanding) with a back-up facility.
- Train a designated person and backup person at the facility to accept vaccine if it must be moved.
- Before moving vaccine, call the location to ensure the facility is available to store the vaccine (e.g., not damaged due to storms).
- If the back-up facility is not available, contact the other facilities on the back-up facility list.

Temperature Monitoring

Temperature monitoring should be the primary responsibility of the provider/facility vaccine coordinator and back up. VFC providers must have protocols for training provider staff on proper assessment and interpretation of temperature data as well as proper documentation of findings. All staff monitoring temperatures must be trained how to respond and document actions taken when temperatures are outside the appropriate range. Temperature monitoring protocols include:

- Designated staff must check and record refrigerator and freezer temperatures twice daily (at the beginning and end of each day).
- Designated staff must check and record the min/max temperatures at the start of each workday.
- Each temperature reading must be accompanied by the time of the reading and the name or initials of the person who assessed and recorded the reading.
- Storage temperatures must be recorded on a temperature log **(Appendix 5)** and maintained for at least 3 years. If a digital data logger has the capability to annotate an electronic temperature check with the time and initials of the person checking the temperature, it is not necessary to manually log the temperature at each temperature check. Manual recording of the daily min/max temperature will be required if not included as part of the annotation.
- Designated back-up staff should review the temperature log at least weekly to ensure proper temperature recording and take action if out-of-range temperatures are found on the logs during review. Digital data logger data should be downloaded, reviewed and printed every two weeks.

Out-of-range Temperatures

Immediate action must be taken if a temperature outside of the recommended range is found. Providers should immediately store vaccine under correct temperature storage conditions and contact the VFC Program at 1-800-831-6293. Vaccine should be marked "Do Not Use" and cannot be administered until the VFC Program has been contacted and decisions have been made regarding viability.

Documentation of a temperature excursion includes recording essential data related to the improper storage temperatures on the Emergency Vaccine Response Worksheet and documenting each vaccine storage incident and action taken on the Vaccine Storage Troubleshooting Record **(Appendix 4)**.

Vaccine Inventory Management

Public and private providers enrolled in the VFC program are responsible for the proper maintenance of their vaccine inventories. Key elements of VFC vaccine inventory management include:

- Complete a monthly count of vaccine and diluent doses prior to ordering. This will ensure enough vaccine inventory to meet the needs of the facility, and is useful for checking accuracy of balance of doses in IRIS or stock record.
- VFC program providers tracking inventory in IRIS should print an inventory list from IRIS at least monthly to verify actual inventory in refrigerator/freezer. IRIS vaccine inventories should match actual refrigerator/freezer vaccine counts. If inventory discrepancies are identified, an inventory hand count should be conducted weekly.
- Rotate vaccine and check expiration dates.
- Expiration dates vary by type of vaccine or diluent and lot number. Expiration dates should be checked at least monthly and stock should be rotated to ensure the soonest to expire is in front. Expiration dates that list only month and year are viable through the last day of the month.

Multi-dose vials of vaccine shall be administered until the expiration date printed on the vial or vaccine package unless otherwise noted in the vaccine package insert.
- Keep public (VFC) vaccine separate from private vaccine and clearly label both. Train staff to distinguish VFC vaccine from private stock.
- Order vaccines in the appropriate amounts.
- Avoid stockpiling or inventory buildup.
- Maintain adequate inventories of VFC and private vaccine to eliminate occurrences of borrowing or transferring vaccine.
- Report VFC vaccine that will not be used and will expire within two to three months to the Iowa VFC Program at 1-800-831-6293, ext. 4.

Vaccine Borrowing

VFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both VFC and non-VFC-eligible patients. Vaccine borrowing should be rare and must be due to an unforeseen delay or circumstance surrounding the vaccine ordered. Borrowing VFC vaccine is the exception rather than the rule, and routine borrowing may be grounds for termination from the VFC Program. If a facility continuously uses private stock or does not document usage appropriately, vaccine accountability procedures will be reviewed which may lead to further investigation and termination.

Providers must document the following information on the Vaccine Borrowing Report Form **(Appendix 10)**.
- Type of vaccine and number of doses borrowed
- Lot numbers of borrowed and replacement vaccine doses
- Reason for borrowing vaccine
- Date borrowed vaccine was replaced

Once the borrowing and payback are completed, submit a copy of the form to the Iowa VFC Program.

In the rare event the primary insurance company denies payment for vaccine and the administration fee, the provider may replace the private vaccine dose with VFC vaccine and bill Medicaid for the administration fee and an appropriate office visit fee. IDPH does not have the ability to reimburse providers for the cost of the private purchased vaccine. Iowa Department of Human Services (DHS) – Medicaid Program will not reimburse for acquisition cost of vaccines provided by the VFC Program. This must be documented on the VFC borrowing form.

All borrowing transactions require corrective action in IRIS to update VFC and private vaccine inventory. The steps to document borrowing transactions are provided in the Vaccine Borrowing Instructions **(Appendix 11)**.

Viable Vaccine Transfers

Prior approval of vaccine transfers between providers must be granted from the VFC Program by calling 1-800-831-6293, ext. 4. The following information is needed by the VFC Program to complete a vaccine transfer:
- Vaccine type
- Lot number
- Expiration date
- Number of doses
- VFC PIN of transferring and receiving providers

Follow these steps to transfer viable VFC vaccine:

- The cold chain must be maintained during the transfer of vaccine. For the safe transport of vaccine, providers should consult CDC's Storage and Handling Toolkit (https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)
- Beginning January 1, 2018, VFC providers will be required to use a data logger during vaccine transport.
- Temperature documentation for the last three months must be available validating the vaccine has not been exposed to out of range temperatures impacting usage of the vaccine and the documentation is included with the transferred vaccines.
- After receiving approval from the VFC Program, providers must:
  - Document vaccine transfer information on the VFC Vaccine Transferred Between VFC Providers form **(Appendix 12)** and fax the form to 1-800-831-6292.
  - Document in IRIS all vaccine transferred to another provider **(Appendix 13)**.

Vaccine Accountability

All administered doses must be entered into IRIS by VFC providers who manage inventory in IRIS. VFC providers who do not manage inventory in IRIS must record and submit the Monthly Doses Administered Report form **(Appendix 14)**.

Management of Expired, Spoiled and Wasted Vaccine

Expired vaccine is considered nonviable vaccine when it is past the manufacturer's expiration date on the vial/syringe.

VFC providers are required to notify the VFC program coordinator of short-dated vaccine doses that will not be used and will expire within two to three months. Short-dated vaccine can be transferred to other VFC providers who are able to administer them prior to expiration, reducing nonviable vaccine wastage. All transfers of soon to expire vaccines must be approved and coordinated by the VFC program.

Spoiled vaccine is nonviable vaccine 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
- Spoiled-other
- Recall

Wasted vaccine is nonviable vaccine as a result of the following:

- Vaccine drawn into the syringe but not administered
- Vaccine in open vial but doses not administered
- Compromised vial, broken vial, or lost vial
- Lost and unaccounted for vaccine doses

VFC provider requirements for the management of expired, spoiled and wasted vaccine

- Remove nonviable vaccine from storage units to avoid unintentional use and label box as "Nonviable Vaccine-Do Not Use".
- Report all vaccine loss to the VFC program:
  - VFC providers using IRIS inventory shall document vaccine loss using appropriate reasons provided in the registry to deduct doses from inventory. Expired vaccine is automatically adjusted by IRIS in the facility inventory. Any adjustments made to VFC inventory in IRIS using the following reason codes will require providers to return vaccines to McKesson Specialty Distribution.
    - Expired
    - Natural Disaster/Power Outage
    - Refrigerator Too Warm
    - Refrigerator Too Cold
    - Failure to store properly upon receipt
    - Vaccine spoiled in transit
    - Mechanical Failure
    - Spoiled
    - Recall
  - For IRIS non-inventory providers, expired and spoiled vaccine shall be reported on the Nonviable VFC Vaccine Return Form **(Appendix 15)** and faxed to the VFC Program. When completing the form, include the reason vaccine is nonviable, number of doses, and vaccine lot number for each vaccine. Doses of vaccine reported in the vaccine loss column without an accompanying lot number cannot be accurately accounted for. Any reported expired and spoiled vaccine must be returned to McKesson Specialty Distribution. Open vials of vaccine are not returnable but must still be documented on this form.

Nonviable Vaccine Return Process

- VFC providers shall return spoiled/expired doses to McKesson Specialty Distribution as soon as possible but not to exceed six months after the expiration date. Return of nonviable vaccine is necessary for the Iowa VFC Program to receive federal excise tax credit.
- Instructions outlining the process to return nonviable vaccine for VFC providers using IRIS inventory are available in **(Appendix 16)**.
- For IRIS non-inventory providers, nonviable vaccine return instructions are available on the Nonviable VFC Vaccine Return Form **(Appendix 15)**.
- Wasted vaccine cannot be returned to McKesson Specialty Distribution and should be discarded according to clinic policy. Open multi-dose vials that are spoiled will remain on the IRIS vaccine returns page until six months after the expiration date.

Vaccine Restitution Policy

The Vaccine Restitution policy outlines requirements for VFC Program providers to replace, at the provider expense, unaccounted for and wasted (expired, spoiled or improperly stored) vaccine due to the provider's negligence. This policy addresses instances of extreme/on-going negligence resulting in the wastage of VFC vaccine **(Appendix 17)**.

Fraud and Abuse

September 2017

Definition of Fraud and Abuse
Examples of Fraud and Abuse

It is essential for providers participating in the VFC Program to fully understand program requirements and what constitutes fraud and abuse. The VFC program definitions on fraud and abuse are consistent with Medicaid regulations (42 CFR § 455.2), and for purposes of this VFC Operations Guide, the following definitions will be used.

Definition of Fraud and Abuse

Fraud
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 himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse
Abuse is defined as provider practices inconsistent with sound fiscal, business or medical practices, and result in an unnecessary cost to the Medicaid Program [and/or including actions resulting in an unnecessary cost to the Immunization Program, a health insurance company or a patient]; or in reimbursement for services not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices resulting in unnecessary cost to the Medicaid Program.

Examples of Fraud and Abuse

The VFC Program provides education during the provider enrollment process and during VFC compliance site visits to help prevent situations that may constitute fraud and abuse. Lack of adherence to VFC Program requirements may lead to fraud and abuse. The VFC Program will investigate all allegations of fraud and abuse and determine appropriate action. If deemed necessary, the VFC Program will notify the proper agencies to conduct a full investigation. Fraud or abuse can occur in different ways. Some examples of fraud and abuse include:

- Providing VFC vaccine to non-VFC eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC vaccine
- Charging more than the established maximum charge ($19.68) for administration of a VFC vaccine to a federally vaccine-eligible child
- Denying VFC-eligible children VFC vaccine due to parents' inability to pay the administration fee
- Failing to implement provider enrollment requirements of the VFC Program
- 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 fully account for VFC vaccine
- Failing to properly store and handle VFC vaccine
- Ordering VFC vaccine in quantities or patterns not consistent with provider profiles or otherwise over ordering VFC doses
- Wasting VFC vaccine

Quality Assurance/Program Accountability

September 2017

VFC Site Visits

VFC Site Visits

VFC site visits are conducted to ensure the quality of the VFC Program and strengthen program accountability. VFC visits help determine a provider's compliance with VFC program requirements. This includes identifying potential issues with VFC vaccine accountability and determining whether VFC vaccines are being handled, stored, and administered in accordance with the laws and policies governing the VFC program.

Quality assurances and review of provider practices takes place during three types of site visits:

- Enrollment site visit
- Compliance site visit
- Drop in storage and handling visit

The goals of these visits are to:

- Identify areas where providers are doing well and areas needing additional follow-up.
- Identify the educational needs of VFC providers in order to support them with meeting program requirements.
- Ensure VFC-eligible children receive properly managed and viable vaccine.

Enrollment Site Visit

VFC staff will conduct an enrollment VFC site visit with all new providers enrolling in the VFC Program. The new enrollment visit ensures provider and office staff are educated on VFC Program requirements, have appropriate resources to implement the VFC Program requirements, that necessary paperwork is completed, and vaccine storage units can maintain appropriate temperatures. Vaccine will not be shipped until the enrollment site visit is complete.

Compliance Site Visit

Federal guidelines require the VFC Program to conduct compliance site visits at each VFC enrolled facility. The purpose of the site visit is to:

- Review VFC eligibility screening procedures
- Verify information in the provider profile
- Administer the VFC provider site visit questionnaire
- Review VFC vaccine administration, storage and handling
- Ensure VFC Program policies are being properly implemented
- Provide feedback and, as necessary, request corrective action and follow up of identified issues

Drop In Storage and Handling Visits

These unannounced visits serve as a "spot check" for proper storage and handling practices. Providers are prioritized and selected based on the provider's previous history with storage and handling compliance issues. The goal of the visits is to provide guidance and educati on on proper storage and handling to ensure all VFC-eligible children are receiving properly managed vaccines.

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