Health and Human Services
Public Health

Iowa's Vaccines for Children Program Operations Guide 2024-2025

Immunization Program

Updated June 1, 2025

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April 2024

Overview of the Iowa Vaccines for Children Program

Overview of 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, created by the Omnibus Budget Reconciliation Act of 1993, 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). VFC-eligible children are entitled to receive all 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 healthcare.

VFC Program Highlights

The VFC Program:

- Provides public-purchased vaccine for eligible children at no charge to VFC-enrolled public and private healthcare 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 and 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. VFC Providers will be notified when new information is posted on the Immunization Program website.

VFC Program E-mail List

The Iowa VFC Program has an email listserv available to update VFC providers with important and timely program information. Providers can join the VFC listserv and receive updates directly to their inbox. Contact the VFC Program at 800-831-6293 or email IowaVFC@hhs.iowa.gov to submit an email address.

Enrollment

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Enrollment Process

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 two days for each unit that will store VFC vaccine. See ***Temperature Monitoring*** *(Page 23)* for further guidance.
- Submit a copy of the Certificate of Calibration for each digital data logger (DDL) used to monitor temperatures in units that will store VFC vaccine and backup temperature monitoring device.
- If applicable, submit a copy of the Accreditation Certificate as an RHC or FQHC.
- 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

√ *REQUIREMENT*

Provider Enrollment Form (*Appendix 1)*

Providers participating in the VFC Program must sign and agree to the requirements contained in the Provider Enrollment Form.

The following are requirements of the Iowa VFC Program:

- Properly screen patients for VFC eligibility and document the eligibility status at each immunization encounter.
- Select and document the VFC eligibility category requiring the least out-of-pocket expense to the patient.
- Comply with the appropriate immunization schedule, dosage, and contraindications established by the Advisory Committee on Immunization Practices (ACIP), that 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 (3) years and upon request make these records available to public health officials or the Iowa Department of Health and Human Services (Iowa HHS). VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records verifying receipt of vaccine, vaccine ordering and vaccine purchase records 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 Iowa 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, or individual of record is unable to pay the administration fee.
- Provide current Vaccine Information Statements (VIS) each time a vaccine is administered or an Immunization Information Statement prior to administration of nirsevimab.
- Maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA) that includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) and adverse events following administration of nirsevimab to MedWatch unless co-administered with a vaccine.
- Comply with Iowa requirements for vaccine management:
    - Order vaccine and maintain appropriate vaccine inventories.
    - Provide at least four consecutive hours open for business on a day other than Monday to receive VFC vaccine shipments.
    - 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 the 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 an FQHC or 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.

- Specialty Providers are defined as providers who offer limited care in a specialized environment or for a specific age group within the general population of children 0-18 years.
- Specialty providers that are a pharmacy, urgent care center or school-located vaccine clinic must:
  - Vaccinate all "walk-in" VFC-eligible children, including VFC-eligible newborn infants at participating birthing hospitals.
  - Not deny immunization services to VFC-eligible children based on a parent's inability to pay the administration fee.
  - Note: *"Walk-in" in this context refers to any VFC eligible child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve VFC 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 all VFC patients as well.*
- Follow the program Vaccine Restitution Policy and as necessary, replace vaccine purchased with state and federal funds deemed non-viable due to provider negligence on a dose-for-dose basis.

√ *REQUIREMENT*

All licensed healthcare providers in the enrolled practice must be listed on the Provider Enrollment Form and include each corresponding professional license number.

The Provider Enrollment Form documents all healthcare providers practicing at the facility and agreement to comply with program requirements. It is necessary to include the NPI (National Provider Identifier) number, medical license number and email address for each provider listed. If the facility does not have a prescriber on staff, or does not have an individual NPI number, include the facility's NPI number if applicable.

The medical director in a group practice (or equivalent) must be authorized to administer vaccines under Iowa law. For the purposes of the VFC program, the term 'vaccine' is defined as any FDA-authorized or licensed, ACIP-recommended product for which ACIP approves a VFC resolution for inclusion in the VFC program. The provider signing the Provider Enrollment Form on behalf of a multi-provider practice must have authority to sign on behalf of the entity. This provider will be held accountable for the entire organization's compliance, including site visit participation and education requirements. If the status of the individual signing the Provider Enrollment Form changes, the provider must notify the Iowa VFC Program.

VFC providers shall re-enroll into the VFC Program annually in IRIS. If healthcare providers practicing at the facility change during the year, the medical facility is responsible for updating the physician list in IRIS.

√ REQUIREMENT

Provider Profile *(Appendix 2)*

The Provider Profile Form, completed as either 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 are administered only to VFC-eligible children.

√ REQUIREMENT

IRIS Enrollment Form *(Appendix 3)*

IRIS is a confidential, computerized repository of individual immunization records from participating public and private healthcare providers. VFC providers are required to use IRIS to submit VFC vaccine orders, track VFC vaccine inventory, and complete annual VFC Program Re-enrollment. If the facility is already enrolled in IRIS, an IRIS Enrollment Form is not required to enroll in the VFC Program.

It is recommended the Primary and Back-Up VFC vaccine coordinators have IRIS Admin Access, which is required for VFC activities such as annual VFC Re-enrollment in IRIS. Each VFC coordinator should complete a form and send to the IRIS Helpdesk if they do not already have Admin Access. Contact the IRIS Helpdesk at 1-800-374-3958 for questions regarding IRIS.

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.

√ REQUIREMENT

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 should be submitted with the Provider Enrollment and Provider Profile forms.

√ REQUIREMENT

Refrigerator and Freezer Temperatures *(Appendix 5)*

Before providers can order and receive VFC vaccine, storage unit temperatures must be evaluated to determine if the units can maintain appropriate temperatures. Providers are required to submit temperature documentation demonstrating a minimum of two consecutive days of in-range temperatures. Temperature readings documented two times each day and a min/max temperature once each day, preferably in the morning is required. Temperatures recorded on the Iowa Immunization Program paper temperature logs or electronic data documentation by a continuous monitoring and recording system (digital data logger) are acceptable for submission.

√ REQUIREMENT

Certificate of Calibration

New VFC providers must provide a copy of the Certificate of Calibration for each DDL used to monitor temperatures in units storing VFC vaccine. Each DDL should have a current and valid Certificate of Calibration Testing (also known as a "Report of Calibration") to ensure device accuracy. Calibration testing should be completed every two to three years or according to the manufacturer's suggested timeline. The valid Certificate of Calibration Testing (Report of Calibration) 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

√ REQUIREMENT

Enrollment Site Visit

Once enrollment forms are submitted and approved, VFC staff 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 into the following groups:

Addiction Treatment Center	Pharmacy
Birthing Hospital or Birthing Center	Private Practice (e.g., family practice, pediatric, primary care)
Community Health Center	Private Practice (e.g.) family practice, pediatric, primary care) as agent for FQHC/RHC-deputized
Community Vaccinator (non-health department)	Public Health Department Clinic (state/local)
Correctional Facility	Public Health Department Clinic (state/local) as agent for FQHC/RHC - deputized
Family Planning Clinic (non-health department)	Refugee Health Clinic
Federally Qualified Health Center (FQHC)	Rural Health Clinic (RHC)
Hospital	School-Based Clinic (permanent location)
Indian Health Service, Tribal, or Urban Clinic	STD/HIV Clinic (non-health department)
Juvenile Detention Center	Teen Health Center (non-health department)
Migrant Health Center	Urgent Care Center
Mobile provider	Women, Infants and Children (WIC) Clinic
Other	

Federally Qualified Health Center (FQHC)

Federally Qualified Health Centers are public and private non-profit healthcare 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 healthcare. 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 healthcare for rural, underserved communities, and expand the use of nurse practitioners, physician assistants, and certified nurse midwives in rural communities. 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 HHS State Office of Rural Health Program at (515) 423-7900.

VFC Delegated Authority

FQHCs and RHCs have the ability to grant FQHC/RHC status to local public health agencies (LPHA) to immunize underinsured children on their behalf. A benefit of delegated authority is the VFC Program will pay for vaccines for underinsured population at additional clinic locations (LPHAs) in the state. Delegated 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 or via email at IowaVFC@hhs.iowa.gov.

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 organization. If there will be a change in clinic status such as address change, please contact the VFC staff for further instruction.

Eligibility

July 2024

VFC Eligibility Criteria
Screening Documentation
Administration Fee
Office Visit Fee

VFC Eligibility Criteria

√ *REQUIREMENT*

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 eligibility includes individuals who have a primary health insurance company and Medicaid as secondary coverage. These children are eligible for the VFC Program.
  - Children enrolled in Medicaid/IA Health Link must present a Managed Care Organization (MCO) member ID card to verify enrollment (*Appendix 6*). MCOs in Iowa include:
    - Wellpoint Iowa (formerly Amerigroup Iowa, Inc.)
    - Iowa Total Care
    - Molina Healthcare of Iowa
- Uninsured
- American Indian or Alaskan Native as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603)
- 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 FQHC, RHC or 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 and Uninsured 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.
    - FQHC, RHC, and LPHA provider locations must agree to vaccinate all VFC eligible children who present requesting a vaccine. This includes all "walk-in" VFC-eligible underinsured children.
    - *Note: "Walk-in" in this context refers to any VFC eligible child (including underinsured) who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve VFC eligible 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 VFC eligible children as well.*
- 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.
- Children enrolled in a Healthcare Sharing Ministry are uninsured. These plans are not considered health insurance and are exempt from ACA requirements.

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 the insurance plan may be only a small portion of the cost of the vaccine, this child is considered insured for the purpose of the VFC Program.

Hawki Program - Not VFC Eligible

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

Non-U.S. Citizen Children

- Refugees, immigrants, foreign-exchange students, and undocumented immigrants must be screened for VFC eligibility.
- Non-U.S. citizen children are VFC eligible if they meet VFC eligibility criteria. While citizenship is not a requirement for VFC eligibility, VFC vaccines are not intended to be used for children who are simply visiting the U.S., temporarily traveling in the United States, or a tourist.

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 the 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.

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 Records (*Private Sector-English*, *Private Sector-Spanish*, *Public Sector-English*, *Public Sector-Spanish*) 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 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.

Child's Insurance Status		VFC Eligibility Category	VFC	Private
Medicaid	Enrolled in Medicaid	Medicaid	X	
	Primary insurance plan with Medicaid as secondary insurance	Medicaid[1]	X	
	Enrolled in Medicaid and is American Indian/Alaska Native (AI/AN)	Medicaid[1] or AI/AN	X	
AI/AN	AI/AN	AI/AN	X	
	AI/AN with no health insurance coverage	AI/AN or Uninsured[2]	X	
Un-insured	No health insurance coverage	Uninsured [2]	X	
	Enrolled in a Healthcare Sharing Ministry	Uninsured [2]	X	
Underinsured[3]	Health insurance but plan does not cover any vaccines	Underinsured [2, 3, 4]	X	
	Health insurance plan does not cover all ACIP-recommended vaccines	Underinsured [2, 3,4]	X	
	Health insurance plan covers all vaccines but has a fixed dollar limit or cap on amount of coverage	Insured until fixed dollar limit is met.		X
		Underinsured after fixed dollar limit is met.[2, 3, 4]	X	
Birthing Hospital	All insurance statuses	Birth dose Hepatitis B is available for the whole birth cohort at enrolled facilities regardless of eligibility.	X	
Insured - Not VFC Eligible	Enrolled in the Healthy and Well Kids in Iowa (Hawki) Program.	Insured - Not VFC Eligible.		X
	Health insurance covers all vaccines but has not yet met plan's deductible or paid for other services at visit.	Insured - Not VFC Eligible.		X
	Health insurance covers all vaccines. Child is referred to LPHA by private clinic when the plan's deductible has not been met, or the private clinic does not stock private vaccines.	Insured - Not VFC Eligible. Children are not automatically considered VFC eligible when seeking vaccines at a LPHA. [3]		X

1. Administer VFC vaccines and bill administration fee to Medicaid to provide the least out-of-pocket expense for the family.
2. Provider may charge an administration fee per vaccine at the time of service.
3. Before administering a vaccine, providers must verify if the child's health insurance plan covers ACIP-recommended vaccines. If the provider cannot verify coverage, the child is considered insured and not VFC eligible at the immunization encounter.
4. Eligible to receive vaccines only if they are served by a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or Local Public Health Agency (LPHA).

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). A vaccine administration fee shall not be charged to Medicaid eligible patients.

√ *REQUIREMENT*

Effective January 1, 2020, VFC providers who choose to bill for the vaccine administration fee of 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. This policy does not apply to vaccine administration fees billed to Medicaid for children who meet the Medicaid eligibility criteria for the VFC Program. Unpaid administration fees may not be sent to collections, and the provider may not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees. 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.

Vaccine Ordering

April 2024

Vaccine Availability
Vaccine Ordering
Ordering and Distribution of Influenza Vaccine
Ordering and Distribution of COVID-19 Vaccine and Nirsevimab
Distribution of Varicella Containing Vaccine
Receiving and Unpacking Vaccine Shipments

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. 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 Vaccine Brand and Presentation Exceptions section (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.
- Maternal RSV vaccine is available on a case-by-case basis. Abrysvo is only indicated for use in pregnant women and should only be administered during the specified gestation period. This is a non-routine vaccine, and providers shall ensure patients meet the defined administration criteria before ordering.
- 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*).

Stocking Non-Routine Vaccines

Non-routine vaccines include but are not limited to pneumococcal polysaccharide (PPSV23), Mpox, meningococcal serogroup B (MenB), RSV maternal vaccines. Maintaining a stock of non-routine, VFC-covered vaccines at all times may not be a viable option due to vaccine availability and demand. Providers should only order non-routine vaccines that have a limited supply on a case-by-case basis.

- Order requests may be emailed to the Iowa VFC Program at IowaVFC@hhs.iowa.gov or added as a note during the routine VFC vaccine ordering process in IRIS.
- Providers must ensure patients meet the administration criteria before ordering.

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 determined by the assigned ordering frequency. Orders outside the assigned ordering frequency may be denied.

Back-to-School or Temporary School Based Vaccination Clinic Procedures

Ordering for school-based clinics by Local Public Health Agencies must be planned and coordinated with the Iowa VFC Program at least four weeks in advance of the scheduled date. Review LPHA School Based Clinic Procedures for guidance.

- Screening for VFC eligibility is required to identify children eligible to receive VFC vaccines.
- Determine what vaccine(s) will be offered and the grades or age cohorts each clinic will cover.
- Orders must be placed at least three weeks in advance and can be combined with a routine vaccine order.
- VFC vaccine already in inventory may be used for school-based clinics.

Vaccine Ordering Process

The order processing and delivery schedule is subject to change during holidays and extreme weather conditions. Vaccine orders are routinely processed and delivered within five to seven business days.

VFC Enrolled Providers:

- Select the day(s) and delivery hours on the Create Order screen in IRIS that 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.
- 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, considering the following:
    - Vaccines expiring 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) and planned specialty clinics

- Doses on hand data automatically display on the vaccine order form
- 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 vaccine doses needed and submit the vaccine order in IRIS.

Iowa VFC Program will:

- Process vaccine orders in the order received.
- Review each vaccine order to verify the need for the quantity of vaccine ordered. The amount of vaccine ordered is compared to:
    - Recommended vaccine order quantity
    - Number of doses on hand and 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
- The Iowa VFC Program will contact healthcare 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 to the health care provider.

Ordering and Distribution of Influenza Vaccine

VFC influenza vaccine is not orderable in IRIS like other VFC vaccines. VFC Providers will be able to pre-book VFC influenza vaccine in IRIS during a designated time frame each year for the upcoming influenza season. VFC Providers enrolling in the VFC Program after the pre-book period will be able to order influenza vaccine as part of the follow-up after the enrollment site visit. Providers should review the following information to determine accurate VFC influenza vaccine pre-book amounts:

- Number of VFC-eligible children seen at the clinic in the previous year
- VFC influenza vaccine ordered the previous year
- Influenza vaccine doses administered during the previous influenza season
- Vaccine wastage data from the previous year
- Order quantity should include the number doses needed for each product
- Order quantity is in doses, not the number of boxes or packages
- Review the pre-book materials for influenza vaccine presentation and age indication information.

Viewing Prebook in IRIS: To review what products and quantities were prebooked by the VFC Provider, go to the 'flu prebook' menu in IRIS. Select the Flu Prebook Window for the appropriate timeframe. The prebooked products and quantities will display.

Shipment of Influenza Vaccine: The VFC Program will distribute influenza vaccine orders when the vaccine is available in the fall. The manufacturers routinely distribute influenza vaccine as it is produced and released by the Food and Drug Administration (FDA). Influenza vaccine will be distributed in partial shipments, possibly shipped with routine vaccines orders, to allow all providers to receive a portion of their vaccine order. The VFC Program will ship remaining vaccines as additional quantities are released.

Ordering and Distribution of COVID-19 Vaccine and Nirsevimab

Since the fall of 2023, VFC Program providers have been granted a flexible, time-limited period to meet the private inventory requirements for COVID-19 vaccines and RSV monoclonal antibody products (nirsevimab). During this period, VFC Program providers were not required to maintain private inventory for these products.

Beginning July 1, 2025, the new requirements will be effective and carry through the 2025-2026 respiratory virus season. The Iowa VFC Program will notify providers of any future updates.

RSV Monoclonal Antibody Products

Providers who serve and plan to vaccinate any privately insured, non-VFC-eligible population, must maintain a separate vaccine inventory to vaccinate their non-VFC-eligible population. Starting July 1, 2025, this policy will include nirsevimab and any other RSV monoclonal antibody product that may be added to the VFC Program.

Routine borrowing of VFC Program vaccines and monoclonal antibody products for use among privately insured, non-VFC-eligible patients is not permitted.

COVID-19 Vaccines

Given the unique considerations of COVID-19 vaccination, it may not be practical for all VFC Program providers to stock this vaccine for VFC-eligible patients. In such cases, the Iowa VFC Program will identify accessible locations where VFC-eligible children can be referred for COVID-19 vaccination and communicate this information to VFC Program providers. All Iowa VFC Program providers are still encouraged to maintain COVID-19 vaccine if it is appropriate for their patient population.

McKesson Specialty Distribution will continue to ship Moderna and Novavax COVID-19 vaccines as well as nirsevimab monoclonal antibody products. Vaccine orders are routinely processed and delivered within five to seven business days. Pfizer COVID-19 vaccine orders will ship directly from the vaccine manufacturer. The CDC contract requires Pfizer COVID-19 vaccines to be delivered within 15 business days after the program submits an order, however, orders are likely to ship out more quickly. Diluent for COVID-19 vaccines will ship separately and will arrive at the same time as or before the vaccine.

VFC Program providers may need to order COVID-19 vaccines or nirsevimab more frequently due to minimum shipping quantities, presentation, availability of vaccine stock, and storage and handling requirements. The Iowa VFC Program will follow routine ordering processes for these products, including following up with providers to discuss vaccine needs when a product is in limited supply.

Distribution of Varicella Containing Vaccine

All VFC varicella-containing vaccine orders will ship directly from the vaccine manufacturer (Merck). These vaccines may arrive on a different date from vaccines shipped directly from McKesson Specialty Distribution. Vaccine orders are routinely processed and delivered within five to seven business days after the order is processed by the program.

Receiving and Unpacking Vaccine Shipments

√ *REQUIREMENT*

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.

√ *REQUIREMENT*

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

- Immediately notify the vaccine or back-up coordinator when deliveries arrive.
- Unpack vaccine shipment immediately.
- Inspect the vaccine and packaging for damage.
- Crosscheck 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.
- Verify shipments of lyophilized (freeze-dried) vaccines include 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 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 (e.g., varicella or COVID-19), 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 if vaccines were received after the acceptable transit time.

- Document on the invoice the date vaccine was received. Maintain vaccine-shipping invoices for public and private inventory for a minimum of three years.
- Store vaccine immediately at appropriate temperatures according to manufacturers' product specifications.
- IRIS functionality automatically adds vaccine orders to the organization inventory. An IRIS message will display to inform users a new vaccine order is in their inventory. Contact the IRIS Help Desk at 800-374-3958 with questions regarding vaccine orders and vaccine shipments.

Vaccine Management

April 2024

Staffing Requirements
Annual VFC re-enrollment and Training Requirements
Vaccine Storage and Handling Plan
Storage Unit Requirements
Temperature Monitoring Devices
Proper Vaccine Storage Temperatures
Best Practices for Storing Vaccines in Storage Units
Temperature Monitoring

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 for the most current guidance and best practices regarding vaccine storage and handling. The toolkit should be the primary resource for vaccine storage and handling information.

Staffing Requirements

√ *REQUIREMENT*

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.

√ *REQUIREMENT*

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, pages 21-23 available on the IRIS website.

Annual VFC Re-enrollment and Training Requirements

√ *REQUIREMENT*

Each VFC provider is required to re-enroll in the VFC Program on an annual basis. The Iowa VFC Program will communicate the re-enrollment due date and provide instructions to VFC providers through the VFC listserv. As part of re-enrollment, **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 CDCs You Call the Shots:

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

In IRIS, VFC providers must also review the VFC Patient Activity chart, review and update the organization's contacts and providers practicing at the facility and complete the VFC Re-enrollment form. VFC providers must complete the re-enrollment in IRIS. The Iowa VFC Program does not accept paper forms for re-enrollment. VFC Providers should not fax or email re-enrollment forms to the Iowa VFC Program. **Failure to complete the re-enrollment process by the due date will result in suspension from the VFC Program and the inability to place VFC vaccine orders in IRIS.**

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 Storage and Handling Plan (*Appendix 4*).

Vaccine Storage and Handling Plan

√ REQUIREMENT

VFC Program providers must develop and maintain a written routine and emergency Vaccine Storage and Handling Plan. A Vaccine Storage and Handling Plan template (*Appendix 4*) is available to assist providers. **The plan should be posted on or near the vaccine storage unit to be 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 members' name and date of training should be kept as documentation.

Storage Unit Requirements

√ REQUIREMENT

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.
- Have power source protected by warnings such as "Do Not Disconnect" labels posted at the electrical outlet and circuit breaker.

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/medical-grade unit (including doorless, auto-dispensing, and auto vending style units)
    - 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 unit

        - Use only the refrigerator compartment for refrigerated vaccines. Typical household single-condenser combination refrigerator/freezer units are less capable of simultaneously maintaining proper storage temperatures in refrigerator and freezer compartments.
        - 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.
    - **Ultra-cold freezers are not required for the VFC Program; however, providers may use them for long-term storage of certain COVID-19 vaccines.**
        - Ultra-cold freezers should maintain temperatures between -130° F and -76° F or -90° C and -60° C. Most standard freezer units do not meet ultra-cold freezer requirements 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 a third party owns the building, work with the building manager to ensure access to circuit breakers.
- Use caution when using power outlets that can be tripped or switched off and avoid using:
    - Built in circuit switches (may have reset buttons)
    - Outlets that can be activated by a wall switch
    - Multi-outlet power strips
- Ensure doors are tightly shut.

X Prohibited – *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.

Temperature Monitoring Devices

√ *REQUIREMENT*

VFC providers must use continuous temperature monitoring devices (DDL) 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. The device must be equipped with:

- A temperature probe
  - A buffered probe is recommended for refrigerators and freezers.
  - For accurate ultra-cold temperature monitoring, use an air-probe or a probe designed specifically for ultra-cold temperatures with the DDL.
- An active temperature display that can be easily read from the outside of the unit
- Continuous monitoring and recording capabilities where the data can be routinely downloaded
- Logging interval (or reading rate) programmed to measure and record temperatures at least every 30 minutes
- Alarm for out-of-range temperatures
- Low battery indicator
- Current, minimum, and maximum temperature display
- Recommended uncertainty of +/-0.5 °C (+/-1°F)
- A current and valid Certificate of Calibration Testing including:
  - Model/Device number
  - Serial number
  - Date of Calibration
  - Confirmation the instrument passed testing (instrument in tolerance)
  - Recommended uncertainty of +/- 0.5°C (+/- 1°F) or less
- A Certificate of Calibration Testing or Report of Calibration must be issued by an appropriate entity as indicated by one or more of the following items:
  - Conforms to International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC) 17025 international standards for calibration testing and traceability
  - Performed by a laboratory accredited by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body
  - Traceable to the standards maintained by the National Institute of Standards and Technology (NIST)
  - Meets specifications and testing requirements for the American Society for
  - Testing and Materials (ASTM) Standard E2877 Tolerance Class F or higher
  - Refers to another acceptable accuracy validation method, such as comparison to other traceable reference standards or tests at thermometric fixed points

Purpose-built or pharmaceutical-grade units, including doorless/venting style units, may have temperature monitoring capabilities as reliable as a DDL in monitoring temperature, but may not be capable of digitally logging temperatures. Contact the Iowa VFC Program regarding VFC Program temperature monitoring device requirements.

Back-up Temperature Monitoring Device

√ REQUIREMENT

Iowa VFC providers shall have at least one back-up DDL with a valid and current certificate of calibration readily available in case a temperature-monitoring device in a storage unit unexpectedly stops working or needs to be replaced during calibration testing. The back-up device must meet the CDC data logger requirements and is recommended to have a different calibration expiration date from the primary DDL. See above ***Temperature Monitoring Devices*** for DDL and Certificate of Calibration Testing 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 an acceptable timeframe to comply with the requirement to assess and record temperatures as required.

Placement of Temperature Monitoring Devices

√ REQUIREMENT

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 the 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 vaccine recipients are not protected. Adhering to proper storage and handling procedures will minimize the potential for vaccine loss and wastage.

√ REQUIREMENT

- **Refrigerated vaccines: stored at 36.0° F to 46.0° F or 2.0° C to 8.0° C.**
- **Varicella-containing vaccines (Varivax and ProQuad): stored at -58.0° F to +5.0°F or -50.0° F to -15.0°C.**
- **Ultra-cold freezer vaccines: stored at -130° F to -76° F or -90° C to-60° C.**

Temperature Alarm Settings

Using temperature alarm settings safeguards vaccine viability by alerting staff of out-of-range temperatures. DDLs provide more accurate and detailed temperature readings and can record temperatures to a tenth of a degree. VFC providers can assure viability of vaccines by utilizing appropriate parameters to evaluate storage unit temperatures.

Instructions to reconfigure temperature alarm settings for LogTag VFC 400 are available on the Vaccine Storage and Handling webpage. The temperature alarm settings are:

Refrigerator:	**Freezer:**	**Ultra-cold freezer:**
35.9°F and 46.1°F	5.1°F	-75.9° F
1.9°C and 8.1°C	-14.9°C	-59.9° C

Best Practices for Storing Vaccine in Storage Units

- Store all varicella-containing vaccine (Varivax and ProQuad) in the freezer at -58.0° through +5.0°F or -50.0° through -15.0°C.
- MMR II (Merck) vaccine can be stored in the freezer. Storing MMR II (Merck) vaccine in the freezer with MMRV may help prevent inadvertent storage of MMRV in the refrigerator. It may also prevent MMR II (Merck) vaccine loss in the event of a temperature excursion. Diluent should NOT be stored in the freezer.
    - **Note: Priorix MMR vaccine (GSK) CANNOT be stored in the freezer. It can only be stored in the refrigerator.**
- Store all opened and unopened vaccines and diluents in the original packaging with lids closed to protect them from light until administration.
- If indicated, stabilize unit 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 in the middle of the compartment, away from the walls, coils, vents, 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

- VFC providers must 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 is the principal responsibility of the primary and back-up vaccine coordinators.

√ *REQUIREMENT*

VFC providers must have protocols for training appropriate staff on proper assessment and interpretation of temperature data as well as proper documentation of findings.

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 note the time of the reading as well as the name or initials of the person who assessed and recorded the reading.
- Storage temperatures must be handwritten on a paper temperature log (Appendix 5) or electronically documented by a continuous monitoring and recording system (digital data logger). Paper logs may be downloaded from the Vaccine Storage and Handling page. If a DDL 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. Providers must maintain all paper temperature logs or electronic data for at least three years.
- DDL data should be downloaded and reviewed every two weeks and whenever the DDL alarms. 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 during review.

Out-of-range Temperatures

√ *REQUIREMENT*

VFC providers must document all temperature excursions and actions taken when temperatures are outside the appropriate range.

Providers should immediately store vaccine under correct temperature storage conditions (do not discard these vaccines) and contact the VFC Program at 1-800-831-6293 or IowaVFC@hhs.iowa.gov. 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 Vaccine Storage and Handling Incident Response Worksheet (*Appendix 10*) including manufacturer recommendations for viability and any action taken.

Vaccine Inventory Management

April 2024

Vaccine Inventory Management
Vaccine Borrowing
Viable Vaccine Transfers Among Enrolled VFC Program Providers
Vaccine Accountability
Management of Expired, Spoiled and Wasted Vaccine
Vaccine Restitution Policy

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 regularly, and stock should be rotated to ensure the soonest to expire is in front. CDC best practice is to rotate weekly and whenever new vaccine is received. 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 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 and do not over order to avoid stockpiling or inventory buildup.
- Order vaccines following the facility's assigned ordering frequency (monthly, bi-monthly, quarterly).
- 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 IowaVFC@hhs.iowa.gov.

Vaccine Borrowing

√ *REQUIREMENT*

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 not routinely occur. Vaccine borrowing must be a rare and unplanned occurrence due to an unforeseen delay or circumstance surrounding the vaccine ordered. All instances of borrowing must be properly documented and reported, and borrowed doses must be replaced.

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 might lead to further investigation and termination.

When it is OK to borrow:

- Borrowing short-dated vaccine to prevent vaccine expiration
- Vaccine delivery delays
- Vaccine damaged in transit

When it is NOT OK to borrow:

- If borrowing from VFC stock would result in vaccines unavailable for VFC patients
- Routine borrowing for any reason
- Repeated human error
- Running out of stock between orders

What to do when borrowing occurs:

- Document every instance of borrowing on the VFC Vaccine Borrowing Report
- Update inventory in IRIS to reflect the borrowing pay back
- Replace all borrowed doses
- Submit completed borrowing reports to IowaVFC@hhs.iowa.gov

√ *REQUIREMENT*

Staff training is essential to avoid accidental use of the wrong vaccine inventory. Annually, all clinic staff must be trained on the following:

- **Proper VFC patient eligibility screening and documentation**
- **Administering the appropriate vaccine inventory to patient per eligibility screening process**
- **Clinic procedures for vaccine inventory management**

VFC providers should use the Vaccine Management and Borrowing Tool (*Appendix 11*) for training guidance and documentation.

A VFC Vaccine Borrowing Report must be completed when a dose of privately purchased vaccine is administered to a VFC-eligible child or a dose of VFC vaccine is administered to a non-VFC-eligible child. Providers must document the following information on the Vaccine Borrowing Report (*Appendix 12*).

- 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

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. Iowa VFC Program does not have the ability to reimburse providers for the cost of the private purchased vaccine. Iowa HHS 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 13*).

Viable Vaccine Transfers Among Enrolled VFC Program Providers

√ REQUIREMENT

All instances of vaccine transfers must be properly documented as indicated below. The vaccine transfer must include the use of a DDL with a current and valid Certificate of Calibration Testing during transport.

The following information is required 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
- **VFC providers are 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.
- Document vaccine transfer on the VFC Vaccine Transferred Between VFC Providers form (*Appendix 14*) and send the form to IowaVFC@hhs.iowa.gov.
- Document in IRIS all vaccine transferred to another provider. Directions may be found in Appendix 15 for filling out the VFC Vaccine Transfer Form.
-

Vaccine Accountability

√ REQUIREMENT

VFC providers must enter all administered doses into IRIS. Providers must also use IRIS to account for transfers, borrowing, spoilage, wastage, and expiration.

√ REQUIREMENT

Temporary, mobile, offsite, or satellite clinic providers should maintain vaccine transport records that detail the type of vaccine, quantity transported, and temperature monitoring. Mobile clinics are movable units (e.g., trailers, buses) acting as extensions of existing providers, and are not the primary site for storage and administration.

Management of Expired, Spoiled and Wasted Vaccine

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

Spoiled vaccine is nonviable vaccine because 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 because 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

√ REQUIREMENT

When managing expired, spoiled, and wasted vaccine, providers must complete the following:

- Notify the VFC Program 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 the vaccine prior to expiration, reducing nonviable vaccine wastage.
- 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 shall document vaccine loss using appropriate reasons provided in the registry to deduct doses from inventory. Expired vaccine is automatically adjusted in IRIS. 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

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*).
- Wasted vaccine cannot be returned to McKesson Specialty Distribution and should be discarded according to clinic policy.
- Spoiled open multi-dose vials cannot be returned. These vaccines 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*). This policy requires healthcare providers to replace vaccine purchased with state and federal funds deemed non-viable due to provider negligence on a dose-for-dose basis.

Fraud and Abuse

April 2024

Definition of Fraud and Abuse
Examples of Fraud and Abuse

It is essential providers participating in the VFC Program 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 are used. 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. VFC Program staff will investigate all allegations of fraud and abuse and determine appropriate action, including notify the proper agencies to conduct a full investigation

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 healthcare. It also includes recipient practices resulting in unnecessary cost to the Medicaid Program.

Examples of Fraud and Abuse

Fraud or abuse can occur in different ways, including:

- 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
- Failing to fully account for VFC vaccine
- Failing to properly store and handle VFC vaccine, including wasting VFC vaccine
- Ordering VFC vaccine in quantities or patterns not consistent with provider profiles or otherwise over ordering VFC doses

Quality Assurance/Program Accountability

VFC Site Visits

VFC site visits 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 vaccine accountability and determining whether VFC vaccines are handled, stored, and administered in accordance with the laws and policies governing the VFC program. 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 to meet program requirements
- Ensure VFC-eligible children receive properly managed and viable vaccine

Enrollment Site Visit

VFC staff conduct an enrollment 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, necessary paperwork is completed, and vaccine storage units can maintain appropriate temperatures, as well as to confirm the provider can store and monitor vaccine supply according to program requirements. 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

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

Birth Dose Hepatitis B Vaccine Program for Birthing Hospitals

April 2024

Perinatal Hepatitis B Program Overview
Enrollment Process and Compliance Site Visits
Birth Dose Hepatitis B Vaccine
Screening Eligibility and Vaccine Administration Documentation
Addendum: RSV product for VFC Eligible Infants at Enrolled Birthing Hospitals

Perinatal Hepatitis B Program Overview

Hepatitis B is a serious disease caused by the hepatitis B virus. Hepatitis B can be transmitted from an infected mother to her child at birth. The Perinatal Hepatitis B Prevention Program works to prevent transmission of hepatitis B infection from the mother to the baby by conducting parent and healthcare provider education, case management of mothers and babies, administration of hepatitis B vaccine and hepatitis B immune globulin (HBIG) and laboratory testing. For more information, please contact:

Shelly Jensen, RN, BSN, Perinatal Hepatitis B Prevention Program
Email: Shelly.Jensen@hhs.iowa.gov
Phone: 1-800-831-6293
Fax: 800-831-6292

Iowa birthing hospitals are eligible to enroll and participate in the VFC Program with the intention of vaccinating all newborns regardless of insurance status with hepatitis B vaccine. Hepatitis B vaccine is provided at no cost to birthing hospitals to vaccinate all infants at birth regardless of the infant's insurance status or race (commonly referred to as a universal birth dose). This service acts as a "safety net" to prevent transmission of hepatitis B. Hospitals participating in the Birth Dose Hepatitis B Program receive state supplied hepatitis B vaccine for 100% of the newborn population, regardless of insurance status. The Iowa Immunization Program utilizes several funding sources to support the Universal Hepatitis B Birth Dose Program, it is imperative hospitals screen for VFC eligibility for each infant and document eligibility status in IRIS. The universal birth dose Hepatitis B benefits Iowa in several ways:

- Hospitals administering universal birth dose at their own cost would be eligible for free vaccine
- Increase the number of newborns in Iowa receiving the birth dose of hepatitis B and therefore providing protection from the consequences of hepatitis B infection
- Children born to hepatitis B positive mothers who may not have been identified in pregnancy will be protected from this disease starting at birth
- All Iowa newborns are eligible for hepatitis B vaccine at no cost

√ REQUIREMENT

- The birthing hospital must enroll as a VFC Program provider.
- The hospital must screen for VFC eligibility. Screening data is utilized to determine the vaccine-funding source.
- Hepatitis B vaccine is available for the entire birth cohort at no cost to the hospital.
- Hepatitis B birth dose standing orders and policies must be in place to make the vaccine the standard of care for each newborn.
- Utilize IRIS to record Hepatitis B doses administered.
- Facility must follow other VFC Program requirements in the VFC Operations Guide.

Enrollment Process and Compliance Site Visits

All birthing hospitals who desire to participate in the Birth Dose Hepatitis B Vaccine Program must complete the VFC Enrollment process, as outlined in the VFC Operations Guide. A site visit of the facility is required for enrollment into the VFC Program to assure storage capability and regulation compliance. A compliance site visit of each hospital enrolled in the VFC Program is required consistent with other enrolled VFC Program providers.

Birth Dose Hepatitis B Vaccine

The Hepatitis B vaccine birth dose is the standard of care for healthcare providers. The first dose of hepatitis B vaccine (birth dose) should be administered to all medically stable infants at birth as a standard of care. Hepatitis B vaccine is available as a single-antigen and in combination with other vaccines.

- **Only single antigen vaccine should be used for the birth dose.**
- Two single-antigen hepatitis B vaccines are licensed for use in infants and young children in the United States: Recombivax HB® (Merck) and Engerix-B® (GlaxoSmithKline).
- Pediarix® (GlaxoSmithKline) and Vaxelis® (Merck and Sanofi Pasteur) are two licensed combination hepatitis B vaccine available for vaccination of infants and young children. These vaccines may be used to complete the remaining doses of the hepatitis B vaccine series.

Screening Eligibility and Vaccine Administration Documentation

While VFC-supplied hepatitis B vaccine can be administered to all infants, it is imperative hospitals screen for VFC eligibility for each infant as a requirement of participating in the VFC Program. Hospitals should document eligibility criteria on the date of service. The Immunization Program requires patient eligibility screening to account for doses provided by federal VFC and state funding. The Immunization Program requires providers to report administered birth dose hepatitis B doses in IRIS or through electronic data exchange.

Addendum: RSV product for VFC-Eligible Infants at Enrolled Birthing Hospitals

Birthing hospitals enrolled in the Birth Dose Hepatitis B Vaccine Program are able to order and administer RSV product to VFC-eligible children. While VFC-supplied hepatitis B vaccine can be administered to the entire birth cohort regardless of VFC eligibility, **VFC-supplied RSV products are available only for VFC-eligible infants.**

√ *REQUIREMENT*

- The hospital must screen for VFC eligibility.
- **RSV product is available only for VFC-eligible infants at no cost.**
- Utilize IRIS to record RSV products administered.
- Facility must follow other requirements in the VFC Operations Guide.

RSV Product Screening Eligibility and Administration Documentation

√ *REQUIREMENT*

VFC-supplied RSV product is not for universal administration and is limited only to VFC-eligible infants at participating birthing hospitals.

It is imperative hospitals screen for VFC eligibility for each infant as a requirement of participating in the VFC Program. Hospitals should document eligibility criteria on the date of service. The VFC Program requires patient eligibility screening to account for doses provided by federal VFC funding. The VFC Program requires providers to report administered RSV product in IRIS or through electronic data exchange.

Infants must meet at least one of the following criteria to receive VFC RSV product:

- **Medicaid enrolled**
  - Children enrolled in Medicaid/IA Health Link as primary or secondary coverage are eligible for the VFC Program. This eligibility includes individuals who have primary health insurance and Medicaid as secondary coverage.
  - Children enrolled in Medicaid/IA Health Link must present a MCO member ID card to verify enrollment (Appendix 6). MCOs in Iowa include:
    - Wellpoint Iowa (formerly Amerigroup Iowa, Inc.
    - Iowa Total Care
    - Molina Healthcare of Iowa
- **Uninsured**
- **American Indian or Alaskan Native** as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603)
- **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 FQHC, RHC or LPHA.
  - The child's parent or guardian must present an insurance card or name and policy number to verify insurance coverage for vaccines. 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.

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