

Vaccines for Children Program

Operations Guide



Iowa Department of Public Health

Immunization Program

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Iowa Vaccines for Children Program

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Iowa Vaccines for Children Program Overview

Welcome to the Iowa Vaccines for Children Program!

The Vaccines for Children (VFC) Program is federally funded and provides vaccines at no cost to children from birth through 18 years of age that meet specific eligibility criteria who might not otherwise be vaccinated due to inability to pay. The VFC Program was created by the Omnibus Budget Reconciliation Act of 1993 and was implemented in October 1994 as part of the President's Childhood Immunization Initiative. Funding for the VFC Program is approved by the Office of Management and Budget and allocated through the Centers for Medicare & Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC). Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices (ACIP).

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

VFC Program Highlights

The VFC Program:

- provides public-purchased vaccine for eligible children at no charge to VFC-enrolled public and private providers,
- covers vaccines recommended by the ACIP,
- saves parents and enrolled providers out-of-pocket expenses for vaccine,
- eliminates or reduces vaccine cost as a barrier to vaccinate eligible children,
- reduces the practice of referring children for vaccination.

About This Guide and Other Resources

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

As changes occur to this guide, an individual module or section will be revised and the date of the latest revision will appear at the top of each page in the module. New information will be posted on the Immunization Program web site, and VFC Program providers will be notified.

Enrollment

Enrollment Process
Facility Types
Provider Identification Number

All providers who administer and store VFC vaccine shall enroll in the VFC Program. Once the enrollment forms are submitted and approved, VFC staff will contact the clinic to set up an initial site visit. This is necessary to comply with federal VFC requirements of an initial site visit to ensure the provider and office staff receives education regarding VFC Program requirements and has appropriate resources to implement the VFC Program.

Some medical providers may have a main clinic and satellite clinics where they provide immunization services. Any satellite clinic must also enroll in the VFC Program.

Enrollment Process

Health care providers must complete three forms to enroll in the Iowa VFC Program. The Medical Director, or equivalent, shall complete and sign the enrollment forms for the facility.

1. Provider Enrollment Form ([Appendix 1](#)),
2. Physician Enrollment Form ([Appendix 2](#)), and
3. Provider Profile ([Appendix 3](#))

Provider Enrollment Form ([Appendix 1](#))

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

1. Screen patients at each immunization encounter for eligibility and administer VFC Program-purchased vaccine only to children who are 18 years of age or younger who meet one or more of the following categories:
 - (a) Medicaid enrolled,
 - (b) no health insurance,
 - (c) American Indian or Alaskan Native, or
 - (d) underinsured, (has health insurance that does not pay for the vaccine). Underinsured patients can only be seen at a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or Local Public Health Agency (LPHA).
2. Comply with the appropriate immunization schedule, dosage, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP), and are included in the VFC Program unless:
 - (a) In making a medical judgment in accordance with accepted medical practice, I deem such compliance to be medically inappropriate, or
 - (b) The particular requirement contradicts the laws of Iowa, including laws relating to religious or medical exemptions.
3. Maintain all records related to the VFC Program for a minimum of three years and make these records available to public health officials or the Department of Health and Human Services (DHHS).
4. Immunize eligible children with VFC-supplied vaccine at no charge to the patient for the vaccine.
5. Not charge a vaccine administration fee to a non-Medicaid VFC-eligible child that exceeds the administration fee cap of \$14.58 per vaccine dose. For Medicaid VFC-eligible children, accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
6. Not deny administration of a federally procured vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.

7. Distribute the most current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA) which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
8. Comply with Iowa's requirements for vaccine ordering, vaccine accountability, and vaccine management. Agree to operate within the VFC Program in a manner intended to avoid fraud and abuse.
9. Permit site visits by authorized representatives of the IDPH to conduct VFC quality assurance visits including vaccine storage and record keeping and assess the immunization rates of VFC eligible patients.
10. Maintain VFC vaccine consistent with manufacturer and Centers for Disease Control and Prevention (CDC) approved vaccine storage and handling guidelines and check and record storage unit temperatures at least twice daily.
11. Monitor and document temperature logs for all storage units (refrigerator and freezer). Temperature logs must be retained for a minimum of 3 years.
12. Develop, maintain, and upon request from IDPH, submit procedures for vaccine storage, handling, and relocation of vaccine in the event of power loss or refrigerator/freezer failure (sample template and guidance available on the IDPH website).
13. Agree to be held financially responsible for the replacement cost of vaccine that cannot be accounted for, that is wasted, stored inappropriately, or is deemed non-viable due to failure of this clinic to comply with established storage and handling guidelines or otherwise failure to comply with this agreement. The IDPH will determine violations by evaluating each case.
14. If improperly stored vaccine was administered to patients, appropriate revaccination of patients will be conducted, as directed by IDPH staff, to assure optimal vaccine protection and assume all financial costs of such revaccination.
15. I understand IDPH may terminate this agreement at any time for failure to comply with these requirements or without cause. I understand that if this agreement is terminated, I must return to the VFC Program all unused (viable and non-viable) VFC vaccine. I will also comply with the VFC Program's procedures for return of the vaccine.

Physician Enrollment Form ([Appendix 2](#))

The Physician Enrollment Form is used to document all health care providers practicing at the clinic and their agreement to comply with program requirements. It is necessary to include the NPI (National Provider Identifier) number, medical license number, and e-mail address for each provider listed. **If the clinic does not have a physician or nurse practitioner on staff, or does not have an individual NPI number, include the facility's NPI number if applicable.** Hospitals enrolled to provide hepatitis B vaccine at birth do not have to list all physicians but may include the medical director, or equivalent, to represent all physicians.

VFC providers must submit an updated Physician Enrollment Form annually. If health care providers practicing at the clinic change during the year, it is the responsibility of the medical facility to contact the VFC Program to update the Physician Enrollment Form.

Provider Profile ([Appendix 3](#))

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

When enrolling in the VFC Program for the first time, an estimated number of VFC-eligible children must be provided. Annually thereafter, the state VFC Program will calculate the provider profile based upon doses administered data obtained from each clinic. The Provider Profile can be updated periodically as the needs of the facility change (e.g., additional medical providers working at the facility or a clinic in the area closes and patients are referred to your clinic).

Facility Types

The VFC Program classifies clinics in the following groups:

- Public Health/County Health Department
- Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC)
- Other Public (maternal child health [MCH], women, infants, and children [WIC], Well Child, Planned Parenthood [PPH], family planning [FP], residential facilities/juvenile detention centers)
- Facility is an agent of an FQHC or RHC
- Hospital
- Private Practice (Individual or Group)
- Other Private Facility

Federally Qualified Health Center (FQHC)

A center that provides health care to a medically underserved population may apply to the Health Resources and Services Administration (HRSA) for FQHC status. HRSA will determine if the center meets qualifications and will provide notice of FQHC status.

FQHCs include community and migrant centers, special health facilities (such as those for the homeless and persons with AIDS) that receive grants under the Public Health Service (PHS) Act, and “look-a-likes” which meet the qualifications, but do not actually receive grant funds. Health centers within public housing and Indian Health Centers also meet the FQHC criteria.

To inquire about FQHC status, contact HRSA, Bureau of Primary Health Care at (301) 594-4300, (877) 477-2123 or by e-mail at hrsagac@hrsa.gov

Rural Health Clinic (RHC)

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

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

To enquire about RHC status, contact the Iowa Department of Public Health (IDPH), Bureau of Oral and Health Delivery Systems, 515-281-7223.

Provider Identification Number (PIN)

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

PINs are composed of a letter designation which is assigned according to the facility type, the county number and the sequential clinic enrollment by county. The letter designation is as follows:

Public Facilities:

H = Hospital

M = Other Public (maternal child health [MCH], women, infants, and children [WIC], Well Child, Planned Parenthood [PPH], family planning [FP])

P = Public Health/County Health Department

F = Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC)

Private Facilities:

R = Private Practice (Individual or Group)

O = Other Private Facility

Y = Pharmacy

Eligibility

VFC Eligibility Criteria Screening Documentation

VFC Eligibility Criteria

The Iowa Department of Public Health (IDPH) administers the VFC Program consistent with federal program requirements. As part of these requirements, VFC Program providers may only administer VFC vaccine to eligible patients. The VFC Program provides vaccines for children from birth through 18 years of age who meet one of the following eligibility criteria:

- Child is enrolled in Medicaid
 - Children enrolled in any type of Medicaid Program are eligible for the VFC Program, such as Medipass Gatekeeper Program, IowaCare, or Medicaid as secondary health coverage. Individuals who have a primary health insurance company and Medicaid as secondary coverage are eligible for the VFC Program and should be immunized using VFC vaccine.
 - If the primary insurance company does not pay for vaccinations and private stock vaccine was used on a Medicaid-eligible child, IDPH does not have the ability to reimburse providers for the cost of the private purchased vaccine. Iowa Department of Human Services (DHS) – Medicaid Program will not reimburse for acquisition cost of vaccines provided by the VFC Program. DHS will reimburse the provider an administration fee and an appropriate office visit fee.
- Child has no health insurance coverage
- Child is American Indian or Alaskan Native
- Child is underinsured - served by a FQHC, RHC or LPHA
 - Underinsured children include those who have health insurance but the benefit plan does not include immunizations, covers only select vaccines, or caps the vaccine cost at an established limit. **Underinsured children are eligible to receive VFC vaccine only if they are served by a Federally Qualified Health Center, Rural Health Clinic or local public health agency.**

As part of the VFC Program, FQHCs and RHCs have the ability to grant FQHC/RHC status to LPHAs to immunize underinsured children on their behalf. Delegation of this authority requires a written agreement between the FQHC/RHC and the LPHA. ([Appendix 4](#))

Underinsured Eligibility Circumstances

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

- Children enrolled in *hawk-i* are not eligible under the VFC Program since the *hawk-i* Program is a full coverage insurance plan. Children enrolled in *hawk-i* must be vaccinated with privately purchased vaccine.
- Some insurance plans limit the coverage to a specific number of provider visits annually. If a child's insurance will not cover the cost of vaccine after the child has exceeded the number of provider visits, the child can be considered underinsured for the purposes of the VFC Program since the insurance would not cover the vaccine. The child would be VFC-eligible only at a FQHC/RHC/LPHA.
- Persons under 19 years of age who do not know their insurance status and who present at family planning clinics for contraceptive services or STD treatment can be considered uninsured for the purposes of the VFC Program. A person under 19 years of age who may have insurance but because of the confidential circumstances for seeking services in a family planning clinic does not have access to that insurance coverage is considered uninsured for the purposes of the VFC Program.
- If a person under 19 years of age loses access to health insurance because of incarceration, the minor is considered uninsured and VFC-eligible.

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

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

Refugees, immigrants, foreign-exchange students, and undocumented immigrants should be screened for VFC eligibility just like U.S. citizens. If their native country insurance covers vaccines, they should be vaccinated with private stock. If they do not have insurance or are eligible for Medicaid they should be vaccinated with VFC vaccine.

Screening Documentation

Screening to determine a child's eligibility for the VFC Program must take place with each immunization visit, but the screening form does not need to be replaced or updated unless the status of the patient changes. The Patient Eligibility Screening Record ([Appendix 5](#)) provides a means of recording parent responses to VFC eligibility questions. Verification of parent/guardian responses is not required. To maximize efficiency, providers may elect to incorporate these screening questions into an existing form; however, any revision must include the core screening information. A parent, guardian, or individual of record must indicate the child's eligibility status by selecting one of the categories below:

- Medicaid enrolled,
- No health insurance,
- American Indian/Alaskan Native,
- Underinsured (served by a FQHC, RHC or LPHA) or
- Is not eligible for the VFC Program because they do not meet the above criteria.

For each child enrolled, a Patient Eligibility Screening Record or equivalent information must be completed and kept on file for at least three (3) years regardless of VFC eligibility. The Immunization Registry Information System (IRIS) serves as an acceptable means of documenting eligibility but the eligibility criteria must be chosen by the patient/parent/guardian.

Vaccine Ordering

Vaccine Availability *Vaccine Ordering* *Ordering Varicella Containing Vaccine* *Receiving Vaccine Shipments*

The Food and Drug Administration (FDA) is responsible for licensure of vaccines. Upon FDA approval, the Advisory Committee on Immunization Practices (ACIP) convenes to make recommendations for use of the vaccine. These recommendations are formalized for the VFC Program and become VFC resolutions. A VFC resolution by the ACIP is required for the inclusion of new vaccines into the VFC Program or for the modification of existing resolutions. After a VFC resolution has been established, the CDC negotiates a contract for the purchase of vaccines. Once the purchasing contract is finalized, the Iowa Medicaid Program must incorporate the vaccine into the Medicaid system. VFC vaccine must be administered according to the guidelines outlined by the ACIP recommendations and VFC resolutions. Each state determines the vaccine implementation date for new vaccines based upon the above process, which is generally four to six months following vaccine licensure by the FDA.

The Advisory Committee on Immunization Practices (ACIP) routinely makes immunization recommendations which represent the standard of care for vaccination practice in the United States. Recommendations from the ACIP and vaccine manufacturer package inserts are usually in agreement. However, the ACIP may make additional recommendations to add flexibility to its recommendations or use of expert opinion such as the American Academy of Pediatrics (AAP) or other medical organization. The ACIP includes representation from many organizations including the American Academy of Pediatrics (AAP) and American Academy of Family Physicians (AAFP). Published recommendations from these groups should be considered equally as authoritative as those on the vaccine manufacturer package insert and in general, the recommendations of the ACIP supersede information in the vaccine package insert.

Vaccine Availability

The Iowa VFC Program will offer each vaccine listed on the Centers for Disease Control and Prevention (CDC) VFC vaccine contract, allowing provider choice between manufacturer and brand. Due to constraints and limitations imposed by CDC or the vaccine manufacturer, particular brands of vaccine may not be available each time a clinic orders. If providers place a vaccine order and the vaccine is unavailable, the VFC Program will substitute ordered vaccine with an equivalent vaccine. IRIS Users: If a vaccine is unavailable, the IRIS order form will be updated to show available products. VFC covered vaccines are listed in [Appendix 6](#).

Vaccine Ordering

Providers are responsible for ordering and maintaining an adequate vaccine supply at their facility. Providers may place vaccine orders using the VFC Vaccine Order Form ([Appendix 7](#)) or by using the VFC Order Form in IRIS. Vaccine ordering should be consistent with the clinic's established provider profile (doses administered reports) and the number of VFC eligible children served. Thimerosal free vaccines are available and are indicated on the VFC Vaccine Order Form ([Appendix 7](#)). Refer to the FDA Web site for additional information regarding thimerosal content -

<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228#t1>.

The VFC Program has implemented Economic Order Quantity (EOQ), a provider ordering schedule that establishes the lowest total cost of distribution by identifying the number of orders providers should place each year. EOQ is determined by the number of doses distributed to a clinic on an annual basis. The goal of EOQ is to balance shipping costs with inventory and vaccine wastage costs. Vaccine orders should include adequate doses of vaccine to immunize children for the period of time determined by the clinic's EOQ. Transitioning to a monthly, bi-monthly or quarterly ordering schedule will standardize order frequency and streamline the vaccine distribution process.

Vaccine Ordering Process

- Orders should not be placed if the clinic is going to be closed for a holiday or an extended vacation. It is the provider's responsibility to contact the VFC Program if the clinic is going to be closed or if there has been a change in business hours or delivery information.
- Review monthly doses administered from the previous year to determine the amount of vaccine needed for the duration of the clinic's EOQ. Doses administered can be found on the reports that are sent to the VFC Program or on IRIS under the General Reports - Inventory Report. Use existing vaccine inventory prior to switching to combination vaccines or other vaccine brands to ensure vaccine is not wasted. Ensure sufficient vaccine is ordered as needed according to assigned EOQ.
- Vaccine orders submitted more frequently than the clinic's established EOQ may be held until the next ordering cycle.
- Providers submitting paper order forms must report ALL doses of VFC vaccine in inventory every time an order is placed.
- Ensure all doses of VFC vaccine that have been administered are reported.
 - All administered doses must be recorded on the monthly doses administered report ([Appendix 8](#)).
 - *IRIS Users:* All administered doses must be entered as a "give" in IRIS and data entry should be up to date. If the actual count of vaccine does not match the inventory in IRIS call the VFC Program at 1-800-831-6293 ext. 4.
- Review the expiration date of each vaccine to ensure that it has not outdated or will outdate soon. If vaccine will not be used prior to the expiration date, contact the VFC Program three months prior to expiration date to discuss the possibility of transferring vaccine to another provider. Any opened multi-dose vials of vaccine should not be transferred to another provider.
- Orders are processed in the order received.
- The maximum time required for vaccine orders to be processed and shipped is 30 days.
- Orders are reviewed by VFC Program staff and then submitted electronically to McKesson for distribution.
- The order processing and delivery schedule is subject to change during holidays and extreme weather conditions.
- *IRIS Users:* When VFC vaccine arrives the order must be "received" into IRIS. VFC vaccine orders should not be manually entered (except for varicella and influenza vaccines). There are two ways to receive a VFC vaccine order:
 1. In the VFC Order Receiving tab, click on the row to highlight the order to be received, then click on the "Receive VFC Order" button located on the inventory toolbar, OR
 2. In the VFC Order Receiving tab, click on the row to highlight the order to be received, then from the inventory menu, select "Receive VFC Order"

Ordering Varicella-containing Vaccine

Prior to ordering varicella-containing vaccine, providers must complete a Varicella-Containing Vaccine Storage Survey ([Appendix 9](#)) and receive approval by the VFC Program Coordinator to ensure varicella vaccine will be stored appropriately. The VFC Program uses this survey to assess the clinic's ability to store varicella-containing vaccine. All VFC varicella-containing vaccine orders will be shipped directly from the manufacturer (Merck); allow 30 days for orders to be processed and shipped.

Receiving Vaccine Shipments

Upon receipt of vaccine, compare and verify vaccine quantity and lot numbers to the shipping invoice, document on the invoice the date vaccine was received, and store vaccine appropriately. If there is a discrepancy with the vaccine order, contact the VFC Program at 1-800-831-6293, ext. 5.

- VFC vaccine shipments received from McKesson contain warm and cold exposure indicators to assure that enclosed vaccines are received in manufacturer-recommended conditions. VFC direct shipments of frozen vaccine (varicella-containing) are shipped in specialized boxes and do not contain temperature indicators.
 - Immediately upon receipt of vaccine, check vaccine temperature monitors and store vaccine according to manufacturers' product specifications.
 - Take proper action if the cold or warm monitors are activated. Instructions for reading the monitors are printed on the monitor cards.
 - Document warm or cold monitor readings if indicative of out-of-range temperature exposure, and contact the Iowa Immunization Program at 800-831-6293, ext 5 for further guidance. Document action taken based on Immunization Program instructions.
 - In the past, varicella-containing vaccines, (Varivax, Zoster, ProQuad) were shipped using dry ice. These vaccines are now shipped with 6 frozen gel packs as refrigerant in the shipping container. No heat exposure indicator is included in the cooler; the gel packs and shipping containers are designed to maintain proper temperatures for three days from the shipment date on the packing list. It is important to verify the date vaccine was shipped on the packing list to assure the vaccine arrived within the three day window.

Vaccine Management

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Vaccine Storage and Handling

Proper management of vaccine is one of the most important activities conducted by a provider. Vaccines must be maintained properly to protect viability. Adhering to proper storage and handling procedures will minimize the potential for vaccine loss and wastage. Providers should consult CDC's *Vaccine Storage and Handling Webpage* available at <http://www.cdc.gov/vaccines/recs/storage/default.htm> for the most current information regarding vaccine storage and handling. This should be the primary resource for vaccine storage and handling questions.

Storage and handling errors in which vaccines are compromised are costly. Vaccines must be stored properly from the time they are manufactured until they are administered. Exposure to temperatures outside recommended ranges will reduce potency and increase the risk that recipients are not protected. When vaccine shipments are received, it is important to immediately store vaccine appropriately.

VFC Program providers are required to develop and maintain a written routine and emergency Vaccine Storage and Handling Plan and annually train ALL staff to safeguard vaccine supplies. The Immunization Program developed a Vaccine Storage and Handling Plan template ([Appendix 10](#)) to assist providers. The plan should be posted on or near the vaccine storage unit so it is easily accessible. At a minimum, the plan must be reviewed and updated annually, more frequently when there is a change in staff that has responsibilities specified in the plan. A log with staff member's name and date of training should be kept as documentation of training.

Storage Unit Requirements

Refrigerators and freezers used for vaccine storage must always maintain appropriate temperature range, be large enough to hold the year's largest inventory, include a certified calibrated thermometer and back-up thermometer, and be dedicated to storage of vaccines. Medical grade (pharmacy or blood bank) purpose built refrigerator units provide a stable, uniform controlled cabinet temperature with minimal temperature fluctuation. Refrigerators without freezers and stand-alone freezers (either manual defrost or automatic defrost) are usually effective at maintaining temperatures required for vaccine storage. Such single-purpose units are less expensive alternatives to medical specialty equipment and are preferable to combination units. A combination refrigerator-freezer unit sold for home use might be adequate for storing limited quantities of vaccines if refrigerator and freezer compartments have separate external doors. Before using any unit for vaccine storage, the temperature should be allowed to stabilize and documented twice daily for at least 5 days.

Use of Dorm-Style Refrigerators

The Centers for Disease Control and Prevention (CDC), VFC Program requirements eliminated the use of dorm-style refrigerators as permanent (overnight) vaccine storage units for vaccine. A dorm-style refrigerator is defined as a combination refrigerator/freezer unit that has one external door and a freezer within the refrigerator. Guidelines indicate dorm-style units should only be used to store a single-day supply of refrigerated vaccines if unit temperatures are monitored and documented twice a day and vaccine is returned to the recommended storage unit at the end of the clinic day. Dorm-style refrigerators are not adequate for long-term or permanent storage of biological products because they do not maintain appropriate temperatures. A dorm-style unit should never be used for storing Varicella-containing vaccines.

Temperature Monitoring

Temperature monitoring is a critical component of good storage and handling practices and vital to cold chain management. All clinic staff should be aware of vaccine storage requirements. Assigning one person in the office primary responsibility for maintaining and reviewing temperature logs generally is most effective, with a second person assigned as backup. The backup person should review the temperature log at least once each week. Temperatures in both the freezer and refrigerator must be checked and recorded twice each day, once in the morning and once before leaving at the end of the day. Two thermometers are required in each storage compartment (2 in the freezer, 2 in the refrigerator) a primary certified calibrated thermometer with a certificate of traceability and calibration and a back up thermometer. Temperature logs ([Appendix 11](#)) must be maintained for each storage unit for a minimum of three years.

Vaccines must be maintained in accordance with vaccine manufacturers recommendations at every link in the cold chain.

Refrigerator Temperature Range

- Refrigerator vaccines require storage temperatures between 35°F and 46°F (2°C to 8°C), with a desired average temperature of 40°F (5°C)

Freezer Temperature Range

- All varicella-containing vaccines (Varivax, Zoster, ProQuad) should be stored in a continuously frozen state at the manufacturer recommended freezer temperature until administered. Varicella-containing vaccines should be stored at +5°F and no colder than minus 58°F (minus 15°C and no colder than minus 50°C). MMR can be stored in either the refrigerator or freezer. Storing MMR in the freezer may help prevent inadvertent storage of MMRV in the refrigerator.

If there is evidence vaccine has been exposed to temperatures outside of recommended temperature ranges, providers should immediately store vaccine appropriately and contact the VFC Program at 1-800-831-6293 ext 2. Vaccine should be marked “do not use” and cannot be administered until the VFC Program has been contacted and decisions have been made regarding viability.

Currently the VFC Program provides a certified calibrated thermometer with a certificate of traceability and calibration for each unit storing VFC vaccine. Periodic recalibration is necessary. It is the responsibility of the clinic to complete recalibration of thermometers provided by the VFC Program according to manufacturer guidelines.

Vaccine Inventory Management

The VFC Program requires providers to maintain VFC vaccine inventory separate from privately purchased vaccine. The following steps are recommended when receiving vaccine:

- Educate all staff about vaccine deliveries and the difference between VFC and private vaccines.
- Unpack vaccine shipment immediately and review the shipping invoice to see if vaccine, number of doses, lot number and expiration dates match the vaccine received.
- Maintain shipping invoices for at least three years to help determine if misplaced or unaccounted for vaccine is from VFC or private inventory.
- Store VFC vaccine in separate refrigerators/freezers or store VFC vaccine on separate shelves.

Accountability

Vaccine accountability is a cornerstone of the VFC Program. The VFC Program is a federally funded program with a national budget approaching \$4 billion. The VFC vaccine budget requires considerable attention regarding program accountability at the federal, state, and provider level. It is critical all doses of vaccine distributed to providers are accurately accounted for.

VFC Program providers not using IRIS are required to complete Monthly Doses Administered Reports (Appendix 8), which includes the total number of vaccine doses administered to VFC eligible patients. Monthly Doses Administered Reports are due to the VFC Program by the fifth day of the following month. If no VFC vaccine is administered, a Doses Administered Report must be completed indicating no vaccine was given during that month.

Vaccine that is wasted or outdated shall be recorded in the vaccine loss column of the Monthly Doses Administered Report. When completing the report, include the reason vaccine is nonviable, number of doses, and vaccine lot number for each vaccine. Doses of vaccine reported in the vaccine loss column without an accompanying lot number cannot be accurately accounted for. Anytime vaccine is wasted because of a storage and handling incident, contact the Iowa VFC Program for further instructions.

VFC Program Providers using 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. All vaccine loss should be documented using appropriate reasons provided in the registry. It is not necessary for IRIS users to submit a Monthly Doses Administered Report, but providers should ensure all doses administered are entered into IRIS as a “give” as soon as possible following vaccination. Refer to the IRIS manual for proper procedures. Call the IRIS Help Desk at 800-374-3958 for assistance regarding IRIS use.

Viable Vaccine Transfers

VFC vaccine should never be transferred to a clinic not enrolled in the VFC Program. Transferring VFC vaccine to another VFC clinic should be the exception and providers should monitor vaccine inventory and vaccine usage patterns closely. Vaccine transfers between providers can occur only after receiving approval from the VFC Program by calling 1-800-831-6293 ext 4. The following information is required by the VFC Program to complete a vaccine transfer:

- Vaccine type,
- Lot number,
- Expiration date,
- Number of doses, and
- VFC PIN of transferring and receiving providers

After receiving approval from the VFC Program, the above information should be documented on the form entitled *VFC Vaccine Transferred Between VFC Providers* ([Appendix 12](#)) and sent to IDPH.

IRIS Users:

All vaccine transferred to another provider should be documented in IRIS using the reason code of “Transferred Between Providers”.

Vaccine Restitution Policy

Effective November 1, 2011, the Iowa Immunization Program will implement the following vaccine restitution policy as mandated by the Centers for Disease Control and Prevention, Vaccines for Children Program requirements.

The purpose of this policy is to establish requirements for VFC Program providers to replace, at the provider expense, VFC vaccine that is unaccounted and wasted (expired, spoiled or improperly stored) due to negligence on behalf of the provider. This policy is intended to address instances of extreme/on-going negligence resulting in the wastage of VFC vaccine.

Restitution Process

1. The Iowa VFC Program will review incidents of vaccine wastage to determine if restitution will be required. Restitution will be required for negligent provider activities or recurring issues that result in vaccine wastage.

Situations that may require provider restitution (this list is not comprehensive)

- Storage and handling errors resulting in vaccine wastage.
- Provider fails to act according to the agency/practice’s Emergency Vaccine Storage and Handling Plan.
- Situations resulting in re-vaccination due to either improper vaccine administration or improper vaccine storage and handling resulting in the administration of non-viable vaccine. The provider may be responsible for purchasing private vaccine to re-vaccinate VFC eligible children.
- Excessive vaccine ordering leading to overstock resulting in vaccine wastage.
- Ordering combination vaccines which results in wastage of single antigen vaccines.

Situations that may not require restitution (this list is not comprehensive)

- A package not delivered to the provider in a timely manner or is otherwise damaged or exposed to improper temperatures during transit.
 - A provider experiences a refrigerator/freezer malfunction, and the contracted alarm company does not notify the provider. The clinic should document the event and include a plan to prevent this from occurring in the future.
 - Power is lost due to inclement weather or natural disaster.
 - A vial is accidentally dropped or broken by a provider.
 - Extraordinary situations, not listed above, deemed by the Iowa VFC Program to be beyond the provider’s control.
2. When restitution is required, the provider will receive notification from the Iowa VFC Program detailing the number of vaccine doses requiring restitution.
 - The invoice will detail the number of doses by vaccine manufacturer, type, and presentation (vials, syringes).

3. The provider will be responsible to purchase vaccine equivalent to the notification received from the Iowa VFC Program. The vaccine shall be replaced within 30 days from the date of the notification unless mutually agreed upon by clinic staff and VFC program staff. The replenished vaccine shall be placed in VFC inventory and used to vaccinate VFC eligible children.
4. The privately-purchased vaccine shall consist of the same manufacturer, type, and presentation of vaccines identified for restitution by the Iowa VFC Program.
 - Substitutions for vaccine manufacturer and presentation must be agreed upon by clinic staff and Iowa VFC Program prior to purchasing the vaccine.
5. A copy of the packing slip for the privately purchased vaccine shall be faxed to the Iowa VFC Program at 1-800-831-6292 attention VFC Program Coordinator.
6. Failure to comply with the restitution policy will result in the clinic being suspended from the VFC Program. Clinics on suspension will not be able to order VFC vaccine until vaccine has been replaced.
7. Failure to replace wasted VFC vaccine within 30 days of the clinic being placed on suspension will result in the clinic being terminated from the VFC Program. The provider may be permitted to re-enroll after the replacement of wasted VFC vaccine. Re-enrollment will be at the discretion of the Iowa VFC Program.
8. Providers who fail to comply with the Vaccine Restitution Policy will be referred to the Iowa Department of Human Services, Medicaid Program for further investigation of fraud and abuse.

Procedures to Minimize Vaccine Loss

Health care providers should implement and adhere to the following items to minimize vaccine loss:

- Provide adequate vaccine storage and monitor storage conditions.
- Do not over-order or stockpile vaccine.
- Never assume vaccine is nonviable in the event of a storage problem. Contact the Iowa VFC Program immediately for instructions.
- Conduct count of vaccine inventory at least monthly.
- Check vaccine expiration dates at least monthly.
- Rotate vaccine stock regularly; move earliest expiration dates to the front.
- Report vaccine that will not be used and will expire within 2-3 months to the Iowa VFC Program.

Return of Non-Viable Vaccine

Vaccine received through the VFC Program that is nonviable must be returned to McKesson Specialty Distribution. Return of nonviable vaccine to McKesson is necessary for the Immunization Program to receive federal excise tax credit. The *Nonviable Vaccine Return Form* ([Appendix 13](#)) must be completed when returning vaccine. Contact the VFC Program at 800-831-6293 ext. 4 to receive UPS postage paid label.

Vaccine Borrowing

Borrowing can occur only after receiving prior approval from the VFC Program by calling 1-800-831-6293 ext. 4. In such situations the following information must be documented on the Vaccine Borrowing Form ([Appendix 14](#)) and a copy submitted to the Iowa VFC Program.

- Type of vaccine, number of doses borrowed and lot numbers
- Reason for borrowing VFC vaccine
- Date borrowed vaccine was replaced with private-purchased vaccine

All VFC-enrolled providers are expected to maintain adequate inventories of vaccine to administer to privately insured and VFC-eligible children. Borrowing of vaccine must be due to an unforeseen delay or circumstance surrounding vaccine that was ordered. Borrowing VFC vaccine to administer to non- VFC eligible patients, and vice versa, should only occur in extreme emergency situations.

Borrowing VFC vaccine is the exception rather than the rule, and routine borrowing and not documenting usage appropriately may be grounds for termination from the VFC Program. VFC vaccine cannot be used as a replacement system for privately purchased vaccine.

Administration Fees

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

Section 1928(c) (2) (c) (ii) of the Social Security Act (42 U.S.C. 1396s (c) (2) (c) (ii)) states: *“The provider may impose a fee for the administration of a qualified pediatric vaccine so long as the fee in the case of a federally vaccine-eligible child does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administrations).”*

The maximum administration fee established by HHS per injection for Iowa is \$14.58 ([Appendix 15](#)). The maximum administration fee is applicable to VFC eligible patients who have no health insurance, are American Indian/Alaskan Native, and are underinsured (seen only at Rural Health Clinics, Federally Qualified Health Centers and Local Public Health Agencies). The administration fees for these patients are charged to the patient, not the VFC Program or Medicaid Program. **Providers may not deny immunization services for a patient’s inability to pay the administration and office visit fees.**

VFC Program legislation allows state Medicaid agencies discretion to pay an administration fee up to the regional maximum amount. The Iowa Medicaid Program has established maximum administration fees for Medicaid patients. The Medicaid fee schedule can be found at http://www.ime.state.ia.us/Reports_Publications/FeeScheduleAgreement.html.

If a child has primary insurance coverage and Medicaid as secondary they can receive VFC vaccine. Generally, providers are required to bill third party payers before Medicaid will make payment. However, in the case of preventive pediatric services (immunization), if the Medicaid agency is billed, it is required to make payment and then seek reimbursement from the third party (CMS refers to this as pay and chase). The Medicaid agency is to seek recovery as long as it is cost effective to do so. Questions regarding Medicaid billing should be directed to Provider Relations at 1-800-338-7909 or (515) 327-5120.

Office Visit Fee

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

Fraud and Abuse

Definition of Fraud & Abuse

Examples of Fraud and Abuse

It is essential for providers participating in the VFC Program to fully understand program requirements and what constitutes fraud and abuse. The VFC Program routinely provides education to enrolled providers regarding VFC Program requirements. Consistent with fraud and abuse as defined in Medicaid regulations at 42 CFR § 455.2, and for purposes of this VFC Operations Guide, the following definitions will be used:

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

Examples of Fraud and Abuse

Fraud or abuse can occur in different ways. Some examples of fraud and abuse are:

- 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 (\$14.58 in Iowa) for administration of a VFC vaccine to a federally vaccine-eligible child
- Not providing VFC-eligible children VFC vaccine due to parents' inability to pay the administration fee
- Not implementing provider enrollment requirements of the VFC Program
- Failing to screen patients for VFC eligibility
- Failing to maintain VFC records and comply with other requirements of the VFC Program
- Failing to fully account for VFC vaccine
- Failing to properly store and handle VFC vaccine
- Ordering VFC vaccine in quantities or patterns that do not match provider profiles or otherwise involves over-ordering of VFC doses
- Wasting VFC vaccine

The VFC Program provides education during the provider enrollment process and during VFC provider site visits to help prevent situations that may constitute fraud and abuse. Lack of adherence to VFC Program requirements may lead to fraud and abuse. The VFC Program will investigate all allegations of fraud and abuse and determine appropriate action. If deemed necessary, the VFC Program will notify proper investigative agencies to conduct a full investigation.

Quality Assurance

Quality Assurance Review Assessment, Feedback, Incentives, and eXchange (AFIX)

Quality Assurance Review

Quality assurance involves review and evaluation of VFC provider practices and is a requirement of the VFC Program. Quality assurance is implemented through VFC provider site visits conducted by VFC Program representatives. The quality assurance (QAR) review involves assessment of verbal, written, and visual evidence encountered during the visit to determine if provider sites are following requirements of the VFC Program and to assist with improving the overall VFC Program at the state level.

Quality assurance takes place during three types of site visits:

- Initial site visit
- Quality Assurance Reviews
- Assessment, Feedback, Incentives, and eXchange (AFIX) visits

Initial Site Visit:

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

Quality Assurance Visit:

VFC provider site visits help determine if VFC vaccines are being distributed, handled, and administered in accordance with laws and policies that govern the VFC Program.

Federal guidelines require the VFC Program to conduct Quality Assurance Reviews (QAR) at each VFC enrolled facility. The purpose of the site visit is to:

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

Assessment, Feedback, Incentives and eXchange (AFIX)

AFIX is one of the most effective strategies for improving immunization coverage levels and standards of practice at the provider level. AFIX stands for

Assessment of immunization levels,
Feedback of immunization information to key staff,
Incentives for performance, and
eXchange of information on best practices to improve immunization coverage levels.

The goal of AFIX is to ensure vaccines reach all children served in accordance with the ACIP schedule. The AFIX process is a partnership between VFC Program staff and the provider to improve immunization coverage levels.

Immunization Program 1-800-831-6293		Fax 1-800-831-6292	
Immunization Program Web Page www.idph.state.ia.us/ImmTb/immunization.aspx			
Immunization Program			
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Program Secretary	Becky Danilson	515-281-4923	Rebecca.Danilson@idph.iowa.gov
Nurse Consultant/Vaccine Storage & Handling	Terri Thornton	515-281-4938	Teresa.Thornton@idph.iowa.gov
CDC Public Health Advisor	Marnell Kretschmer	515-281-4917	Marnell.Kretschmer@idph.iowa.gov
Immunization Services Contracts/Fiscal Liaison	Rose Anthony	515-281-5424	Rose.Anthony@idph.iowa.gov
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IRIS Help Desk Staff	Tory King	515-281-7992	Tory.King@idph.iowa.gov
IRIS Help Desk Staff	Cindy Oliver	515-281-6983	Cindy.Oliver@idph.iowa.gov
IRIS Help Desk		800-374-3958	
Vaccines For Children Program			
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