

Vaccines for Adults Operations Guide

OVERVIEW

The Vaccines for Adults (VFA) Program provides vaccines at no cost for uninsured and underinsured adults seeking vaccination services in Iowa at enrolled VFA provider locations. VFA program vaccines are purchased with limited State and Federal funds called Section 317 funds. Most vaccines routinely recommended for adults by the federal Advisory Committee on Immunization Practices (ACIP) are available through the program.

VFA OPERATIONS GUIDE

The VFA Operations Guide and other noted resources are intended for the management of the VFA Program. The requirements are applicable to all providers receiving VFA vaccines. As changes to this guide occur, the date of the latest revision will appear in the footer of the document. VFA providers will be notified when the updated guide is available and posted on the Immunization Program website.

VFA PROVIDER CRITERIA

To participate in the VFA program, providers must:

- Be a local public health agency
- Have the capacity to serve as a safety net for uninsured and underinsured adults
- Be enrolled in the Iowa Immunization Registry Information System (IRIS)
- Agree to comply with program requirements outlined in the VFA Provider Agreement and VFA Operations Guide

VFA PROVIDER ENROLLMENT

Providers wanting to participate in the VFA Program must complete the VFA Program Agreement. All providers who administer and store VFA vaccine are required to enroll in the VFA Program. Vaccines available through this program are limited. Completing enrollment does not guarantee the facility will receive VFA vaccines. Initial enrollment begins September 5th, 2024, and will be ongoing. After initial enrollment, re-enrollment will occur on an annual basis. The Iowa VFA Program will communicate the re-enrollment due date and provide instructions to VFA providers.

PROVIDER IDENTIFICATION NUMBER

A Provider Identification Number (PIN) is assigned to each enrolled VFA provider site. This number will be the same PIN used by the Vaccines for Children (VFC) program. If the provider is not a VFC site, a new PIN will be assigned. Using the assigned PIN on all correspondence allows the Program to quickly and accurately respond to providers.

VFA VACCINE

VFA program vaccines are purchased with limited federal and state funds. The following vaccines are currently available through the program:

- COVID-19
- Hepatitis A
- Hepatitis B
- Human papillomavirus (HPV)
- Influenza
- Measles, mumps, and rubella (MMR)
- Meningococcal
- Pneumococcal
- Polio
- RSV
- Tetanus, diphtheria, and pertussis (Tdap)
- Varicella

ELIGIBILITY AND SCREENING

Eligibility Criteria for VFA Vaccine

Adults 19 years of age and older who are:

- Uninsured – Has no health insurance
- Underinsured -
 - Has health insurance that does not cover vaccines (eligible only for the specific vaccine that insurance does not cover)
 - Has health insurance that caps prevention services (eligible after cap is reached).
 - Has insurance that does not provide first-dollar coverage for vaccines
 - First dollar Coverage: Insurance covers ACIP-recommended vaccines without any cost sharing (copay or deductible) to the patient,

Individuals Not Eligible for VFA Vaccine

- Patient has private insurance
- Patient has Medicaid
- Patient is an Iowa Health Link Member enrollee or is receiving Medicaid coverage through a Fee-for-Service model (Iowa Medicaid)
- Patient has Medicare Part D

Medicare

Adults who have Medicare Part D are considered insured. Medicare Part D covers all ACIP recommended vaccines. Adults who only have Medicare Part B are considered underinsured and are only eligible for VFA vaccines not covered by their plan.

Other Eligibility Scenarios

Refugees, immigrants, foreign-exchange students over age 19, and undocumented immigrants must be screened for VFA eligibility. If the individual does not have insurance or is underinsured, the patient is considered VFA eligible.

Screening and Verification

VFA providers must screen adults 19 years and older to determine if they are eligible for VFA vaccine at each immunization encounter. Patients may self-attest to having no insurance. If the patient has insurance, coverage must be verified prior to administering vaccines.

- If Uninsured, patient should not have documentation of insurance, Medicaid or Medicare enrollment
- If Underinsured, patient should provide documentation of insurance (e.g., copy of card or name/policy #)

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

Eligibility status must be documented either on paper or in the electronic health record at each encounter and retained for three (3) years.

Adults receiving vaccines at a local public health agency cannot automatically be considered VFA eligible. Adults must be screened for eligibility, and VFA vaccine can be administered only to VFA-eligible adults. VFA-eligible adults regardless of the state of residence, may be seen at Iowa VFA enrolled provider sites and receive vaccine provided by the Iowa VFA Program.

VACCINE ADMINISTRATION AND OFFICE VISIT FEES

The VFA Program provides vaccines at no cost to enrolled sites for eligible patients. Sites cannot charge the patient for the cost of the vaccine. Sites can only charge an administration fee of up to \$19.68 per dose but must waive this charge if the patient is unable to pay. Providers who choose to bill for the vaccine administration fee may issue only a single bill to the patient within 90 days of vaccine administration. It is unacceptable for these bills to go to collections; if a site does not waive this fee, their enrollment in this program will be terminated. Participating providers cannot refuse vaccination to any patient due to the patient's inability to pay an administration fee.

While allowable, it is not recommended to charge an office visit fee. If an office visit fee is charged, discretion should be used to ensure the office visit fee does not create barriers for patients to receive immunizations.

VACCINE ORDERING

Vaccine Ordering

Because funding for this program is extremely limited, it is important to implement storage and handling and ordering best practices, such as ordering in small quantities, to minimize vaccine waste. Ancillary supplies (needles, alcohol swabs) are not included with the vaccine shipments for the VFA Program.

Vaccine orders must be submitted in IRIS. The vaccines available to order are listed by Vaccine Group, Trade Name, Packaging, NDC number, and Ordering Intention. VFA and VFC program vaccines are purchased with different state and federal funding sources. The ordering intention dictates the funding source for VFC and VFA vaccines. Please be sure to select the appropriate ordering intention when ordering vaccines:

- Adult (ADU) Ordering Intention must be used when ordering VFA vaccine.
- Pediatric (PED) Ordering Intention is for vaccines for the Vaccines for Children (VFC) Program.

Providers should order vaccines in small quantities. Vaccine orders are routinely processed and delivered within five to seven business days. The Iowa VFA Program will contact healthcare providers as necessary if order quantities require follow up:

- Review vaccine needs with the provider to verify and approve the vaccine order
- Adjust vaccine order if the need is not supported
- Discuss vaccine needs when a product is in limited supply and to accommodate a decreased allocation quantity

Ordering and Distribution of Influenza Vaccine

VFA influenza vaccine is not orderable in IRIS like other VFA vaccines. VFA providers will be able to pre-book VFA influenza vaccine in IRIS during a designated time frame each year for the upcoming influenza season. The VFA Program will distribute influenza vaccine orders when the vaccine is available in the fall. Influenza vaccine for the 2024-2025 season has already been pre-booked and cannot be distributed to providers who did not prebook in January 2024.

VACCINE MANAGEMENT

Staffing requirements

Each VFA provider must designate one staff member as the primary vaccine coordinator and at least one back-up coordinator who is able to perform the same responsibilities as the primary vaccine coordinator. These positions shall be responsible for oversight of vaccine management within the facility and serve as the VFA contact for the office. Changes to these positions must be communicated to the VFA Program by emailing iowaVFA@hhs.iowa.gov when there is a change in vaccine coordinators.

Inventory Management

Providers are encouraged to offer as many vaccines through the VFA program as possible to serve the needs of the population.

- Providers are **not** required to carry all vaccines offered through the program.
- Providers are **not** required to carry private stock vaccine inventory to match vaccines available through the VFA program.

Vaccines will be shipped directly to facilities providing vaccines through the VFA Program and should not be transferred to non-VFA providers.

Currently, vaccines for the VFA programs will be displayed as VFC inventory in IRIS. For some vaccines, the NDC for VFC and VFA products will be the same and for other vaccines it will be different. **Providers can store and maintain VFA and VFC Program vaccines together and use the vaccine interchangeably to serve eligible populations.** However, when placing vaccine orders please ensure the ordering intention, Adult and/or Pediatric, are used to reflect planned uses for vaccine.

Providers enrolled in the VFA Program are responsible for the proper maintenance of their vaccine inventories. Key elements of VFA vaccine inventory management include:

- Complete a monthly count of vaccine and diluent doses prior to ordering. This will ensure enough vaccine inventory to meet the needs of the facility and is useful for checking accuracy of balance of doses in IRIS or stock record.
- VFA Program providers tracking inventory in IRIS should print an inventory list from IRIS at least monthly to verify actual inventory in refrigerator/freezer. IRIS vaccine inventories should match actual refrigerator/freezer vaccine counts. If inventory discrepancies are identified, an inventory hand count should be conducted weekly.
- Rotate vaccine and check expiration dates.
- Expiration dates vary by type of vaccine or diluent and lot number. Expiration dates should be checked regularly, and stock should be rotated to ensure the soonest to expire is in front. CDC best practice is to rotate weekly and whenever new vaccine is received. Expiration dates that list only month and year are viable through the last day of the month. Multi-dose vials of vaccine shall be administered until the expiration date printed on the vial or vaccine package unless otherwise noted in the vaccine package insert.
- Keep VFA vaccine separate from private vaccine and clearly label both. Train staff to distinguish VFA vaccine from private stock.
- Order vaccines in the appropriate amounts and do not over order to avoid stockpiling or inventory buildup.

Vaccine Borrowing

Borrowing of VFA vaccines to supplement private stock is not allowed. The Immunization Program will monitor vaccine administration and patient eligibility to ensure proper use of VFA vaccine.

Soon to expire Vaccine

It is acceptable to use age-appropriate VFA vaccine for the VFC program in efforts to minimize vaccine waste.

If inventory will expire within three months and will likely not be used, providers should contact the VFA program to find an acceptable transfer to prevent waste due to expiration.

Vaccine Transfers

Due to limited quantities, the transfer of VFA Program vaccines beyond the primary distribution location should be a rare circumstance. Only participating VFA Program Providers can receive transferred doses. All instances of vaccine transfers must be properly documented as indicated below. Contact the VFA Program (iowaVFA@hhs.iowa.gov) for approval to transfer vaccine.

The following information is required to complete a vaccine transfer:

- Vaccine type
- Lot number
- NDC
- Expiration date
- Number of doses
- Provider PIN of transferring and receiving providers

Management of Expired, Spoiled and Wasted Vaccine

Providers must also use IRIS to account for transfers, spoilage, wastage, and expiration.

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

Spoiled vaccine is nonviable vaccine because of the following:

- Natural disaster/power outage
- Refrigerator too warm or too cold
- Failure to store properly upon receipt
- Vaccine spoiled in transit
- Mechanical failure
- Spoiled-other
- Recall

Wasted vaccine is nonviable vaccine because of the following:

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

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

- Notify the VFA Program of short-dated vaccine doses that will not be used and will expire within two to three months. Short-dated vaccine can be transferred to other VFA providers who are able to administer the vaccine prior to expiration, reducing nonviable vaccine wastage.
- Remove nonviable vaccine from storage units to avoid unintentional use and label box as “Nonviable Vaccine-Do Not Use”.
- Report all vaccine loss to the VFA Program: VFA providers shall document vaccine loss using appropriate reasons provided in the registry to deduct doses from inventory. Expired vaccine is automatically adjusted in IRIS. Any adjustments made to VFC inventory in IRIS using the following reason codes will require providers to return vaccines to McKesson Specialty Distribution.
 - Expired
 - Natural Disaster/Power Outage
 - Refrigerator Too Warm
 - Refrigerator Too Cold
 - Failure to store properly upon receipt
 - Vaccine spoiled in transit
 - Mechanical Failure
 - Spoiled
 - Recall

Nonviable Vaccine Return Process

- VFA 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 VFA Program to receive federal excise tax credit.
- Wasted vaccine cannot be returned to McKesson Specialty Distribution and should be discarded according to clinic policy.
- Spoiled open multi-dose vials cannot be returned. These vaccines will remain on the IRIS vaccine returns page until six months after the expiration date.

VACCINE STORAGE AND HANDLING

Storage Unit Requirements

Refrigerators and freezers used for vaccine storage must:

- VFA providers must have at a minimum, one refrigerator to use for the VFA Program, and are not required to have ultra-cold freezers.
- Always maintain appropriate temperature range.
- Provide sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer to stabilize the temperature. (Water bottles may not be recommended for use with certain pharmaceutical-grade or purpose-built units. For these units, follow manufacturer guidance).
- Be large enough to hold the year's largest inventory without crowding.
- Have power source protected by warnings such as "Do Not Disconnect" labels posted at the electrical outlet and circuit breaker.

Proper Vaccine Storage Temperatures

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

- Refrigerated vaccine must be stored at 36.0° F through 46.0° F or 2.0° C through 8.0° C.
- Freezer vaccine must be stored at -58.0°F through +5.0°F or -50.0°C through -15.0°C.
- Ultra-cold freezers should maintain temperatures between -130° F and -76° F or -90° C and -60° C (for Pfizer COVID-19 Ultra Cold storage if applicable)

Temperature Monitoring Devices

VFA providers **must use** continuous temperature monitoring devices, digital data loggers (DDLs), with a valid and up to date certificate of calibration to monitor VFA vaccine temperatures during routine clinic storage, transport of vaccine between providers and during offsite vaccination clinics. The use of digital data loggers is required as they provide more accurate and comprehensive documentation of storage unit temperatures. DDLs are available at no cost to VFA providers and can be requested by emailing IowaVFA@hhs.iowa.gov.

Temperature Alarm Settings

Using temperature alarm settings safeguards vaccine viability by alerting staff of out-of-range storage temperatures. Data loggers provide more accurate and detailed temperature readings and can record temperatures to a tenth of a degree. Instructions to reconfigure temperature alarm settings for LogTag VFC 400 are available on the Immunization Program, Vaccine Storage and Handling webpage.

Temperature Excursions

VFA providers must document all temperature excursions and actions taken when temperatures are outside the appropriate range. Providers should immediately store vaccines under correct temperature storage conditions (do not discard these vaccines) and contact the Immunization Program at 1-800-831-6293. Vaccines should be marked “Do Not Use” and cannot be administered until the VFA Program has been contacted and decisions have been made regarding viability.

VACCINE ADMINISTRATION AND REPORTING

IRIS

Providers must enter vaccine administration data for all VFA Program vaccines into IRIS. Providers must also use IRIS to manage inventory, including accounting for transfers, spoilage, wastage, and expiration.

Reporting Vaccines Administered

Providers should select the appropriate patient eligibility in IRIS and select the lot number administered from IRIS “VFC” inventory:

- N- No Insurance
- U- Underinsured

QUESTIONS

Direct all questions to iowaVFA@hhs.iowa.gov.