

Iowa Vaccines for Children (VFC) Program Operations Guide 2026-2027

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Table of Contents

Vaccines for Children (VFC) Program Overview 5
- Overview 5
  - VFC Program Highlights 5
  - VFC Operations Guide and Resources 5
- VFC Program History 6
  - Medicaid 6
- VFC Program Funding 6
- VFC Program Oversight 6
- ACIP and VFC Program Resolutions 7
- Vaccine Administration Fees, Office Visit Fees and Fee Caps 7

Module 1 – Patient Eligibility and Insurance Criteria 8
- Overview 9
  - Program Eligibility Criteria 9
- VFC Eligibility Criteria for Patients 9
  - American Indian or Alaska Native (AI/AN) 10
  - Medicaid-Eligible/Medicaid Enrolled 10
  - Medicaid Billing and Coding 10
  - Medicaid as Secondary Insurance 10
    - Medicaid as Secondary Insurance—Billing Option 1 11
    - Medicaid as Secondary Insurance—Billing Option 2 11
  - Underinsured 11
  - FQHCs, RHCs and LPHAs 12
  - Special Circumstances 12
- Screening Documentation 14
- Quick View of VFC Eligibility and Insurance Situations—Table 15

Module 2 – Provider Enrollment **17**
- Overview 18
  - Eligibility 18
  - Who Can be a VFC Program Provider? 18
  - Provider Facility Types 19
  - Federally Qualified Health Centers (FQHCs) 19
  - Rural Health Clinics (RHCs) 19

VFC Delegated Authority 20
Specialty Providers 20
VFC Program Enrollment Process 20
VFC Program Administration Fees and Guidance 21
Enrollment Forms 21
Enrollment Site Visit 24
Provider PIN 24
Reenrollment, Recertification and Review 25
Provider Training Requirements 25
Disenrollment or Termination 25
Module 3 – Vaccine Management **27**
Overview 28
Vaccine Ordering 28
Vaccine Availability 28
Vaccine Ordering 29
Ordering and Distribution of Influenza Vaccine 31
RSV Monoclonal Antibody Products, COVID-19, and Non-Routine Vaccines 31
Distribution of Varicella Containing Vaccines 32
Receiving and Unpacking Vaccine Shipments 33
Vaccine Compromised During Shipment 34
Vaccine Management Plan 34
Staffing Requirements and Vaccine Coordinators 35
Staff Training Requirements 35
Vaccine Storage and Handling 36
Storage and Handling Plan 36
Storage and Handling Equipment Requirements 36
Best Practices for Vaccine Storage 38
Temperature Monitoring and Temperature Monitoring Devices 39
Vaccine Inventory Management 42
Vaccine Borrowing 43
Vaccine Transfers Between VFC Program Providers 44
Types of Vaccine Loss 45
Management of Expired, Spoiled and Wasted Vaccines 45
Vaccine Handling and Preparation 46

Emergency Situations 46
Vaccine Accountability 47
Temporary, Mobile, Off-Site, or Satellite Clinics 47
Fraud and Abuse 48
Fraud and Abuse Examples 48
Vaccine Restitution Policy 48
Module 4 – Program Operations, Accountability, Quality Assurance and Compliance 49
Program Operations-Overview 50
Record Retention 50
Records Management 50
Program Operational Policies and Procedures 50
Provider Annual Review 50
Provider Biannual Recertification 50
Site Visits 51
Enrollment Site Visits 51
Compliance Site Visits 51
Storage and Handling Site Visits 52
Provider Training and Education 52
Provider Responsibility to Train Staff 52
Module 5 – Birth Dose Hepatitis B Vaccine Program for Birthing Hospitals 53
Perinatal Hepatitis B Program Overview 54
Enrollment and Compliance Site Visits 55
Birth Dose Hepatitis B Vaccine 55
Eligibility Screening and Vaccine Administration Documentation 55
RSV for VFC-Eligible Infants at Enrolled Birthing Hospitals 55
RSV Eligibility Screening and Administration Documentation 56
VFC Resources **57**
Glossary 58
Provider Type Definitions 61
VFC Program Resources 66

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Vaccines for Children Program Overview

Overview

The Vaccines for Children (VFC) Program is a federally funded program established by Congress in 1994 to increase access to vaccination for children who might not get vaccinated because of financial barriers. The VFC Program serves children through 18 years of age who meet at least one of the following criteria:

- American Indian or Alaska native (AI/AN)
- Medicaid-eligible
- Uninsured
- Underinsured

For full information on patient eligibility, see Module 1—Patient Eligibility and Insurance Criteria.

The VFC Program is a unique component of the federal Medicaid Program. The Program is now in its fourth decade and has been recognized for its success in raising immunization coverage rates among high-risk children and reducing disparities in access to healthcare.

VFC Program Fast Facts

- VFC Program benefits over 350,000 children in Iowa each year
- Approximately 600 enrolled health care provider sites in Iowa
- Nearly 650,000 doses of vaccine are distributed to Iowa providers annually

VFC Program Highlights

- Provides publicly purchased vaccine for eligible children at no cost to VFC-enrolled public and private healthcare providers
- Saves VFC-enrolled providers and patients out-of-pocket expenses for ACIP-recommended vaccines
- Eliminates or reduces vaccine cost as a barrier to vaccinating eligible children
- Reduces referrals of children from private providers to state and local health departments for vaccination

VFC Operations Guide and Resources

The VFC Program Operations Guide and other resources are intended for the management and operations of the VFC Program. The requirements and procedures are applicable to all providers enrolled in the VFC Program and receiving vaccines. VFC Program providers will be notified when new information is available or updates to the guide are made. Updated documents will be posted to the Iowa VFC website.

The Iowa VFC Program provides programmatic and other time-sensitive information through an email listserv. Providers can join the VFC listserv and receive updates to their inbox. Contact the VFC Program at 800-831-6293 or email IowaVFC@hhs.iowa.gov to have an email address added.

VFC Program History

- Congress created the VFC Program in response to the 1989-1991 measles outbreak in the United States, at a time when vaccination coverage was low. The measles epidemic resulted in tens of thousands of cases and hundreds of deaths.
- The VFC Program was established as a new entitlement program required to be part of each state's Medicaid plan. The VFC Program is a Title XIX Medicaid program.
- Section 1928 of the Social Security Act (42 U.S.C.§1396S) provides the legal authority for the VFC Program by requiring each state to establish a program for pediatric vaccine distribution to registered provider locations. It provides authority for purchase of vaccines for administration to eligible children using federal Medicaid and state funds (including 317).
- The VFC Program is available in all 50 states, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam and the Commonwealth of the Northern Mariana Islands.

VFC Program Funding

- Funding for the VFC Program is approved annually by the Office of Management and Budget (OMB).
- The funds are allocated through the Centers for Medicare and Medicaid Services (CMS) to CDC.
- CDC awards VFC Program funding through a cooperative agreement to 66 state, local and territorial immunization programs.

Medicaid

Title XIX of the Social Security Act is a federal/state entitlement program that pays for medical assistance for certain individuals and families with low incomes and limited resources.

This program, known as Medicaid, became law in 1965 as a cooperative venture, jointly funded by the federal and state governments (including the District of Columbia and the territories) to assist states in furnishing medical assistance to eligible persons. Medicaid is the largest source of funding for medical and health-related services for America's low-income citizens.

Within broad national guidelines established by the federal government, each state Medicaid program can:

- Establish its own eligibility standards
- Determine the type, amount, duration and scope of services
- Set the rate of payment for services
- Administer its own program

As a result, Medicaid programs vary considerably from state to state.

VFC Program Oversight

The VFC Program is administered at the national level by CDC through its National Center for Immunization and Respiratory Diseases (NCIRD). CDC is responsible for VFC Program policy development and national program oversight with Iowa HHS Immunization Program implementing the VFC Program in Iowa.

ACIP and VFC Program Resolutions

The Advisory Committee on Immunization Practices (ACIP) has unique legal authority from Congress to provide recommendations for the VFC Program. When recommending a new vaccine or a change in vaccine use, ACIP votes on a resolution to include the vaccine change in the VFC Program. VFC Program resolutions passed by ACIP form the basis for VFC Program policies on vaccine availability and use.

Vaccines procured through the VFC Program must be administered according to guidelines outlined by ACIP on VFC Program resolutions. VFC vaccines may also be administered in accordance with Iowa's state school attendance laws. A current list of VFC vaccines and their current CDC price is available online.

Vaccine Administration Fees, Office Visit Fees and Fee Caps

VFC Program providers cannot charge an eligible child's parent a fee for the vaccine itself. However, they can charge a fee to administer each vaccine.

The legislation that created the VFC Program sets a limit on the dollar amount a provider can charge and be reimbursed for administering vaccines to VFC-eligible children. This means a provider may charge a patient an amount up to, but not exceeding, the regional vaccine administration fee cap. This fee cap in Iowa is $19.68 per vaccine dose. There is no lower limit, so providers have the option to charge what they feel is fair. This includes not charging a fee at all.

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. Discretion should be used to ensure the office visit fee does not create barriers for patients to receive immunizations.

Administration Fees

According to VFC Program legislation, enrolled providers agree to the following vaccine administration fee requirements:

- Access cannot be denied to federally purchased vaccines to an established patient whose parent is unable to pay the vaccine administration fee
- Providers cannot charge a vaccine administration fee to non-Medicaid, VFC-eligible children that exceeds the federal administration fee cap of $19.68 per vaccine dose.
- For Medicaid VFC-eligible children, the provider must accept the reimbursement for vaccination set for Iowa.

Note: Providers may charge an office visit fee in addition to the vaccine administration fee. This is not prohibited by the VFC Program statute.

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.

Module 1 – Patient Eligibility & Insurance Criteria

Table of Contents

Overview 9
Program Eligibility Criteria 9
VFC Eligibility Criteria for Patients 9
American Indian or Alaska Native (AI/AN) 10
Medicaid-Eligible/Medicaid Enrolled 10
Medicaid Billing and Coding 10
Medicaid as Secondary Insurance 10
Medicaid as Secondary Insurance—Billing Option 1 11
Medicaid as Secondary Insurance—Billing Option 2 11
Underinsured 11
FQHCs, RHCs and LPHAs 12
Special Circumstances 12
Screening Documentation 14
Quick View of VFC Eligibility and Insurance Situations—Table 15

Overview

VFC Program providers agree to screen patients for program eligibility at each immunization encounter and document their eligibility status. VFC Program vaccines can be administered only to children who meet the congressionally mandated eligibility requirements for the program. Learn more about VFC Program provider requirements in Module 2 – Provider Enrollment.

When screening patients, providers should select and document the VFC eligibility category requiring the least out-of-pocket expense to the parent or guardian.

Program Eligibility Criteria

The VFC Program provides vaccines at no cost to children 18 years of age or younger meeting at least one of the following criteria:

- American Indian/ Alaska Native (AI/AN)
- Medicaid-eligible
- Uninsured
- Underinsured

VFC Eligibility Criteria for Patients

VFC-eligible children must be 18 years old or younger and meet at least one of the following criteria:

VFC Program Eligibility Criteria for Patients

VFC Eligibility Criteria	Definition
American Indian or Alaska Native (AI/AN)	This population is defined by the Indian Health Care Improvement Act (25 U.S.C. 1603) (AI/AN children are VFC-eligible under any circumstance)
Medicaid-eligible	Children who are eligible for the Medicaid Program (For the purposes of the VFC Program, the terms “Medicaid-eligible” and “Medicaid-enrolled” are used interchangeably)
Uninsured	Children not covered by any health insurance plan
Underinsured	Children who have health insurance, but coverage does not include any vaccines Children who have health insurance, but coverage does not include all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) Children who have health insurance, but there is a fixed dollar limit or cap for vaccines Children who have health insurance, but insurance does not provide first-dollar coverage[1]
Fully insured **(not eligible)**	A child with insurance that covers the cost of vaccine. This includes patients who must meet a plan’s deductible before vaccine cost and administration fee are covered. These children are not VFC-eligible.

[1] First dollar coverage: Any copay, co-insurance, or other cost that must be paid by the patient prior to their health insurance plan paying the remainder of the cost. This applies only to the cost of the vaccine, not to any administration fee or office visit fee (which may have separate copay).

American Indian or Alaska Native (AI/AN)

The American Indian or Alaska Native (AI/AN) population, for the purposes of the VFC Program, is defined by the Indian Health Care Improvement Act [25 U.S.C. 1603].

AI/AN children are VFC-eligible under any circumstance. However, because the VFC Program is an entitlement program, participation is voluntary.

When an AI/AN child also fits a second VFC eligibility category, the provider should always choose the category that will cost less for the family. Depending on the facility where an AI/AN parent chooses to have their child vaccinated, the parent may be responsible for the vaccine administration fee if the vaccines are delivered through the VFC Program. Therefore, if the child has private insurance (non-grandfathered plan under the Affordable Care Act (ACA) of 2010) or is enrolled in the Healthy and Well Kids in Iowa (Hawki) Program, it may result in fewer out-of-pocket costs for the child to receive vaccinations through these programs than through the VFC Program, as there would be no cost-sharing. Likewise, if the AI/AN child is also Medicaid-eligible, Medicaid should be used for the administration fee because it will provide the least out-of-pocket expense.

Medicaid-Eligible / Medicaid Enrolled

Under the legislation that created the VFC Program, the term “Medicaid-eligible” is defined as a child entitled to medical assistance under a Medicaid state plan. 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.

Children enrolled in Medicaid/IA Health Link must present a Managed Care Organization (MCO) member ID card to verify enrollment. MCOs in Iowa include:

- Wellpoint Iowa
- Iowa Total Care
- Molina Healthcare of Iowa

Medicaid Billing and Coding

Iowa Medicaid maintains an Iowa Immunization Provider Manual to define immunization coverage and billing requirements for providers administering immunizations to Iowa Medicaid members. Reference this guide for:

- Coverage guidelines
- Healthcare Common Procedure Coding System (HCPCS) Codes
- Current Procedural Terminology (CPT) Codes related to VFC vaccine administration

Direct further questions to Iowa Medicaid Provider Services at 800-388-7909 or imeproviderservices@hhs.iowa.gov.

Medicaid as Secondary Insurance

Some children may have a private primary health insurance plan with Medicaid as their secondary insurance. These children are considered VFC-eligible because of their Medicaid enrollment. However, their parents are not required to participate in the VFC Program.

There are billing options for the parent and provider in this situation. **The provider should choose the most cost-effective option for the family.** The parent of a child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

Medicaid as Secondary Insurance—Billing Option 1:
Provider can administer VFC vaccines and bill Medicaid for the administration fee.

In most health care situations, Medicaid is considered the "payer of last resort." This means claims must be filed with and rejected by all other insurers before Medicaid considers payment for the service.

This is not true of the vaccine administration fee for Medicaid-eligible VFC children. Medicaid must pay the VFC Program provider the administration fee because vaccinations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. However, once a claim is submitted to Medicaid, the state Medicaid agency has the option to seek reimbursement for the administration fee from the primary insurer.

Note: If Iowa MCOs reject a claim for a vaccine administration fee and state the claim must first be submitted to the primary insurer for payment, the provider should notify the Iowa HHS Vaccines for Children Program. Iowa HHS will work with CDC to educate the state Medicaid agency and correct the situation.

Considerations regarding this option:

- Easiest way for a provider to use VFC vaccines and bill Medicaid for the administration fee
- No out-of-pocket costs to the parent for the vaccine or the administration fee

Medicaid as Secondary Insurance—Billing Option 2:
Provider can administer private stock vaccines and bill the primary insurance carrier for both the cost of the vaccine and the administration fee.

If the primary insurer reimburses less than Medicaid for the vaccine administration fee, the provider can bill Medicaid for the balance, up to the amount Medicaid pays for the administration fee.

If the primary insurer denies payment of a vaccine and the administration fee, such as in cases where a deductible must be met, the provider may replace the privately purchased vaccine with VFC vaccine and bill Medicaid for the administration fee. The provider must document this replacement on the VFC Program Borrowing Form.

Considerations regarding this option:

- The provider may be reimbursed a higher dollar amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer.

Underinsured

Underinsured means the child has health insurance, but the insurance policy:

- Does not cover any ACIP-recommended vaccines
- Does not cover all ACIP-recommended vaccines (underinsured for vaccines not covered), or
- Does cover ACIP-recommended vaccines but has a fixed dollar limit or cap for payment. The child is considered underinsured once the fixed dollar amount is reached

- Children who have health insurance, but insurance does not provide first-dollar coverage

Before administering a vaccine, providers must verify whether the child's health insurance plan covers ACIP-recommended vaccines. If the provider cannot verify the plan's vaccination coverage, for the purposes of the VFC Program, the child is considered insured and not eligible to receive VFC vaccines at that immunization encounter.

Note: As required by the ACA, insurance plans purchased through the Health Insurance Marketplace are required to cover ACIP-recommended vaccines (including seasonal flu vaccine) for children of all ages without charging a deductible, copayment or billing co-insurance.

Federally Qualified Health Centers (FQHCs), Rural Health Clinics (RHCs) and Local Public Health Agencies (LPHAs)

Underinsured children can receive VFC vaccines only at federally qualified health centers (FQHCs), Rural Health Clinics (RHCs) or at an Iowa Local Public Health Agency (LPHA). These locations provide health care for medically underserved areas of the state and meet certain criteria under Medicare and Medicaid programs.

Special Circumstances

Where vaccination services are delivered is generally not a factor in determining VFC eligibility. However, there are some eligibility situations, provider locations and provider types that require additional consideration when offering VFC vaccines.

Insurance limits

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 number of provider visits has been met, the child is considered underinsured for the purposes of the VFC Program. They are eligible to be seen at an FQHC, RHC or LPHA.

Non-U.S. Citizen Children

Non-U.S. citizen children are VFC eligible if they meet the basic VFC eligibility criteria (≤18 years and AI/AN, Medicaid-eligible, uninsured or underinsured). Additionally, 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 U.S. or a tourist.

Refugees, immigrants, foreign-exchange students and undocumented immigrants must be screened for VFC eligibility.

Temporary, Mobile, Off-Site or Satellite Clinics

Providers should not assume a child is VFC-eligible when vaccinating in temporary, mobile, off-site or satellite clinics. All children must be screened and their eligibility documented prior to administering VFC vaccines.

Bordering State

Some children may receive health care in a bordering state instead of their state of residency. These children should be screened for VFC eligibility, and can be vaccinated using Iowa VFC vaccines, if VFC eligible. 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.

Family Planning, Sexually Transmitted Infection (STI)/HIV Clinics and Juvenile Detention Facilities

Family planning clinics, sexually transmitted infection (STI)/HIV clinics and juvenile detention facilities may have special VFC eligibility circumstances.

People 18 years of age and younger who do not know their insurance status and who present at family planning clinics for contraceptive services or STI treatment can be considered uninsured for the purposes of the VFC Program. Further, those who may have insurance but due to confidential circumstances seek services at a family planning clinic and do not have access to insurance coverage, are considered uninsured for purposes of the VFC Program.

Incarceration

If a person 18 years of age or younger loses access to health insurance because of incarceration, the minor is considered uninsured and VFC eligible.

Healthcare Sharing Ministry

Children enrolled in a Healthcare Sharing Ministry are uninsured. These plans are not considered health insurance and are exempt from ACA requirements.

Hawki Program Enrolled – Not VFC Eligible

Children enrolled in Healthy and Well Kids in Iowa (Hawki) are not eligible under the VFC Program because the Hawki Program is a full coverage insurance plan. Children enrolled in Hawki must be vaccinated with private-purchased vaccine.

Children enrolled in Hawki are members of the MCOs serving Medicaid patients. MCO member ID cards for Hawki patients look like Medicaid cards but the Hawki name and/or logo replaces the Iowa Health Link logo. Children presenting a Hawki MCO member ID card are NOT eligible to receive VFC vaccine. Examples of cards are found on the VFC Program website.

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 insurance due to the plan's deductible (high-deductible plan) not yet having 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 vaccines because all recommended vaccines are covered.

Screening Documentation

Patient eligibility screening and documentation must occur at each immunization visit. To be considered properly documented, questions must be incorporated into an electronic medical record (EMR) or screening form. Patient Eligibility Screening Records or equivalent information must be completed and retained for a minimum of 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 then select eligibility status when adding new immunizations.

Quick View of VFC Eligibility and Insurance Coverage Situations

	Child's insurance Status	VFC Eligibility Category	VFC	Private
Medicaid	Enrolled in Medicaid	Medicaid	✓	
	Primary insurance plan with Medicaid as secondary insurance	Medicaid[1]	✓	✓
	Enrolled in Medicaid and is American Indian/Alaska Native (AI/AN)	Medicaid or AI/AN	✓	
AI/AN	AI/AN	AI/AN	✓	
	AI/AN with no health insurance coverage	AI/AN or Uninsured[2]	✓	
Un-insured	No health insurance coverage	Uninsured[2]	✓	
	Enrolled in a Healthcare Sharing Ministry	Uninsured[2]	✓	
Birthing Hospital	All insurance statuses	Birth Dose Hepatitis B is available for the whole birth cohort at enrolled facilities regardless of eligibility	✓	
Underinsured	Health insurance, but plan does not cover any vaccines	Underinsured[2,3,4]	✓	
	Insurance does not provide first-dollar coverage	Underinsured[2,3,4,5]	✓	
	Health insurance plan does not cover all ACIP-recommended vaccines	Underinsured[2,3,4]	✓	
	Health insurance plan covers all vaccines, but has a fixed dollar limit or cap on amount of coverage	Underinsured after fixed dollar limit is met[2,3,4]	✓	
		Insured until fixed dollar limit is met		✓
	Health insurance covers all vaccines but has not yet met plan's deductible (high-deductible plans)	Underinsured if the visit is for immunizations-only and deductible has not been met[2,3,4,5,6]	✓	
		Insured if visit is not for Immunizations-only, or deductible has been met		✓
Not VFC-Eligible	Enrolled in the Healthy and Well Kids in Iowa (Hawki) Program	Insured – Not VFC Eligible		✓
	Health insurance covers all vaccines	Insured – Not VFC Eligible		✓

1. Providers have two options but must choose the option that results in the least out-of-pocket expense for the patient.
    a. Option 1: Administer VFC Program vaccines and bill Medicaid for the administration fee.
        - Medicaid must pay the VFC Program provider for the administration fee. Medicaid may then seek reimbursement from the primary insurer.
        - Providers should notify the VFC Program if Medicaid rejects a claim for vaccine administration fee or requires the provider to submit the claim to primary insurance first.
    b. Option 2: Administer Private vaccine and bill primary insurance for the cost of vaccine and administration fee.
        - Primary insurance may reimburse less than Medicaid for the administration fee. In this case, the provider may bill Medicaid for the balance up to the amount that Medicaid pays for the administration fee.
        - If primary insurance denies payment of a vaccine and administration fee, the provider may replace the private dose with a VFC Program dose and bill Medicaid for the administration fee. This must be documented on a Vaccine Borrowing Report.
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 vaccination coverage, the child is considered insured and not eligible to receive VFC Program vaccines 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).
5. First-dollar coverage: Any copay, co-insurance, or other cost that must be paid by the patient prior to their health insurance plan paying the remainder of the cost. *This applies only to the cost of the vaccine, not to any admin fee or office visit fee (which may have separate copay.)*
6. Patients with a high-deductible plan are VFC-eligible if the visit is for immunizations-only and the deductible has not yet been met. These patients are considered underinsured and must be served by an FQHC, RHC or LPHA. *If insurance is billed for other services received during the visit, or the deductible has been met, patients are not VFC-eligible.*

Module 2 – Provider Enrollment

Table of Contents

Overview 18
Eligibility 18
Who Can be a VFC Program Provider? 18
Provider Facility Types 19
Federally Qualified Health Centers (FQHCs) 19
Rural Health Clinics (RHCs) 19
VFC Delegated Authority 20
Specialty Providers 20
VFC Program Enrollment Process 20
VFC Program Administration Fees and Guidance 21
Enrollment Forms 21
Enrollment Site Visit 24
Provider PIN 24
Reenrollment, Recertification and Review 25
Provider Training Requirements 25
Disenrollment or Termination 25

Overview

Health care providers who vaccinate children are essential to extending the reach of the VFC Program. These providers increase the potential number of children vaccinated in Iowa and allow the VFC-eligible children to stay in their medical homes.

New VFC provider enrollment is ongoing as the program strives to increase access to vaccines for children in Iowa. Providers who meet the eligibility requirements are encouraged to contact the VFC Program at IowaVFC@hhs.iowa.gov with questions about Iowa VFC Program enrollment.

Eligibility

To be eligible* to participate in the VFC Program, providers must:

- Be licensed in Iowa to administer vaccines to children 18 years of age and younger
- Be willing to follow all VFC program requirements, policies and procedures
- Have the capacity to order, receive, manage, store, and monitor the temperature of public vaccines
- Be open to receive VFC vaccine shipments for at least four consecutive hours on a day other than a Monday to accommodate CDC's delivery shipment window requirements

*If Iowa HHS has been notified by Medicaid that a provider is on the Office of Inspector General's (OIG) List of Excluded Individuals and Entities (LEIE), the provider location is not eligible for enrollment in the VFC Program.

Who can be a VFC Program provider?

Health care provider locations serving VFC-eligible populations can include (but are not limited to):

- Pediatricians
- Family practitioners
- General practitioners
- Local health departments

Specialty care provider locations can include (but are not limited to):

- Birthing facilities (e.g., birthing hospitals/centers)
- OB/GYNs
- Pharmacies**
- Providers serving adolescents in nontraditional environments (e.g., long-term juvenile correctional facilities, family planning, STI/HIV clinics)
- School-based vaccination clinics**
- Specialty provider practices
- Urgent Care Centers**

**These providers must agree to vaccinate all "walk-in" VFC-eligible children requesting vaccines, in addition to meeting all general VFC Program requirements.

Provider Facility Types

A list of provider type definitions can be found in the Provider Type Definitions Appendix.
The VFC Program classifies facilities into the following groups:

- Behavioral Health Clinic
- Birthing Hospital or Birthing Center
- Community Vaccinator
- Correctional facility
- Family Planning Clinic
- Federally Qualified Health Center (FQHC)
- Hospital
- Indian Health Service, Tribal or Urban Clinic
- Juvenile Detention Center
- Migrant Health Cener
- Mobile Provider
- Pharmacy
- Private Practice
- Private Practice as agent for FQHC/RHC-deputized
- Public Health Department (state/local)
- Public Health Department (state/local) as agent for FQHC/RHC-deputized
- Refugee Health Clinic
- Residential/Congregate Care Facility
- Retail Health Clinic
- Rural Health Clinic
- School-based Clinic (permanent location)
- Specialty Provider
- STI/HIV Clinic (non-health department)
- Teen Health Center (non-health department)
- Urgent/Immediate Care Center
- Women, Infants and Children (WIC) Clinic
- Other

Federally Qualified Health Centers (FQHCs)

Federally Qualified Health Centers are public and private non-profit healthcare organizations meeting certain criteria under the Medicare and Medicaid Programs. Criteria are from Sections 1861(aa)(4) and 1905(I)(2)(B), respectively of the Social Security Act and receive funds under the Health Center Program (Section 330 of the Public Health Services 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 Clinics (RHCs)

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 associates and certified nurse midwives in rural communities. RHCs make up one of the largest outpatient primary care programs for underserved rural communities. RHCs provide comprehensive, family-oriented primary health service for medically underserved and disadvantaged populations experiencing financial, geographic, or cultural barriers to care. To inquire about RHC status, contact the Iowa State Office of Rural Health at 515-423-7900.

VFC Delegated Authority

FQHCs and RHCs may grant (delegate) FQHC/RHC status to local public health agencies (LPHAs) to immunize underinsured children on their behalf. A benefit of delegated authority is the VFC Program will pay for vaccines for the 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 800-831-6293 or email IowaVFC@hhs.iowa.gov.

Specialty Providers

For purposes of the VFC Program, "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 aged 0-18 years. Specialty providers that are a pharmacy, urgent care center or school-based clinic must:

- Vaccinate all "walk-in" VFC-eligible children, including VFC-eligible newborn infants at participating birthing hospitals.
- 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 all patients must make an appointment to receive immunizations, then the policy would apply to all VFC patients as well.
- Not deny immunization services to VFC-eligible children based on a parent's inability to pay the administration fee.

VFC Enrollment Process

Providers wanting to participate in the VFC Program must complete required paperwork and submit relevant data as part of the enrollment process. All providers who administer and store VFC vaccines are required to enroll in the VFC Program. Required documentation for enrollment includes:

- Provider Enrollment Form
- Provider Profile Form
- Immunization Registry Information System (IRIS) Enrollment Form for new IRIS enrollment and/or Administrative User access for the Primary and Back-up VFC Coordinators
- Completed Vaccine Storage and Handling Plan
- Submit refrigerator and freezer temperatures for a minimum of two days for each unit that will store VFC vaccine. See the Temperature Monitoring section for additional guidance.
- Certificates of Calibration for each digital data logger (DDL) used to monitor temperatures in each unit that will store VFC vaccine and a back-up temperature monitoring device
- A copy of the Accreditation Certificate for any RHC or FQHC.

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

Enrollment Forms

Provider Enrollment Form

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

The following requirements are detailed in the Provider Enrollment Form:

- Screening of patients for VFC eligibility and documentation of the eligibility status at each immunization encounter.
  - Selection of the VFC eligibility category requiring the least out-of-pocket expense to the patient
  - Maintaining screening records for a minimum of three (3) years in electronic or paper format
- Comply with the appropriate immunization schedule, dosage and contraindications established by the Advisory Committee on Immunization Practices (ACIP), 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 requirement contradicts Iowa law, including laws relating to religious or medical exemptions.
- Maintain all records relating 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 (HHS). VFC records include but are not limited to VFC screening and eligibility documentation, billing records, medical records verifying receipt of vaccine, vaccine ordering, vaccine purchase and accountability records.
- Provide current Vaccine Information Statements (VIS) each time a vaccine is administered or an Immunization Information Statement prior to administration of RSV preventative antibody.

  Note: Providers should not delay use of an ACIP-recommended vaccine because a VIS is unavailable. For any ACIP-recommended vaccine or immunization product that does not have a VIS or Immunization Information Statement available, a provider may use the package insert, written FAQs, or any other document to inform patients about the benefits and risks of the vaccine. Once a VIS is available, providers should use it.

VFC Program Administration Fees & Guidance

VFC Provider should:

- Immunize VFC-eligible children with VFC vaccine at no charge to the patient for the vaccine
- Not charge a vaccine administration fee to non-Medicaid VFC-eligible children that exceeds the Iowa fee cap of $19.68 per dose
- Accept reimbursement fees set by the Iowa Medicaid agency or contracted Medicaid health plans for Medicaid-eligible children
- Not deny administration of VFC vaccine to an established patient because of the child's parent, guardian or individual of record's inability to pay the administration fee

- Maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA) that includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) and adverse events following administration of RSV Preventative Antibodies to MedWatch unless co-administered with a vaccine.
- Comply with Iowa requirements for vaccine management:
  - Order and maintain an appropriate vaccine inventory.
  - Maintain at least one four-hour window for vaccine delivery on a day other than Monday to receive VFC vaccine shipments.
  - Do not store vaccine in dormitory-style combination units at any time.
  - Always store vaccine under proper conditions.
  - Ensure vaccine storage units, temperature monitoring equipment and practices meet the Iowa Immunization Program storage and handling requirements.
  - Return all spoiled/expired public vaccines to CDC centralized distributor within six months of spoilage/expiration.
- Operate the VFC Program in a manner intended to avoid fraud and abuse.
- Participate in compliance site visits, unannounced visits and other educational opportunities associated with VFC Program requirements.
- Local Public Health Agencies with a signed deputization Memorandum of Understanding (MOU) with an FQHC or RHC to serve underinsured VFC-eligible children as well as enrolled FQHCs and RHCs must agree to vaccinate “walk-in” VFC-eligible children.

  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 requires all patients to make an appointment to receive immunizations, then the policy would apply to underinsured patients as well.
- Follow the Vaccine Restitution Policy and as necessary, replace vaccine purchased with state and federal funds and 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.

Provider Profile Form

The Provider Profile Form, completed by either an individual physician or provider group, is used to establish the number of VFC-eligible children served by the facility in a one-year period. This allows the Iowa VFC Program to determine how much vaccine a facility is eligible to receive.

The Provider Profile Form also documents all healthcare providers practicing at the facility and their agreement to comply with program requirements. It is necessary to include the National Provider Identifier (NPI) number, medical license number and email address for each provider listed.

If the facility does not have an individual NPI number, include the facility's NPI number when applicable. The medical director in a group practice (or equivalent) must be authorized to administer vaccines under Iowa law. The provider signing the Provider Enrollment Form on behalf of a multi-provider practice must have the 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 compliance with educational requirements. If the status of the individual signing the Provider Enrollment Form changes, the provider must notify the Iowa VFC Program.

Providers shall reenroll in the VFC Program annually through IRIS. If healthcare providers practicing at the facility change during the year, the medical facility is responsible for updating the physician list in IRIS.

IRIS Enrollment Form

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, complete annual VFC program reenrollment and other VFC-related activities. If the facility is already enrolled in IRIS, an IRIS Enrollment Form is not required to enroll in the VFC Program.

It is recommended that the Primary and Back-up VFC vaccine coordinators both have Admin User Access to IRIS. Each VFC Coordinator should complete the IRIS Enrollment Form and submit it to the IRIS Help Desk if they do not already have Admin Access. Contact the IRIS Help Desk at 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. All enrolled IRIS users shall review and abide by the IRIS Security and Confidentiality Policy.

Vaccine Storage and Handling Plan

New VFC providers must complete the Vaccine Storage and Handling Plan Template to document vaccine management procedures, processes to safeguard vaccine supplies and respond to vaccine storage and handling incidents. The Vaccine Storage and Handling Plan is required for program enrollment and should be submitted with the Provider Enrollment and Profile Forms.

Refrigerator and Freezer Temperature Logs

Before providers can order and receive VFC vaccine shipments, storage unit temperatures must be evaluated to confirm 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 must be documented two times each day along with a minimum/maximum 24-hour temperature range once each day. Preferably, the min/max temperatures are recorded in the morning. Temperatures recorded on the Iowa Immunization Program paper temperature logs or through electronic data collection from digital data loggers (DDLs) are acceptable submissions.

Certificate(s) 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 vaccines. 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 according to the manufacturer’s recommendations. A valid Certificate of Calibration Testing includes:

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

Enrollment Site Visit

Once enrollment forms are submitted, reviewed and approved, VFC staff will schedule an enrollment site visit with the facility. The enrollment site visit ensures the provider and office staff receive education regarding VFC program requirements and have appropriate resources to implement the program.

All newly enrolled or re-enrolling VFC providers have the option to complete their Enrollment Site Visit virtually. If the enrollment visit is conducted virtually, the initial in-person compliance site visit will be completed within six months of enrollment.

Provider Identification Number (PIN)

A Provider Identification Number (PIN) is assigned to each enrolled VFC provider site. PINs are unique to each organization. Using the PIN allows the VFC Program to quickly and accurately respond to correspondence. It is important to notify the VFC Program and update information in IRIS if there are any changes to facility enrollment information. This includes changes to organizational contacts, mailing addresses, shipping addresses, practice hours, email addresses or medical providers. Updating facility information ensures accurate provider data and allows for timely delivery and receipt of vaccine orders.

Reenrollment, Recertification and Review

Each VFC provider location is required to reenroll in the VFC Program on an annual basis. The Iowa VFC Program will communicate the reenrollment due date and provide instructions to VFC Providers through the VFC listserv. As part of reenrollment, in IRIS, providers will review the VFC Patient Activity chart, update the organization's contacts and providers practicing at the facility. They will also review the Provider Agreement and complete the reenrollment form in IRIS.

Note: The Iowa VFC Program does not accept paper forms for reenrollment. They should not be faxed or emailed to the program.

Failure to complete the reenrollment process by the due date will result in suspension from the VFC Program and inability to place VFC vaccine orders in IRIS.

Provider recertification occurs no less frequently than every 24 months with a VFC compliance site visit. VFC nurse clinicians will review provider successes and areas for potential improvement. They will also review clinic procedures to ensure vaccines are handled, stored and administered in accordance with the laws and policies governing the VFC Program.

Further details on VFC Program Enrollment, Compliance, and Storage & Handling Site Visits are covered in the Quality Assurance and Accountability Section of this Operations Guide.

Provider Training Requirements

Every VFC Provider location must receive programmatic training at the initial VFC enrollment site visit. Annual trainings are also required in two areas. At a minimum, these must be completed by the Primary and Back-up VFC Coordinators but are encouraged for all staff involved with handling vaccines. Completion of these trainings is documented during annual VFC reenrollment:

- VFC Program Training: This training covers all VFC Program requirements, including those in the Provider Agreement.
- Vaccine Management Training: Training on proper storage and handling procedures for all staff involved the receipt, management, administration or transport of vaccines.

CDC's You Call the Shots modules satisfy this annual training requirement:

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

Disenrollment or Termination

Either the provider or Iowa VFC Program may terminate the VFC Provider Agreement at any time. Termination initiated by the VFC Program may result from the following situations:

- A provider location has not ordered vaccine in the past 12 months
- The state is notified by Medicaid that a provider is on the List of Excluded Individuals and Entities (LEIE)
- Instances of fraud and abuse

If a provider wishes to disenroll from the VFC Program, they must first ensure all federal or state funded public vaccines are used or transferred from their VFC inventory to another enrolled VFC Program provider. For details on the vaccine transfer process and cold-chain requirements, please refer to the Vaccine Management section in Module 3 of this Operations Guide.

Disenrolling or terminated providers will also need to complete management of vaccine returns and waste in their IRIS inventory. Failure to comply before ending program participation may result in implementation of Iowa's Vaccine Restitution Policy. **Additionally, all VFC Program records must be retained for a minimum of three (3) years after disenrollment.**

Module 3 – Vaccine Management

Table of Contents

Overview 28
Vaccine Ordering 28
Vaccine Availability 28
Vaccine Ordering 29
Ordering and Distribution of Influenza Vaccine 31
RSV Monoclonal Antibody Products, COVID-19 and Non-Routine Vaccines 31
Distribution of Varicella Containing Vaccines 32
Receiving and Unpacking Vaccine Shipments 33
Vaccine Compromised During Shipment 34
Vaccine Management Plan 34
Staffing Requirements and Vaccine Coordinators 35
Staff Training Requirements 35
Vaccine Storage and Handling 36
Storage and Handling Plan 36
Storage and Handling Equipment Requirements 36
Best Practices for Vaccine Storage 38
Temperature Monitoring and Temperature Monitoring Devices 39
Vaccine Inventory Management 42
Vaccine Borrowing 43
Vaccine Transfers Between VFC Program Providers 44
Types of Vaccine Loss 45
Management of Expired, Spoiled and Wasted Vaccines 45
Vaccine Handling and Preparation 46
Emergency Situations 46
Vaccine Accountability 47
Temporary, Mobile, Off-Site, or Satellite Clinics 47
Fraud and Abuse 47
Fraud 48
Abuse 48
Fraud and Abuse Examples 48
Vaccine Restitution Policy 48

Overview

Vaccine loss is both costly and preventable. The Iowa VFC Program and enrolled VFC Program providers are responsible for maintaining vaccine quality from the time a shipment arrives until a dose is administered. Vaccine management practices relating to ordering, inventory maintenance, and storage and handling are critical to minimizing vaccine waste, and ensuring the viability of vaccines administered to children.

Vaccine Ordering

VFC Program 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 Program. VFC vaccines must be administered according to the guidelines outlined by the ACIP in the VFC Program resolutions.

Vaccine Availability

Iowa VFC Program Vaccine Brand and Presentation Policy

The Iowa VFC Program offers all vaccines listed on the CDC VFC contract unless noted in the Vaccine Brand and Presentation Exceptions section below. Providers are allowed to choose between manufacturer, brand and presentation when multiple options are available.

Vaccine Brand and Presentation Exceptions

The Iowa VFC Program will limit or restrict vaccine products or quantities due to constraints and limitations imposed by CDC or vaccine manufacturers.

- PPSV23 is available only on a case-by-case basis. Cases shall be identified as high-risk as defined by the VFC Program 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 patients and should only be administered during the specified gestation period and seasonality. This vaccine is considered non-routine, and providers shall ensure patients meet the defined administration criteria before ordering.

- If a vaccine is unavailable, the IRIS order form will be updated by VFC Program staff to show only available products. A list of available vaccines is found on the Iowa VFC Program website.

Vaccine Definition

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 Program resolution for inclusion in the VFC Program.

Vaccine Ordering

Vaccine loss due to expiration is frequently a consequence of over-ordering and/or poor inventory management. To prevent this, providers should determine the appropriate amounts to order for their private and public vaccine inventories.

Providers are responsible for ordering and maintaining an adequate vaccine supply at their facility. Orders shall be submitted based upon the facility's assigned ordering frequency (monthly, bi-monthly, quarterly). Ordering frequency is based on the provider's patient population and is intended to balance shipping costs while reducing potential waste. Orders placed outside the assigned ordering frequency may be denied. Providers shall place orders for adequate doses of vaccine to immunize children for the period determined by their assigned ordering frequency. CDC recommends providers always maintain a minimum of a four-week supply of vaccine to allow for potential shipping delays.

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 clinic date. Review the 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/age cohorts each clinic will cover.
- Place orders at least three weeks in advance (can be combined with routine orders).
- VFC vaccine already in inventory may also be used for school-based clinics.

Vaccine Stocking Requirements and Exempt Vaccines

VFC providers are required to stock all ACIP-recommended vaccines for VFC-eligible patients. Some vaccines are exempt from this stocking requirement:

- COVID-19 vaccine
- Monkeypox vaccine
- Pneumococcal polysaccharide (PPSV23) vaccine
- RSV maternal vaccine

Stocking these vaccines may not be a viable option for all provider facilities. If a VFC provider does not routinely stock VFC vaccines exempt from the stocking requirement for VFC-eligible children, the provider's procedures must have a plan for making these vaccines available to VFC-eligible patients.

Vaccine Ordering Process

VFC vaccine orders are routinely processed within five to seven business days, but providers should maintain enough inventory to accommodate a potential two-week delivery timeframe. The order processing schedule is subject to change during holidays or due to extreme weather affecting delivery.

VFC-Enrolled Provider Responsibilities

- Order vaccine quantities consistent with the facility's provider profile, number of VFC-eligible children served, and doses administered data.

- Review and confirm vaccine delivery hours in the *Create Order* screen in IRIS when submitting each order. Delivery hours will carry over to subsequent vaccine orders.
  - Providers must be open for at least four consecutive hours on a day other than Monday to receive VFC vaccines.
  - Provider staff must be available in the stated window to receive vaccine shipments, inspect the contents and place vaccines in the appropriate storage unit.

    Note: IRIS will only retain changes to delivery times when an order is placed.
- Do not place orders if the facility will be closed for an extended period.
- Consider the following when placing VFC vaccine orders:
  - Vaccines expiring before the next order will be placed based on the provider profile and ordering frequency
  - Current vaccine inventory including single antigen and combination vaccines
  - Seasonality (school physicals, kindergarten round-up, etc.) and planned specialty clinics
  - IRIS Recommended Ordering Quantity (ROQ) is based on administration data from the same period the previous year to account for seasonality

    Note: Newly enrolled VFC Program providers and/or products without an ordering history will not have historical data to rely on. Providers should refer to Doses Administered Reports.
- Validate quantities of doses on hand which display on the vaccine order form. If physical inventory does not match quantities displayed in IRIS, the provider should contact the IRIS help desk.
- Determine the appropriate quantity for an order based on the inventory on hand, recommended ordering quantity and doses administered data. Enter the quantities on the *Create Order* screen and submit the order.

Iowa VFC Program Responsibilities

- Process vaccine orders in the order received
- Review each order to verify the quantity needed when compared to:
  - Recommended order quantity (based on administration data from the previous year)
  - Quantity of doses on hand and expiration dates
  - Doses administered since the last order was placed, or assigned ordering frequency
- Contact providers as necessary if the requested order quantities are not supported by administration data, inventory on hand and/or recommended ordering quantities
- Iowa VFC Program staff will adjust vaccine orders if the need is not supported or supply is limited due to allocations set by CDC
- Approve vaccine orders in IRIS after making any adjustments and submit the order through CDC's Vaccine Tracking System (VTrckS)

Ordering and Distribution of Influenza Vaccine

VFC Influenza vaccine is not orderable in IRIS like other vaccines. VFC Program providers pre-book VFC influenza vaccine in IRIS during the annual influenza pre-book period before the upcoming influenza season. VFC Program providers enrolling in the VFC Program after the pre-book period will be able to request influenza vaccine. Iowa VFC Program maintains an additional inventory from which additional provider requests and new enrollments throughout the season are covered.

Providers should review the following information to determine accurate influenza vaccine pre-book quantities:

- Number of VFC-eligible children seen at the clinic in the previous year
- Quantity of influenza vaccine ordered in the previous season
- Influenza vaccine doses administered in the previous season
- Vaccine wastage due to expiration in previous season(s)
- Desired quantity for each product
- Ordering quantities are in doses, not the number of packages
- Review the pre-book materials for influenza vaccine presentations and age indications

Viewing Pre-book in IRIS

Review products and quantities pre-booked by the VFC Program provider by selecting the “flu prebook” menu in IRIS. Select the appropriate “Flu Prebook Window” for the appropriate timeframe. The pre-booked products and quantities will display.

Shipment of Influenza Vaccine

The VFC Program will distribute influenza vaccine orders when vaccines are delivered to CDC distribution centers and become available on CDC’s state vaccine allocations. This usually occurs from late summer to early fall. Manufacturers routinely distribute influenza vaccine as it is produced and released by the FDA. Influenza vaccine will be distributed in partial shipments, possibly shipped with routine vaccine orders, ensuring all providers receive a portion of their vaccine request before all requests are fulfilled. Remaining vaccines will be shipped by the Iowa VFC Program as they become available on vaccine allocations.

RSV Monoclonal Antibody Products, COVID-19 and Non-Routine Vaccines

Since the fall of 2023, VFC Program providers have been granted flexibility in meeting private inventory requirements for COVID-19 vaccines and RSV monoclonal antibody products. VFC Program providers were not required to maintain private inventory for these products.

New requirements became effective July 1, 2025, and carry through subsequent respiratory virus seasons. 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. As of July 1, 2025, this policy includes all RSV monoclonal antibody products available through 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 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.

VFC Program providers may need to order COVID-19 vaccines or RSV monoclonal antibody products 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.

Non-Routine Vaccines

Non-routine vaccines include but are not limited to pneumococcal polysaccharide (PPSV23), monkeypox, meningococcal serogroup B (MenB), COVID-19 and maternal RSV products. Providers shall make available those vaccines identified in their Provider Profile based on provider type and patient population served.

Maintaining a stock of non-routine vaccines is not always a viable option due to availability and demand. Providers should only order non-routine vaccines on a case-by-case basis for eligible patients except for COVID-19 vaccines; providers may order COVID-19 vaccine as needed.

- Non-routine vaccine order requests may be emailed to IowaVFC@hhs.iowa.gov or added to the *special comments for order* section of a new order on the IRIS order form.

Distribution of Varicella-Containing Vaccines

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

Receiving and Unpacking Vaccine Shipments

Requirement:
CDC requires facilities receiving vaccine shipments to be able to receive the shipments at least one day per week on a day other than Monday. There must be at least a four-hour delivery window available on that day. VFC Program providers must also develop and post a protocol for accepting vaccine deliveries that indicates who is permitted to accept vaccine shipments and ensure vaccines are stored appropriately immediately after delivery.

All facility staff involved in accepting deliveries shall be trained on receiving and appropriately handling vaccine shipments. They must also follow and complete the following with each vaccine shipment:

- Immediately notify the primary or back-up vaccine coordinator when deliveries arrive.
- Unpack the vaccine shipment immediately.
- Inspect the vaccine and packaging for damage.
- Crosscheck the vaccine received with the shipping invoice to confirm the number of doses, lot number and expiration dates. Discrepancies should be immediately reported to the Iowa VFC Program at 800-831-6293 or IowaVFC@hhs.iowa.gov.
- Verify shipments containing 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 shipping container and should be stored separately in the refrigerator.
- Check the Temperature Monitoring Device (TMD) for indication of a temperature excursion during transit.
  - McKesson shipments use TagAlert temperature monitor devices. Upon receipt, providers should immediately press the blue Stop/Start button until the Stop icon appears. Then, read the indicator status to determine if appropriate temperature was maintained during transit.
  - TMDs, also called Cold Chain monitors (CCM) are single-use devices. Providers should dispose of them after verifying shipment viability. *Note: TMDs may not be included when vaccines are shipped directly from the manufacturer*
  - Cold or warm temperatures should be immediately reported to the Iowa VFC Program. Orders are only able to be contested/replaced within the first 24 hours of receipt.
  - Vaccines that appear to have been involved in a temperature excursion should be immediately stored at the appropriate temperature and marked as “Do Not Use” so potentially compromised vaccines can be easily identified and not used until viability of vaccine is determined.

Temperature Excursion
A temperature excursion occurs when a vaccine is exposed to any temperatures outside the recommended range found on the package insert for any duration of time.

- VFC direct-ship frozen vaccine (e.g. Varicella-containing vaccines or COVID-19 vaccine) will show permissible transit time on the packing slip. The Iowa VFC Program should be contacted if vaccine was delivered outside of this window. As stated above, these vaccines should be stored at appropriate temperatures and marked as “Do Not Use” until further guidance is received.
- Document the date vaccine was received on the Packing Slip. Vaccine shipping invoices for private and public inventory must be maintained for a minimum of three years.
- Store immediately at appropriate temperatures according to the manufacturers’ product specifications.
- IRIS functionality allows Iowa HHS to add vaccine shipments to IRIS inventory. A message will display in IRIS informing users of a new vaccine order in their inventory. Contact the IRIS Help Desk at 800-374-3958 with any questions regarding inventory.

Vaccine Compromised During Shipment

If a provider believes a vaccine shipment was compromised, they must immediately contact the Iowa VFC Program at 800-831-6293, or IowaVFC@hhs.iowa.gov. **Do not dispose of the shipment** until guidance has been received.

Providers should also contact:

- McKesson Centralized Distribution: Contact centralized distribution immediately at 877-TEMP123 (877-836-7123). This must be done the same day vaccines arrive. Reporting later may result in the Iowa VFC Program being responsible for the spoiled vaccines regardless of the reason for the excursion.
- Direct Ship vaccines (Merck or Pfizer frozen vaccines): Contact the Iowa VFC Program. Shipment issues may also be reported directly to Merck via their CDC/VFC Vaccine Inquiry Form.

Providers must contact the manufacturer directly with questions about storage temperature or temperature excursions for specific vaccines. Manufacturers have access to internal thermostability data concerning the impact of exposures to inappropriate temperatures or light for each vaccine lot.

Vaccine Management Plan

Proper management of vaccine is one of the most important activities conducted by a VFC Program provider. Implementing proper inventory maintenance along with storage and handling procedures will ensure the vaccine cold chain is maintained at the clinic. Appropriate vaccine management practices minimize vaccine loss and waste. Consult CDC’s Vaccine Storage and Handling Toolkit for the most current guidance and best practices for vaccine storage and handling. The toolkit should be the primary resource for vaccine storage and handling information.

Staffing Requirements and Vaccine Coordinators

Each VFC Program provider location is required to designate a primary vaccine coordinator and at least one back-up coordinator. The back-up coordinator must be 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 Program contacts for the office.

The vaccine coordinator is responsible for overseeing all vaccine management within the facility, including:

- Developing and maintaining the Vaccine Management Plan
- Monitoring storage and handling and vaccine administration practices in the facility
- Overseeing vaccine ordering and notifying the Iowa VFC Program if vaccines will expire before they are administered
- Ensuring and documenting annual vaccine management training for designated staff, as well as training new staff upon hire. If providers need assistance in training new personnel, they should contact the Iowa VFC Program to schedule an educational call or visit.
- Participating in and documenting completion of annual training on VFC Program requirements
- Storing required documentation for a minimum of three (3) years

To effectively perform their duties, the vaccine coordinator must be fully trained on routine and emergency standard operating procedures (SOPs) for vaccine ordering, storage, handling, transport and inventory management.

Requirement:
Providers are required to notify the Iowa VFC Program when there is a change in vaccine coordinator staff. Contact information must also be updated by the provider in IRIS. Instructions can be found in the IRIS Amin User Training Handout starting on page 21.

Staff Training Requirements

Each VFC Program provider is required to re-enroll in the VFC Program on an annual basis. The Iowa VFC Program will communicate the reenrollment due date and provide instructions to providers through the VFC listserv.

As part of reenrollment, the primary and back-up vaccine coordinators are required to complete CDC's web-based You Call the Shots modules each year. The two required modules are:

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

Vaccine Storage and Handling

All VFC Program vaccine storage and handling requirements and recommendations are in place to ensure the vaccine cold chain is maintained. The cold chain begins at the manufacturing plant, includes delivery to and storage at the provider location, and ends with administration of vaccine to the patient. Too much exposure to heat, cold or light at any step in the cold chain can result in a loss of vaccine potency. Once potency is lost, it cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced even further. With loss of potency, vaccines become useless and are unable to provide immunity for the vaccinated individual.

Vaccine Storage and Handling Plan

Requirement:
VFC Program providers must develop and maintain a written routine and emergency Vaccine Storage and Handling Plan. The plan should be posted on or near vaccine storage units to be easily accessible. The plan must be reviewed and updated annually, or any time there is a change in staff or programmatic responsibilities. A Vaccine Storage and Handling Plan Template is available on the VFC Program website.

Storage and Handling Equipment Requirements

Vaccine storage units must always maintain appropriate temperature ranges. They must be big enough to hold the year's largest inventory without crowding and have a power source protected by warnings. Warnings should include "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
- Vaccine storage units that conform to NSF/ANSI Standard 456 (which have been tested rigorously to be used for the storage of vaccines)*
- Stand-alone refrigerator and freezer units—these units can vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical-grade unit
- Combination household refrigerator/freezer unit, using only the refrigerator compartment to store vaccines—a separate stand-alone freezer should then be used to store frozen vaccines**

*American National Standards Institute (ANSI) is the organization that accredits the National Sanitation Foundation (NSF).

**Any provider enrolled before July 1, 2024, who currently uses both compartments of a household combination unit may continue to do so. If temperature excursions cannot be attributed to another cause (e.g., power outage), the provider must discontinue that unit's use, even if doing so necessitates the purchase of a separate unit. Providers enrolled in the VFC Program are prohibited from using dormitory or bar-style units with a single exterior door and an evaporator plate or cooling coil, which is usually located in an icemaker or freezer compartment.

Equipment Safeguards

Safeguards should be in place to protect vaccine inventory. Safeguards include, but are not limited to:

- Plug in only one unit per electrical outlet to avoid creating a fire hazard or triggering a 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.
- Place labels on circuit breakers to alert staff not to turn off power to VFC vaccine storage unit circuits. Labels should include immediate steps to take if power is interrupted. If the building is owned by a third party, work with the manager to establish access to circuit breakers.
- Use caution when using power outlets that can be tripped or switched off. Avoid using:
  - Built-in circuit switches (those with reset switches)
  - Outlets that can be activated by a wall switch
  - Multi-outlet power strips
- Ensure doors are tightly shut.

VFC Program Storage and Handling Equipment Requirements

To ensure the viability of VFC vaccines, providers must have:

- Storage units that always maintain correct temperatures
- Provide sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer to stabilize temperatures.
- Refrigerator temperature between 2°C and 8°C (36°F and 46°F).
- Freezer temperature between -50°C and -15°C (-58°F and +5°F)
- Digital data loggers (DDLs) with continuous monitoring capabilities and a current Certificate of Calibration testing for each unit and at least one back-up.

Best Practices for Vaccine Storage

To protect the viability of vaccines, the following best practices should be followed:

- Never store food or beverage in a unit with vaccines
- Store all varicella-containing vaccines (Varivax and ProQuad) in the freezer between -58.0°F and +5.0°F (-50.0°C and -15.0°C).
  - MMRII vaccine (Merck) can be stored in the freezer. Storing MMRII in the freezer with MMRV may help prevent inadvertent storage of MMRV in the refrigerator. It may also prevent MMRII vaccine loss in the event of a temperature excursion. Diluent should **not** be stored in the freezer.
  - Priorix MMR vaccine (GSK) **cannot** be stored in the freezer. It should only be stored in the refrigerator.
- Store all vaccines and diluents in the original packaging with lids closed to protect them from light until administration.

- If indicated by unit type, use proper placement of water bottles or frozen packs to help stabilize unit temperatures. Place water bottles on the top shelf, floor and in the door racks.
- Do not store vaccine in the door of the unit, crisper or other drawers within the unit.
- Store vaccines in the middle of the compartment, away from walls, coils, vents and peripheral areas.
- Store vaccine products that have similar packaging in different locations in the unit to avoid confusion and reduce the possibility of administration errors.
- Open only one box of a specific vaccine at a time to control vaccine use and better track inventory.
- VFC vaccine should be organized and separated from private vaccine stock. Both inventories should be clearly labeled.
- Limit access to vaccine supply to authorized personnel only.

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.

Back-up Supplies and Facilities

VFC Program providers must have a back-up plan to appropriately store vaccine if storage equipment malfunctions or there is a power outage. Providers must:

- Make formal arrangements (memorandum of understanding) with an alternate facility.
- Train a designated person and a back-up at the facility to manage vaccine if it must be moved.
- Call the back-up location to ensure the facility and staff are available to receive and store vaccine. If they are not, the provider will need to contact alternate facilities.

Temperature Monitoring and Temperature Monitoring Devices (TMDs)

Temperature monitoring is a primary responsibility of the Primary and Back-up VFC Program Coordinators. VFC Program providers must have protocols for training appropriate staff in assessment and interpretation of temperature data as well as proper documentation of findings. Staff must also know how to appropriately respond in the event of a vaccine temperature excursion.

VFC Program providers must use continuous temperature monitoring devices with a valid and current certificate of calibration to monitor VFC vaccine temperatures during routine clinic storage, transport of vaccine between providers and during offsite vaccination clinics.

Requirement:

Use of a digital data logger (DDL) is required when storing or transporting vaccine. They provide accurate and comprehensive documentation of storage unit temperatures.

Digital data loggers must be equipped with:

- Temperature probe
  - A buffered probe is recommended for refrigerators and freezers
  - Ultra-cold monitoring requires an air-probe or other probe specifically designed for ultra-cold temperatures
- An active temperature display that can be easily read from the outside of the unit
- Continuous monitoring and recording with data download capability
- Logging intervals (reading rates) no less frequent than every 30 minutes
- Alarm for out-of-range temperatures
- Low battery indicator
- Current, minimum, and maximum temperature displays
- Recommended uncertainty of +/- 0.5°C (+/- 1°F) or less
- Valid Certificate of Calibration testing including
  - Mode/Device number
  - Serial number
  - Date of Calibration
  - Recommended uncertainty of +/- 0.5°C (+/- 1°F) or less
  - Confirmation of the instrument passing testing

Certificate of Calibration Testing

A Report of Calibration must be issued by an entity supporting one or more of the following:

- Conformance to Internation Organization for Standardization (ISO)/International Electrotechnical commission (IEEC) 17025 standards for calibration testing and traceability
- Performed by a lab accredited by the International Laboratory Accreditation Cooperation (ILAC)
- Traceable to National Institute of Standards and Technology (NIST) standards
- Meets specifications ant testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877
- Other acceptable accuracy validation method (e.g. 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 like a DDL, but may not be capable of digitally logging temperatures. Contact the Iowa VFC Program for temperature monitoring device requirements.

Back-up Temperature Monitoring Device

Iowa VFC Program providers shall have at least one back-up DDL with a valid certificate of calibration available in case of failure of one of the primary units or use while another unit is calibrated and tested. The back-up DDL should have a different calibration testing date than the other DDLs.

If the back-up device is not physically on-site, a plan must be in place documenting how it will be accessed within an acceptable timeframe compliant with the requirements for temperature recording in the event of a primary unit failure.

DDLs must always be used in the event of VFC vaccine transfer or when moving vaccine in the event of a temperature excursion.

Back-up DDL Storage

Back-up DDLs should not be stored in the storage unit. This can result in conflicting temperature readings between the back-up and primary DDLs, which may lead to confusion.

Placement of Digital Data Loggers

In household or commercial units, the device must be placed in a central area of the storage unit adjacent to 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. Pharmaceutical or purpose-built units may allow placement in other locations. Providers should follow manufacturers' recommendations for these units.

Temperature Monitoring

Temperature monitoring protocols include:

- Designation of staff to check and record refrigerator and freezer temperatures twice daily (at the beginning and end of each day).
- Recording min/max temperatures at the start of each workday. CDC requires reviewing and recording min/max temperature readings at the beginning of the workday, then resetting the min/max reading.

Notation of the time of the reading and the name or initials of the designated staff.

- Storage temperatures must be handwritten on a paper temperature log or electronically documented by a continuous monitoring and recording system.
  - Any electronic documentation must be capable of capturing the time and initials of staff performing the check along with temperature to one decimal place.
  - If electronic monitoring and documentation has the capacity to capture the required information, paper logs are not required.
  - Paper logs may be downloaded from the Vaccine Storage and Handling page.
- Download and review DDL data at least every two weeks and whenever the DDL alarms. Designated staff should review temperature logs at a minimum of once per week to ensure proper temperature documentation and recording. Action must be taken in the event of errors or out-of-range temperatures.

Requirement:
VFC temperature logs and DDL data must be retained for a minimum of three years. Storage in paper or digital format is acceptable.

Providers have two options for documenting temperature readings:

Option 1: Handwrite the temperature on a paper log. The log should be posted on each vaccine storage unit door or nearby in a readily accessible and visible location.

Option 2: Use a continuous temperature monitoring and recording system that allows providers to electronically document all required information.

Temperature Alarm Settings

Temperature alarms help to safeguard vaccine viability in the event of out-of-range temperatures. DDLs are a requirement of enrollment in the VFC Program. Temperature measurements should be taken to the tenth of a degree.

VFC Program providers should utilize the appropriate parameters when evaluating storage unit temperatures. Instructions for configuration of LogTag VFC 400 DDLs are available on the Vaccine Storage and Handling website. Temperature alarm settings are:

Refrigerator	Freezer	Ultra-Cold Freezer
35.9°F and 46.1°F	5.1°F and warmer	-75.9°F and warmer
1.9°C and 8.1°C	-14.9°C and warmer	-59.9°C and warmer

Out-of-Range Temperatures

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

Providers should immediately store vaccine under correct storage temperatures. **Do not discard** vaccines until guidance has been received from the manufacturer and/or the Iowa VFC Program. The VFC Program may be contacted at 800-831-6293 or IowaVFC@hhs.iowa.gov. Vaccines should be marked “Do Not Use” and cannot be administered until vaccine viability has been verified by the manufacturer(s).

Documentation of a temperature excursion includes recording essential data related to the improper storage temperatures on the Vaccine Storage and Handling Incident Response Worksheet. A fillable form is found on the Vaccine Storage and Handling website.

Vaccine Inventory Management

VFC and Private Inventories

If a VFC Program provider does not carry privately purchased stock, they are not permitted to use VFC stock on non-VFC-eligible patients.

If a VFC Program provider serves and plans to vaccinate privately insured (non-VFC-eligible) populations, they should stock a separate vaccine supply for the specific vaccines they plan to offer non-VFC-eligible patients. CDC is not requiring VFC Program providers to maintain a full stock of all ACIP-recommended vaccines for non-VFC-eligible patients if they do not plan to offer all ACIP-recommended vaccines to this population. This guidance includes, but is not limited to, RSV monoclonal antibodies.

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

- Completing counts of vaccines and diluent doses in inventory monthly and prior to ordering
  - IRIS inventory should be validated at least once per month.
  - If discrepancies are identified, hand counts and reconciliation should be performed weekly until the issue is resolved.
  - Inventory errors should be reported to the VFC Program and/or IRIS help desk to be resolved before placing vaccine orders.
- Check expiration dates and place soonest to expire vaccines in the front
  - Expiration dates vary by vaccine type, diluent, and lot number.
  - CDC's best practice is to rotate weekly and whenever new vaccine is received.
  - Expiration dates listing only month and year are viable through the last day of the month.
  - Multi-dose Vials (MDVs) shall be administered until the expiration date printed on the vial or the Beyond Use Date (BUD), whichever is sooner.
- Separate VFC vaccine from Private vaccine inventory and clearly label both. Staff must be able to distinguish VFC vaccine from private stock.
- Order vaccine in quantities appropriate for the patient population, ordering frequency and doses administered.
  - Ordering frequencies of monthly, bi-monthly, and quarterly are based on VFC-eligible patient population.
  - Do not over-order or stockpile vaccine. It may result in vaccine waste due to expiration.
- Maintain adequate inventory of VFC and private inventories to eliminate occurrences of borrowing or transfer.
  - CDC recommends providers place vaccine orders while they still have four weeks' supply of vaccine available to allow for potential delays.

- Orders placed on the provider's routine cadence should be in sufficient quantity to ensure adequate inventory until their next order.

- Report any vaccine expiring within three months to the Iowa VFC Program at IowaVFC@hhs.iowa.gov to find a potential transfer.
  - The VFC Program will provide a list of providers in the surrounding area that carry a similar inventory.
  - Providers should work to transfer any expiring doses to prevent waste due to expiration.

Vaccine Borrowing

VFC-enrolled providers are expected to maintain and manage an adequate inventory of vaccine for both VFC and non-VFC-eligible patients. Vaccine borrowing should not be a regular occurrence. Vaccine borrowing due to rare and unplanned occurrences may result from unforeseen delays or circumstances surrounding the vaccine(s) ordered. All instances of borrowing must be properly documented and reported. Borrowed doses must be replaced.

Borrowing VFC vaccine is the exception to the rule and routine borrowing may be grounds for termination from the VFC Program. If a facility consistently uses private stock or does not document usage appropriately, vaccine accountability procedures will be reviewed. This may result in further investigation and/or termination.

When is borrowing ok?	When *not* to borrow
Borrowing short-dated vaccine to prevent waste due to expiration	If borrowing from VFC stock would result in vaccines being unavailable for VFC patients
Vaccine delivery delays	Repeated human error
Vaccine spoiled/damaged in transit	Running out of stock between orders
New staff calculated ordering intervals incorrectly, leading to a lack of stock.	When hosting a temporary, mobile or off-site satellite clinic without appropriate amounts of public and private vaccine
VFC seasonal influenza vaccine stock is not yet available. Providers may use private stock and replace it when VFC vaccine is available	Routine borrowing of VFC vaccines/monoclonal antibody products for privately insured patients

What to do when borrowing occurs:

- Document every instance of borrowing on the VFC Program Vaccine Borrowing Report and submit it to IowaVFC@hhs.iowa.gov. Borrowing reports must be completed when:
  - VFC vaccine is administered to a privately insured child, or
  - Privately purchased vaccine is administered to a VFC-eligible child
- Update IRIS inventory to reflect the payback
- Replace all borrowed doses as soon as doses are available in the appropriate stock.

Requirement:
All clinic staff handling or administering VFC vaccine must complete annual training, including:

- **Proper VFC Program patient eligibility screening and documentation**
- **Administration of appropriate vaccine inventory based on patient eligibility**
- **Clinic procedures for vaccine inventory management**

Providers may use the Vaccine Management and Borrowing Tool for training, guidance and documentation.

A VFC Program 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. Completed Borrowing reports should be emailed to IowaVFC@hhs.iowa.gov or faxed to 800-831-6292.

In the rare event when a patient has Medicaid and private insurance and primary insurance 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 private-purchased vaccine. Iowa HHS Medicaid Program will not reimburse for acquisition cost of vaccines provided by the VFC Program. Borrowing in this instance must be documented on the VFC Program Vaccine Borrowing Report.

All borrowing transactions require corrective action in IRIS to update VFC and private vaccine inventory. If needed, refer to the Vaccine Borrowing Instructions.

Vaccine Transfers Between VFC Program Providers

Proper vaccine inventory management plays a major role in preventing the need to transfer vaccines. Providers may experience a situation in which they have soon-to-expire vaccine stock. When practical, and if the cold chain is maintained, transfer of short-dated vaccine can occur between VFC provider locations to avoid wasting vaccine. Providers must notify the Iowa VFC Program of short-dated vaccine so a transfer can be coordinated. This should be a rare occurrence with appropriate vaccine inventory management.

Requirement:
All vaccine transfers must be properly documented on the VFC Program Vaccine Transfer Form. The vaccine transfer must include a DDL with a valid Certificate of Calibration testing during transport.

The cold chain must be maintained during the transfer of vaccines. Providers should consult CDCs Storage and Handling Toolkit for additional information on cold chain requirements.

Follow these steps to transfer viable VFC vaccine:

- Notify the VFC Program of the intent to transfer vaccine.
- Document vaccine transfers on the VFC Vaccine Transfer Form and email the form to IowaVFC@hhs.iowa.gov.
- Ensure temperature documentation validating the vaccines have not been exposed to a temperature excursion is available and transported with the vaccine(s).
- A DDL with a valid Certificate of Calibration Testing must be used while transporting vaccine.
- Maintain the appropriate cold chain while transferring vaccine.
- Document the vaccine transfer in IRIS. If needed, directions may be found in the VFC-IRIS Transfer Instructions.

Management of Expired, Spoiled and Wasted Vaccine

When managing expired, spoiled and wasted vaccine, providers must:

- Remove the vaccines from any storage unit that stores viable vaccines.
- Label vaccines “Do Not Use.”
- Report all vaccine loss to the VFC Program. VFC Program providers shall document vaccine loss using appropriate reasons in IRIS to deduct doses from inventory. Expired vaccine is automatically adjusted in IRIS.
- Complete the Nonviable Vaccine Return Process. Adjustments to VFC inventory in IRIS using the following reason codes will require providers to return vaccines to McKesson Specialty Distribution:
  - Expired
  - Refrigerator too cold
  - Refrigerator too warm
  - Natural disaster/ power outage
  - Failure to store properly upon receipt
  - Vaccine spoiled in transit
  - Mechanical failure
  - Spoiled
  - Recall

Types of Vaccine Loss

Expired or Spoiled Vaccine:
Nonviable vaccine in its original container (i.e., vial, syringe) that can be returned for excise tax credit. This includes expired vaccine or vaccine spoiled due to:

- Temperature excursions
- Transport conditions
- Emergency situations such as power failure

Wasted Vaccine:
Nonviable vaccine that cannot be returned for excise tax credit. This includes vaccine:

- In an open vial
- Drawn into a syringe
- Compromised because its container was dropped or broken

Lost or Unaccountable Vaccine:
Vaccine that is missing its physical vial or syringe.

Nonviable Vaccine Return Process

VFC Program 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 vaccine return process are found in the Nonviable Vaccine Return Instructions.

Note: Wasted vaccines cannot be returned to McKesson Specialty Distribution and should be disposed of using clinic policy to follow state and local disposal requirements. Open multi-dose vials cannot be returned and will remain in IRIS inventory until six months after the expiration date.

Vaccine Handling and Preparation

Proper vaccine handling and preparation are equally as important as storing vaccines properly.

Providers should follow the best practices including:

- Vaccines should be prepared immediately prior to administration.
- Prepare vaccines in a designated, clean medication area away from any space where potentially contaminated items are placed.
- Always check expiration dates prior to preparing the vaccine. Never administer expired vaccines.
- Reconstitute lyophilized vaccine with the diluent that came with the vaccine—nothing else.
- Single-dose vials contain one dose and should only be used for one patient.
- A separate, sterile needle and syringe should be used for each injection.
- Discard any predawn dose no later than the end of the workday or per the manufacturer's package insert (if sooner).

In instances where providers anticipate high volumes of patients needing vaccines (e.g. flu season, back-to-school clinic), it is important to remember:

- CDC strongly recommends against pre-drawing doses before they are needed.
- As an alternative to pre-drawing vaccines, CDC recommends using manufacturer-filled syringes.

Emergency Situations

Provider locations should plan for emergency situations such as power outages, natural disasters and equipment failure. This information should be incorporated into a Vaccine Management Plan so providers can follow the protocol for protecting vaccines, including possible transport methods and alternative storage locations. Provider locations should maintain supplies and have them ready to access in the event of emergency vaccine transport. It is recommended that alternative storage locations should be inspected upon establishment or at least once prior to an emergency to validate that proper vaccine storage conditions can be maintained. Should the alternative location change, the new location should also be inspected.

Note: Alternate vaccine storage locations should be other enrolled VFC Program providers whenever possible.

In large clinics, back-up power systems and security systems to alert appropriate staff in the event of a power outage may be feasible. If used, back-up power systems should be tested quarterly and serviced annually based on manufacturer specifications for testing procedures and maintenance schedules.

Requirement:
Vaccine Accountability—VFC Program providers must enter all administered doses into IRIS. Providers must also use IRIS to account for all transfers, borrowing, spoilage, wastage and expiration.

Temporary, Mobile, Off-Site or Satellite Clinics

Temporary, mobile, offsite or satellite clinic providers must maintain vaccine transport records detailing the type of vaccine, quantity and DDL data. They are required to adhere to all general program requirements, including screening and documentation of VFC eligibility, and maintain enhanced storage and handling practices, including:

- Base the number of VFC vaccines transported to a temporary, mobile, off-site or satellite clinic on the anticipated number of VFC-eligible children to be served.
- Vaccines may be transported, not shipped, to a clinic site using vaccine transportation procedures outlined in CDC's Vaccine Storage and Handling Toolkit. Temperatures must be monitored and recorded using a DDL with a probe in buffered material.
- Upon arrival at the clinic, vaccines must be stored correctly to maintain appropriate temperatures throughout the clinic day.
- Temperature data must be reviewed and documented every hour during the clinic using a DDL with a digital display and probe in buffered material.
- At the end of the clinic day, temperature data must be assessed prior to placing vaccines back into storage units to prevent administration of vaccines that may have been compromised.

Mobile Clinics
Mobile clinics are movable units (i.e. trailers, buses, etc.) acting as extensions of existing providers. These units are not the primary site for vaccine storage and administration. Do not confuse them with mobile providers who exclusively store and administer out of a mobile facility.

If vaccines are exposed to temperature excursions, they must be labeled "Do Not Use" and stored at the appropriate temperature until further information can be gathered on viability.

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. VFC Program staff will investigate allegations of fraud and abuse and determine appropriate action, including notifying the proper agencies to conduct a full investigation. Providers participating in the VFC Program must fully

understand program requirements and what constitutes fraud and abuse. VFC Program definitions of fraud and abuse are consistent with Medicaid regulations (42 CFR § 455.2), and for purposes of this VFC Program Operations Guide, the following definitions are used.

Definitions 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, resulting 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 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. This list is not exhaustive, but examples may 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 an 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 Program records for a minimum of three years
- Failing to fully account for VFC-funded vaccine
- Failing to properly store and handle VFC vaccine including wasting VFC vaccine
- Ordering VFC vaccine in quantities or patterns inconsistent with provider profiles

Vaccine Restitution Policy

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

Module 4 – Program Operations, Accountability, Quality Assurance and Compliance

Table of Contents

Program Operations-Overview 50
Record Retention 50
Records Management 50
Program Operational Policies and Procedures 50
- Provider Annual Review 50
- Provider Biannual Recertification 50

Site Visits 51
- Enrollment Site Visits 51
- Compliance Site Visits 51
- Storage and Handling Site Visits 52

Provider Training and Education 52
- Provider Responsibility to Train Staff 52

Overview

The Iowa VFC Program ensures federally established VFC requirements are adhered to by enrolled VFC providers. The Program has established, implemented and monitors operational policies to ensure provider actions are compliant with CDC requirements.

Record Retention

All VFC Program documentation must be retained for a minimum of three years. Digital and/or paper storage of records is permitted. Documentation should be stored and maintained in a location and manner such that multiple staff can access the information and provide it to the Iowa VFC Program upon request, even if the provider and/or clinic leave the program.

Records Management

Providers must maintain all records related to the VFC Program for at least 3 years. These records must be available upon request from the VFC Program.

VFC Program records include, but are not limited to:

- Documentation of VFC Program screening and eligibility
- Billing records
- Medical records that justify vaccine administration
- Vaccine ordering records
- Vaccine purchase records
- Other accountability records for vaccines (e.g., packing lists, borrowing forms, transfer forms)
- Storage unit temperature logs

Program Operational Policies and Procedures

All VFC Program providers perform vital functions of the VFC Program, including eligibility screening, vaccine storage and handling, and vaccine administration. It is essential for providers to have a clear understanding of VFC Program requirements and how the program operates. Site visits, training, and other oversights help maintain and improve the location's compliance with VFC Program policies and procedures.

Provider Annual Review

Provider locations must complete an annual review to remain in the program. This requirement is satisfied through the annual reenrollment process in IRIS. For further details on annual reenrollment, refer to Module 2 in this guide.

Provider Biannual Recertification

Provider locations must be recertified every 24 months to remain in the program. This requirement is satisfied through compliance site visits. Iowa VFC Program nurse clinicians visit provider locations at least once every two years. Site visits are discussed in more detail in the following section.

Site Visits

VFC Program site visits ensure the quality of the VFC Program and strengthen program accountability. VFC Program 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 those needing additional follow-up
- Identify the educational needs of VFC Program providers to meet program requirements
- Ensure VFC-eligible children receive properly managed and viable vaccine

Enrollment Site Visits

VFC Program 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 about VFC Program requirements
- Understand proper vaccine storage and handling
- Have the appropriate resources to implement requirements
- Know whom to contact if problems arise, especially with storage and handling issues
- Complete a Vaccine Storage and Handling Plan

The enrollment site visit must be conducted before the provider location can order, receive, administer, transfer or borrow VFC vaccines.

Compliance Site Visits

The purpose of the compliance site visit is for reviewers to evaluate whether providers are complying with and understand VFC Program requirements, including those outlined in the Provider Agreement. Before receiving their first compliance site visit, provider locations must be enrolled in the VFC Program for at least three to six months and have experience ordering and administering VFC vaccines. This must be completed no later than 12 months after the provider's enrolment. If the enrollment visit was conducted virtually, the compliance visit must be completed within six months of enrollment.

During a compliance site visit, providers can expect to:

- Review VFC eligibility screening procedures
- Verify provider profile information
- Answer questions from the VFC Program provider site visit questionnaire
- Review VFC Program vaccine administration, storage and handling

- Validate compliance with VFC Program policies and appropriate implementation
- Provide feedback and, as necessary, request corrective action and follow-up

Storage and Handling Site Visits

Storage and handling site visits are intended to allow the reviewer to assess a provider's compliance with and knowledge of VFC Program storage and handling requirements. The requirements are based on recommendations and best practices outlined in CDCs Vaccine Storage and Handling Toolkit.

Providers are selected based on the provider's previous history with storage and handling compliance issues. The goal of the visit is to provide guidance and education on proper storage and handling to ensure all VFC-eligible children receive properly managed vaccines.

Provider Training and Education

VFC Program providers must complete annual training related to the VFC Program and program management. Refer to Module 2 in this guide for additional information on required CDC "You Call the Shots" (YCTS) courses.

- The modules can produce a certificate of completion and continuing education if the user successfully completes the posttest.
- If the user is unsuccessful after two attempts, they will be locked out of the YCTS modules. If this occurs, the user will still be able to access the training via CDC TRAIN and receive a certificate of completion to meet Iowa's VFC Program requirements.
- YCTS now has a refresher option. This is a pretest available for providers already familiar with VFC Program and vaccine storage and handling requirements who have already completed the YCTS modules previously. The refresher options (25 questions each) include content from the original YCTS modules. Continuing education credits are not offered for the refresher options.

Provider Responsibility to Train Staff

VFC Program providers are responsible for training staff on proper vaccine storage and handling procedures. Trainings should target staff who:

- Receive vaccine deliveries. Training should include how to open, record and store vaccine shipments immediately
- Handle or administer vaccines
- Transport vaccine. Training should include routine, off-site and emergency vaccine management.

Provider Vaccine Storage and Handling Plans should include documentation of staff training.

At a minimum, the Primary and Back-up Vaccine coordinators for each VFC Program location must complete the annual training. All staff who handle or administer VFC vaccines are encouraged to complete the training as well.

Module 5 – Birth Dose Hepatitis B Program for Birthing Hospitals

Table of Contents

Perinatal Hepatitis B Program Overview 54
Enrollment and Compliance Site Visits 55
Birth Dose Hepatitis B Vaccine 55
Eligibility Screening and Vaccine Administration Documentation 55
RSV for VFC-Eligible Infants at Enrolled Birthing Hospitals 55
RSV Eligibility Screening and Administration Documentation 56

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 the Perinatal Hepatitis B Prevention Program Coordinator at 800-831-6293.

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 for hospitals to screen for VFC eligibility for each infant and document eligibility status in IRIS. 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



Requirements for Birthing Hospitals to participate:

- Enroll as a VFC Program provider
- Screen for VFC eligibility. This determines the vaccine funding source
- 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
- Follow other VFC Program requirements covered in this Operations Guide

Enrollment and Compliance Site Visits

Hepatitis B vaccine is available for the entire birth cohort at no cost to the hospital. All birthing hospitals who desire to participate in the Birth Dose Hepatitis B Vaccine Program must complete the VFC Program Enrollment process, as outlined in the VFC Program Operations Guide. Refer to Module 2 in this guide for requirements. 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.

Eligibility Screening 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 Program and state funding. The Immunization Program requires providers to report administered birth dose hepatitis B doses in IRIS or through electronic data exchange.

RSV for VFC-Eligible Infants at Enrolled Birthing Hospitals

Birthing hospitals enrolled in the Birth Dose Hepatitis B Vaccine Program can 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.**

Hospitals must screen for VFC eligibility. RSV products are available only for VFC-eligible infants at no cost. Borrowing VFC-supplied RSV products for private-pay patients is not permitted.

RSV Eligibility Screening and Vaccine Administration Documentation

VFC-supplied RSV product is not for universal administration and is limited only to VFC-eligible infants at participating birthing hospitals. Hospitals must 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 Program funding. The VFC Program requires providers to report administered RSV doses 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. MCOs in Iowa include:
    - Wellpoint Iowa
    - 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*: the child has health insurance, but the insurance policy:
  - Does not cover any ACIP-recommended vaccines
  - Does not cover all ACIP-recommended vaccines (underinsured for vaccines not covered), or
  - Does cover ACIP-recommended vaccines but has a fixed dollar limit or cap for payment. The child is considered underinsured once the fixed dollar amount is reached
  - Children who have health insurance, but insurance does not provide first-dollar coverage

*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.

VFC Program Resources

Table of Contents

Glossary 58
Provider Type Definitions 61
VFC Program Resources 66

Glossary

Abuse (related to Fraud)

Practices of providers or provider locations that are inconsistent with sound fiscal, business, or medical practices, and that result in an unnecessary cost to the Medicaid Program. Also includes:

- Actions that result in an unnecessary cost to the immunization Program, a health insurance company, or a patient.
- Actions that result in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care; and
- Program recipient practices that result in unnecessary cost to the Medicaid Program.

Advisory Committee on Immunization Practices (ACIP)

For more information, see General Committee-Related Information | ACIP | CDC

Affordable Care Act (ACA)

For more information, see About the ACA | HHS.gov

American Indian or Alaska Native (AI/AN)

As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603):

- “Indians” or “Indian,” unless otherwise designated, means any person who is a member of an Indian tribe, as defined in subsection (d) of this section, except that, for the purpose of sections 1612 and 1613 of this title, such terms shall mean any individual who (1) irrespective of whether he or she lives on or near a reservation, is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member, or (2) is an Eskimo or Aleut or other Alaska Native, or (3) is considered by the Secretary of the Interior to be an Indian for any purpose, or (4) is determined to be an Indian under regulations promulgated by the Secretary.
- (d) “Indian tribe” means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or group or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 et seq.], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

Deputization Agreement

A formal agreement through a memorandum of understanding (MOU), whereby federally qualified health centers (FQHCs) or rural health clinics (RHCs) delegate their VFC Program authority for vaccinating underinsured children to other VFC-enrolled provider locations. These locations are usually public health department clinics, which then vaccinate underinsured children as agents of the FQHC/RHC.

Department of Health and Human Services, Office of Inspector General (OIG)

Federal office mandated to protect the integrity of DHHS programs and their beneficiaries by identifying, communicating, and correcting waste, fraud, or abuse within DHHS programs. The OIG maintains the List of Excluded Individuals and Entities (LEIE).

Expiration Date

The last date on which a vaccine may be used. Expired vaccine includes vaccine that is past the manufacturer expiration date on the vial or expiration date after reconstitution, depending on the vaccine and according to manufacturer instructions.

Fraud (related to Abuse)

An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself, or to another person. Includes any act that constitutes fraud under applicable federal or state law.

Health Care Sharing Ministries (HCSMs)

Nonprofit alternatives to purchasing health insurance from private, for-profit insurers. Generally, HCSMs are organizations whose members share a common belief system and "share" the cost of their members' medical care.

Insurance

A plan that is:

- Regulated by a state's insurance commissioner
- Subject to the Employee Retirement Income Security Act of 1974 (ERISA)
- Both of these conditions

Note: *ERISA is a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry. This provides protection for individuals enrolled in these plans.*

List of Excluded Individuals and Entities (LEIE)

Providers on the LEIE are excluded from participating in federally funded health care programs because of issues that include:

- Program-related fraud
- Patient abuse
- Licensing board actions
- Default on Health Education Assistance Loans

This list is maintained by the OIG of DHHS. The Centers for Medicare and Medicaid (CMS) require state Medicaid agencies to use the LEIE to identify ineligible Medicaid providers. Since the VFC Program falls under the auspices of CMS, provider locations with providers on the list are not eligible to enroll, re-enroll, or otherwise participate in the VFC Program in any way.

Shipping

Shipping, as compared to transport, typically involves longer distances and more time to move vaccine between locations. This often refers to the process of moving vaccine using a large shipping service, requiring adherence to shipping standards that go beyond CDC's guidance for vaccine transport.

Specialty Provider

A provider that only serves:

- A defined population due to the practice specialty (e.g., Obstetrician/gynecologist, sexually transmitted infections, family planning)
- A specific age group within the general population of children ages 0-18 years

Local public health agencies and pediatricians are not considered specialty providers. Pharmacies, Urgent Care facilities and birthing hospitals may also enroll as specialty providers.

Transport (Transporting)

Transport involves moving vaccine over a short time and distance between provider locations. Transport is typically performed over the course of less than eight hours. Vaccine transport should be rare.

Vaccine Administration Fee (Maximum Regional Charge)

The amount that a VFC-enrolled provider can charge for each vaccine administered to a VFC-eligible child who is not enrolled in Medicaid. This is also known as the administration fee or "admin fee." In Iowa, this amount is $19.68.

State Medicaid agencies have the authority to reimburse at a lower level than the set vaccine administration fee.

Provider Type Definitions

Behavioral Health Clinic

Locations that provide counseling, behavioral therapy, medication, case management and other types of services to people with behavioral health disorders. This provider type is used for behavioral health treatment centers where on-site vaccination services are provided.

Birthing Hospital or Birthing Center

Birthing centers or birthing hospitals where on-site vaccination services are provided. A birthing hospital or birthing center is defined as a facility with:

- More than one birth within the past calendar year or
- At least one maternity bed

Community Vaccinator

Community-wide vaccinators that are external to public or private conventional healthcare providers, offer vaccination services only, and conduct vaccination clinics in mobile, temporary or offsite locations exclusively (e.g., non-permanent school-located vaccination clinics).

Correctional Facility

Juvenile correctional facilities as well as adult correctional facilities where juveniles are confined, and on-site vaccination services are provided. Unlike juvenile detention centers, confinement in correctional facilities is generally long-term in nature; youths are confined in secure correctional facilities for periods generally ranging from a few months to years.

Family Planning Clinic (non-health department)

Clinic that provides contraceptive services for clients who want to prevent pregnancy and/or space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services (including HIV) and other preconception health services (e.g., screening for obesity, smoking, and/or mental health). This provider type is used for family planning clinics where vaccination services are provided.

Note: *Non-health department clinics that offer only STI/HIV screening and treatment services should be categorized as "STD/HIV Clinic (non-health department)."*

Federally Qualified Health Center (FQHC)

Community-based health care providers that offer primary care services in underserved areas and meet the criteria for "Federally Qualified Health Center (FQHC)" certification as set by the Centers for Medicare and Medicaid Services (CMS) (Section 1861(aa)(4)(B) and section 1905(l)(2)(B) of the Social Security Act). FQHCs include HRSA Health Center Program award recipients and HRSA Health Center Program look-alikes, which are health centers that meet Health Center Program requirements but do not receive federal award funding.

Note: *Certain tribal organizations are also FQHCs. However, for tribal or urban Indian health clinics enrolled as FQHCs, use the "Indian Health Service, Tribal, or Urban Clinic" designation. The FQHC provider type includes any satellite, temporary, or offsite locations where the provider of record (i.e., FQHC personnel) is administering vaccine.*

Hospital

All hospitals, including medical school or university-affiliated hospitals but excluding birthing hospitals, where on-site vaccination services are provided.

Note: *For birthing hospitals, use the "Birthing Hospital or Birthing Center" designation. The Hospital provider type includes any temporary, mobile, off-site or satellite locations where the provider of record (i.e., hospital or hospital-contracted personnel) is administering vaccine.*

Indian Health Services, Tribal, or Urban Clinic

Indian Health Service (IHS), Tribal or Urban Indian Health Program facilities that provide vaccination services. Urban Indian Health Centers are also designated Federally Qualified Health Centers and provide comprehensive primary care and related services to American Indians and Alaska Natives. Alaska Village Clinics should be included in this provider type.

Juvenile Detention Center

Juvenile detention centers where on-site vaccination services are provided. Juvenile detention is defined as the temporary and safe custody of juveniles who are accused of conduct subject to the jurisdiction of the court who require a short-term restricted environment for their own or the community's protection while pending legal action or dispositional placement in a correctional facility.

Migrant Health Center

Centers that provide health services, including on-site vaccination services, to migratory and seasonal agricultural workers and their families.

Mobile Provider

Providers who offer vaccination as well as other healthcare services exclusively out of a mobile facility. This designation should NOT be used for providers who have a mobile unit associated with their facility, but the unit is not the primary location for vaccine storage and administration.

Pharmacy

Stand-alone retail pharmacy (e.g., CVS, Walgreens, independently owned pharmacies, etc.) or retail pharmacy within a hospital or health system where on-site vaccination services are provided. This category also includes retail pharmacies that conduct community vaccination clinics at offsite or mobile locations.

Note: *This provider type does not include retail health clinics (e.g., Minute Clinic) or centralized pharmacies within a hospital or healthcare facility that dispense vaccines to be administered by facility staff. In those cases, the provider type is determined by who administers the vaccine. The*

Pharmacy provider type includes any temporary, mobile, off-site or satellite locations where the provider of record (i.e., pharmacy personnel) is administering vaccine.

Private Practice (e.g., family practice, pediatric, primary care)

Private practice locations, including solo, group or HMO practitioners, where vaccination services are provided.

Note: *Includes any temporary, mobile, off-site or satellite locations where the provider of record (i.e., provider location personnel) is administering vaccine.*

Private Practice as agent for FQHC/RHC-deputized

A deputized provider has been delegated by a Federally Qualified Health Center (FQHC) or a Rural Health Clinic (RHC) as an agent to vaccinate underinsured children. This provider type is used for deputized private practices, including solo, group or HMO practitioners, that provide vaccination services.

Note: *Includes any temporary, mobile, off-site or satellite locations where the provider of record (i.e., deputized private practice personnel) is administering vaccine. This is not a provider type in Iowa.*

Public Health Clinic (state/local)

State or local public health clinics that provide vaccination services. This category includes public health-run STD/HIV clinics, family planning clinics, and teen health centers.

Public Health Clinic (state/local) as agent for FQHC/RHC-deputized

A deputized provider that has been delegated by a Federally Qualified Health Center (FQHC) or a Rural Health Clinic (RHC) as an agent to vaccinate underinsured children. This provider type is used for deputized state or local public health clinics that provide vaccination services.

Note: *Includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., deputized public health clinic personnel) is administering vaccine.*

Refugee Health Clinic

Clinics that are designated to improve the health care and monitor medical conditions of refugees who have relocated to the United States. This provider type is used for refugee health clinics that provide vaccination services.

Note: *If vaccination services are provided in a location that is co-located in a physical facility with a refugee health clinic but are not administered by refugee health staff, select the category of the provider with oversight of vaccination services.*

Residential/Congregate Care Facility

Out-of-home settings, including group homes, childcare institutions, congregate foster care facilities, where onsite vaccination services are provided.

Note: *If children in these settings receive vaccinations from a mobile provider or community vaccinator, then that provider type should be used.*

Retail Health Clinic

Health clinics located within grocery, drug, or retail stores that provide onsite vaccination services. Retail health clinics generally provide a focused range of protocol-driven healthcare services, such as the treatment of minor illnesses or injuries and vaccination services (e.g., Minute Clinic, Take Care Clinic).

Rural Health Clinic

Clinics located in a non-urbanized Health Professional Shortage Area, Medically Underserved Area, or governor-designated and secretary-certified shortage area. This provider type is used for rural health clinics that provide vaccination services.

School-Based Clinic (permanent clinic location)

Permanent school-based clinics that provide vaccination services through 12th grade.

Note: *For non-permanent school-based clinics, use the "Community Vaccinator" designation. The School-Based Clinic (permanent clinic location) provider type includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., school-based clinic personnel) is administering vaccine.*

STI/HIV Clinic (non-health department)

Clinics that provide timely STI/HIV diagnosis, testing with on-site treatment, and partner services. This provider type is used for STI/HIV clinics **not** located within a health department where on-site vaccination services are provided.

Note: *this category should be used by non-HD clinics that exclusively offer STI/HIV screening and treatment services.*

Student Health Services

Permanent school-based clinics that provide vaccination services for college/university students (e.g., Job Corps).

Teen Health Center (non-health department)

Teen health centers that are **not** public health department-sponsored and provide on-site vaccination services.

Urgent/Immediate Care Center

Locations that provide immediate medical outpatient care for the treatment of acute and chronic illness and injury. This provider type should be used for urgent care centers or walk-in clinics where on-site vaccination services are provided.

Women, Infants, and Children (WIC) Clinic

Locations that serve low-income pregnant, postpartum, and breastfeeding women, infants, and children up to age 5 years who are at nutritional risk by providing nutritious foods to supplement

diets, information on healthy eating including breastfeeding promotion and support, and referrals to health care. This provider type is used for WIC clinics that also provide vaccination services.

Note: *If vaccination services are provided in a location that is co-located in a physical facility with a WIC clinic but are not administered by WIC staff, select the category of the provider with oversight of vaccination services.*

Other

Any provider type not captured in one of the other provider type options.

IOWA | Health and Human Services
Public Health

VFC Program Resources

Immunization Program Directory

Iowa HHS Immunization Program Website

Iowa VFC Program Website

Phone: 800-831-6293

Fax: 800-831-6292

Vaccines for Children Program (VFC) and Assessments (IQIP)

IowaVFC@hhs.iowa.gov

Contact	Phone/Extension
VFC and Assessment Manager	800-831-6293 ext. 5
VFC Coordinator	800-831-6293 ext. 2
Vaccine Distribution Coordinator	800-831-6293 ext. 3
Assessment Coordinator (IQIP)	800-831-6293 ext. 4

Perinatal Hepatitis B Program

Contact	Phone/Extension
Perinatal Hepatitis B Coordinator	800-831-6293 ext. 1

Iowa's Immunization Registry Information System (IRIS)

Contact	Phone/Extension	Email
Help Desk	800-374-3958	IRISProgram@hhs.iowa.gov