

RESOURCE BOOK FOR VFC PROVIDERS

Program Overview

The Vaccines for Children (VFC) Program was created on August 10, 1993, under the *Omnibus Budget Reconciliation Act of Section 1928 of the Social Security Act*. The VFC Program provides an unprecedented national approach to providing free vaccines to VFC-eligible children (see next page for eligibility guidelines). Qualifying children are entitled to receive all pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices (ACIP).

The success of the VFC Program is built upon the cooperation, collaboration, and participation of many agencies. Michigan providers have been participating in the VFC Program since 1995. In 2010, nearly 1,500 provider sites representing approximately 4,500 physicians enrolled in Michigan's VFC Program. Your active participation in the VFC Program is vital to increasing Michigan's childhood immunization rates and ensuring that all children are protected against vaccine-preventable diseases. Your commitment to a healthier Michigan is commendable!

The past year has presented many new opportunities as we continue to train and educate providers on the Michigan Care Improvement Registry's (MCIR) Vaccine Inventory Module (VIM) and E-ordering. We anticipate several MCIR enhancements in the coming year, including new reports that will make the VIM easier to use. If you have suggestions on work flow processes that you feel would make the VIM more effective and efficient please contact your MCIR Regional Coordinator.

All the information you need to enroll and participate in the VFC Program can be found in this *Resource Book for VFC Providers*. Various forms and resources are updated throughout the year and are posted online at www.michigan.gov/vfc. Click on Providers and follow the links to the forms or resources you need.

As with any program, there are different levels of commitment and adherence to the program requirements. We challenge you to achieve the Michigan Department of Community Health's (MDCH) GOLD standard: to be a provider that knows the guidelines of the program, works within those guidelines, and consistently promotes education regarding the importance of immunizing against vaccine preventable diseases. We are always open to hearing how you, the provider, apply the GOLD standard to the VFC Program within your practice. If you have a question regarding any of the policies, forms or documents provided, or want to share how your practice uses the GOLD standard within your VFC Program, please contact the immunization staff at your local health department (LHD).

Again, thank you for your commitment to a healthier Michigan!

Vaccines for Children (VFC) Program Definitions

VFC Eligibility: Who can receive VFC vaccines?

Children less than 19 years of age are eligible to receive VFC vaccines if they meet one of the following federal requirements:

- are Medicaid eligible
- have no health insurance (uninsured)
- are American Indian or Alaska Native
- are underinsured and served at a FQHC or RHC and Michigan private provider offices*

** In Michigan, LHDs operate under agreements that allow them to act on behalf of Federally Qualified Health Centers (FQHCs) and 317 covers private provider offices for underinsured.*

Underinsured: For the purpose of determining eligibility for the VFC Program, children are considered to be underinsured if the child's insurance does not include **ANY** reimbursement for the cost of the vaccine. A child with health insurance that has no immunization benefit at the time the child presents, is considered to be underinsured and is eligible to receive VFC vaccine. When a child's health insurance generally covers immunizations but a particular VFC vaccine is not covered, that child is VFC-eligible for purposes of administration of that particular vaccine. However, eligibility must be again confirmed at future immunization visits.

Insured: A child is considered to be insured if all or a part of the vaccine is covered by insurance. Co-pays, deductibles, or other charges associated with the cost of a vaccine are considered to be routine costs of health care and the child would not qualify to receive VFC vaccine. A child with insurance that has a cap on preventive care is considered to be fully insured until the cap is fulfilled. Once the cap has been met, the child will then be considered as underinsured. An insured child (including MI-Child enrollees) is ineligible for the VFC Program.

VFC Funding: Where do the funds come from to support Michigan's VFC Program?

The federal government provides two sets of funding for Michigan's VFC Program:

VFC Funding - Provides vaccines for children and adolescents less than 19 years old who are: (a) Medicaid-eligible; (b) uninsured; (c) American Indian/Alaskan Native; (d) underinsured and served at a FQHC or RHC. The VFC Program is an entitlement program and appropriations for entitlement programs are required to be maintained pursuant to federal law. Vaccines are, therefore, required to be provided to all children falling within established guidelines.

317 Funding - Provides vaccines for underinsured children served in private provider offices and for programs like the Michigan Adult Vaccine Replacement Program (MI-VRP), the Universal Hepatitis B Program (for all newborns), and the High Risk Hepatitis A & B Program. Use of 317 funds is set by state policy, based on available federal funds. The Michigan Department of Community Health (MDCH) strives to utilize 317 funds in a manner which best promotes the health of Michigan's citizens.

Administrative Fees: Federal policy has established the maximum fee for administration of VFC vaccine to be \$16.75 per vaccine. Providers using federally procured VFC vaccines **cannot** deny administration of these vaccines due to the inability of a child's parent or guardian to pay the administration fee. Eligibility is required to be reviewed and documented at every VFC immunization visit. Providers may bill parent but cannot send unpaid bill to collection.

VFC: Frequently Asked Questions

(Taken from CDC's VFC Program Q & A Guide. For a complete list of CDC's

Q & A Guide, visit <http://www.cdc.gov/vaccines/programs/vfc/projects/faqs-doc.htm>)

What is the process for including a new vaccine in the VFC program and how are immunization programs informed about the changes?

The Advisory Committee on Immunization Practices (ACIP) has the advisory role to determine what vaccines should be recommended for administration to children, adolescents, and adults in the U.S. and the operational role to approve which vaccines should be available through the VFC program. The ACIP meets three times a year, and during these meetings newly licensed vaccines may be discussed and recommended for use. Once a vaccine is recommended by ACIP, a vote is taken about whether or not to include the new vaccine in the VFC program through consideration of a VFC resolution. VFC resolutions are specific to each vaccine and include who is eligible to receive the vaccine, the vaccination schedule, and precautions or contraindications to the vaccine. Once the VFC resolution is approved, CDC must negotiate a contract for the vaccine to make it available under the VFC program. VFC resolutions are posted on CDC's website.

Do CDC and grantees have any federal requirement to implement ACIP-recommended vaccines?

CDC and immunization programs that receive VFC funds are required to implement ACIP-recommended vaccines for which there are VFC resolutions and for which federal contracts have been established to purchase these vaccines. When using 317, state and local funds for immunizations, implementation of all ACIP recommendations is not required.

Is Medicaid federally mandated to cover ACIP's VFC-recommended vaccines for the Medicaid population?

Yes, all of ACIP's VFC-recommended vaccines are part of the EPSDT benefit package for Medicaid children under age 21. Immunizations through age 18 years are covered by the VFC Program. Children 19 years through 20 years are covered by Medicaid program funds.

How long should VFC records be retained by a provider?

At minimum, the VFC Program provider records must be kept for a period of three (3) years after service to the patient has been completed unless state law/policy establishes a longer archival period.

Who should pay the vaccine administration fee for Medicaid-eligible children?

The state Medicaid agency should be billed for the administration fee for Medicaid-eligible VFC children immunized by a Medicaid-enrolled VFC provider. State Medicaid agencies establish their own policies and administration fees that may be lower than the regional maximum charges established in 1994. For Medicaid VFC-eligible children, the state Medicaid agency determines and CMS approves the reimbursable amount for their fee-for-service and managed care enrolled recipients. If the provider bills Medicaid the regional maximum charge instead of the Medicaid agency's allowable rate, the provider will be reimbursed only the allowable rate and not the amount billed. The difference between the allowable rate and the amount billed cannot be collected from the parents or guardian of the child.

How does a VFC-enrolled provider who is not already a Medicaid provider file for Medicaid reimbursement for vaccine administration?

It is necessary to be a Medicaid provider in order to receive payment from Medicaid for vaccine administration services provided to Medicaid-eligible children. Providers should consult the state Medicaid agency about the procedures necessary to become a Medicaid provider. This agency can be reached by phone at 800-292-2550 or by e-mail at providersupport@michigan.gov.

Can a private provider refuse to administer VFC vaccine to VFC-eligible child?

Section 1928 (c)(2)(C)(iii) of the *Social Security Act* states, "The provider will not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parents to pay an administration fee." The statute further notes at *Section 1928(c)(2)(C)(i)* that "A program-registered provider is not required under this section to administer such a vaccine to each child for whom an immunization with the vaccine is sought from the provider." CDC interprets this to mean that private VFC providers, unless otherwise required by another statute, do not have to honor vaccine requests by VFC-eligible children who "walk in" for immunizations only and are not established patients in the practice. For established VFC-eligible patients and other VFC-eligible patients that the provider chooses to immunize, VFC immunization can not be denied due to the inability to pay an administration fee.

If a family has a medical savings account or health savings account does that account affect a child's VFC eligibility?

Individuals covered by medical savings accounts or health savings accounts must also have high deductible health plan coverage. Therefore, such individuals are insured.

If a child presents for vaccines and does not have health insurance but the parent plans to insure the child, would this child be eligible for VFC vaccine?

If the child has no health insurance on the day he/she presents at the office for immunizations, the child would be VFC-eligible because he/she is uninsured. VFC eligibility screening must take place with each visit even though the patient screening form needs to be updated only when the eligibility status of the child changes.

If a child is eligible for insurance and the parents choose not to insure the child, would the child be eligible for VFC vaccine?

If the child has no health insurance on the day he/she presents at the office for immunizations, regardless of the reason, the child would be VFC-eligible because he/she is uninsured.

Are all children enrolled in Medicaid programs automatically VFC-eligible?

Yes, all children from birth through 18 years of age who are covered by Medicaid are considered VFC-eligible because of their Medicaid status.

Are all children who have Medicaid as a secondary insurance covered by VFC?

Yes, all children who have Medicaid as a secondary insurance are covered by VFC. The state Medicaid agency will pay the claim for the administration fee and seek reimbursement from the primary insurance.

How should providers bill administration fees for VFC vaccines administered to children who are covered by Medicaid and have another form of health coverage?

Generally, providers are required to bill third parties before Medicaid will make payment (we refer to this as cost avoidance). However, there are a few exceptions to the cost avoidance rules. In the case of preventive pediatric services including EPSDT, if the Medicaid agency is billed, it is required to make payment and then seek reimbursement from the third party (CMS

refers to this as pay & chase) - see *Section 1902(a)(25)(E)* of the *Social Security Act*. The Medicaid agency is to seek recovery as long as it is cost effective to do so, i.e., where the amount of reimbursement the State can reasonably expect to recover exceeds the cost of recovery (see *1902(a)(25)(B)*). Since child immunizations fall under this exception, the provider has several options for billing the administration fee: The provider could bill the Medicaid agency first and Medicaid would be responsible for seeking reimbursement from the primary insurance. The provider could bill the primary insurance. If the primary insurance is billed first and the insurance company denies the claim, the provider could then bill the administration fee to Medicaid. The Medicaid agency should bypass their cost avoidance edit allowing the claim to be considered for payment. Also, if the third party payer pays less than the Medicaid amount, the provider can bill Medicaid for the balance up to the amount Medicaid pays.

If a VFC-eligible child starts a vaccine series (such as hepatitis B) at age 18, can the series be completed using VFC vaccine after the child turns 19?

No. Children are eligible to participate in the VFC Program only through age 18 years regardless of the child's immunization status (series completed or not completed) when they age out of VFC.

Other than age and not meeting at least one of eligibility requirements for the VFC Program, are there any other factors that would make a child ineligible to receive vaccine through the VFC Program?

No. As long as the child is under 19 years of age and meets at least one of the following eligibility criteria: enrolled in Medicaid, uninsured, American Indian/Alaska Native, or underinsured, the child is eligible to participate in the VFC Program. No other factors can be considered when screening children for eligibility for participation in the VFC program (e.g. residency status or family income).

If an American Indian/Alaska Native has insurance that covers vaccines (full or partial) is the child still eligible for VFC vaccine?

Yes, American Indian/Alaska Native are eligible to participate in the VFC program regardless of insurance coverage.

Are children who have health insurance but whose insurance covers only a percent of the cost of one or more vaccines eligible for the VFC Program? For example, the insurance covers 80% of the cost of MCV4.

No, these children are considered to be insured for the purposes of the VFC Program and are not eligible to receive VFC vaccine.

Can all children who receive immunizations in a school-based clinic be considered VFC-eligible because of the health care setting where they are obtaining care?

No, all children must be screened for VFC-eligibility prior to each immunization encounter. Since the parents/guardians are not present during the immunization encounter, verbal screening is not possible. In a school-based clinic, the screening process can be incorporated into the immunization consent process. The consent form can incorporate the appropriate screening question; when consent is provided for the immunization, there is documentation of VFC or state-purchased vaccine eligibility status and the appropriate vaccine stock (public or private) can be used to vaccinate the child. School-based clinics must work closely with the state/urban/territory VFC Program to develop an acceptable process to screen for VFC eligibility and, as applicable, state eligibility that meets the federal requirements.

How can clinics with only an occasional non-VFC-eligible child manage such a small amount of private stock vaccine efficiently to prevent loss of the vaccine through expiration?

In these situations, the facility must maintain a stock of privately purchased vaccine to administer to these children. CDC would find it acceptable for these clinics to actively implement the two-directional borrowing policy (using MCIR VIM to record borrowing) to prevent loss of private stock vaccine due to expiration before it can be administered. To properly implement the borrowing policy, the facility must purchase an initial inventory of appropriate private stock vaccines. If the private stock vaccine is not used and is nearing the expiration date, the clinic can use the private stock on VFC-eligible children and document on the borrowing form that private stock vaccine was administered to a VFC-eligible child because the private stock was short-dated. The clinic can then replace the used private stock with VFC vaccine and document when that private stock was replaced.

Where can I get more information on vaccine cold storage and handling?

CDC's Vaccine Storage and Handling Toolkit is available on-line. The link to download the toolkit is <http://www2a.cdc.gov/vaccines/ed/shtoolkit/default.htm>.

What type of storage equipment does the VFC Program require enrolled providers to have to keep VFC vaccine in their practices?*

VFC providers must have appropriate equipment that can store and assist with maintenance of proper conditions of vaccines. Vaccine storage units must be selected carefully and used properly. If a provider does not have the appropriate storage units, the state must work with the provider to obtain storage units that are acceptable. Refrigerators without freezers, and stand-alone freezers, may be better at maintaining the required temperatures. However, a combination refrigerator/freezer unit sold for home use is acceptable for vaccine storage if the refrigerator and freezer compartments each have a separate external door. Refrigerators or freezers used for vaccine storage must comply with the following requirements

1. Be able to maintain required vaccine storage temperatures year-round;
2. Be large enough to hold the year's largest inventory;
3. At a minimum, have a working calibrated and certified thermometer inside each storage compartment. Michigan requires VFC providers to have a calibrated certified thermometer inside each storage compartment. Calibration must be traceable to standards provided by the National Institute of Standards and Technology (NIST) (a U.S. Government agency within the Commerce Department) or a laboratory recognized by NIST. Calibration can be traceable to NIST using American Society for Testing and Materials (ASTM) methods for the calibration process;
4. Be dedicated to the storage of vaccines. (Food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.)

* See Section III for more information on thermometers and refrigeration/freezer units.

Are “dorm-style” refrigerators acceptable storage units for VFC vaccines?

Dormitory-style refrigerators should only be used to store a clinic's single-day supply of **refrigerated** vaccines and these vaccines should be returned to the main refrigerator storage unit at the end of each clinic day. Dormitory-style refrigerators are not adequate for long-term or permanent storage of biological products because they do not maintain appropriate temperatures. Storage of VFC vaccine in refrigerators that are designed for use in small household spaces such as dorm rooms **are never acceptable for permanent storage** of VFC vaccines. Permanent storage is defined as the vaccine supply is maintained in the unit 24 hours a day/7 days a week.

“Dorm-style” refrigerators are only acceptable for short-term storage of select VFC vaccines under **very limited conditions** which are listed below:

- The purpose of using these units is for temporary storage when it is not reasonable for the staff administering the vaccine to go to the main storage unit to obtain vaccine for each and every patient.
- **The unit is never used for storing varicella-containing vaccines.**
- Only small amounts of inactivated vaccines can be maintained in these units. The amount of inactivated vaccines stored in the unit must never exceed the amount used in the clinic in one day.
- The vaccine is returned to the main storage unit at the end of each clinic business day and vaccine is never stored in these units overnight or during periods of time when the practice is not open for business.
- Each unit has a dedicated certified thermometer in place.
- **Temperatures are monitored and documented twice a day on temperature log specifically for that unit.** Appropriate action is immediately taken when the temperatures are outside the appropriate range.
- These units must be included and examined during the VFC compliance visit and corrective actions taken and documented by the LHD and MDCH if the above conditions are not met.

How does CDC define a dorm-style refrigerator?

A dorm-style refrigerator is a small combination refrigerator/freezer unit that is outfitted with one external door, an evaporator plate (cooling coil) which is usually located inside an ice-maker compartment (freezer) within the refrigerator, and is void of a temperature alarm device. Its temperature control sensor reacts to the temperature of the evaporator rather than the general air in the storage compartment. When the compressor is on, the evaporator cools to lower the temperature in the refrigerator, in most cases to below 0°C. The problem with dorm-style refrigerators is that they place vaccine at a high risk of freezing. Ideally, vaccine storage units should be temperature-monitored/alarm-equipped, stand-alone refrigerators and stand-alone freezers. These units, unlike the dorm-style units, will have an evaporator that is located behind the surface of the walls, the back of the refrigerator compartment or, in most cases, in the back of the unit.

What type of guidance can be given to a VFC enrolled provider who is using a small refrigerator that falls into CDC’s definition of a dorm-style refrigerator that has maintained the appropriate temperature according the provider’s log and the field staff’s thermometer regarding why the office must replace the unit?

The LHD and Immunization field representative should educate the provider that while this unit has performed well, these types of units are not reliable in maintaining temperatures needed to keep vaccine safely within the required ranges to prevent unintentional loss of vaccine because it was stored at inappropriate temperatures. CDC has never recommended that these small dorm-type refrigerators be used as permanent storage units for VFC vaccine.

In 2008-2009, CDC started requiring all VFC Programs to work with their enrolled VFC providers to eliminate the use of dorm-style refrigerators as permanent storage units for VFC vaccine.

Effective immediately, VFC providers cannot use a dorm-style refrigerator as a permanent storage unit for VFC vaccine. One of the main reasons that CDC has taken this action is due to the rising cost of VFC vaccine. As VFC vaccine cost approaches \$3 billion, it is essential for the integrity and continuation of the VFC Program to ensure that VFC vaccine is stored in appropriate units which decrease the chance of vaccine loss due to inappropriate

storage conditions. When possible, the LHD and Immunization field representative should share with provider the monetary amount that the VFC vaccine represents in that specific practice to further illustrate the need to store and manage the vaccine appropriately.

Some of our providers have been removing VFC vaccine that comes in manufacturer prefilled syringes from the original packaging to store in plastic containers if storage space is a concern. What is CDC's position on this?

CDC's position is to have providers store vaccine in their original containers to help protect the vaccine from damage due to storage errors. As well as to decrease the possibility of administration errors from inadvertently confusing similarly packaged vaccines.

What is CDC's new policy on two-directional borrowing between VFC and private stock vaccine?

Since November 2007, CDC has allowed borrowing of VFC vaccine to be administered to non-VFC eligible patients in limited circumstances due to an unexpected lack of private stock vaccine. VFC providers are expected to maintain an adequate inventory of vaccine for their non-VFC eligible patients. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory. Providers that care for VFC-eligible and privately insured children must maintain two separate inventories of vaccines, one inventory of privately purchased vaccine for the provider's privately insured children and the inventory of publicly purchased vaccine supplied to the provider for administration to VFC-eligible children. Borrowing between the two inventories of vaccines may occur but must be a rare occurrence. Michigan providers who borrow VFC vaccine are now required to follow the MCIR VIM borrowing policy and provide information detailing the borrowing situation and when the borrowed vaccine was replaced. Beginning in 2010, CDC will begin to collect data on two-directional borrowing of VFC and private stock vaccine from MDCH via MCIR VIM. MDCH will generate MCIR reports to be reviewed by LHDs with providers. In 2010, the borrowing information will be reviewed during the VFC site visit and data collected on vaccine borrowing in the VFC Site Visit Questionnaire as new high priority questions. The results of the questions will be submitted to CDC.

Vaccines Available for Children Less Than 19 Years of Age

Vaccines Available for all VFC-Eligible Children served by any VFC Provider According to Advisory Committee on Immunization Practices' (ACIP) Recommendations:

IPV, DTaP, DTaP-IPV-HepB, DTaP-IPV, DTaP-IPV/HIB, DT, Td, Tdap, MMR, MMRV, Hib, Hep B-Hib, Hep B, PCV13, Varicella, Hep A, HPV2, HPV4, MCV4, Influenza, Rotavirus

Vaccines Available for VFC-Eligible Children with Specific High Risk Conditions served by any VFC Provider:

Influenza – Pediatric

VFC providers may administer routine annual flu vaccine to all VFC-eligible children aged 6 months through 18 years. Children 6 months through 8 years of require 2 doses of flu vaccine during their first season of vaccination. Please reference the 2 dose schedule at www.michigan.gov/flu

Providers are to begin to offer flu vaccinations as soon as vaccine is available. Providers who run out of VFC flu vaccine should contact their LHD to request additional doses. Influenza vaccinations should continue to be offered throughout the influenza season.

23-Valent Pneumococcal Polysaccharide (PPV23) – Pediatric

VFC providers may administer PPV23 to children aged 2 through 18 years to those listed below:

1. Children who have chronic disorders of the pulmonary or cardiovascular systems (excluding asthma).
2. Children who have chronic liver disease or diabetes mellitus.
3. Children who have functional or anatomical asplenia (e.g., sickle cell disease or splenectomy), CSF leaks, or nephrotic syndrome.
4. Children with immunocompromising illness or medications, including those with asymptomatic or symptomatic HIV or who have received a bone marrow transplant.
5. Children who are Alaska Native or American Indian.

DT – Pediatric for ages less than 7 years

1. Can be given only if child has a documented valid contraindication to a previous dose of pertussis containing vaccine.
2. Parents must be counseled by medical provider on risks of lack of pertussis protection.

Requirements of the VFC Program

FEDERAL

1. The immunization schedule, dosage, and contraindications established by the Department of Health and Human Services (DHHS) and ACIP shall be complied with unless: (a) a physician, when making a medical judgment in conformance with accepted medical practice, deems compliance to be medically inappropriate; or (b) a particular requirement is not in compliance with state law, including state laws relating to religious beliefs or other exemptions. The ACIP immunization schedule is compatible with recommendations of both the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).
2. Vaccine Information Statements (VISs) (see Section V of this Resource Book titled *Vaccine Information Statements*) shall be provided to patients/parents/guardians at each visit and must be maintained in accordance with the *National Childhood Vaccine Injury Act (NCVIA)*.
3. A charge shall not be imposed for the cost of vaccine purchased with federal funding. Charging a fee for VFC vaccine is considered to be a fraudulent activity.
4. The administration of a federally procured vaccine shall not be denied due to the inability of the child's parent/guardian/individual of record to pay an administration fee.
5. VFC vaccine shall be administered to a child less than 19 years of age who is:
 - A. Medicaid eligible, or
 - B. Uninsured, or
 - C. Native American or Alaska Native, or
 - D. Underinsured and receives services at a FQHC or a RHC*.

** In Michigan, LHDs operate under agreements that allow them to act on behalf of FQHCs for childhood immunization purposes.*

If private stock vaccine is used to vaccinate a child that is VFC-eligible, it is acceptable to replace a private stock vaccine dose with a VFC dose. If private stock vaccine is unavailable, and the child will not otherwise be vaccinated, it is acceptable to vaccinate the child with VFC vaccine as long as the dose is replaced with a private stock vaccine dose as soon as the provider's private stock vaccine arrives. The above should not be the regular practice of the clinic and shall occur only under exceptional circumstances. Borrowing and replacement of vaccine must be documented in MCIR VIM.

6. Physicians shall maintain records of the authorized representative's responses concerning a child's VFC eligibility. These records shall be maintained for a **minimum period of three years** and release of patient records is governed by the privacy protections set forth in Federal Medicaid law. A provider shall make such records available to a local or state health department or DHHS when requested.
7. Vaccine administration fees for a VFC-eligible child shall not exceed the maximum fee of \$16.75 per injection established by the DHHS.

STATE AND LOCAL

1. Physicians shall use the State's green *Official Certificate of Immunization* to reflect doses of vaccine administered or a copy of the child's immunization record printed from the Michigan Care Improvement Registry (MCIR). The physician shall provide this information to the parent/guardian/individual of record at the time of administration.
2. Physicians shall account for all doses of VFC vaccine received and administered to children in the practice. Physicians shall use either electronic reporting or reporting forms provided by MDCH. Reports are to be provided to the LHD when ordering additional vaccine. Physicians must keep copies of all vaccine orders, doses administered reports, ending inventory reports and temperature logs for three years.
3. Physicians shall comply with the CDC's *Recommendations for Handling and Storage of Vaccines* (<http://www.cdc.gov/vaccines/pubs/vac-mgt-book.htm>) and the storage and handling procedures described in this Resource Book. In the event that a vaccine obtained through the VFC Program is wasted due to expiration, negligence, and/or improper vaccine storage and handling practices, a VFC provider shall reimburse MDCH for the replacement cost of the vaccine(s) wasted. Please review the VFC Lost/Wasted/Borrowed Policy in this Resource Book under Section III, starting on Page 16.
4. Physicians (regardless of whether they use VFC vaccines) shall report the immunizations of any child, born on or after January 1, 1994, seen in their practices to the MCIR (*Public Health Act 540 of 1996*). Physicians are encouraged to report records of all children and adults. Physicians who are not authorized users of the MCIR should call their regional MCIR office to enroll. Your regional MCIR contact number can be found in this Resource Book under Section IV – Page 6.
5. Local Health Departments (LHDs) are expected to perform the following activities:
 - A. Work with each VFC provider to assure that their annual *VFC Provider Enrollment Form* is accurately completed and submitted in a timely manner.
 - B. Submit a *VFC Provider Enrollment Form* for the LHD and each of the LHD's satellite clinics.
 - C. Receive vaccine orders from VFC providers and review supporting documents, approve and place orders with MDCH.
 - D. Be accountable to MDCH for all doses of vaccine administered
 - E. Conduct VFC site visits with VFC providers. Site visit objectives are to:
 - i. ensure that providers have the most current resource materials available on immunization,
 - ii. review methods for VFC vaccine storage and handling, vaccine accountability, record-keeping, and compliance with VFC regulations,
 - iii. assess the quality of immunization practices, and
 - iv. prepare a corrective action plan when necessary and a process to track follow-up activities related to the corrective action plan.
 - F. Disseminate immunization information and updates about the program to all providers within their jurisdiction as needed.
 - G. Provide ongoing education and technical assistance to private providers and staff as needed.
 - H. Keep all VFC-related documents for 3 years, including: LHD temperature logs, all provider enrollments, site visit questionnaires/follow up, provider orders, and vaccine losses.
6. Local Health Departments that border other states (Wisconsin, Ohio, and Indiana) will have agreements in place with those states to vaccinate VFC-eligible children with VFC vaccine regardless of which state the child resides in.

Vaccines Available Through the VFC, MI-VRP, High Risk Hepatitis A & B Programs, and Medicaid Programs (as of 08/11/11)

Vaccine Name	Manufacturer(s)	VFC Program	MI-VRP Program	High Risk Hepatitis A & B Program	Medicaid Coverage for Adults
DT (Pediatric)	sanofi pasteur	√			
DTaP	sanofi pasteur, GlaxoSmithKline	√			
DTaP-IPV	GlaxoSmithKline	√			
DTaP-IPV-Hep B	GlaxoSmithKline	√			
DTaP-IPV/HIB	Sanofi Pasteur	√			
Hepatitis A (adult)	GlaxoSmithKline, Merck		√	√	√
Hepatitis A (pediatric)	GlaxoSmithKline, Merck	√		√	
Hepatitis B (pediatric)	GlaxoSmithKline, Merck	√		√	
Hepatitis B (adult)	GlaxoSmithKline, Merck		√	√	√
Hib-Hepatitis B	Merck	√			
Hib-ActHIB-OmniHIB Hiberix (PRP-T)	sanofi Pasteur, GSK	√			
Hib-PedvaxHIB (PRP-OMP)	Merck	√			
HPV4 and HPV2	Merck, GlaxoSmithKline	√			√ (19-26 yr)
Influenza (split)	sanofi pasteur	√			√
Influenza (intranasal)	MedImmune	√			√
IPV	sanofi pasteur	√			
Meningococcal Conjugate (MCV4)	sanofi pasteur, Novartis	√			√
MMR	Merck	√	√		√
MMRV	Merck	√			
Pneumococcal Polysaccharide (PPV23)	Merck	√			√
Pneumococcal Conjugate (PCV13)	Pfizer	√			
Rotavirus	Merck, GlaxoSmithKline	√			
Td (Peds)	sanofi pasteur	√			√
Td (Adult)	Merck		√		√
Tdap	sanofi pasteur GlaxoSmithKline	√	√		√
Varicella	Merck	√			√
Zoster Vaccine	Merck				Medicare D

VFC vaccine is for eligible children less than 19 years of age, at all VFC provider offices, except HPV4 for under-insured males, must refer to LHD. High Risk Hepatitis A & B Program is for adolescents and young adults regardless of insurance status, at LHDs, STD clinics, teen health centers, and family planning clinics.

MI-VRP is available for uninsured and underinsured adults 19 years of age and over who meet certain risk factors, and are seen at LHDs, FQHCs, Tribal and Migrant Health Centers.

Medicaid covers adult vaccines except zoster vaccine. Medicare Part D may cover all or part of the zoster vaccine.

Michigan's Vaccines for Children (VFC) Program Fraud and Abuse Policy

The purpose of this document is to outline the policy and procedures to prevent, detect, investigate, and resolve fraud and abuse regarding Michigan's VFC Program.

FRAUD AND ABUSE PREVENTION

Fraud, as it is defined in *42 CFR 455.2*, is "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."

Abuse is defined as "provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care..."

The Division of Immunization of the MDCH has defined the following roles and responsibilities as part of the daily operation of the VFC Program regarding identification and prevention of fraud and abuse.

A. Provider Role/Responsibility

- Prior to enrolling in the VFC Program, new immunization providers shall receive training and education regarding the VFC Program's objectives and requirements.
- All immunization providers, who participate in the VFC Program, are required to submit a signed *VFC Provider Enrollment Form*, which includes a provider profile. Providers shall receive a pre-enrollment VFC site visit before they can receive vaccine. Providers shall update their forms annually to continue to receive vaccine. The *VFC Provider Enrollment Form* outlines provider requirements for participation in the VFC Program. By signing the *VFC Provider Enrollment Form*, providers certify that they will comply with all VFC Program requirements.
- The Michigan VFC Program requires providers to reimburse for VFC vaccines that are wasted due to expiration and/or improper vaccine storage and handling practices.

B. Local Health Department (LHD) Roles/Responsibilities

- Provide training and education to new and existing VFC providers regarding the VFC Program's objectives and requirements.
- Conduct AFIX/VFC site visits.
- Be observant for indicators of fraud and abuse.
- Conduct on-site reviews of providers who have vaccine storage and handling problems.
- Review all incoming vaccine orders, inventory reports, temperature logs and doses administered reports. If inconsistencies are found on these reports (e.g., ordering more vaccines than usual, reports of wasted/expired vaccines), the LHD shall follow-up with the provider to resolve any issues.
- Follow-up on problems until improvements are made and maintained.
- Make referrals to the MDCH INE program if additional provider education is indicated regarding the VFC Program and/or vaccine safety, storage and handling concerns.

C. Division of Immunization Role/Responsibilities

- Develop VFC Program policy, including an annual update of the *Resource Book*.
- Conduct site visits and educational trainings with LHD staff.
- Monitor the VFC Program at the LHD level.
- Act as a resource to LHD inquiries regarding the VFC Program.
- Collaborate with Medicaid staff on fraud and abuse policies, and on **suspected** fraud and abuse cases.
- Operate as the liaison with the Medicaid Program.
- Screen VFC providers for suspended, revoked licenses or exclusion from CDC contracts

Examples of Fraud and Abuse

Instances of fraud and abuse are often reported as complaints or referrals from outside sources regarding a provider who has inappropriately used vaccines or who has billed Medicaid or private insurers for the cost of VFC vaccines. Fraud and abuse may also be detected during a review of a provider's vaccine order or during AFIX/VFC site visits.

Examples of fraud and abuse that VFC staff may encounter include (list is not exhaustive):

- Providing VFC vaccine to a non-VFC-eligible child
- Providing VFC vaccine to clinics or persons for which it is not intended or to individuals not enrolled in the VFC Program
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC vaccine
- Charging more than the established maximum vaccine administration fee involving an eligible child
- Refusal to provide VFC vaccine to an eligible child due to a parents'/guardian's inability to pay the administration fee
- Failure to implement provider enrollment requirements of the VFC Program
- Failure to screen patients for VFC eligibility
- Failure to maintain VFC records and to comply with other requirements of the VFC Program
- Failure to fully account for VFC vaccine
- Failure to properly store and handle VFC vaccine
- Ordering VFC vaccine in quantities or patterns that do not match provider profiles or otherwise involves excessive ordering of VFC doses
- Wastage of VFC vaccine

REPORTING ALLEGATIONS OF FRAUD OR ABUSE

Private Sector

A patient, who suspects a physician of committing fraud and/or abuse concerning VFC vaccines, shall contact the local health department of their county and supply them with detailed information. To access a map and link of Michigan's local health departments, go to: <http://www.michigan.gov/mdch/0,1607,7-132-2945-96747--,00.html>.

A private provider, who suspects another physician of committing fraud and/or abuse concerning VFC vaccines, shall contact the local health department and supply them with detailed information.

Local Health Department

A local health department, who suspects a provider of VFC fraud and/or abuse, shall contact the MDCH Immunization Program.

The MDCH Immunization Program phone number for reporting fraud and abuse is: (517) 335-8159. This phone number is staffed Monday through Friday from 8:00 am – 5:00 pm.

To report suspected Medicaid Fraud or Abuse online, go to:

<http://www.michigan.gov/mdch/0,1607,7-132-2943-220188--,00.html>.

RESPONSE TO AN ALLEGATION OF FRAUD OR ABUSE

If you are contacted regarding a suspicion of VFC fraud or abuse, the following information should be collected when possible:

- name and contact information of the person reporting the fraud/abuse (assure them this information will be kept confidential)
- name and contact information of the suspected provider
- relationship between the reporting person and the provider
- detailed information regarding the fraud/abuse
 - dates
 - timeline
 - examples of what took place

Assure the individual that you will look into the allegation and thank them for reporting.

All allegations will be assessed in conformance with the requirements of *42 CFR 455.15*. If it is determined that there was no intentional deception, misrepresentation or negligent deception or misrepresentation of the VFC Program by the provider or office staff, the situation may be appropriate for correction through an educational referral process.

The following criteria will be utilized to determine if an incident is appropriate for an educational referral:

- amount of money lost by the VFC Program
- any inadvertent financial gain of the provider
- how the incident was identified
- length of time the situation occurred
- provider's willingness to replace lost VFC vaccine with privately purchased vaccine
- provider's willingness to participate in the educational referral and post-education follow-up process

It should be noted that incidents involving unintentional abuse (clearly excusable lack of knowledge or understanding of the VFC Program) are nevertheless unacceptable. The response to instances of unintentional abuse will vary depending on the circumstances of the incident and whether other instances of fraud or abuse (either intentional or unintentional) have previously occurred. In most circumstances, education will be the proper response in lieu of criminal enforcement. However, the investigative/enforcement referral requirements of *42 CFR 455.15* shall be followed to determine if an educational intervention is appropriate.

PROCEDURES FOR RESPONSE TO ANY ALLEGATION OF FRAUD OR ABUSE

Investigation of an allegation involving fraud or abuse begins with the local and/or the assigned MDCH Immunization Field Representative contacting the provider and reviewing the allegation with the provider. A critical component of this review is to Document, Document Document!

1. The MDCH VFC Program staff will immediately discuss the alleged fraud and abuse case with the Immunization Program Management staff.
2. The MDCH VFC Program and the MDCH Immunization Program will respond to any allegation of fraud and abuse within five working days of the allegation.
3. Where possible, an on-site visit shall be conducted within five business days of the allegation.
4. Attempts shall be made to educate providers and to provide them with an opportunity to change their policies/procedures to ensure future compliance with VFC guidelines. If a provider was unaware that their practices were fraudulent and intends to immediately rectify the situation, documentation of these facts shall be made and a copy of the investigation's findings and corrective action shall be given to the provider.
5. Follow up with the provider shall occur at 30 days and again at six months. If the provider continues to comply with VFC guidelines, the investigation may be closed. A copy of all documentation regarding the investigation shall be kept on file with the local health department and a copy shall be submitted to the MDCH Immunization Program.

An investigation in which a provider refuses to acknowledge wrongdoing and cannot/will not provide documentation to demonstrate compliance with VFC guidelines, will be referred to the appropriate State agency for further investigation.

1. If appropriate, the MDCH VFC Program staff shall refer the allegation of fraud and/or abuse to the CDC and Centers for Medicaid and Medicare Services (CMS) Investigation Section-Medicaid Integrity Group via email within ten working days from assessment.
2. The CMS referral should be sent to the Medicaid Program Investigation Manager.
3. The referral document shall be submitted in a hard copy format, written on department letterhead and sent via inter-departmental mail. Supporting documentation shall be included.
4. In addition to the above-mentioned information, MDCH VFC Program staff will provide any additional information requested by Medicaid or CDC. No HIPAA-sensitive material will be e-mailed.

A Fraud and Abuse Algorithm, outlining the educational follow-up steps to take with a fraud and/or abuse allegation, can be found in this section beginning on page 18.

SHOULD VACCINES BE REMOVED FROM THE PRACTICE?

If an allegation of fraud or abuse has been substantiated and the matter has moved forward for investigation by the offices of Medicaid Integrity Group or the Michigan Attorney General's Office, all VFC vaccine in the provider's possession shall be collected and returned to the LHD. MDCH may provide an on-site visit with the provider to explain the procedures and to assist in removal of VFC vaccines. The provider shall be prohibited from receiving future shipments of VFC vaccine and their VFC PIN number shall be inactivated in VTrckS and MCIR.

Providers who have been determined to have engaged in intentional fraud and/or abuse, shall be required to re-apply for VFC Program participation. Providers will receive education and follow-up from the MDCH Immunization Program staff. Providers prosecuted for fraud/abuse shall be added to the VFC fraud file until reinstatement of their medical license.

MDCH Immunization Program Fraud and Abuse Contacts:

Terri Adams, VFC Coordinator.....Fraud and Abuse Coordinator
Kevin Czubachowski, MDCH Immunization Field Representative.....Back-up Person #1
Darcy Wildt, VFC Accountability Coordinator.....Back-up Person #2

COLLABORATING AGENCIES

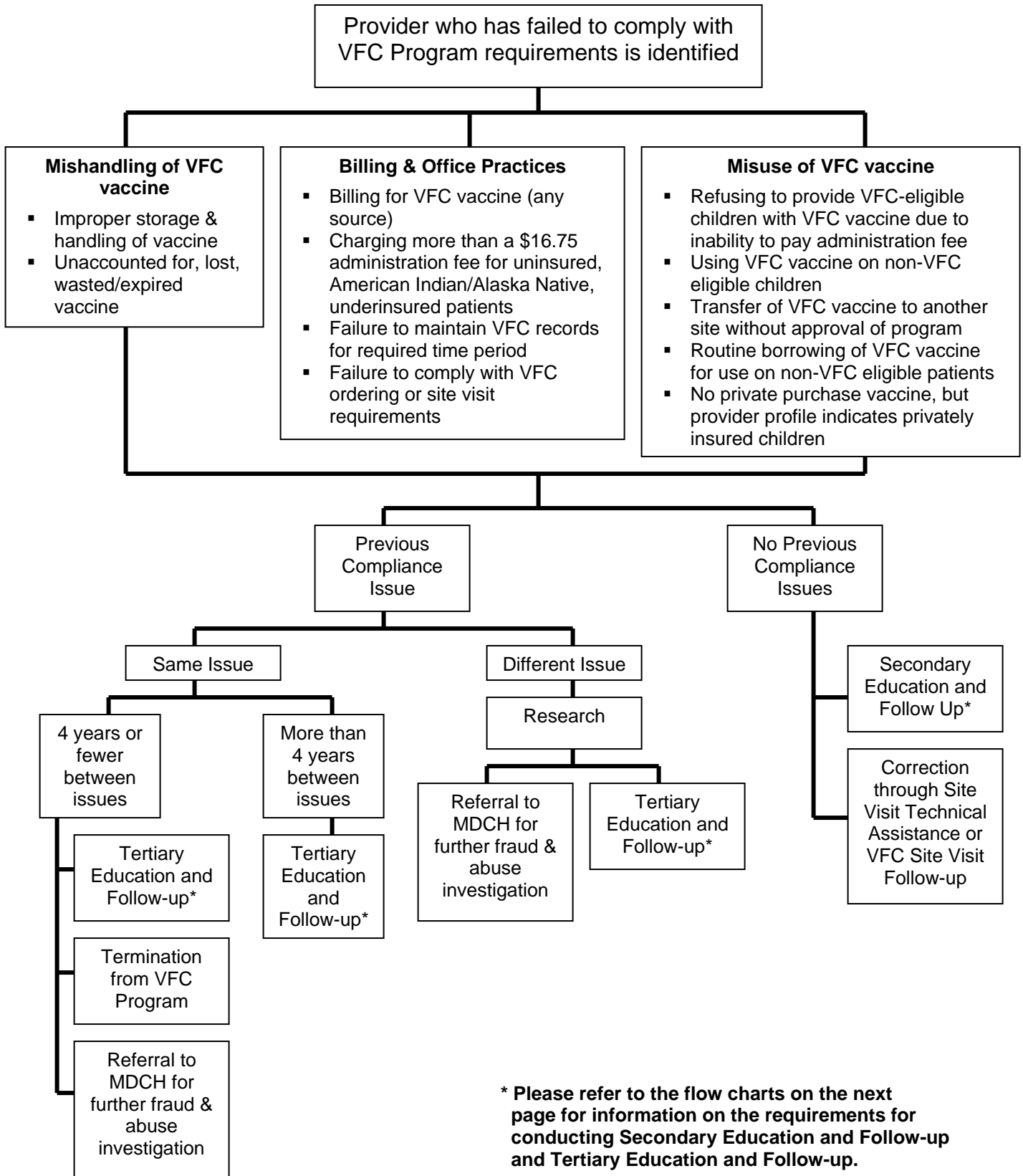
Michigan Medicaid

Identifies questionable provider practices and conducts preliminary investigations into complaints of Medicaid fraud and abuse. If there is sufficient information to conclude that fraud or abuse has occurred, a full investigation may be conducted and the case referred to the Medicaid Integrity Group or appropriate law enforcement agency.

Medical Fraud Control Unit (MFCU)

Investigates and prosecutes (or refers for prosecution) violations of State law pertaining to fraud in the administration of the Medicaid Program, the provision of medical assistance, or the activities of providers of medical assistance under the State Medicaid plan. The MFCU also works with State Medicaid agencies to develop methods and procedures to identify, detect, and investigate potential fraud and abuse. The MFCU is located within the Department of the Attorney General’s office, which has statewide authority to prosecute individuals for violations of criminal laws involving the Medicaid Program.

FRAUD AND ABUSE ALGORITHM



Secondary Education and Follow-up

- Provider is educated regarding VFC Program requirements
- Provider completes a Corrective Action Plan
- LHD conducts 1-2 Follow-ups (e-mail, phone or in-person) post identification
- LHD conducts focused VFC Compliance Site Visit 3-12 months after entry into education

Education Effective?

Yes. Return to routine follow-up

NO. Intervention by MDCH Field Representative

Tertiary Education and Follow-up

Referral to MDCH for further fraud & abuse investigation

Termination from program.

Tertiary Education and Follow-up

- Provider is educated regarding VFC Program requirements and completes a Corrective Action Plan
- LHD conducts 2-3 Follow-ups (e-mail, phone or in-person) between corrective action plan and six months
- LHD conducts focused VFC Compliance Site Visit 6-12 months after entry into education

Full VFC Compliance visit between 1-2 years after focused VFC Site Visit

Education Effective?

Yes. Return to routine follow-up

NO. Intervention by MDCH Field Representative

Repeat Tertiary Education Process

Referral to MDCH for further fraud & abuse investigation

Termination from program.