

## VFC ELIGIBILITY – WHO CAN RECEIVE VFC VACCINES?

Children through 18 years of age (under 19) who meet at least one of the following criteria are eligible to receive VFC vaccine:

- Medicaid – eligible or Medicaid enrolled
- Uninsured
- American Indian or Alaska Native
- Underinsured (has insurance, but the insurance does not include vaccines or does not cover all ACIP recommended vaccines) – Consider the child underinsured if they have subsequent visits while still on the same policy to avoid the borrowing and replacing of vaccines.

MI-Child has merged with Medicaid and those children are now eligible for VFC vaccine under the Medicaid eligibility code.

Occasionally, children may be VFC-eligible for more than one eligibility category. A provider must select and document the eligibility category that will require the least amount of out of pocket expense to the parent/guardian for the child to receive necessary immunizations. When vaccinating a child who presents with dual insurance coverage – both Medicaid and private insurance – you must choose to either vaccinate with VFC vaccine, bill Medicaid for the administration fee and record the child as Medicaid in MCIR OR use private stock vaccine, bill the private insurance company for the vaccine and the administration fee and record child as fully insured in MCIR. You cannot use VFC vaccine and bill the private insurance company for the administration fee. It's one or other – not a combination of both.

Children who have a Medicaid spend down are considered uninsured. Once the spend down amount has been met and they are eligible for Medicaid the eligibility code would change to Medicaid.

Children whose health insurance covers the cost of the vaccinations are not eligible for VFC vaccines. This applies even when a claim for the cost of the vaccine and its administration fee would be denied for payment by the insurance carrier because the plan's deductible has not been met. A child is considered to be insured if all or a part of the vaccine is covered by insurance. Unfortunately, co-pays and deductibles (even very large ones) 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 insurance cap is fulfilled. Once the insurance cap has been met, the child is then considered underinsured and eligible for VFC vaccine because the insurance will no longer cover vaccines.

VFC eligibility must be reviewed and documented at every immunization visit. In Michigan, the maximum fee for administration of VFC vaccine is \$23.03 per vaccine. Providers using VFC vaccines **cannot** deny administration of these vaccines due to the inability of a child's parent or guardian to pay the administration fee. Providers may bill the parent, but cannot send an unpaid bill to a collection agency.

## VFC PROGRAM FUNDING

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

VFC Federal Funding - Provides vaccines for children and adolescents through 18 years old who are: Medicaid - eligible or Medicaid enrolled; Uninsured; American Indian or Alaska Native;

Underinsured and served at a Federally Qualified Health Center (FQHC) or Rural Health Center (RHC). The VFC Program is an entitlement program and appropriations for entitlement programs are required to be maintained pursuant to federal law. Vaccines must be provided to all children who meet the eligibility criteria at no cost to the children who might not otherwise be vaccinated because of the inability to pay. In Michigan, Local Health Departments (LHDs) operate under agreements that allow them to act on behalf of FQHCs to serve underinsured children within LHD clinics.

317 Federal Funding - Provides vaccines for underinsured children served in private provider offices and at select locations for special 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 Health and Human Services (MDHHS) strives to utilize 317 funds in a manner which best promotes the health of Michigan's citizens.

In Michigan, state funds are budgeted to support both the Universal Hepatitis B Program as well as some of the vaccines available under the MI-VRP Program for adult vaccination.

## **VACCINES AVAILABLE THROUGH THE VFC PROGRAM**

The following vaccines are available and must be provided for all VFC-eligible children served by all VFC providers (excluding specialty clinics and Universal Hep B hospitals) according to Advisory Committee on Immunization Practices' (ACIP) recommendations:

DTaP, DTaP-IPV, DTaP-IPV-HepB, DTaP-IPV/HIB, Hep A, Hep B, Hib, HibMenCY, 9VHPV, Influenza, IPV, MCV4, MENB, MMR, MMRV, PCV13, Rotavirus, Td, Tdap, Varicella

### **Influenza – Pediatric**

VFC providers should administer routine annual flu vaccine to all VFC-eligible children aged 6 months through 18 years. Children 6 months through 8 years of age may require 2 doses of flu vaccine during the flu season. Please reference the 2 dose schedule at [www.michigan.gov/flu](http://www.michigan.gov/flu).

Providers are asked to pre-book flu vaccine in January or February (dependent on CDC's timeline). Flu vaccine is automatically shipped to providers, usually beginning in late August. Providers should offer flu vaccine to their patients as soon as the vaccine is available. Vaccinating against influenza disease should continue throughout the influenza season. Providers who run out of VFC flu vaccine should contact their LHD to request additional doses. Providers may not borrow VFC flu vaccine for their private pay patients under any circumstances

## **VACCINES AVAILABLE FOR VFC-ELIGIBLE CHILDREN WITH SPECIFIC HIGH RISK CONDITIONS SERVED BY ANY VFC PROVIDER:**

### **23-valent Pneumococcal Polysaccharide Vaccine (PPSV23) after PCV13:**

**VFC providers may administer PPSV23 to children and adolescents aged 2 through 18 years with underlying medical conditions listed below:**

1. Chronic heart disease, particularly cyanotic congenital heart disease and cardiac failure
2. Chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy)
3. Chronic liver disease, chronic renal failure or nephrotic syndrome

4. Congenital or acquired asplenia or splenic dysfunction
5. Sick cell disease (SCD) and other hemoglobinopathies
6. Cerebrospinal fluid leaks
7. Diabetes mellitus
8. Cochlear implant
9. Diseases associated with treatment with immunosuppressive drugs or radiation therapy including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; generalized malignancy; solid organ transplantation; or multiple myeloma
10. HIV infection
11. Congenital or acquired immunodeficiency
12. Children who are Alaska Native or American Indian

### **Serogroup B Meningococcal Vaccines (MenB):**

1. Children aged 2 months through 10 years who are at increased risk for meningococcal disease attributable to serogroups A, C, W, and Y, including:
  - a. Children who have persistent complement component deficiencies (including inherited or chronic deficiencies in C3, C5-C9, properdin, factor H, factor D, or taking eculizumab [Soliris®])
  - b. Children who have anatomic or functional asplenia, including sickle cell disease
  - c. Children infected with Human Immunodeficiency Virus (HIV)
  - d. Children traveling to or residing in countries in which meningococcal disease is hyperendemic or epidemic, particularly if contact with local population will be prolonged (MenACWY vaccines only)
  - e. Children identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroups A, C, W, or Y
2. All children aged 11 through 18 years

### **DT – Pediatric for ages less than 7 years**

Can be ordered only if child has a documented valid contraindication, precaution or reason for delay from a previous dose of pertussis containing vaccine and

- Parent(s) has been counseled by medical provider on risks of lack of pertussis protection.
- Order has been pre-approved by LHD and MDHHS.

## FEDERAL REQUIREMENTS OF THE VFC PROGRAM

1. Providers must comply with the immunization schedule, dosage, and contraindications established by the Department of Health and Human Services (DHHS) and ACIP 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) must 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 children through 18 years of age who meet at least one of the following criteria:
  - Medicaid – eligible or Medicaid enrolled
  - Uninsured
  - American Indian or Alaska Native
  - Underinsured (has insurance, but the insurance does not include vaccines or does not cover all ACIP recommended vaccines)

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 an insured 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. This must occur only under exceptional circumstances. Borrowing and replacement of vaccine must be documented in the MCIR Vaccine Inventory Module (VIM). VFC flu vaccine is an exception to the borrowing rule – VFC flu vaccine cannot be used on private pay patients under any circumstances.

6. Physicians shall maintain records of the authorized representative's responses concerning a child's VFC eligibility for a **minimum period of three years**. 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 \$23.03 per injection established by the DHHS.
8. Vaccine Manager and Back-up Manager must receive (and have documentation of) annual training on VFC Program requirements and vaccine storage and handling.

## STATE & LOCAL REQUIREMENTS OF THE VFC PROGRAM

Health care providers using VFC vaccines must:

1. Order appropriate amounts of vaccine per their assigned ordering pattern (no more than a 1-3 month supply) and use the vaccines with the earliest expiration dates first. Notify LHD of vaccine stock that is expiring within 6 months and not expected to be used before the expiration date so that it can be redistributed.
2. Store and handle vaccines per Vaccine Management guidelines in Section II.
3. Immediately contact the LHD in the event of suspected vaccine loss or for questions about vaccine storage or viability of the vaccine. MDHHS requires dose for dose replacement with private stock vaccine for VFC vaccine wasted due to expiration, negligence, or improper vaccine storage and handling practices.
4. Administer VFC vaccines only to VFC-eligible children. Have private stock vaccine on hand for non-VFC-eligible patients. Public and private vaccine stock must be separated and clearly marked.
5. Account for vaccines received and administered by completing and submitting ending inventory and doses administered reports and temperature logs when ordering additional VFC vaccine. Providers must keep copies of these reports and logs for 3 years.
6. Document as required by *Statute 42 US Code 300aa-25* and CDC (see page 11 in this section).
7. Screen and document VFC eligibility at each immunization visit and maintain records for 3 years.
8. Allow the LHD to conduct a VFC site visit, including: a) access to 10 charts to review VFC eligibility screening and documentation, and b) chart reviews related to quality assurance activities.
9. Record doses of vaccine administered for the patient's personal record by using the State's *Official Certificate of Immunization* (green immunization record card), a printed record from the Michigan Care Improvement Registry (MCIR), or a vaccine administration record generated from the provider's Electronic Medical Record (EMR).
10. Provide a current VIS for each vaccine administered at each visit. In Michigan, each VIS must contain the MCIR statement. Visit [www.michigan.gov/immunize](http://www.michigan.gov/immunize) for the most current VIS.
11. If the patient is a Medicaid beneficiary enrolled in a qualified health plan (QHP), provide information on the beneficiary's immunization status to the QHP. For information on the QHP's requirements for immunization services, contact the QHP or refer to the contract between the provider and the QHP. For Medicaid beneficiaries not enrolled in health plans who are receiving traditional fee-for-service care, bill the Medical Services Administration for the vaccine administration fee, using the appropriate codes. For more information about Medicaid billing, contact Medicaid Information at 1-800-292-2550 or [providersupport@michigan.gov](mailto:providersupport@michigan.gov).
12. Report all immunization records of vaccinated children to the MCIR within 72 hours. For further information on the MCIR, please contact the Immunization program at your LHD or your regional MCIR contact. A listing of MCIR contacts can be found in on page 8 in Section III – Resources.
13. Share immunization data with LHDs, schools, and other medical providers according to HIPAA guidelines. Using MCIR to share immunization records assures HIPAA compliance.
14. Routinely re-assess the quality and effectiveness of immunization practices, using the *Standards for Child and Adolescent Immunization Practices* (see page 9 in this section) as the guideline for that assessment.
15. Have a Vaccine Manager and a Back-up Manager physically onsite who are responsible for the day-to-day operations of the VFC Program. Report any changes in these two staff to the LHD.

# MICHIGAN'S SPECIAL PURPOSE IMMUNIZATION PROGRAMS

## Universal Hepatitis B Vaccination Program for Newborns

To encourage the immunization of **all** newborns with the birth dose of hepatitis B vaccine before discharge from the hospital, MDHHS makes vaccine available with state and federal funding to hospitals for all newborns born in Michigan. The *Vaccines for Children (VFC) Program Enrollment Form* and the *Universal Hepatitis B Vaccination Program for Newborns - Hospital Provider Profile Form* must be updated and submitted annually. The vaccine is available for **all** newborns **for the first dose**, regardless of eligibility status.

Hospitals are required to report hepatitis B vaccinations to the MCIR. The easiest way to submit this data is to note the immunization on the electronic birth certificate (EBC). The data may also be provided to the MCIR by other methods. Hospitals must use MCIR VIM and order Hepatitis B vaccine through MCIR E-ordering.

## High Risk Hepatitis A & B Program

The High Risk Hepatitis A & B Program is designed to protect the health of adolescents and adults at increased risk for hepatitis A or B infection, and whose age and/or dependency status may be a barrier to seeking health care related to these risks. Under this program, pediatric and adult hepatitis A & B vaccines are available to STD clinics, teen health centers, and family planning clinics (including those types of clinics located within a LHD setting) across the state to vaccinate adolescents and adults of any age regardless of insurance status\* who meet one of the high risk criteria listed on page 7 under the Michigan Adult Vaccine Replacement Program (MI-VRP) vaccine indications for hepatitis A and/or B vaccines.

The program provides hepatitis A & B vaccines for participating clinics, but does not provide reimbursement for vaccine administration fees. Providers may be reimbursed for vaccine administration fees for vaccinating Medicaid-eligible clients. Providers should use MI-VRP as the eligibility code when documenting the dose in MCIR.

\*Youth less than 19 years of age who qualify for the VFC Program should be served with VFC hepatitis A or B vaccine.

## Michigan Adult Vaccine Replacement Program (MI-VRP)

Only the vaccines listed below are provided for uninsured and underinsured adults 19 years of age or older, who meet certain risk factors and are seen at LHDs, FQHCs, Migrant Health Centers (MHCs) and Tribal Health Centers (THCs). Rural Health Centers (RHCs) and private providers cannot participate in this program. **Adults with vaccine insurance coverage or Medicaid do not qualify for this program, however, adults with a Medicaid spend down are considered uninsured and would be eligible.** Medicaid will cover vaccine and administration costs for the vaccines included in the MI-VRP Program. LHDs, FQHCs, MHCs and THCs must use privately purchased vaccine for adult Medicaid-enrolled clients and bill Medicaid.

### Tdap or Td

Tdap is recommended to be given to all persons aged 19 years and older:

- If they have no documentation of a previous dose of Tdap
  - Regardless of the interval since their last Td dose (when pertussis protection is

needed, there is no minimal interval between the last dose of Td and a dose of Tdap)

- Even if they are not in contact with infants less than 12 months of age

Persons aged 19 and older should receive a Td booster every 10 years once they have received one dose of Tdap.

## **MMR**

Adults **born on or after 1/1/57**, who do not have a documented history of having received one or more doses of MMR vaccine at least 28 days apart. An adult that previously had only one dose of MMR and qualifies for MI-VRP may receive the second dose of MMR under this program.

## **Hepatitis A**

People who meet one of the following criteria:

- Household and/or sexual contact of a hepatitis A virus (HAV)-infected person
- Man who has sex with other men
- Person with an acute or chronic liver disease, including those with hepatitis B virus (HBV) and/or hepatitis C virus (HCV) and persons who receive clotting factor concentrates
- Injecting drug user or a non-injecting methamphetamine user
- Persons traveling to or working in countries where HAV is endemic
- Unvaccinated persons who anticipate close personal contact (e.g., household or regular babysitting) with an international adoptee during the first 60 days after arrival in the United States from an endemic country

## **Hepatitis B**

Persons who meet one of the following criteria:

- A household and/or sexual contact of a hepatitis B surface antigen (HBsAg)-positive person
- Sexually active person who is not in a long-term mutually monogamous relationship (e.g., a person with more than one sex partner during the previous six months)
- Person seeking evaluation or treatment for a sexually transmitted disease
- Man who has sex with other men
- Current or recent injection-drug user
- Person with end-stage renal disease; predialysis, hemodialysis, peritoneal dialysis, or home dialysis
- Person with acute or chronic liver disease, including those with hepatitis C virus (HCV)
- Person with diabetes
- Person with HIV infection
- Persons seeking treatment at: STD treatment facilities, HIV testing and treatment facilities, facilities providing drug abuse treatment and prevention services, health care settings targeting services to injection drug users or men who have sex with men, correctional facilities, end-stage renal disease programs and facilities for chronic hemodialysis patients, and institutions and nonresidential day care facilities for persons with developmental disabilities.
- Persons susceptible to HBV infection who are foreign-born from HBV endemic countries (for a list of these countries, visit CDC's website at <http://wwwnc.cdc.gov/travel/yellowbook/2016/infectious-diseases-related-to-travel/hepatitis-b>).

Pre- and/or post-vaccination serology may be considered for at-risk adults. For more information, please refer to:  
<http://www.cdc.gov/vaccines/pubs/pinkbook/hepb.html#serologic>.

## **HPV**

Individuals who meet one of the following criteria:

- Females age 19 years through 26 years, without history of completed series
- Males age 19 years through 21 years, without history of completed series
- Males age 22 through 26 years, within a high risk group
  - Immunocompromised due to infection (including HIV), disease or medication
  - Men having sex with men

## **PCV13\***

Individuals 19 years and older with one of the following criteria:

- Have CSF leak
- Cochlear implant
- Functional or anatomic asplenia (including sickle cell disease or splenectomy)
- Immunocompromising conditions including: HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure or nephrotic syndromes, congenital or acquired immunodeficiencies
- Receiving treatment using corticosteroids or radiation therapy
- Persons who have received a solid organ transplant
- Persons 65 years and older who have never received one dose of PCV13

## **PPSV23\***

Persons who meet the following criteria:

- Ages 19-64 years with asthma or who smoke cigarettes
- Persons 65 and older - vaccinate with one dose if have not received a dose at or after age 65

## **Zoster**

Adults age 60 years and older, regardless of zoster disease history, who have no insurance coverage for this vaccine (a high co-pay does not make them eligible for the vaccine).

An adult with a complete documented series of a vaccine is considered up to date and not eligible for MI-VRP. The administration fee for MI-VRP vaccines should not exceed \$23.03. If the administration fee poses a barrier to receiving the vaccine, please consider waiving the fee.

\*For a schedule of pneumococcal vaccines refer to Use of Pneumococcal Vaccines (PCV13, PPSV23) for Adults handout.

## VACCINES AVAILABLE THROUGH THE VFC, MI-VRP, HIGH RISK HEPATITIS A & B PROGRAMS, AND MEDICAID PROGRAMS (as of December 19, 2016)

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-ActHIB (PRP-T)	sanofi Pasteur	√			
Hib-Hiberix	GlaxoSmithKline	√			
Hib-PedvaxHIB (PRP-OMP)	Merck	√			
9VHPV	Merck	√	√		√ (19-26 yrs)
Influenza (split)	sanofi Pasteur, GlaxoSmithKline	√			
Influenza (intranasal)	MedImmune	√			√
IPV	sanofi pasteur	√			
Meningococcal Conjugate (MCV4)	sanofi pasteur, GlaxoSmithKline	√			√
MENB	GlaxoSmithKline, Pfizer	√			
MMR	Merck	√	√		√
MMRV	Merck	√			
Pneumococcal Polysaccharide (PPSV23)	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

\* 19 year olds eligible for Hepatitis B vaccine under the High Risk Hepatitis A & B Program and/or MI-VRP Program should be vaccinated with a pediatric dose of Hepatitis B. The dose should be coded as MI-VRP in MCIR.

## Standards for Child and Adolescent Immunization Practices

### Availability of vaccines

1. Vaccination services are readily available.
2. Vaccinations are coordinated with other healthcare services and provided in a medical home when possible.
3. Barriers to vaccination are identified and minimized.
4. Patient costs are minimized.

### Assessment of vaccination status

5. Healthcare professionals review the vaccination and health status of patients at every encounter to determine which vaccines are indicated.
6. Healthcare professionals assess for and follow only medically indicated contraindications.

### Effective communication about vaccine benefits and risks

7. Parents/guardians and patients are educated about the benefits and risks of vaccination in a culturally appropriate manner and in easy-to-understand language.

### Proper storage and administration of vaccines and documentation of vaccinations

8. Healthcare professionals follow appropriate procedures for vaccine storage and handling.
9. Up-to-date, written vaccination protocols are accessible at all locations where vaccines are administered.
10. Persons who administer vaccines and staff who manage or support vaccine administration are knowledgeable and receive ongoing education.
11. Healthcare professionals simultaneously administer as many indicated vaccine doses as possible.
12. Vaccination records for patients are accurate, complete, and easily accessible.
13. Healthcare professionals report adverse events following vaccination promptly and accurately to the Vaccine Adverse Events Reporting System (VAERS), and are aware of a separate program, the Vaccine Injury Compensation Program (VICP).
14. All personnel who have contact with patients are appropriately vaccinated.

### Implementation of strategies to improve vaccination coverage

15. Systems are used to remind parents/guardians, patients, and healthcare professionals when vaccinations are due and to recall those who are overdue.
16. Office- or clinic-based patient record reviews and vaccination coverage assessments are performed annually.
17. Healthcare professionals practice community-based approaches.

The *Standards for Child and Adolescent Immunization Practices* is endorsed by 43 organizations including the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), the American Medical Association (AMA) and the Immunization Action Coalition (IAC). <http://pediatrics.aappublications.org/content/112/4/958/T1.expansion.html>

## **ENROLLING AS A VFC PROVIDER**

Enrollment into the VFC Program is done via MCIR. New providers can complete an online enrollment by going into the Enroll in VFC Program from their MCIR home page. Once the form is completely filled out they must submit the form, which goes to the local health department for their county. LHD staff will follow up with new providers once a VFC PIN has been assigned for next steps, which include training on the VFC Program, an initial enrollment site visit, and MCIR VIM & E-order training.

### **Vaccines for Children (VFC) Enrollment Form/Provider Agreement**

The Vaccines for Children (VFC) Program enrollment form collects basic information about the practice as well as a listing of the licensed health care providers within the practice. The form must be signed by the Medical Director of the practice who takes responsibility for the practice's use of VFC vaccines and agrees that all staff members within the practice will follow the outlined requirements for the administration and storage of VFC vaccine. The Medical Director must be licensed to administer pediatric vaccines in Michigan.

### **Provider Profile**

The Provider Profile information is a projection of the children served annually in the practice who need immunizations, and the portion of that group of patients who are eligible to receive VFC vaccines. The profile data allows MDHHS to estimate the state's annual need for federally-funded vaccine and monthly ordering patterns. Profile data also provides documentation of vaccine use for auditing purposes. New providers should work with their LHD to complete the profile. In the case of a new practice, the profile may be estimated, but the rationale for the estimate and the source of the data must be stated.

### **Ordering Vaccines**

Before a provider can order VFC vaccines the provider must have completed the initial enrollment visit and been trained on VFC guidelines and how to use the MCIR VIM and E-order functions. In addition, the LHD must review one month's worth of temperature logs that show temperatures are being recorded twice a day and the storage units are maintaining consistent acceptable temperatures.

### **Re-Enrollment of Active Providers**

Re-enrollment in the VFC Program is an annual process at the beginning of the calendar year. LHDs will notify their providers that the link to re-enroll is available. Providers should re-enroll by April 1. MDHHS will inactivate all providers who have not re-enrolled by May 1st. If you have any questions on enrolling or re-enrolling in the VFC Program, please contact your local health department.

### **Medicaid Health Plan (MHP) Providers**

The following information is taken from the Practitioner section, 3.12 Immunizations, in the Medicaid Provider manual (July 1, 2015 version). The complete manual can be found at: <http://www.mdch.state.mi.us/dch-medicare/manuals/MedicaidProviderManual.pdf>

“For Medicaid beneficiaries enrolled in a MHP, the health plan must ensure that the beneficiary has access to receive complete and timely immunizations. When a provider contracts with a health plan to provide primary care (which includes immunizations), the provider should immunize the beneficiaries assigned to them by the plan. MHP providers enrolled in the VFC program are encouraged to immunize and are discouraged from referring beneficiaries to a LHD for these services.”

## VFC SITE VISITS

VFC site visit data provides MDHHS with information necessary to complete annual reports used to assess the degree to which Michigan meets CDC requirements for the VFC Program.

Providers new to the VFC Program will receive an initial site visit, which includes a detailed review of the site's vaccine storage and monitoring equipment, an overview of the site's general vaccine handling procedures and review of VFC Program requirements.

LHDs must conduct site visits with at least 50% of their providers every year with the remaining 50% of providers visited the following year. MDHHS recommends that LHDs work toward the goal of visiting as many providers as possible every year.

LHDs are responsible for conducting VFC provider site visits within their jurisdiction to assure vaccine storage and handling requirements are being followed and appropriate standards for immunization practices are being met. The site visit presents a face-to-face opportunity for the LHD to answer any questions a provider might have about the VFC Program as well as work with the provider to develop a corrective action plan to address any issues found during the visit.

CDC requires MDHHS to conduct unannounced site visits throughout the state every year. These visits may be randomly selected or based on storage and handling concerns.

At minimum, personnel identified as the Primary Vaccine Manager and the Back-up Manager of the provider site are required to complete annual educational training, by (ideally) being present at the entire site visit OR by completing and documenting two in-person INE trainings or two CDC You Call the Shots web module trainings (VFC and Vaccine Storage and Handling modules), or a combination of one training of each. It is recommended that ALL office staff who work with VFC vaccine receive training on the requirements of the VFC program and correct vaccine storage and handling procedures. In addition, staff identified as the Primary Vaccine Manager and Backup Manager must complete MCIR VIM training.

Participating in an Assessment, Feedback, Incentive & eXchange of information (AFIX) visit provides physician offices with successful immunization strategies which identify information about their pediatric patients' immunization status, vaccination coverage levels and barriers to immunizing patients. Provider sites with children 19-36 months old and/or adolescents 13-17 years of age will receive an AFIX quality assurance review in conjunction with their VFC site visit.

## DOCUMENTATION REQUIRED AT EACH IMMUNIZATION VISIT

(Required by 42 US Code 300aa-25 and CDC, unless otherwise noted)

### Immunization Records

- ⇒ Type of vaccine given (i.e. DTaP, MMR)
- ⇒ Date vaccine and VIS given
- ⇒ VIS version date
- ⇒ Vaccine manufacturer
- ⇒ Vaccine lot number
- ⇒ Site vaccination given (i.e., left arm)\*
- ⇒ Route of vaccination (i.e. IM or SC)\*
- ⇒ Signature and title of vaccine administrator
- ⇒ Name and address of clinic
- ⇒ VFC eligibility status<sup>ψ</sup>

\*Documentation is encouraged.

<sup>ψ</sup>VFC eligibility must be recorded on the immunization record or somewhere in the chart. Electronic Medical Records (EMRs) are becoming the future of medical documentation. Providers with EMRs must assure all required fields are contained in their EMR.

**State law (*Public Health Act 540 of 1996*)  
requires documenting immunizations in the MCIR  
within 72 hours of vaccination regardless  
of whether the child receives VFC or private stock vaccine.**

## VACCINES FOR CHILDREN (VFC) VACCINE LOSS POLICY (Rev. 1/24/17)

The Vaccines for Children (VFC) Vaccine Loss Policy applies to all providers actively enrolled in the Michigan VFC Program. This policy supersedes all policies previously issued by the Michigan Department of Health and Human Services (MDHHS) addressing lost, wasted or borrowed VFC vaccine.

MDHHS, the Centers for Disease Control and Prevention (CDC), and VFC providers share a common interest in ensuring that all eligible children receive immunizations. It is important that VFC providers account for and store VFC vaccine appropriately to avoid loss of vaccine due to expiration, storage and handling issues, and administration errors. This helps ensure that all Michigan's VFC-eligible children have access to an adequate supply of vaccine. The focus of Michigan's restitution policy is poor vaccine management, specifically, loss due to expiration and loss due to cold chain failures.

### Expired Vaccine

It is MDHHS's expectation that expired VFC vaccine is replaced dose for dose with privately purchased vaccine. CDC policy requires that the dose for dose replacement with privately purchased vaccine take place within 90 days of the expired vaccine loss.

Following these simple steps will help you avoid having to replace expired vaccine:

- Check and rotate your stock on a monthly basis
- Administer shorter-dated vaccines first
- Post a vaccine expiration date table on your refrigerator
- Use the Reminder/Recall function in MCIR to administer doses that will soon expire. Recalls must be done before requesting your LHD to redistribute the vaccine.
- Watch MCIR – vaccines expiring in six months are highlighted in green; purple means they're due to expire in only three months!
- Share MCIR expiration email notifications with all staff to ensure vaccine gets used before the expiration date
- Notify your local health department (LHD) three to six months prior to expiration if you believe you will not be able to administer the vaccine before the expiration date. Under this timeframe, and as long as appropriate storage and handling procedures were followed as evidenced by temperature logs and/or data logger files, the LHD is obligated to receive the vaccine and either use it within their own clinic or redistribute the vaccine to another clinic for use. If a LHD takes vaccine from a provider and there is less than three months to the expiration date and the doses subsequently expire, the provider who originally ordered the vaccine is responsible for replacement of the expired doses.

Due to the seasonal nature of flu vaccine and the difficulty of accurately predicting distribution of the vaccine and public demand for the vaccine, dose for dose replacement of **expired** flu vaccine is not required.

### Cold Chain Failures

Vaccine must be stored, handled, administered, and transported according to VFC vaccine storage and handling guidelines. Whenever the viability of a vaccine is in question due to improper storage and handling, the vaccine manufacturer(s) must be contacted. If the manufacturer determines the vaccine is acceptable to use, written documentation from the manufacturer must be obtained. If the manufacturer(s) determines that the vaccine is non-viable, the doses must be transferred out of inventory using the correct MCIR transaction:

1. Return to Distributor or
2. Non Return Open MDV – for open multi-dose vials

The vaccine must be removed from the unit and marked DO NOT USE. Once the transactions have been recorded in MCIR you must go to your MCIR home screen and under the Vaccine Mgmt section choose the Return/Waste Reporting link, select Create a New Return/Waste Report and then check the boxes of all vaccine being reported. Add a corrective action plan, including any information (lot & exp. date) on replacement of the vaccines, and submit the report for approval. Note: Once you create a report and hit submit the information cannot be changed.

Dose for dose replacement is usually required for vaccine non-viable due to a storage and handling issue, however, these are some of the things MDHHS reviews in determining the level of vaccine replacement:

- Was the provider available to accept the vaccine delivery during stated vaccine delivery hours?
- Was the vaccine stored promptly upon arrival?
- Was the vaccine stored within the appropriate temperature range?
  - Refrigerator 2 - 8°C / 36 - 46°F
  - Freezer -15°C / 5°F to -58°F
- Did the provider respond to alarms or out-of-range temperatures?
- Is the provider using data loggers and downloading and reviewing the data weekly?
- Was the emergency response plan followed?
- Did the provider do everything they could to ensure the viability of the vaccine?

If dose for dose replacement of non-viable doses is determined, the replacement must take place within 90 days of the vaccine loss. If private vaccine was stored in the same storage unit as the compromised VFC vaccine, the provider must submit a paid invoice for private vaccine used to replace lost VFC doses.

Providers with losses that exceed a VFC dollar value of \$1500 are required to complete a Vaccine Accountability INE training session before the loss is considered resolved. If the provider site received a Vaccine Accountability INE session within 90 days of the vaccine loss, this requirement can be waived unless the LHD feels the provider staff would benefit from a repeated training.

## **Wasted Doses**

Dependent upon the storage and handling practices conducted by the clinic, dose for dose replacement of the vaccine is not usually required for the following types of vaccine loss:

- Accidental breakage
- Drawn but not used (which includes parent changed mind; vaccine/syringe/needle compromised; child moved and dose was unable to be administered)

These types of vaccine wastage should be recorded in MCIR using the corresponding transaction under Adjustment. An educational training/intervention may be required if a provider office has an above average occurrence of these types of vaccine losses.

All wastage must now be reported to CDC. At minimum once per month you should create a Wastage report in MCIR and submit that report for approval.

## **Withholding VFC Vaccine Due to an Unresolved Vaccine Loss**

The LHD and MDHHS have the authority to withhold VFC vaccines from a clinic with an open, unresolved (90 days or older) vaccine loss until doses are replaced and all corrective action to avoid occurrence of another loss is completed.

## Medical Errors Requiring Revaccination

When a vaccine has been administered in error (incorrect vaccine, wrong age group, improper administration, using non-viable vaccine, etc.) and the patient is required to be re-vaccinated, a provider must re-vaccinate the patient with privately purchased vaccine.

## Short-Dated Vaccine

If vaccine has been assigned a shortened expiration date by the manufacturer due to an out-of-range temperature excursion, the vaccine cannot be re-distributed to another clinic unless the receiving clinic is notified of the circumstances and agrees to accept the vaccine. If the receiving clinic is unable to administer the vaccine prior to the shortened expiration date, the original provider shall be responsible for the dose for dose replacement of that vaccine.

## Borrowed Vaccine

VFC providers must maintain an adequate inventory of vaccine to administer to both privately insured and VFC-eligible children. CDC allows borrowing of vaccine between two vaccine inventories only as a rare, unplanned occurrence. Borrowing can occur only when there is:

1. A lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment,
2. Vaccine spoiled in-transit to the provider, or
3. New staff calculated ordering time incorrectly.

Replacement of VFC vaccine with private vaccine stock is required upon receipt of the private vaccine stock. Vaccine doses must be replaced with like-kind vaccine (e.g., if one dose of VFC ActHIB vaccine is used, one dose of privately purchased vaccine stock ActHIB must be used for replacement). Providers must have private stock inventory in VIM in order to accurately replace borrowed VFC doses under these guidelines. **Providers must not borrow VFC vaccine that they are unable to replace with private stock vaccine.**

For seasonal flu vaccine, providers may use private-stock seasonal flu vaccine to vaccinate VFC-eligible children if VFC seasonal flu stock is not yet available. Those private stock doses used on VFC-eligible children can later be replaced when VFC stock becomes available. The replacement must be for the exact same product including the same presentation (Fluzone for Fluzone, prefilled syringes for prefilled syringes, single antigen vials with single antigen vials, etc.). You should not borrow more private stock vaccine than what you have pre-booked through VFC. **VFC flu vaccine should never be used on private pay patients.** This one-directional borrowing exception is unique to seasonal flu vaccine and a new requirement of CDC.

If at the time of service the child was reported as fully insured, private pay vaccine administered and insurance was billed with eligibility code of “private pay/fully insured” recorded in MCIR, but 3-6 months later vaccine payment was rejected by insurance, VFC will replace the private vaccine doses with VFC vaccine doses. This is because the child at the time of service was actually VFC eligible as “underinsured” but parent/guardian was unaware. Provider office staff must change this child’s eligibility in MCIR for the doses rejected from “private pay” to “underinsured”, which will create a borrowed transaction from the private inventory. Now VFC

owes vaccine to the private stock and provider office staff must go into MCIR VFC inventory and create a “replace borrowed” transaction for the doses that were rejected and now have eligibility changed to “underinsured”. VFC vaccine must also be physically moved from VFC vaccine inventory to private vaccine inventory in the vaccine storage units. Replacing doses for underinsured rejections must be completed in a 6-8 months from time of service or as soon as rejection is received.

### **Lost VFC Vaccine Doses**

Pursuant to *Public Health Act 540 of 1996*, all healthcare providers are required to enter vaccine doses administered into the Michigan Care Improvement Registry (MCIR) within 72 hours. MCIR is the primary system used by the VFC Program to account for VFC vaccine doses received and administered by VFC providers. Based on the data entered by providers, MCIR tracks the number of doses that are received, administered, wasted, returned to McKesson, and borrowed.

Prior to submitting a VFC vaccine order, it is required that an *Ending Inventory Report* be completed in MCIR. To do this, providers must conduct a physical inventory of the vaccines stored in their refrigerator(s) and freezer(s) and enter these numbers into MCIR. Ideally, the number of doses in your refrigerator(s) and freezer(s) will match what is reflected in MCIR. In the event the numbers do not match, it is necessary to thoroughly review the administration history of your vaccines and determine if all data has been entered into MCIR and if a data entry error has occurred regarding doses administered or wasted. It is also recommended that you physically re-count your vaccines. Every effort should be made to reconcile unaccounted for doses of VFC vaccine. In those circumstances where you are unable to reconcile your current vaccine inventory with what is reflected in MCIR, doses that cannot be accounted for are considered lost doses. You must have approval from your LHD before using the Unable to Locate/Lost transaction in MCIR. LHDs and MDHHS may withhold vaccine orders until improved accountability is demonstrated by the provider office. If accountability for lost VFC doses does not improve, dose for dose replacement of those lost doses with private stock vaccine will be required. Lost doses must be recorded in MCIR and reported to CDC through the Returns/Wastage reporting process.

### **Returning Non-viable Vaccine to McKesson (what to do with the vaccine vials)**

1. Record transactions in MCIR for vaccines that have expired or have not been stored according to CDC’s guidelines. If you don’t know the correct transaction please contact your LHD or MCIR Region Contact. Incorrect transactions cannot be corrected once a loss report has been submitted.
2. Under Vaccine Mgmt on your MCIR home page, select the Return/Waste Reporting link
3. Create the report and submit the report to your LHD for approval. Be sure to check the boxes for all vaccines being reported and add a corrective action plan. In addition, if doses have been replaced with private stock vaccine, add the lot number and expiration date of the replaced doses as well as the date they were transferred into your VFC inventory.
4. Once the report has been processed at the MDHHS level, a return label will be emailed to the VFC Primary Contact as outlined under the VFC Enrollment section in MCIR.

**See page 35 in Section II for more information on returning vaccine to McKesson.**

## **MICHIGAN’S 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 within 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..."

### **Examples of fraud and abuse (list is not exhaustive):**

- Providing VFC vaccine to a non-VFC-eligible patient
- 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

The following roles and responsibilities are part of the daily operation of the VFC Program regarding identification and prevention of fraud and abuse.

### **A. Provider Role/Responsibility**

- Complete educational trainings regarding the VFC Program as provided by the LHD. These trainings include education on VFC program requirements, ACIP immunization recommendations, reporting requirements, and vaccine storage and handling.
- Complete training requirements for MCIR VIM as provided by Regional MCIR staff.
- Comply with all VFC Program requirements as outlined in this Resource Book.
- Replace with private stock all VFC vaccines that are wasted due to expiration and/or improper vaccine storage and handling practices.
- Be observant for indicators of fraud and abuse within your practice. Report any suspected fraud and abuse to:
  - your LHD

- The MDHHS Fraud & Abuse hotline at 517-335-8159 (staffed Monday – Friday, 8 am to 5 pm),
- The Medicaid Fraud & Abuse hotline at 1-855-MI-FRAUD (643-7283), or
- online at <http://www.michigan.gov/MDHHS/0,1607,7-132-2943-220188--,00.html>

## **B. LHD Roles/Responsibilities**

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

## **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.
- Screen VFC providers for suspended, revoked licenses or exclusion from CDC contracts.
- Act as a resource to LHD inquiries regarding the VFC Program.
- Collaborate with Medicaid staff on fraud and abuse policies.
- Substantiate reported fraud and abuse incidents.
- Report suspect fraud cases to Medicaid and CDC for further investigation.

## **DOCUMENTING FRAUD OR ABUSE ALLEGATIONS**

When possible, the following information should be collected regarding a suspicion of VFC fraud or abuse:

- 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

All allegations are confidential and will be assessed in conformance with the requirements of *42 CFR 455.15*. If it is determined 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 educational training(s).

The following criteria will be utilized to determine if an incident is appropriate for correction through educational training(s):

- 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
- Provider's willingness to revaccinate, if necessary

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.

## **INVESTIGATION OF SUSPECTED FRAUD**

Investigation of an allegation involving fraud begins with the LHD and/or the assigned MDHHS Immunization Field Representative contacting the provider and reviewing the allegation with the provider. All aspects of the review should be well documented.

1. The MDHHS VFC Program staff will immediately discuss the alleged fraud and abuse case with the Immunization Program Management staff.
2. The MDHHS VFC Program and the MDHHS 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 LHD and a copy shall be submitted to the MDHHS 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 MDHHS 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, MDHHS VFC Program staff will provide any additional information requested by Medicaid or CDC. No HIPAA-sensitive material will be e-mailed.

### **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. MDHHS may provide an on-site visit with the provider to explain the procedures and to assist in removal of VFC vaccines, if necessary. 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 prosecuted for fraud/abuse shall be added to the VFC fraud file until reinstatement of their medical license.

#### **MDHHS Immunization Program Fraud and Abuse Contacts:**

Ninah Sasy, MDHHS VFC Coordinator.....Fraud and Abuse Coordinator  
 Kevin Czubachowski, MDHHS 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.

Providers who have been removed from the program for intentional fraud and/or abuse, shall be required to re-apply for VFC Program participation.