Mississippi Vaccines for Children Handbook

2021

MISSISSIPPI STATE DEPARTMENT OF HEALTH
Office of Immunization

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SECTION 1 – OVERVIEW OF THE VFC PROGRAM

VACCINES FOR CHILDREN (VFC)

The Vaccines for Children (VFC) program was established by Congress in 1994 to increase access to vaccinations for children who might not get vaccinated because of financial barriers. The benefits of the VFC Program include:

- Reducing referrals of children from private providers to state health departments for vaccination
- Saving VFC-enrolled providers out-of-pocket expenses for vaccines
- Eliminating or reducing vaccine cost as a barrier to immunizing eligible children

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 (self-pay)
- Underinsured (children who have limited coverage or caps on the number of vaccines allowed annually). VFC vaccine can only be administered to these children at federally qualified health centers (FQHCs), rural health clinics (RHCs), or local health departments.

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

CDC's immunization program awardees enroll public and private health care providers into the VFC Program to meet the immunization needs of VFC-eligible children in their respective jurisdictions. Awardees educate enrolled providers on VFC Program requirements, vaccine management and accountability, and fraud and abuse violations. Awardees also monitor providers to ensure VFC compliance and provide guidance, with the goal of vaccinating more infants, children, and teens on schedule.

VFC providers agree to follow all VFC requirements, which include:

- Screening patients for VFC eligibility at each immunization encounter and documenting their eligibility status. VFC-purchased vaccines can be administered only to children who are eligible.
- Complying with current ACIP recommendations and VFC resolutions
- Making available vaccines identified in the Provider Profile based on provider type and population served, including non-routine vaccines, if applicable
- Understanding state laws related to vaccination requirements
- Assessing a patient's immunization status at every visit, and administering needed vaccinations

ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee that was established in 1964 to provide advice and guidance on the most effective means to prevent vaccine-preventable diseases. In 1993. Congress gave ACIP unique legal authority to determine

recommendations for routine administration of vaccines to children and adults in the civilian population. The ACIP is the only entity in the federal government that makes such recommendations.

These recommendations include:

- Age for vaccine administration
- Number of doses and dosing intervals
- Precautions and contraindications

Major functions of the ACIP are as follows:

- Develops technical recommendations on vaccine use and immunization practices.
- Approves vaccines to be provided through the VFC Program.
- Recommends immunization schedules that are harmonized with recommendations of other advisory groups, such as the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).

The following table represents ACIP-recommended vaccines covered by the VFC Program.

Table: Diseases and ACIP-Recommended Vaccines Covered by the VFC Program			
Disease	**Vaccine**	**Disease**	**Vaccine**
Chickenpox	Varicella, MMRV§	Measles	MMR,** MMRV§
Diphtheria	DTaP,* DT,** Td,** Tdap,* Kinrix, ¶ Quadracel,¶ Pentacel,§§ Pediarix¶¶	Mumps	MMR,** MMRV§
Hib (*Haemophilus influenzae* type b)	Hib, Pentacel	Pertussis (whooping cough)	DTaP,* Tdap, Kinrix,¶ Quadracel,¶ Pentacel,§§
Hepatitis A	HepA	Polio	IPV, Pentacel,§§ Pediarix¶¶
Hepatitis B	HepB, Pediarix¶¶	Pneumococcal	PCV13, PPSV23
Human Papillomavirus (HPV)	HPV	Rotavirus	RV
Influenza (Flu)	Flu	Rubella	MMR,** MMRV§
Meningococcal	MenACWY, MenB	Tetanus	DTaP,* DT,** Td,** Tdap,* Kinrix,¶ Quadracel,¶ Pentacel,§§ Pediarix¶¶

*DTaP and Tdap combine protection against diphtheria, tetanus, and pertussis.
**DT and Td combine protection against diphtheria and tetanus.
**MMR combines protection against measles, mumps, and rubella.
§MMRV is a combination vaccine containing MMR and varicella.
¶Kinrix and Quadracel are combination vaccines containing DTaP and IPV.
§§Pentacel is a combination vaccine containing DTaP, IPV, and Hib.
¶¶Pediarix is a combination vaccine containing DTaP, IPV, and HepB.
Source: Centers for Disease Control and Prevention (CDC)

VACCINE ADMINISTRATION FEES AND FEE CAPS

VFC 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 any amount up to, but not exceeding, the regional vaccine administration fee cap. **The vaccine administration fee cap for Mississippi is $10.00.** There is no lower limit, so providers have the option to charge less, including 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.

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.

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

- Providers cannot deny access 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 Mississippi's administration fee of $10.00.
- For Medicaid VFC-eligible children, the provider must accept the reimbursement for vaccination set by the state Medicaid agency or contracted Medicaid health plans.

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

CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP)

The Children's Health Insurance Program (CHIP) was created through the Balanced Budget Act of 1997 to address the fact that one in seven children is uninsured and, therefore, at significantly increased risk for preventable health problems. Many of these children are part of working families who earn too little to afford private insurance on their own but earn too much to be eligible for Medicaid.

In Mississippi children who have CHIP coverage are considered to be insured and are not eligible for VFC vaccines. These children must receive CHIP vaccine which is provided by the state.

SECTION 2 – PROVIDER ENROLLMENT

VFC PROGRAM REQUIREMENTS SUMMARY

REQUIREMENT	COMPONENT
VFC Provider Requirements	VFC providers must: • Be licensed in MS to administer vaccines to children aged 18 years and younger* • Be willing and able to follow all VFC Program requirements, policies, and procedures, including participation in site visits and educational opportunities • Have the capacity to order, receive, manage, store, and monitor the temperature of public vaccines • Be open at least four (4) consecutive hours on a day other than a Monday to receive VFC vaccines
Provider Agreement	• Providers must complete and submit a signed VFC Program Provider Agreement at least every 24 months, or annually if requested, and with any changes • The medical director in a group practice must be authorized to administer pediatric vaccines under state law • The provider signing the Provider Agreement on behalf of a multi-provider practice must have the authority to sign on behalf of the entity • All licensed health care providers in an enrolled practice must be listed on the VFC Enrollment Form • Providers must submit a Provider Profile at the initial program enrollment and update at least annually or when order patterns indicate a change
Patient Eligibility Screening	• Providers must at every immunization encounter screen and document patient eligibility in the patient's permanent medical record and in the state registry (MIIX)
MS Immunization Information Exchange (MIIX)	• Providers must document all childhood immunizations in MIIX per MS Code of 1972, Section 41-88-3 • Providers must enter all VFC, and CHIP administered vaccines in MIIX as "administered" within one business day.

REQUREMENT	COMPONENT
Vaccine Management	VFC providers must comply with vaccine management guidelines in the CDC's Vaccine Storage and Handling Toolkit, including: • Correct storage units • Digital data loggers (DDLs) with continuous monitoring capabilities and a current Certificate of Calibration • Receiving and documenting vaccines; Daily monitoring and recording of unit temperatures, including responding to any temperature excursion • Managing expired, spoiled, or wasted vaccine • Vaccine handling and preparation • Procedures for emergency situations
Vaccine Accountability and Emergency Management Plan (VAMP)	VFC providers must have standard operating procedures for routine and emergency vaccine management: • Contact information for medical director, current primary and back-up vaccine coordinators • Provider staff roles and responsibilities • Documented training related to vaccine management • Proper storage and handling practices, including how to handle a temperature excursion • Procedures for vaccine ordering, receiving, inventory control, stock rotation, and handling vaccine loss and waste • Procedures for emergency situations, including transport, equipment malfunction, power failure, natural disaster • Plans must be updated annually or more frequently with any major staff changes and responsibilities
Immunization Schedule	VFC providers must: • Comply with current ACIP recommendations and VFC resolutions • Make available the vaccines identified in the Provider Profile based on provider type and population served, including non-routine vaccines, if applicable

REQUIREMENT	COMPONENT
	• Understand state laws related to vaccination requirements • Access a patient's immunization status at every visit and administering needed vaccinations, required, and recommended • Provide a current Vaccine Information Statement (VIS) at every immunization visit and document the publication date of the VIS and the date it was given to the parent in the patient's medical record and MIIX
Fraud and Abuse	• VFC providers must operate in a manner intended to avoid fraud and abuse.
Vaccine Loss and Replacement	• VFC providers agree to replace vaccines purchased with state and federal funds that are deemed non-viable due to provider negligence or excessive wastage due to unaccountability on a dose-for dose basis with privately purchased vaccines
VFC Visits	• VFC providers agree to VFC Program site visits, which may include compliance visits, unannounced storage and handling visits, or educational site visits
VFC Record Retention	• All records pertaining to the VFC Program must be retained for a minimum of three (3) years and made available upon request. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, temperature documentation and downloaded data, vaccine ordering records, and vaccine purchase and accountability records

*According to the *Personnel Aspects of the Indian Self-Determination and Education Assistance Act,* Public Law 93-638 (1986), IHS health professionals who are assigned or detailed to tribes or tribal organizations under the IPA or MOA are not required to be licensed in the state in which they are assigned or detailed. It is required that the medical licenses of these IHS providers with out-of-state credentials be validated.

RECERTIFICATION OF PROVIDER ENROLLMENT

All VFC providers must be recertified at least every twenty-four (24) months, or annually if requested, to continue their participation in the VFC Program. The required Provider Agreement and instructions are sent to each VFC provider by the MSDH Immunization Program. Providers are required to complete and submit the Provider Agreement within the time frame allowed. Failure to submit the Agreement within the designated time frame could result in ordering privileges being suspended or termination from the VFC Program.

Provider agreement forms (Forms 117, 124, and 1174) must be signed by the medical director or the equivalent in a group practice. The health care provider signing the agreement must be authorized to administer pediatric vaccines under state law. The provider signing the Provider Agreement on behalf of a multi-provider practice must have the authority to sign on behalf of the entity. That provider will be held accountable for the entire organization's compliance, including site visit participation and educational requirements.

All licensed health care providers in an enrolled practice and their corresponding professional license numbers must be listed on the Provider Agreement.

The Provider Agreement form represents the provider's agreement to comply with all the conditions of the VFC Program, as well as ensuring that the practice, facility, staff, and all the providers listed on the agreement adhere to the requirements of the program.

If the status of the individual signing the Provider Agreement changes, the provider must notify the MSDH Immunization Program immediately.

Providers requesting re-enrollment after an absence may be required to resolve any inventory issues or outstanding vaccine replacements before a new enrollment may be approved.

All VFC providers are required to annually submit:

- VFC Provider Profile
- Certificates of required training for the primary vaccine coordinator and back-up vaccine coordinator(s) on:
    - Vaccine for Children (VFC)
    - Vaccine Storage and Handling
- Updated and signed Vaccine Accountability and Emergency Management Plan
- Valid Certificates of Calibration for all Digital Data Logger (DDLs)used in vaccine storage units, including back-up DDL(s)

Providers and all staff who handle or administer vaccines must read and be familiar with:

- MS VFC Provider Handbook
- CDC's Storage and Handling Toolkit

VFC ENROLLMENT VISITS

All newly enrolled providers or providers re-enrolling after an absence in the VFC Program must have an enrollment site visit before being approved to order VFC vaccines. The purpose of this visit is to:

- Educate providers about VFC Program requirements.
- Educate providers on proper vaccine storage and handling.
- Certify providers have the appropriate resources to implement requirements.
- Confirm providers know whom to contact if problems arise, especially with storage and handling issues.
- Complete a Vaccine Accountability and Emergency Management Plan
- Verify the provider has the appropriate storage and handling equipment in place to receive and store vaccines
- Verify the facility has a primary vaccine coordinator and at least one back-up vaccine coordinator.

A compliance site visit will be conducted within six to twelve months after the initial enrollment visit.

By the end of the initial enrollment visit, the provider and staff will understand:

- The eligibility requirements for the VFC Program
- Where to refer underinsured children for VFC vaccine if the child is not eligible in that practice – federally qualified health center (FQHC), rural health clinic (RHC), or a local health department
- How to screen and document VFC eligibility appropriately
- How to identify CHIP-covered patients and the vaccine stock for use with these patients.
- How to enter vaccinations into the statewide immunization registry (MIIX)

EDUCATION REQUIREMENT

All vaccine coordinators and back-up vaccine coordinators are required to receive training annually. The vaccine coordinators must be fully trained on routine and emergency standard operating procedures for vaccine shipments, storage and handling, transport, and inventory management. Other provider staff may also need training, including those who are involved with vaccine management, storage, handling, and administration of vaccines. Education is available through the CDC online training, "You Call the Shots – Module 10 – Storage and Handling, and Module 16 – Vaccines for Children Program,". Education is also available through VFC compliance visits and VFC educational visits.

Vaccine coordinators' training certificates are to be submitted annually with the re-certification packet and a copy of the training certificates should be attached to the Vaccine Accountability and Emergency Management plan and available upon request.

DIS-ENROLLMENT/TERMINATION FROM THE VFC PROGRAM OR REQUEST FOR A CHANGE IN CURRENT PROVIDER AGREEMENT

The MSDH Immunization Program or the provider may terminate this agreement at any time. Providers who wish to dis-enroll due to office closure, loss of provider, not seeing VFC-eligible children, or other changes must notify the MSDH Immunization Program at least 30 days prior to their intended date of

dis-enrollment. This will allow time for the MSDH Immunization representative to transfer any remaining viable vaccines to another VFC provider.

If a VFC facility adds a new provider to the practice, a revised provider agreement must be submitted to the MSDH Immunization Program. A new Provider Agreement must be submitted if there is a change in the signing medical director.

If a VFC provider office is planning to relocate, the office must notify the MSDH Immunization Program at least 30 days prior to the move. A revised Provider Agreement and Provider Profile must be submitted. The facility's ordering privileges will be temporarily suspended to prevent vaccine shipments from going to the wrong location. Data logger report with at least two (2) full consecutive days of current and min/max in-range temperatures must be recorded at the new location prior to transferring vaccines from the previous location. A MSDH Immunization representative will schedule a walk-through of the new facility to verify proper storage units and temperature recording equipment is in place and that the units are maintaining correct temperatures. Once this has been completed ordering privileges will be reinstated.

Providers must notify the MSDH Immunization Program of any changes, such as name change, mailing or shipping address, contact information, changes in vaccine coordinators, phone number(s), fax number(s), or VFC population within one (1) week of the change(s). These changes must be documented on the Provider Agreement, Provider Profile, and Vaccine Accountability and Emergency Management Plan and submitted to the MSDH Immunization Program.

The MSDH Immunization Program has the right to terminate a VFC Provider Agreement at any time due to non-compliance of the VFC Program requirements. If the agreement is terminated, any remaining viable vaccine will be transferred to another enrolled VFC provider by an MSDH Immunization representative within 30 days of the termination date and a dis-enrollment form will be completed. The provider is to return any expired or non-viable vaccines to McKesson. A return form is to be submitted to the MSDH Immunization Program so a shipping label can be requested. Providers who are terminated due to non-compliance will not be eligible to request re-enrollment in the VFC Program for a period of twelve (12) months from the termination date and will be subject to approval based on the previous non-compliance issues.

SECTION 3 – ELIGIBILITY

VFC ELIGIBILITY CRITERIA

Providers must screen, document, and verify VFC eligibility at every immunization encounter before administering vaccines.

To be eligible to receive VFC vaccine, children (regardless of their state of residency) through the age of 18 (until the day of their 19th birthday) must meet at least one of the following criteria:

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 (self-pay)	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 ACIP • Children who have health insurance, but there is a fixed dollar limit or cap for vaccines • Underinsured children are only eligible to receive VFC vaccines at a federally qualified health center (FQHC), rural health clinic (RHC), or a local health department

Children with state-funded coverage (CHIP) are **NOT** eligible for VFC vaccines and must receive CHIP vaccines.

Any patient 19 years of age or older is **NOT** eligible for VFC or CHIP vaccines, regardless of coverage.

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 circumstances. However, because VFC 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 CHIP program, it may result in fewer out-of-pocket costs for the child to receive vaccinations through these programs than through VFC, 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

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 make up the largest category of VFC eligibility.

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 option that is most cost-effective for the family. The parent of the child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee. Options include:

Option 1: The 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 is not true of the vaccination administration fee because vaccinations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program.

Patient Eligibility and Insurance Criteria 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

Option 2: The provider can administer private stock vaccine 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 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 administration fee are billed to the primary insurer.

MEDICAID AS SECONDARY INSURANCE AND HIGH-DEDUCTIBLE PLANS

If a child has Medicaid as secondary insurance and the primary insurance is a high-deductible insurance plan requiring the parent to pay out-of-pocket for vaccines, the child should be considered VFC-eligible if the family has not yet reached its deductible. VFC vaccines should be administered, and the administration fee should be billed to Medicaid until the deductible is reached. If a child does not have Medicaid as secondary insurance, the child is **NOT** VFC-eligible even if a child's family has a high-deductible plan.

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 the vaccines not covered)
- Does cover ACIP-recommended vaccines but has a fixed dollar limit or cap for vaccines. This child is considered underinsured once the fixed dollar amount is reached.

Before administering a vaccine, providers must verify whether the child's health insurance plan covers ACIP-recommended vaccines. If the provider cannot verify vaccination coverage, for 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 Affordable Care Act, 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 coinsurance.

FEDERALLY QUALIFIED HEALTH CENTERS (FQHCs) AND RURAL HEALTH CLNINCS (RHCs)

Underinsured children can receive VFC vaccines **ONLY** at federally qualified health centers (FQHCs), rural health clinics (RHCs), or local MSDH health departments. FQHCs and RHCs provide health care to medically underserved areas and meet certain criteria under Medicare and Medicaid programs.

What is an FQHC?

An FQHC is a health center designated by the Bureau of Primary Health Care (BPHC) of the Health Resources and Services Administration (HRSA) to provide health care to medically underserved population. FQHCs include community and migrant health centers, special health facilities such as those for the homeless and persons with acquired immunodeficiency syndrome (AIDS) that receive grants under the Public Health Service (PHS) Act, and "look-alikes," which meet qualifications but do not actually receive grant funds. They also include health centers within public housing and Indian Health Centers.

What is an RHC?

An RHC is a clinic located in a Health Professional Shortage Area, a Medically Underserved Area, or a Governor-Designated Shortage Area. RHCs are required to be staffed by physician assistants, nurse practitioners, or certified nurse midwives at least half of the time the clinic is open.

VFC ELIGIBILITY AND INSURANCE SITUATIONS

Child's Insurance Status	VFC-Eligible?	VFC Eligibility Category
Enrolled In Medicaid	Yes	Medicaid
Has private health insurance with Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit	No	Insured: This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration fee because the plan's deductible has not been met
Has health insurance covering all vaccines, but has not met plan's deductible or paid for other services received at visit and has Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccine, but plan has a fixed dollar limit or cap on amount that it will cover	Yes	• Insured until the fixed dollar amount is met • Underinsured after the fixed dollar amount is reached
Has an insurance plan that does not cover all ACIP-recommended vaccines	Yes	Underinsured: Child can only receive vaccines not covered by plan and must be administered at a FQHC, RHC, or health department
Has health insurance, but plan does not cover any vaccines	Yes	Underinsured: Child can only receive at FQHC, RHC or health department (with ACA this situation should be rare)
Enrolled in a Health Care Sharing Ministry	Depends	• Underinsured unless plan is recognized as insurance by the state insurance department, regardless of vaccine coverage provided by plan • Insured if plan is recognized by the state insurance department and covers vaccines • Underinsured if plan is recognized by the state insurance department and does not cover ACIP-recommended vaccines

Enrolled in Children's Health Insurance Program (CHIP)	No	CHIP: These children must receive CHIP funded vaccines
Has no health insurance coverage	Yes	Uninsured
Has private health insurance that covers all vaccinations and is AI/AN	Yes	AI/AN: However, provider should choose the eligibility category most cost-effective for the child and family
Has Medicaid and is AI/AN	Yes	Medicaid or AI/AN: Provider should use Medicaid for the administration fee because this provides the least out-of-pocket expense for the family.

STATE OF RESIDENCY

At times, VFC-eligible children receive health care in a bordering state instead of their state of residency. VFC eligibility is not dependent upon state of residency for the child. VFC providers may vaccinate children through the age of 18 who are VFC-eligible residing in another state. If a provider administers VFC vaccines to a Medicaid VFC-eligible child from a neighboring state, the provider must be Medicaid-enrolled for the child's state of residency in order to receive administration fee reimbursement from that Medicaid program.

CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP)

The Children's Health Insurance Program (CHIP) was created through the Balanced Budget Act of 1997 to address the fact that one in seven children is uninsured and, therefore, at significantly increased risk for preventable health problems. Many of these children are part of working families who earn too little to afford private insurance on their own but earn too much to be eligible for Medicaid.

In Mississippi children who have CHIP coverage are considered to be insured and are **NOT** eligible for VFC vaccines. These children must receive CHIP vaccine which is provided by the state.

PROVIDER RESPONSIBILITY TO SCREEN FOR VFC ELIGIBILITY

Screening to determine a child's eligibility to receive vaccines through the VFC Program must take place with each immunization encounter. Providers must correctly document VFC eligibility in MIIX and the patient's medical record for each dose of vaccine administered.

Before administering vaccines, providers must check eligibility status and type of coverage at every immunization encounter.

SECTION 4 – MISSISSIPPI IMMUNIZATION INFORMATION EXCHANGE (MIIX)

OVERVIEW

The Mississippi Child Immunization Act of 1994 established a centralized registry to be operated by the Department of Health for health care providers to report all childhood immunizations given in the state. The goal of the Mississippi State Department of Health Immunization Program is to ensure that accurate and valid immunization data is available to health care providers, parents, and others who have a legitimate and tangible interest in immunization information.

MIIX ACCESS

To obtain access to MIIX, the provider must submit to the Immunization Program a MIIX User Agreement form. Each MIIX user is required to have their own log-in ID to MIIX and must not use another user's log-ins. A MIIX Remove User Form must be completed and submitted to the Immunization Program for any user that is no longer at the facility. The MIIX User Agreement and the MIIX Remove User forms can be found by clicking on the links provided or at MSDH.ms.gov .

Quick Reference and Printable Guides

- Creating a Vaccine Order
- Receiving Vaccine Order in MIIX
- Search/Add Patients & Add Vaccinations
- Add/Edit Vaccinations
- Report Duplicate Patients
- Reminder/Recall

Web-Based Video Trainings

- Vaccine Ordering Management Systems (VOMS) in MIIX
- Vaccine Ordering
- Receiving Vaccine Inventory in MIIX

MIIX MESSAGE of the DAY

The Message of the Day contains important information and updates pertaining to VFC, immunizations, and ordering schedules.

MS CODE OF 1972

MS Code of 1972, Section 41-88-3 states:

(1) The State Department of Health is responsible for assuring that all children in the state are appropriately immunized against vaccine-preventable diseases. In order to improve the state's immunization levels in children, the State Department of Health shall enhance current immunization activities and focus on children receiving all recommended immunizations by twenty-four (24) months of age. The immunizations shall be administered according to the recommendations of the national Advisory Committee on Immunization Practices (ACIP). The administration of vaccine shall not be delayed due to a reluctance of the health care provider to administer multiple immunizations in a visit. The department shall improve parent compliance

and provide more timely scheduling, recall, and follow-up in order to achieve national and state immunization level goals.

(2) The state Department of Health shall establish a statewide childhood immunization registry (MIIX) to which all health care providers will report the administration of childhood immunizations. The State Board of Health will promulgate rules and regulations needed to implement this section. The department shall make information regarding the immunization status of children in the registry available to parent/guardians of the child, health care providers, and individuals or organizations that are required to report on the immunization status of children in their care.

SOURCES: Laws, 1994, Ch. 365, Sec. 2, eff from and after passage (approved March 14, 1994)

VACCINE ADMINISTRATION REQUIREMENTS

It is a VFC Program requirement that all administered VFC and CHIP vaccines are linked to a patient in MIIX. Administered doses of vaccines are to be entered into MIIX as "administered" within one business day of the day it was given along with the following required information:

- VFC eligibility
- Name of vaccine
- Date administered
- Lot number (from the box) and manufacturer
- Vaccinator
- Anatomical site
- Anatomical route
- Volume
- VIS Publication date
- Date VIS form is given

All administered VFC and CHIP vaccines must be accounted for in MIIX and administered doses must decrement from the MIIX inventory. Failure to comply with this requirement may lead to implementation of MSDH Immunization Program's Vaccine Loss and Replacement policy and possibly dis-enrollment from the VFC Program.

Vaccinations administered should never be entered into MIIX as historical. The use of the historical button may be used for the following reasons:

- Immunization records brought in from another provider or from another state
- The provider chooses not to enter their private stock of vaccines into the MIIX inventory. Children receiving these vaccines are to be entered in as "historical".

Please note VFC or CHIP vaccines that were given at your facility on a previous date are not considered historical.

MyIR

My IR provides easy, one stop access to immunization records for individuals and families. Individuals or parents can now look up their own or child's immunization record.

MyIRMobile - MyIR Mobile

Registering for MyIR can help:

- Find out if up to date on recommended and required vaccinations for school entry
- To find out if not fully up to date, what is needed per the immunization schedule
- If up to date to print out a certified copy of the Form 121 required for school registration

You can find more information about MyIR at Immunization Records: MyIR - Mississippi State Department of Health (ms.gov)

SECTION 5 – VACCINE STORAGE AND HANDLING

VACCINE STAFF AND TRAINING

VACCINE COORDINATORS

During the enrollment process, VFC providers are required to designate a primary vaccine coordinator and at least one back-up vaccine coordinator that must be on site for each facility. The primary vaccine coordinator is responsible for overseeing all vaccine management within the facility, including:

- Developing and maintaining the Vaccine Accountability and Management Plan
- Monitoring storage and handling of vaccines and vaccine administration practices in the facility
- Overseeing vaccine ordering and notifying the MSDH Immunization 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
- Participating and documenting completion of annual training on VFC requirements
- Storing all required documentation for three (3) years, or longer if required by state statutes or rules

The primary vaccine coordinator responsibilities also include, but are not limited to:

- Overseeing proper receipt and storage of vaccine deliveries
- Physical inventory and reconciliation of vaccines in MIIX. This must be done at least monthly, or more often if issues arise, and prior to placing a vaccine order
- Organizing vaccines within storage units
- Assessing and recording current temperatures of the storage units at the beginning of each workday
- Assessing and recording minimum/maximum temperatures at the beginning of each workday
- Downloading and reviewing temperature data at least monthly for any shifts in temperature trends and anytime the temperature falls outside of normal ranges
- Responding to temperature excursions (out-of-range temperatures)
- Setting up new digital data loggers
- Rotating stock at least weekly so vaccines with the earliest expiration date are used first

- Removing expired vaccines from storage units
- Organizing vaccine-related training and ensuring staff completion of training
- Overseeing proper vaccine transport (when deemed necessary)

Coordinator responsibilities may be completed by the primary or back-up coordinator delegated. **The primary coordinator must ensure the back-up coordinator(s) are trained and can perform any of the primary coordinator's duties in their absence.**

To effectively perform their duties, the primary vaccine coordinator and back-up coordinator(s) must be fully trained on routine and emergency standard operating procedures (SOPs) for vaccine ordering, storage, handling, transport, inventory management, and administration of vaccines.

VFC providers are required to notify the MSDH Immunization Program anytime there is a change in vaccine coordinator staff or the medical director.

If any of the vaccine coordinators do not respond after three (3) attempts to contact them regarding resolution of current or ongoing issues, the MSDH Immunization Program may contact the signing physician to seek resolution.

STAFF TRAINING

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

- Staff receiving vaccine deliveries – how to open, record, and store vaccine shipments immediately
- Staff handling or administering vaccine
- Staff transporting vaccine off-site – routine and emergency vaccine management

All staff members who receive vaccines deliveries as well as those who handle or administer vaccines should be trained in vaccine-related practices and be familiar with the facility's Vaccine Accountability and Management Plan.

VACCINE STORAGE AND HANDLING

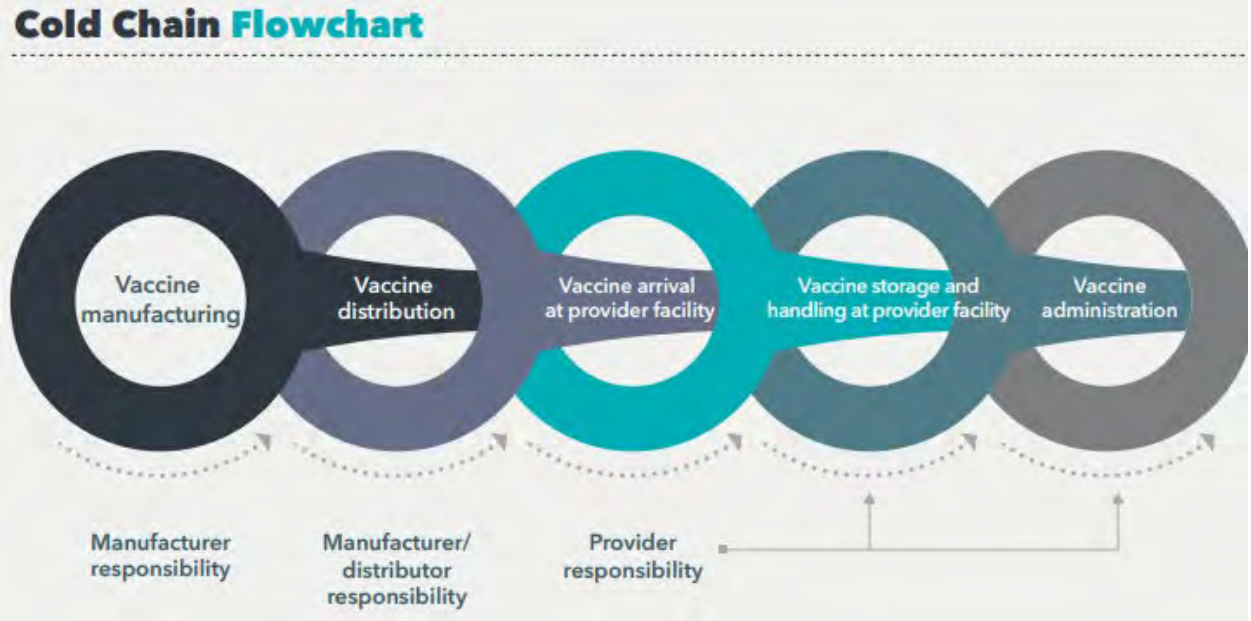
All VFC vaccine storage and handling requirements and recommendations are in place to ensure the vaccine cold chain is maintained. The cold chain begins at the manufacturing plant, includes delivery to and storage at the provider facility, and ends with administration of vaccine to the patient. Too much 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. An effective cold chain relies on three (3) main elements:

- A well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate inventory management

Vaccine loss is both costly and preventable. Providers are responsible for maintaining vaccine quality from the time a shipment arrives at the facility until a dose is administered. Therefore, sound vaccine management practices related to storage and handling are critical to minimizing vaccine loss and waste.

CDC's Vaccine Storage and Handling Toolkit provides guidance on safe and effective vaccine management practices for all health care providers. Though VFC providers are required by the VFC Program to implement only certain recommendations and best practice guidance, the MSDH Immunization Program has additional requirements that providers must adopt and strongly encourages providers to adopt all recommendations and best practices in the Toolkit. Following the Toolkit's guidance can minimize financial burden for providers due to vaccine loss and prevent the need for revaccination. The result is maximum vaccine effectiveness and patient protection.

The CDC Vaccine Storage and Handling Toolkit is available at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.



VACCINE STORAGE AND TEMPERATURE MONITORING EQUIPMENT REQUIREMENTS

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

- Storage units that maintain correct temperatures at all times
- **Refrigerator temperatures between 36.0° F and 46.0°F (2.0°C and 8.0°C)**
- **Freezer temperature between -58.0°F and +5.0°F (-50.0°C and -15.0°C)**
- Digital data loggers with continuous monitoring capabilities and a current and valid calibration certificate for all units that store VFC/CHIP vaccines as well as a portable back-up digital data logger

To protect the viability of vaccines these storage unit practices must be followed:

- Never store food or beverages in a unit with vaccines

- Store biologics or other medications on the bottom shelf to avoid inadvertent administration and medication errors
- Do not store vaccines on the top shelf, in the deli, fruit, or vegetable bins (remove bins if possible), in the doors or on the floor of the unit, or under or near cooling vents
- Place water bottles, marked as “do not drink” throughout the refrigerator and freezer – against walls, in the back, on the floor, and in the doors – to help maintain proper temperatures
- Place vaccines in the center of the unit, two to three inches away from walls, ceiling, floor, and door of the unit
- Store vaccines in their original packaging with lids closed until ready for administration

The diagram below shows the proper vaccine storage unit setup.

REFRIGERATOR AND FREEZER UNITS

Storage units must have enough room to store the largest inventory a provider may have at the busiest point in the year without crowding.

MSDH Immunization Program recommends the following units, in order of preference, for the storage of VFC vaccines:

- Purpose-built or pharmaceutical/medical-grade units, including doorless and dispensing units
- 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 storage unit

- Combination household refrigerator/freezer unit, using only the refrigerator compartment to store vaccines. These units must have a separate temperature control for the refrigerator. A separate stand-alone freezer must be used to store frozen vaccines

If a provider office is purchasing a new refrigerator or freezer they are required to purchase stand-alone units.

The use of dormitory or bar-style refrigerator/freezers is prohibited at all times for VFC providers. These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. The following examples are dormitory or bar-style units and are **NOT** allowable to store VFC vaccines at any time.



The following refrigerators are the size of a household refrigerator, but they are still classified as a dormitory-style refrigerator because they have the one exterior refrigerator door with the freezer compartment located within the refrigerator sections. These units are not allowable to store VFC vaccines.


Providers should follow the manufacturer's storage specifications for each vaccine, found in the manufacturer's package insert.

PURPOSE-BUILT VACCINE STORAGE UNITS

Numerous vaccine storage units have entered the market that are designed specifically for the storage of vaccines. These purpose-built for vaccine storage units can take on many physical forms. Some may look like traditional stand-alone units, while others may appear as a dispensing or vending type unit with or without a door. Although these units may be similar to pharmaceutical or medical grade units, they are specifically designed and tested to keep vaccines at their appropriate storage conditions.

Purpose-built vaccine storage units must meet the same requirements as other VFC vaccine storage units.

- Temperature monitoring
    - Many purpose-built units have multiple temperature probes or sensors. It is important these probes or sensors have current Certificates of Calibration
    - Purpose-built closed or doorless units may utilize air sensors (non-buffered probes). Since these units have very limited exposure to ambient air, the use of a buffered probe is not essential.
    - Digital Data Logger – Many of these type units have built in data loggers with electronic interfaces that allow continuous temperature tracking and/or provide min/max temperatures. Providers should ensure the purpose-built unit will meet the same temperature monitoring device requirements as defined for other VFC storage units.
    - VFC providers are required to monitor, assess, and document current temperatures on a paper log, and the minimum and maximum temperatures at the beginning of every workday.
    - All temperature documentation must contain the time and date of each reading and the name (or initials) of the person who assessed and recorded the readings.
    - Digital data logger data must be download and reviewed at least monthly.
    - Temperature files, including paper logs and downloaded data must be accessible at VFC site visits and upon request and kept for three (3) years.
- Vaccine storage
    - Purpose-built units have undergone testing and temperature mapping to have the probe placed in the most appropriate location
    - Although purpose-built units can have multiple temperature probes, a back-up temperature monitoring device is still needed for transport in an emergency situation
    - Many purpose-built units do not need water bottles to serve as a thermal ballast
- Vaccine Management
    - Purpose-built units must have the ability to separate public and private vaccine stock either physically or electronically.
    - If stock is separated electronically, an inventory printout must be accessible at VFC site visits and upon request
    - If unable to physically remove expired vaccine from a purpose-built unit immediately, the unit must be able to make expired vaccines inaccessible. An inventory printout must list those inaccessible expired vaccines.

- The only NDC and lot number that should be used to report inventory and administered vaccine in MIIX, or to submit vaccine returns is the NDC and lot number of the vaccine box
- In situations of a temperature excursion or power outage, the provider must ensure they are able to remove and relocate the vaccines, if necessary, per their Vaccine Accountability and Management Plan

For questions or concerns whether your purpose-built vaccine storage unit meets VFC temperature monitoring device requirements, please consult the MSDH Immunization Program.

STORAGE UNIT SET UP AND PLACEMENT

Providers should only plug one storage unit into an electrical outlet to avoid creating a fire hazard. Providers should avoid using power outlets that can be tripped or switched off, including built-in circuit switches (as they may have reset buttons), outlets that can be activated by a wall switch and multi-outlet power strips.

Providers are required to protect the power source of all vaccine storage units, by means of posting, "Do Not Unplug" signs on the front of the unit and wall next to the outlet. Providers are also required to have a "Do Not Turn Off Circuit Breaker" sign on their circuit breaker box, the number of the breaker that corresponds to the outlet the unit is plugged into and a contact person's name and number.

Good air circulation around the outside of any storage unit is important. Place a storage unit in a well-ventilated room, leaving space between the unit, ceiling, and any wall. Nothing should block the cover over the motor compartment. The unit should be level, with the bottom of the unit above the floor. Make sure the unit door opens and closes smoothly and fits squarely against the body of the unit. If not secured properly, unit doors pose a particular risk to maintaining appropriate internal temperatures of vaccine storage units. Studies find most units work best when placed in an area with standard indoor room temperatures, usually between 68°F and 77°F (20°C and 25°C). Check the manufacturer-supplied owner's manual for additional guidance on placement and spacing.

STABILIZING TEMPERATURES IN NEW, MOVED, AND REPAIRED UNITS

It may take two (2) to seven (7) days to stabilize the temperature in a newly installed or repaired refrigerator and two (2) to three (3) days for a freezer.

Before using a unit for vaccine storage, check and record the min/max temperatures and the current temperatures twice a day on each workday for two (2) to seven (7) days. Once two (2) consecutive days of temperatures are recorded within the recommended range, the unit is stable and ready for use.

TEMPERATURE RANGES

Refrigerators should maintain temperatures between 36°F and 46°F (2°C and 8°C). Freezers should maintain temperatures between -58°F and +5°F (-50°C and -15°C). Refrigerator or freezer thermostats should be set at the factory-set or midpoint temperature, which will decrease the likelihood of temperature excursions.

Consult the owner's manual for instructions on how to operate the thermostat. Thermostats are marked in various ways and, in general, show levels of coldness rather than temperatures. The only way to know the temperature where vaccines are stored is to measure and monitor it with a temperature monitoring device.

DIGITAL DATA LOGGERS (DDLs)

VFC providers must use digital data loggers (DDLs) with continuous temperature monitoring capability and a current and valid Certificate of Calibration Testing in each unit storing public vaccines. DDLs must be used during routine, on-site vaccine storage, vaccine transport, and off-site, and mass vaccination clinics.

To meet VFC Program requirements, the DDL must be equipped with:

- A detachable temperature probe or sensor (a buffered probe is recommended)
- An active temperature display outside the unit that can easily be read without opening the storage unit's door
- Continuous temperature monitoring and recording capabilities and the capacity to routinely download data

Additional MSDH VFC Program requirements for DDLs include:

- Alarm for out-of-range temperatures
- Temperature display showing current, minimum, and maximum temperatures
- Low battery indicator
- Accuracy of +/-1°F (0.5°C)
- User-programmable logging interval (or reading rate) at a maximum time interval of no less frequently than every 30 minutes
- DDLs must be programmed to record the correct time and date for each temperature reading. Provider may need to consult the DDL manufacturer for guidance.

Certificates of Calibration must include:

- Model/device number
- Serial number
- Date of calibration (report or issue date)
- Confirmation the instrument passed testing (or instrument in tolerance)

The certificate must indicate at least one of the following items in regard to calibration testing:

- Conforms to ISO 17025
- Testing was performed by an ILAC/MRS Signatory body accredited laboratory
- Is traceable to the standards maintained by NIST
- Meets specifications and testing requirements for the American Society for Testing and Materials (ASTM) Standard E2877 tolerance Class F (0.5°C) or better

Calibration testing should be done every two (2) to three (3) years to ensure the accuracy of the device continues to conform to nationally accepted standards.

The probe of the DDL should be placed in the center of the unit, 2 to 3 inches away from the walls, ceilings, and door of the unit to allow cold air to circulate. DDLs should be downloaded, and the data reviewed for any shifts in temperature trends. The MSDH VFC Program recommends this be done weekly, however, it **MUST** be done monthly and with any alarm or temperature excursion. The downloaded data must be kept for a minimum of three (3) years and made available upon request.

A back-up DDL must be readily available in case a DDL or calibration testing is required and for emergency transport of vaccines. The back-up DDL should have a different calibration retesting date than other DDLs to avoid requiring all DDLs to be sent out for recalibration at the same time. If a back-up DDL has the same calibration retesting date, providers must have the unit retested prior to expiration, ensuring that a valid DDL is available for required temperature monitoring. Back-up DDLs should be maintained on site. The back-up DDL must be portable to be used in the event of vaccine transport.

NOTE: MSDH recommends keeping just the probe of the back-up DDL (not the digital display) in the refrigerator, so it is acclimated in case it is needed to be used in the event of an emergency. If providers opt to keep the probe in the refrigerator, the digital display of the back-up DDL must not be operational or on the storage unit to avoid conflicting temperature readings between the back-up and main DDLs, which can lead to potential confusion.

DAILY TEMPERATURE MONITORING AND RECORDING

Providers are required to have protocols for reviewing and recording the current and the minimum and maximum (min/max) temperature readings in vaccine storage units daily. Procedures should be in place for training appropriate staff to document, assess, and interpret temperature monitoring data.

The MSDH VFC Program requires reviewing and recording the current and min/max temperature readings at the beginning of each workday, then resetting the min/max readings. This helps to identify temperature excursions quickly so corrections can be made to prevent vaccine loss. The MSDH VFC Program also recommends checking the current temperature of the storage unit prior to accessing and administering vaccine.

Information to include when documenting a temperature reading:

- At least one min/max and current temperature per day at the beginning of each workday
- Time and date of each reading
- Name or initials of the person who assessed and recorded the reading

Providers must maintain all paper temperature logs and downloaded data for a minimum of three (3) years.

TEMPERATURE EXCURSIONS

Temperature excursions or inappropriate storage conditions for any vaccine requires immediate action.

If a temperature excursion is suspected, providers are to follow their SOPs in their Vaccine Accountability and Management Plan, including but not limited to:

- Notify the Primary or back-up vaccine coordinator immediately
- Quarantine the affected vaccine and label "Do Not Use". **DO NOT DISCARD VACCINES**
- Store the vaccine in a unit maintaining correct temperatures if possible
- Download DDL to determine the lowest or highest temperature and length of time out of range
- General description of the event (i.e., what happened)
- Inventory of affected vaccines
- Determine if any of the affected vaccine has been involved in a previous excursion and adjust time out of range if it has
- Contact vaccine manufacturers for stability information
- If vaccine is viable, mark it with excursion information in case it is involved in future excursions, and lift quarantine
- If vaccine is not viable, complete the *Return or Wasted* form and submit to the MSDH VFC Program for a return shipping label
- Contact MSDH VFC Program with findings and for further guidance
- Document all steps taken and outcome
- Name of person completing report

Never discard or assume the affected vaccine is not viable until it has been determined by the manufacturers. Vaccine that is considered spoiled because the provider did not take immediate or appropriate action on out of range temperatures may require the provider to replace the wasted public vaccine dose-for-dose with privately purchased vaccines according to the VFC Vaccine Loss and Replacement Policy.

SECTION 6 – VACCINE MANAGEMENT AND ACCOUNTABILITY

VACCINE ORDERING

Vaccine loss due to expiration is frequently a consequence of over-ordering and poor inventory management. Providers should order vaccine in accordance with actual vaccine need for one month and avoid stockpiling or build-up of more than a three-month supply.

CDC and MSDH Immunization Program recommends providers:

- Reconcile MIIX inventory at least monthly and prior to vaccine ordering.
- Place vaccine orders while they still have a four-week supply of vaccine available to allow for potential delays
- Place smaller, more frequent orders rather than large orders to minimize the amount of vaccine loss should an incident occur during shipment or in the vaccine storage unit.

When establishing vaccine needs, please consider:

- Vaccine deliveries usually take 7-10 days to arrive
- Vaccine usage patterns (e.g., increased usage during July and August for “back-to-school”)
- Length of time before next order is approved, shipped, and received
- Storage capabilities (do not order more vaccine than you can store)

All vaccine orders are submitted through MIIX. Providers must ensure the following information is completed or updated prior to submitting an order:

- All doses of VFC and CHIP vaccines administered are linked to a patient in MIIX
- No expired vaccines are showing in the MIIX inventory.
- A physical count of the vaccine on hand
- The clinic’s physical inventory matches the inventory in MIIX
- Any discrepancies between the physical and MIIX inventory have been resolved. “Matches physical inventory” or “administered, but not linked to a vaccine” are not valid reasons to use to correct inventory issues. The only time doses should be adjusted are for doses that are expired, spoiled (e.g., a temperature excursion), wasted (dropped, broken, or spilled), or a recall has occurred from the manufacturer.
- The vaccine order is enough for at least one month’s inventory but does not exceed three months

NOTE: Providers with ongoing wastage issues may be asked to reconcile their inventory more frequently and place smaller orders weekly.

VFC providers should consider their clinic’s delivery hours for the next two to three weeks to ensure a VFC vaccine coordinator will be on site to accept the delivery before placing an order. The provider may be held financially responsible for any vaccine that is delivered during the provider’s stated business hours (based on most current Provider Profile) and the office is closed.

Providers must notify the MSDH VFC Program when there has been a change in the hours or days of operation, or provider population from the most current Provider Profile.

Orders may be placed on hold or denied for the following reasons:

- Excessive wastage of doses in the last 90 days
- No administered doses in the last 90 days
- Previous order(s) have not been received in MIIX
- Continued issues with discrepancies in MIIX inventory
- Expired vaccine in MIIX inventory

A member from the MSDH VFC vaccine ordering team will contact you if your order has been placed on hold or denied. Vaccine orders may not be approved until the issue has been resolved, therefore prompt response is crucial.

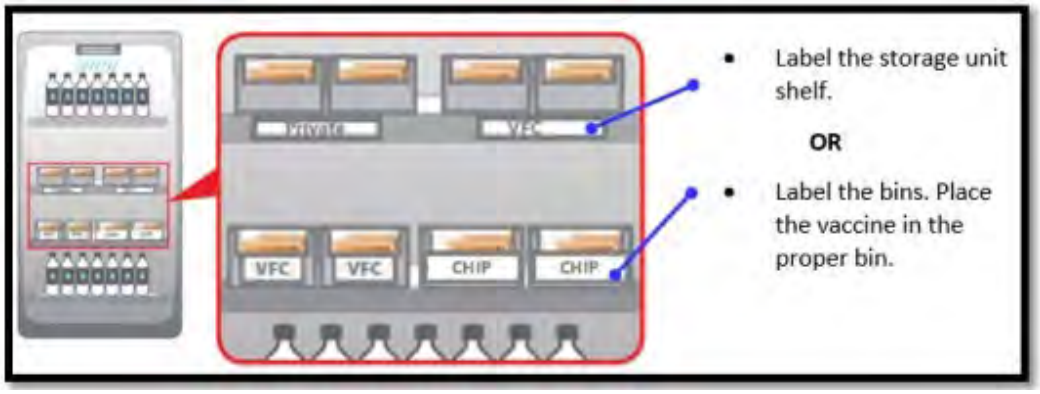
VFC providers are required to place a vaccine order and administer vaccine within a 12-month period in order to remain active in the program. Providers who fail to do so will be considered inactive and dis-enrolled from the MSDH VFC Program.

VACCINE FUNDING STOCK

Providers are required to keep separate vaccine inventories for the patient population seen:

- VFC vaccines
- CHIP vaccines
- 317 vaccines (if applicable)
- Private-purchased vaccines

These vaccines are to be separated and clearly labeled in the vaccine storage units to avoid any confusion when choosing vaccine from the correct funding source.



VACCINE BORROWING

VFC-enrolled clinics are expected to maintain adequate inventories of vaccine for their privately insured, CHIP, and VFC-eligible patients so borrowing between stocks should be a **RARE** occurrence. Borrowing of vaccines must be due to unforeseen delays or circumstances. Borrowing activities will be monitored as part of the compliance with the MSDH VFC Program and follow-up actions will be taken when excessive, continued, or inappropriate borrowing activities are noted. If a VFC vaccine is intentionally or unintentionally administered to a non-VFC eligible patient, the provider must replace the misused VFC doses with a privately purchased dose and document it immediately on the Vaccine Borrowing Report.

The same applies with misused CHIP vaccines. Continued or habitual borrowing may result in the provider being terminated from the MSDH VFC Program.

Borrowing is allowed only for instances when:

- There is a lack of vaccine stock due to delayed or spoiled shipments. Failure to place vaccine orders on time does not constitute a shipping delay.
- Vaccine will expire soon and will be lost if not used. Providers may use this option to administer short-dated vaccine from another funding source to a VFC-eligible child and replace it with a longer-dated VFC dose.

A Vaccine Borrowing Report must be completed when:

- VFC vaccine is administered to a non-VFC-eligible patient
- CHIP vaccine is administered to a non-CHIP-eligible patient
- Private vaccine is administered to a VFC or CHIP patient

VFC vaccines cannot be used to replace a clinic's privately purchased vaccine inventory due to misuse. Providers need to maintain invoices that validate privately purchased vaccine was used to replace borrowed VFC/CHIP doses. The invoice date should correspond with the replacement date on the Vaccine Borrowing Report.

RECEIVING VACCINE SHIPMENTS

Proper handling and temperature maintenance of any vaccine shipment is imperative to the cold chain and viability of the vaccines. Vaccines can cost thousands of dollars so proper handling of each dose is critical in preventing unnecessary loss or wastage. The provider may be held responsible for any mishandled VFC vaccine shipments. Therefore, it is essential that all staff be properly trained in the storage and handling of VFC vaccines.

Any staff who accepts a vaccine delivery should immediately notify the primary vaccine coordinator, back-up vaccine coordinator or delegate.

The primary vaccine coordinator, back-up coordinator, or delegate must immediately unpack, store and document vaccines and diluents upon receipt. Actions include:

- Examining the shipping container and vaccines for signs of physical damage
- Determining the length of time the vaccines were in transit by looking at the packing list (frozen vaccine only) or checking the cold chain monitor for any indication of a temperature excursion during transit
- Comparing the contents of the container to the packing list to be sure they match (this includes checking number of doses, expiration dates, lot numbers)
- Checking the order received against the order placed in MIIX to ensure all vaccines ordered were received and correct number of doses, manufacturer, lot numbers, and expiration date are entered and clicking "received". Vaccines cannot be administered until this has been done.
- Making sure lyophilized (freeze-dried) vaccines came with the correct type and quantity of diluent (diluents for varicella-containing vaccines are stored in a separate compartment in the lid of the shipping container)

- Checking both vaccine and diluent expiration dates to ensure none are expired or soon-to-expire
- Immediately storing vaccines in the appropriate storage unit (MSDH Immunization Program recommends that MMR be stored in the freezer)
- Labeling vaccines per funding source (VFC, CHIP, 317)

WITHIN TWO (2) HOURS OF VACCINE DELIVERY: If any problem is noted with the delivery such as damage, excessive shipping time, cold chain breach, or a delivery shortage, VFC providers must **IMMEDIATELY** contact the MSDH VFC Vaccine Ordering Team at 601-576-7751.

If a provider does not call the MSDH VFC Vaccine Ordering Team within two (2) hours of the vaccine delivery to report an issue, this may constitute provider negligence in accordance with the Vaccine Loss and Replacement Policy due to storage and handling mishaps by provider staff. Shipments that result in vaccine loss can negatively impact the VFC vaccine budget and can jeopardize the VFC Program.

Providers should **NEVER** refuse a shipment. Providers should receive the package and **IMMEDIATELY** report any concerns to the MSDH VFC Vaccine Ordering Team. Shipments refused at the provider site cannot be returned in a timeframe that is possible for the vaccine to remain viable. Providers may be responsible for replacing any vaccines wasted due to refusal to accept a shipment.

When calling the MSDH VFC Vaccine Ordering Team about a vaccine delivery issue, staff will need to report on temperature indicators if there is a concern regarding the cold chain. A picture of the temp indicator, packing list or shipping box may be requested. The vaccine should be stored at the correct temperatures and the vaccine should be marked "Do Not Use" until advised of its viability. **DO NOT** throw away the shipping container or temp indicators.

MANAGEMENT OF EXPIRED, SPOILED, OR WASTED VACCINES

Type of vaccine loss:

- Expired or spoiled vaccine: Nonviable vaccine in its original container (vial or syringe) that is able to be returned for excise tax credit. This includes expired vaccine or vaccine spoiled due to temperature excursions, transport conditions, or emergency situations such as a power failure.
- Wasted vaccine: Nonviable vaccine that is unable to be returned for excise tax credit. This includes vaccine in an open vial, drawn into a syringe, or compromised because its container was dropped or broken.
- Lost or unaccountable vaccine: Vaccine for which the physical vaccine vial or syringe is missing.

Vaccines that are expired must be documented in MIIX within one (1) week of the expiration date. All unopened vials and pre-filled syringes of spoiled or expired vaccines received from the VFC Program must be returned to McKesson within six (6) months of the expiration date. Spoiled or wasted vaccines must be documented in MIIX immediately.

Wasted doses of vaccine that cannot be returned to McKesson must be disposed of according to usual medical biosafety procedures for your state.

A *Vaccine Return Form* must be submitted to the MSDH Immunization Program for all non-viable returnable vaccines.

A *Vaccine Wasted and Disposed Form (Form 132)* must be submitted to the MSDH Immunization Program for all non-viable vaccine that cannot be returned to McKesson.

Once a *Vaccine Return Form (Form 131)* is received by the MSDH Immunization Program a request for a return shipping label is sent to McKesson. Providers should expect to receive a return label via email in a few days. Return labels are only valid for 30 days. If the return label is not used within 30 days, you must contact the MSDH Immunization Program. **DO NOT RETURN VACCINE TO THE MSDH IMMUNIZATION PROGRAM.**

VACCINE TRANSFER/TRANSPORT

Proper vaccine inventory management at the provider level plays a major role in preventing the need to transfer vaccines. However, even with proper inventory management, providers may experience a situation where they have soon-to-expire vaccine stock. Where practical, and as long as the cold chain is maintained, transfer of short-dated vaccine can occur between VFC providers to avoid wasting vaccine. This should be a rare occurrence with proper inventory management. Please note, MSDH Immunization Program does not allow the use of vaccine depots for VFC vaccine. Therefore, a VFC provider cannot order large quantities of VFC vaccine for re-distribution to their other VFC facilities.

Vaccine viability is essential for preventing vaccine preventable diseases and transport of vaccines is strongly discouraged by CDC, therefore, transport of vaccines is allowed **ONLY** with prior approval from the MSDH Immunization Program and **ONLY** under the following circumstances:

- Soon-to-expire vaccine (three (3) to six (6) months prior to expiration date)
- Clinic closure requiring redistribution of remaining vaccine
- Area outbreak resulting in an unexpected surge of walk-in patients
- Emergency situations resulting in the activation of the facility's emergency handling plan (prior approval from the MSDH Immunization Program is not required in emergency situations)
- Any other circumstances based on prior approval from MSDH Immunization Program

VFC providers must have a proper process in place to ensure vaccine viability during transfer, as outlined in CDC's Vaccine Storage and Handling Toolkit. The process must include the use of a digital data logger (DDL) with a current and valid Certificate of Calibration Testing for temperature monitoring during transfer, as well as other appropriate equipment. Temperature monitoring documentation must validate the vaccine has not been exposed to a temperature excursion – this documentation must be transported with the vaccine.

Transfer of Varicella and MMR/Varicella (ProQuad) is not recommended except in an emergency due to their fragile nature. If these vaccines must be transported, the following guidelines must be followed:

- Transport only in a portable freezer unit that maintains the temperature between -58°F and +5°F (-58°C and -15°C)
- Use of dry ice is prohibited for transport of frozen vaccines.

TRANSPORT SYSTEM RECOMMENDATIONS

	Emergency Transport	Transport for Off-Site Clinic, Satellite Facility, or Relocation of Stock
Portable Vaccine Refrigerator or Freezer	Yes	Yes
Qualified Container and Packout	Yes	Yes
Conditioned Water Bottle Transport System†	Yes	No
Manufacturer's Original Shipping Container	Yes (last resort only)	No
Food/Beverage Coolers	No	No

Coolants for Transport

PCMs at 4° C–5° C (39° F–41° F) can also be purchased to maintain proper temperatures. Follow the manufacturer's instructions" for use to reduce the risk of freezing vaccines during transport.

Do not use frozen gel packs or coolant packs from original vaccine shipments to pack refrigerated vaccines. They can still freeze vaccines even if they are conditioned or appear to be "sweating."

In emergency situations, a system using conditioned water bottles can be used. Manufacturers' original shipping containers may also be used as a last resort in an emergency situation.

1 Gather the Supplies

Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes.

Insulating material — You will need two of each layer

- **Insulating cushioning material** - Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** - Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

Temperature monitoring device - Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of Insulating cushioning material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

2 Pack for Transport

Conditioning frozen water bottles (this normally takes less than 5 minutes)

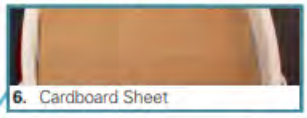
- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.


8. Temperature Monitoring Device Display (on lid)

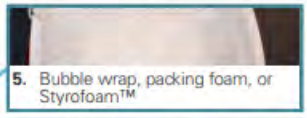
Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.


7. Conditioned Water Bottles

Conditioned frozen water bottles – Fill the remaining space in th cooler with an additional layer of conditioned frozen water bottles.


6. Cardboard Sheet

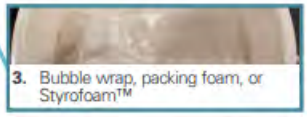
Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.


5. Bubble wrap, packing foam, or Styrofoam™

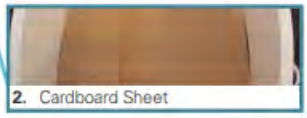
Insulating cushioning material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™


4. Vaccines, Diluents, and Temperature Monitoring Device Probe

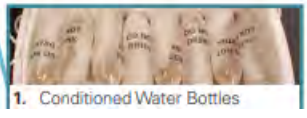
Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.
Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
Vaccines – Stack boxes of vaccines and diluents on top of insulating material.


3. Bubble wrap, packing foam, or Styrofoam™

Insulating cushioning material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).


2. Cardboard Sheet

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.


1. Conditioned Water Bottles

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:
This pack-out can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

1. Conditioned Water Bottles

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.
Storage – Transfer boxes of vaccines quickly to storage refrigerator.
Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

MOVING TO A NEW LOCATION

VFC providers planning to move their clinic to a new location must notify MSDH Immunization Program within 30 days **before** the clinic moves so VFC Program staff can do a "walk-thru" of the new facility to ensure proper storage equipment is in place and review the plan to transport the vaccine. Plans to ensure the vaccine cold chain is maintained before, during, and after the move should include the following:

- Date of the move
- Current address
- New address
- Any changes to the clinic/organization name
- Any change to the medical director who signed the Provider Agreement
- Any change to the vaccine coordinators – primary and backup(s)
- Vaccine storage equipment – new equipment or moving existing equipment
- Vaccine storage plans during the move
- Vaccine storage plan until the storage equipment temperatures are stabilized
- Plans for transporting the vaccines

VFC ordering privileges will be suspended before the move to ensure a vaccine shipment is not compromised by going to a wrong location.

Moving or installing a new refrigerator and freezer will take time to stabilize the temperatures within the unit. You must have at least two (2) consecutive days of documented acceptable temperature readings (36^0F-46°F/2^0C-8°C for refrigerator; -58°F to +5°F/ -50°C to -15°C for freezer) before using units to store vaccines.

It is the VFC provider's responsibility to ensure the current and min/max temperatures are being monitored and documented daily regardless of where the vaccine is located prior to, during, and after the move. The provider will be asked to replace any publicly supplied vaccine that is deemed non-viable due to failure to monitor temperatures as required.

SECTION 7 – SPECIAL CLINIC SETTINGS

TEMPORARY, OFF-SITE, OR SATELLITE CLINICS

VFC providers may conduct temporary, off-site, or satellite clinics. These opportunities can improve access and vaccination coverage for VFC-eligible children. VFC providers **MUST** notify the MSDH Immunization Program prior to holding any temporary, off-site, or satellite clinics. A Temporary, Off-Site, Satellite Provider Agreement must be submitted and approved before these types of clinics can be held as these situations require additional oversight and vaccine accountability.

Not only are these providers required to adhere to all general VFC Program requirements, including screening and documenting VFC eligibility, they must maintain enhanced storage and handling practices, including:

- Only the number of vaccines that are needed for the workday should be transported to the clinic site.
- Vaccines may be transported – not shipped – to a clinic site using vaccine transportation procedures outlined in CDC's Vaccine Storage and Handling Toolkit. This includes transporting vaccines to and from the site at appropriate temperatures and using appropriate equipment (MSDH Immunization Program requires the use of portable vaccine refrigerator units or qualified containers and pack-outs), as well as monitoring and documenting temperatures using a DDL with a probe in buffered material.
- The total time for transport plus clinic workday should be a maximum of eight (8) hours (e.g., if transport to an off-site location is 1 hour each way, the clinic may run up to 6 hours).
- Upon arrival at the clinic site, vaccines must be stored correctly to maintain appropriate temperature 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, the vaccines must be transported back to the VFC provider's permanent location in the approved transport method. Temperature data must be assessed prior to placing vaccines back into storage units to prevent administration of vaccines that may have been compromised.

NOTE: Providers must screen for eligibility, therefore, vaccines from all funding sources (VFC, CHIP, private) should be available at the site.

MSDH Immunization Program does not allow the transport of frozen vaccines to temporary, off-site, or satellite locations. If frozen vaccine must be transported the use of a portable vaccine freezer that maintains temperatures between -58°F and +5°F (-50°C and -15°C) is required and immediately upon arrival to the site, the vaccine must be unpacked and placed in a stand-alone freezer that maintains the previously described temperatures.

MOBILE VACCINE CLINICS

Vaccine storage in mobile vaccine clinics must meet the same VFC storage unit requirements:

- Pharmaceutical/medical grade or stand-alone refrigerators and freezers permanently installed within the mobile clinic. These units may be either under-the-counter or upright units depending on the need.
- The mobile clinic should be plugged into the home site location to either generators or another power source when the mobile clinic is not being used.
- The mobile clinic vaccine storage units must be continuously monitored by a digital data logger with current and min/max temperatures manually checked at least once a day preferably first thing in the morning. The DDLs must be downloaded and reviewed at least monthly and with all temperature excursions.
- The vaccines must be delivered to the VFC provider's "brick and mortar" site, as with all the other VFC vaccines.
- If vaccines are to be permanently stored in the mobile vaccine clinic, the mobile unit must have a permanent source of power, either a generator or other permanent power source, and temperatures monitored daily.

The mobile vaccine clinic is treated as another exam room within the VFC provider site that happens to have wheels and a motor. The mobile vaccine clinic must be inspected as part of the VFC compliance visit. The mobile vaccine clinic will be inspected separately if it has its own VFC Pin number.

The pictures on the following page show an example of a mobile vaccine clinic.


Wellness on Wheels

SECTION 8 – VACCINE ACCOUNTABILITY AND EMERGENCY MANAGEMENT PLAN

STANDARD OPERATING PROCEDURES (SOPs)

VFC providers must develop, maintain, and implement a Vaccine Accountability and Emergency Management Plan with detailed and up-to-date standard operating procedures for routine and emergency vaccine management.

The MSDH Immunization Program has created a Vaccine Accountability and Emergency Management Plan template, which is available on the MSDH website.

A copy of the Vaccine Accountability and Emergency Management Plan must be posted on the vaccine storage unit. All staff handling or administering vaccines should be familiar with this plan, which includes vaccine storage, emergency response plan, and ensuring vaccines are maintained within the required temperature range.

The MSDH Immunization Program recommends that providers use the developed template as it covers all CDC and MSDH required elements. Providers may create their own Vaccine Accountability and Emergency Management Plan; however, it must include all the following items:

- Facility Name, address, and VFC Pin number
- Name and contact information for the medial director, primary vaccine coordinator, and back-up vaccine coordinator(s)
- Emergency vaccine storage facility, physical address, phone number, contact person, and driving directions
- Vaccine Storage Units and Digital Data Logger (DDL) information
    - Make and model of storage units (Pharmaceutical/Household; Stand-alone/Combo)
    - Storage units' serial number
    - Date of last routine maintenance
    - Type of DDL
    - Serial number of DDLs
    - DDLs' calibration and expiration dates, including back-up DDL(s)
- Storage and Handling practices
    - Proper storage and handling practices, including how to handle a temperature excursion or other storage and handling issues
    - Temperature monitoring
    - Vaccine storage (e.g., equipment, placement)
    - Vaccine ordering procedures
    - Vaccine shipping and receiving procedures
    - Inventory control (e.g., stock rotation)
    - Vaccine expiration, spoilage, and wastage handling and prevention
- Staffing
    - Descriptions of the roles and responsibilities of the primary and back-up vaccine coordinators
    - Policy on education and training of facility staff
    - Documentation of training on VFC requirements, including proper storage and handling

- Emergency Response Plan
    - Instruction on what to do in the event of refrigerator or freezer malfunctions, power failure, natural disasters, or other emergencies that could compromise vaccine storage conditions
    - Contact information for refrigerator and freezer maintenance and repair companies
    - Contact information for the vaccine storage unit alarm company (if applicable)
    - Contact information for electric company
    - Sources for packing materials, back-up DDLs, and portable refrigerator/freezer units or qualified containers for transport
    - Policies and procedures for maintaining the vaccine cold chain during transport to and while in emergency storage location

Vaccine Management Plans must be reviewed, updated, signed, and dated annually or more frequently as needed, by the primary vaccine coordinator.

An on-site generator can prevent having to transport vaccines to an alternative storage location during a power outage. A back-up battery power source can be used in lieu of a generator. Backup generators or battery power sources should be tested quarterly and serviced annually (check the manufacturer's guidance for testing procedures and maintenance schedules).

SECTION 9 – SITE VISITS

To ensure the quality of VFC vaccines and the integrity of the VFC Program the MSDH Immunization Program conducts the following type of provider site visits:

- Enrollment
- Compliance
- Unannounced Storage and Handling
- Educational

VFC visits help to determine compliance with VFC Program requirements. This includes identifying potential issues with VFC vaccine accountability and verifying publicly funded vaccines are being stored, handled, and administered in accordance with the laws and policies governing the VFC Program.

The goals of these visits are to:

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

Additionally, the site visits are critical opportunities to engage the provider and provider staff and develop and strengthen ongoing relationships.

As defined in the VFC Provider Agreement, VFC providers agree to participate in these required VFC Program compliance visits, including unannounced storage and handling visits, and other educational opportunities associated with VFC Program requirements. These visits are conducted by MSDH Immunization Program Site Reviewers.

Any MSDH Immunization Program site reviewer who finds or observes storage and handling practices that compromise the safety and efficacy of the VFC vaccines have the authority to act on behalf of the MSDH Immunization Program to retrieve and remove the VFC vaccines from the provider. Replacement may be required under the VFC Vaccine Loss and Replacement policy.

ENROLLMENT VISITS

All new and re-enrolling VFC providers must receive a VFC enrollment visit and meet all CDC-defined criteria prior to receiving public vaccine. The purpose of the enrollment visit is to educate providers on implementing VFC Program requirements and supply appropriate resources.

Newly enrolled VFC providers will receive a site visit which will include training and education on VFC Program requirements. This visit will include:

- Education about VFC Program requirements and confirmation of provider understanding
- Education on proper vaccine storage and handling
- Assessment of vaccine storage equipment and DDLs
- Assessment of temperature monitoring of the storage units
- Usage of MIIX
- Confirmation the providers know whom to contact with questions or if problems arise, especially with storage and handling issues

Providers must supply ten (10) consecutive days of in-range current and min/max temperatures at the time of the visit, copies of the DDLs' valid certificates of calibration and a completed copy of the Vaccine Accountability and Emergency Management Plan with documentation of the primary and back-up vaccine coordinator(s) You Call the Shots training.

MSDH Immunization Program site reviewer must ensure that all providers have the required cold storage units and DDLs in place and that they are maintaining proper temperatures before a vaccine order can take place.

A VFC compliance visit will take place approximately six (6) months after the enrollment visit. Providers must place an order within three (3) months of the enrollment visit to be compliant with the VFC Program and for the required VFC compliance visit to be conducted.

VFC providers are required to maintain all records pertaining to the VFC Program for a minimum of three (3) years and made available upon request. VFC records include, but are not limited to, VFC screening and documentation, temperature documentation and DDL data reports, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.

VFC COMPLIANCE VISITS

The purpose of VFC compliance visits is to evaluate whether providers are complying with and understanding VFC requirements, including those outlined in the Provider Agreement such as:

- Proper screening of VFC eligibility
- Vaccine administration documentation
- Vaccine ordering protocols
- Vaccine management, which includes storage and handling requirements

All enrolled and active VFC providers must receive a VFC compliance site visit every 24 months, at minimum, to ensure compliance with VFC Program standards. Providers may receive a VFC compliance site visit on a more frequent basis. A provider must have ordered and administered vaccines within the past 12 months to remain active.

The VFC compliance visit is designed to protect against fraud and abuse and observe office practices to:

- Ensure compliance with VFC Program reporting, documentation, storage, and handling requirements
- Minimize vaccine loss and wastage
- Ensure vaccines purchased with public funds are administered only to eligible children
- Ensure VFC vaccine stewardship and accountability

A VFC compliance site visit will be scheduled in advance and each visit may take approximately two (2) to three (3) hours or longer based in information obtained prior to and during the compliance visit and training needs at the provider site. The MSDH Immunization Program site reviewer will work with the provider to schedule a time that will cause the least interruption of office practice if at all possible. Either the primary vaccine coordinator, the back-up vaccine coordinator, or both are required to be

present for the compliance visit. MSDH Immunization Program also strongly encourages participation of the medical director or provider(s) during the visit or at least during the wrap-up session.

UNANNOUNCED STORAGE AND HANDLING SITE VISITS

These visits will occur at any time with no notice. The purpose of an announced storage and handling site visit is to assess a provider's compliance with and knowledge of VFC storage and handling requirements. The goal of these visits is to provide guidance and education and to ensure VFC-eligible children are receiving properly managed vaccines.

VFC providers may be chosen at random for an unannounced storage and handling site visits or providers may be prioritized to receive such visits based on:

- The provider's previous history with storage and handling compliance issues
- Time since last VFC compliance site visit
- Excessive or habitual wastage of publicly supplied vaccines in the previous 12 months

During an unannounced storage and handling site visit the site reviewer will assess the vaccine storage units, digital data loggers and temperature documentation. They may also address any areas that were found out of compliance on a previous visit.

AFTER SITE VISIT FOLLOW-UP

At the end of the compliance or unannounced storage and handling site visits the MSDH Immunization Program site reviewer will discuss and document any non-compliant issues found during the site visit with provider staff. These findings will be provided using verbal and written feedback and a time frame in which corrective actions should be completed. Some non-complaint issues can be resolved immediately during the site visit, while others may require follow-up in the form of a written corrective action plan or other required documentation, phone call, or a follow-up visit to ensure corrections were made. Failure to comply with the issues found may result in suspension of ordering privileges or termination from the VFC Program. If any of the vaccine coordinators do not respond after three (3) attempts to contact them regarding resolution of current or ongoing issues the MSDH Immunization Program may contact the signing physician to seek resolution.

EDUCATIONAL VISITS

VFC providers are responsible for training their staff on proper vaccine storage and handling procedures. However, the MSDH Immunization Program staff members are available to help with any additional training needed to ensure compliance with VFC Program requirements.

SECTION 10 – VACCINE LOSS AND REPLACEMENT

Vaccine accountability is the cornerstone of the VFC Program and one of the program's highest priorities. All VFC providers must be accountable for every dose of publicly supplied vaccine distributed to them. VFC providers should continually monitor their facility's vaccine storage and handling practices.

The MSDH Immunization Program acknowledges that providers make good faith efforts to store and handle vaccines appropriately as outlined in this provider handbook. However, the MSDH Immunization Program may require providers to make a dose for dose replacement for any doses of publicly supplied vaccines, this includes VFC, CHIP or 317 vaccines, that have been wasted due to the provider's failure to properly receive, store, or account for the vaccine. VFC providers are required to report all wasted, expired, spoiled, or lost vaccine to the MSDH Immunization Program.

Dose-for-dose replacement with privately purchased vaccine may be required for excessive or habitual wastage of publicly purchased vaccine and the provider's ordering privileges may be suspended until the appropriate replacement has been made. Excessive wastage is defined as wasted vaccine amounts that either exceed $1,500 in value or five (5) percent of the total amount of vaccines received in the previous twelve (12) months.

DEFINITIONS

Wasted: Any vaccine that cannot be used. Wasteful or avoidable loss. Publicly supplied vaccines that are spoiled, expired, lost, or unaccounted.

Expired: Any vaccine with an expiration date that has passed.

Spoiled: Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within the acceptable time frames. Always check with the vaccine manufacturers and the MSDH Immunization Program before determining that a vaccine is spoiled or non-viable.

Lost: Vaccines the provider cannot locate, account for, or has disposed of against VFC policies.

NEGLIGENT SITUATIONS REQUIRING REPLACEMENT

The following negligent situations may require financial replacement if vaccine is deemed wasted, expired, spoiled, or lost. This list includes, but is not limited to:

- Storing vaccine in a dormitory or bar-style refrigerator
- Storing vaccine in a storage unit that cannot consistently maintain proper temperatures
- Failure to document current and min/max temperatures daily
- Failure to download and review DDL data at least monthly and with any temperature excursion
- Not being available for vaccine delivery during vaccine delivery hours as stated on the Provider Profile
- Failure to take immediate or appropriate action for out-of-range temperatures
- Storing refrigerated vaccine in the freezer
- Storing frozen vaccine in the refrigerator
- Spoiled vaccine due to unit being unplugged, disconnected, or door left open or ajar
- Failure to rotate stock leading to excessive expired vaccine
- Provider orders that exceed the provider profile on file leading to excessive expired doses
- Publicly supplied vaccines given to patients who are not eligible to receive it

- Discarding vaccine before the manufacturer's expiration date
- Adjusting doses in MIIX inventory as "administered, but not linked to a vaccine", "matches physical inventory", or "drawn-up, not used".
- Publicly supplied vaccine the provider cannot locate, account for, or has thrown away, or disposed of against VFC policies
- Failure to contact the MSDH VFC Ordering team within two (2) hours to report a damaged or compromised vaccine delivery
- Transfer of publicly supplied vaccines to another provider without prior approval from MSDH Immunization Program.
- Transfer of publicly supplied vaccine to a non-VFC provider
- Any other situations which result in excessive or habitual wastage of vaccine

PROCEDURE FOR VACCINE REPLACEMENT

- The provider will receive a notice from the MSDH Immunization Program director that replacement of publicly supplied vaccine with privately purchased vaccines is required and the reason for replacement.
- Proof of purchase of the private vaccines is required and must be submitted to the MSDH Immunization Program within 60 days of receipt of the notice. Acceptable proof of purchase is the packing list or paid invoice showing type, amount, lot number, and expiration date of the privately purchased vaccine.
- The vaccine will then be added to their MIIX inventory as "public" and used for VFC-eligible patients only (or CHIP-eligible patients if the vaccine purchased is to replace CHIP vaccine).
- The provider will not be able to order VFC/CHIP vaccines until restitution has been made.
- Failure to adhere to this policy will result in suspension of ordering privileges and possibly termination from the VFC Program
- If a provider dis-enrolls or is terminated from the program they will not be allowed to re-enroll until full restitution has been made

Additional information:

- Replacement vaccine: VFC providers who must re-vaccinate due to negligence in failure to keep vaccine viable (temperatures out of range) or improper administration may be responsible for the replacement of the vaccines needed to re-vaccinate.
- Depending on the outcome of any suspected fraud and abuse investigation, providers may be required, among other things, to replace any mishandled VFC vaccines.

SECTION 11 – FRAUD AND ABUSE

OVERVIEW

As childhood vaccinations become more expensive and immunization programs more complex, the VFC Program becomes more vulnerable to fraud and abuse. The MSDH Immunization Program is responsible for ensuring that VFC providers are meeting all VFC Program requirements. Failure to comply with these requirements will result in fraud and abuse charges for the provider. The terms "fraud" and "abuse" related to VFC are consistent with the definitions in Medicaid regulations (42 CFR § 455.2).

Fraud: 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: Provider practices inconsistent with sound fiscal, business, or medical practices and result in unnecessary cost to the Medicaid program (and could include actions that result in unnecessary cost to the MSDH 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 health care. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

Well-organized and correctly administered VFC accountability programs are the cornerstones for preventing potential fraud and abuse incidents. The MSDH Immunization Program strives to emphasize accountability measures through strong educational components carried out during the provider enrollment process, as well as during any VFC site visit. Additionally, communication between MSDH Immunization Program staff and providers can also reinforce training and further prevent situations that may develop into fraud and abuse.

EXAMPLES OF FRAUD AND ABUSE

Some examples of potential fraud and abuse include, but are not limited to:

- Failing to comply with any part of the Provider Agreement or the requirements as outlined in the MS VFC Providers Handbook
- Providing VFC vaccine to non-VFC-eligible patients
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC vaccine
- Charging more than the established maximum regional fee for administration of VFC vaccine (the administration fee for MS is $10.00)
- Over-ordering VFC vaccine in quantities or patterns that do not match the Provider Profile or otherwise stockpiling doses of VFC vaccine
- Failing to comply with ordering guidelines
- Wasting of VFC vaccine
- Denying VFC-eligible children VFC-funded vaccine because of parents' inability to pay the administration fee
- Failing to screen for and document eligibility status at each visit
- Failing to fully account for VFC-funded vaccine
- Failing to properly store and handle VFC vaccine
- Transfer of VFC vaccine without prior approval

- Inappropriate vaccine administration practices
- Failing to maintain VFC records for a minimum of three (3) years

Analyzing VFC Program information is critical to identifying compliance issues and potential fraud and abuse patterns. The MSDH Immunization Program will use Provider Profiles, ordering patterns, VFC site visits, temperature documentation, inventory transaction reports, and doses administered reports to monitor provider compliance with VFC Program requirements.

ADDRESSING PROVIDER NON-COMPLIANCE WITH VFC PROGRAM REQUIREMENTS

Providers agree to comply with VFC Program requirements upon enrollment in the VFC Program and during the recertification period by signing the Provider Agreement. Lack of adherence to the VFC Program requirements by an enrolled provider could lead to fraud and abuse charges for that provider.

Failure to comply with VFC requirements is defined as:

- Any VFC provider who does not maintain the federal and/or state requirements associated with implementation of the Provider Agreement. The details of the federal and state requirements are discussed throughout this provider handbook.

Instances of non-compliance or fraud and abuse may be identified by:

- VFC Program staff
- The enrolled provider's staff
- A third party

The MSDH Immunization Program will investigate all allegations of suspected fraud and abuse and will determine if the situation is intentional fraud and abuse or unintentional abuse or error due to an excusable lack of knowledge of the VFC Program requirements with no purposeful intent to misrepresent or defraud the VFC Program. If the situation is found to be unintentional, an educational intervention will be made, and arrangements will be established to replace any vaccine used inappropriately or unaccounted.

The MSDH Immunization Program staff will provide in-depth education to the provider's key staff regarding the VFC Program and MSDH provider accountability requirements. The provider will be required to submit a signed corrective action plan detailing the steps that will be implemented and taken to prevent further incidents. The signed plan must be submitted to the MSDH VFC manager within thirty (30) days. The provider will be advised that any recurrence of non-compliance or suspected fraud and abuse may result in immediate termination for the VFC Program and possibly referral to an external agency for investigation.

If the allegation is determined to be intentional it will be immediately referred to an external agency for investigation. All suspected cases of fraud and abuse that require further investigation will be referred to the MSDH Epidemiology director and the department's legal counsel and auditor. Suspected cases of fraud and abuse will then be referred to the State Medicaid Fraud Control Unit for investigation and CDC. VFC ordering privileges may be suspended. Depending on the outcome of the investigation providers may be required to, among other things, return all VFC vaccine, replace misappropriated

vaccines, and possible termination from the VFC Program. MSDH reserves any and all rights with respect to any future actions.

FRAUD AND ABUSE CONTACTS

Suspected fraud and abuse may be reported to any of the following MSDH Immunization Program staff:

- Michelle Robertson, VFC Manager: michelle.robertson@msdh.ms.gov
- Jennifer Fulcher, Immunization Program Director: Jennifer.fulcher@msdh.ms.gov
- Dana Thomas, Vaccine Manager: dana.thomas@msdh.ms.gov
- Lois Moore, Community Resources Manager: lois.moore@msdh.ms.gov

Please provide:

- Provider's name
- Facility Name and address
- Brief detail of allegations of fraud and/or abuse
- Reporter's name and contact information

Definitions and Acronyms Used in this Guide

Abuse	**Provider practices inconsistent with sound fiscal, business, or medical practices and result in unnecessary cost to the Medicaid program (and could include actions that result in unnecessary cost to the MSDH 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 health care. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.**
ACIP	**Advisory Committee on Immunization Practices**
Awardee	**Refers to the MS State Department of Health Immunization Program responsible for Implementation of the VFC Program**
CDC	**Centers for Disease Control and Prevention**
Cold Chain	**A temperature-controlled supply chain. An unbroken cold chain is an interrupted series of storage and distribution activities which maintain a given temperature range. It is used to help extend the shelf life and viability of vaccines**
Diluent	**A substance used to dilute. In vaccine use, diluent is used to reconstitute lyophilized (powder) vaccine. Diluents may be sterile water, sodium chloride, or other components. Only the diluent provided with the vaccine should be used with that vaccine. Diluents are not interchangeable.**
Expired Vaccine	**Any vaccine with an expiration date that has passed.**
Facility	**Refers to a specific VFC provider location**
Fraud	**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.**
Lost Vaccine	**Vaccines the provider cannot locate, account for, or has disposed of against VFC policies.**
Lot Number	**An identification number assigned to a particular quantity of vaccines from the manufacturer. The lot number helps to identify the vaccine in case of a recall.**

MSDH Immunization Program/VFC Program	**Mississippi State Department of Health Immunization Program and VFC Program are used interchangeably.**
NDC	**National Drug Code – universal product identified for drugs**
Parent	**Refers to anyone who has legal authority to make decisions on behalf of a child. This can refer to parents, legal guardians, or individuals of record.**
Potency	**Vaccine effectiveness**
Provider	**A health care provider licensed to administer vaccines, as well as the staff within a provider facility who is involved in the storage, handling, and administration of vaccines.**
Recertification	**The act or process of certifying or being certified again. VFC providers must recertify annually to continue participation in the VFC Program.**
Re-enrollment	**To enroll in the VFC Program again after an absence.**
Restitution/Dose for Dose Replacement	**Replacement of lost, wasted, expired, or spoiled publicly supplied vaccines due to provider negligence.**
Spoiled Vaccine	**Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within the acceptable time frames. Always check with the vaccine manufacturers and the MSDH Immunization Program before determining that a vaccine is spoiled or non-viable.**
Vaccine Coordinator(s)	**The staff person(s) in a provider's office designated as the primary contact and who oversees the management of vaccines. This refers to the primary vaccine coordinator and/or back-up vaccine coordinator(s).**
VFC Pin Number	**A special identifier assigned to a provider upon enrollment in the VFC Program**
Viable	**In vaccines, the state in which vaccines are effective.**
Wastage/Wasted Vaccine	**Any vaccine that cannot be used. Wasteful or avoidable loss. Publicly supplied vaccines that are spoiled, expired, lost, or unaccounted for.**

VFC Resources

State Websites:

MS State Department of Health

www.msdh.ms.gov

Federal Websites:

Vaccines and Immunizations

www.cdc.gov/vaccines/

Federal Vaccines for Children (VFC) Program

https://www.cdc.gov/vaccines/programs/vfc/index.html

CDC Storage and Handling Toolkit

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

Advisory Committee on Immunization Practices (ACIP)

http://www.cdc.gov/vaccines/pubs/ACIP-list.htm

CDC – Morbidity and Mortality Weekly Report (MMWR)

www.cdc.gov/mmwr/

National Immunization Organizations

Immunization Action Coalition (IAC)

http://www.immunize.org/

Vaccine Manufacturers

Merck:

https://www.merckvaccines.com/is-bin/INTERSHOP.enfinity?WFS/Merck-MerckVaccines-Site

GSK:

http://www.gsk.com/

Pfizer:

http://www.pfizer.com/home/

Sanofi Pasteur:

http://www.sanofipasteur.com/en/

Seqirus:

http://www.seqirus-us.com/

AstraZeneca:

https://www.astrazeneca-us.com/

Dynavax:

https://www.dynavax.com/