

*Excerpts from CDC's 2016*  
**The Vaccines for Children  
Operations Guide**



**VFC**

National Center for Immunization and Respiratory Diseases  
Immunization Services Division



## Important Note from the Alaska Immunization Program

The purpose of CDC's VFC Operations Guide is to communicate VFC programmatic information to state, local, and territorial immunization programs (a.k.a. "awardees"). This document contains excerpts from CDC's 2016 VFC Operations Guide. It does **not** replace the Alaska Vaccine Distribution Program Handbook which includes all federal and state requirements for receiving state-supplied vaccine. The purpose of this document is to provide additional information to assist providers in their efforts to comply with VFC requirements.

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# VFC Program At-A-Glance

The Vaccines for Children (VFC) program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of an inability to pay.

Publicly purchased vaccine for eligible children are supplied at no charge to VFC-enrolled public and private providers in all 50 states, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands.

## VFC FAST FACTS

- The VFC program represents an unprecedented approach to improving vaccine availability nationwide by making federally purchased vaccine available to both public and private immunization providers.
- VFC was created by the Omnibus Budget Reconciliation Act of 1993 as a new entitlement program to be a required part of each state's Medicaid plan.
- The program was officially implemented in October 1994 as part of the President's Childhood Immunization Initiative.
- The VFC program, as a component of each state's medical assistance plan, is considered a Title XIX Medicaid program.
- The VFC program is different from the Medicaid medical assistance program.
- Funding for the VFC program is approved by the Office of Management and Budget and allocated through the Centers for Medicare & Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC).
- Section 1928 of the Social Security Act (42 U.S.C. §1396s) provides for purchase of vaccine for administration to VFC-eligible children using federal Medicaid funds and state funds (including 317 funds), respectively.
- Through passage of VFC resolutions, VFC covers vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).
- Medicaid-eligible children and those providers who provide care for the Medicaid population (i.e., Medicaid providers) represent the majority of VFC federally vaccine-eligible children and VFC providers.

## HOW VFC WORKS

- CDC awards federal funding to state health departments and certain local and territorial public health agencies to implement and oversee VFC program activities.
- State, local and territorial public health agencies (awardees) actively enroll public and private providers into the program to meet the specific needs of eligible children in their jurisdiction.
- CDC buys vaccines at a discount from manufacturers.
- CDC distributes the vaccines at no charge to registered VFC providers in private physicians' offices and public health clinics.

## HOW CDC AND AWARDEES MANAGE VFC

- CDC has the lead responsibility for policy development, operational oversight, and technical assistance to immunization program awardees for the VFC program.
- Awardees manage and implement the VFC program at the state, local, and territorial levels.

## **VFC VACCINES AND THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)**

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee that was established in 1964 to provide guidance on the most effective means to prevent vaccine-preventable diseases. In 1993, Congress gave the ACIP unique legal authority to determine recommendations for the routine administration of vaccines to children and adults in the civilian population.

The ACIP is the only entity in the federal government that makes such recommendations. These recommendations include:

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

The overall goals of the ACIP are to provide advice that will assist the Department of Health and Human Services and the nation in reducing the incidence of vaccine-preventable diseases and to increase the safe use of vaccines and related biological products.

The ACIP consists of 15 experts in fields related to immunization and infectious diseases. In addition to the 15 voting members, the ACIP includes eight members who represent other federal agencies with responsibility for immunization programs in the United States, and 30 non-voting representatives of liaison organizations with related immunization expertise.

Major functions of the ACIP are as follows:

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

The ACIP process to add or revise the U. S. immunization schedule is lengthy and deliberate. It can begin two to five years prior to licensure of a particular vaccine. Work groups headed by ACIP members work with CDC staff and other consultants to examine issues around particular vaccines or disease epidemiology and present this information to the full ACIP membership several times throughout the year. Focused policy options, science, and other information supporting these policy choices are presented to, deliberated upon, and voted on by ACIP members in open, public meetings. When approved by the ACIP and the director of CDC, final immunization recommendations are published in CDC's Morbidity and Mortality Weekly Report (MMWR).

### **ACIP'S ROLE IN THE VFC PROGRAM**

ACIP's congressional mandate includes the authority to determine the vaccines, dosing, schedule, and contraindications for the VFC program as well as for the general population. ACIP is legislatively linked to the VFC program.

The Committee also approves the specific recommendations for inclusion of a vaccine in the VFC program. The approval is written in the form of a VFC resolution. After the ACIP recommends a new vaccine or a change in vaccine use, a VFC resolution is voted on for inclusion of the vaccine in the VFC program. VFC resolutions passed

by the ACIP form the basis for VFC program policies on vaccine availability and use.

CDC contracts for vaccines available through the VFC program are established only after a VFC resolution is in place. VFC vaccines must be administered according to the guidelines outlined by the ACIP in the VFC resolutions. These consolidated resolutions are placed on the VFC website (<http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html>) soon after ACIP approval.

## **COLLABORATING AGENCIES**

Successful implementation of this program requires close collaboration and participation by these programs and agencies:

- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS)
- State Medicaid agencies
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- National, state, and local organizations representing the private healthcare sector
- State, local, and territorial health departments

Active involvement by the Medicaid program is essential. A majority of VFC-eligible children are eligible to receive other benefits through Medicaid, and Medicaid staff has experience providing preventive care through programs such as the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) service.

State, local, and territorial health departments and Medicaid agencies are pivotal in recruiting private physicians for the VFC Program and informing parents and guardians of eligible children that vaccines are available through the VFC program.

## **MEDICAID AND THE VFC PROGRAM**

Title XIX of the Social Security Act is a federal/state entitlement program that pays for medical assistance for certain individuals and families with low incomes and limited resources. This program, known as Medicaid, became law in 1965 as a cooperative venture jointly funded by the federal and state governments (including the District of Columbia and the territories) to assist states in furnishing medical assistance to eligible persons. Medicaid is the largest source of funding for medical and health-related services for America's low income citizens.

Within broad national guidelines established by the federal government, each state Medicaid program:

- Establishes its own eligibility standards.
- Determines the type, amount, duration, and scope of services.
- Sets the rate of payment for services.
- Administers its own program.

As a result, the Medicaid program varies considerably from state to state.

By far, the largest category of children eligible for the VFC program is "Medicaid-enrolled." In addition, awardees will find that those providers who serve the Medicaid population represent the largest provider pool for VFC recruitment. It is important for the immunization programs and state Medicaid agencies to collaborate on policies that affect the VFC program. Both programs should discuss policy changes that affect participating children and providers well in advance of any program changes. State government is ultimately responsible for ensuring that its agencies comply with Medicaid requirements.

## MEDICAID REQUIREMENTS

While CDC has the lead responsibility for policy development and implementation of the VFC program, the VFC program is included in the Medicaid law and is funded by the federal government through the CMS Medicaid program.

## FEE CAPS ON VACCINE ADMINISTRATION

The legislation that created the VFC program requires that the secretary, Department of Health and Human Services, establish a limit on the amount that a provider can charge and be reimbursed for administration of vaccines to VFC-eligible children.

An initial Federal Register notice setting forth the interim maximum amounts a participating provider may charge for administering a vaccine to a VFC child was published on October 3, 1994. The administration fees/charges were based on national charge data that were obtained under a federal contract with the American Academy of Pediatrics.

Charge data were used rather than cost data, because accurate, useable nationwide cost data were not available, nor could CMS obtain them by October 1, 1994. Recognizing the importance of using cost data in developing the regional maximum charges, CMS published the interim maximum charges based on charge data with the intention of conducting a study to accumulate cost data with the goal of revising the maximum charges based on cost. Since then, CMS's Office of Research and Demonstrations contracted the Center for Health Policy Studies (CHPS) to conduct a study, under an existing grant, to derive physician cost data. This information was found to be in agreement with the charge data.

A final rule was published on November 6th, 2012. The final rule updated the interim regional maximum fees that providers may charge for the administration of pediatric vaccines to federally vaccine-eligible children.

### **CDC Requirement:**

**A provider must not charge a vaccine administration fee to non-Medicaid VFC-eligible children that exceeds the administration fee cap of \$ state specific vaccine administration fee per vaccine dose. For Medicaid VFC-eligible children, accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.**

<b>Maximum Regional Charges for Vaccine Administration by State</b>	
<b>Region</b>	<b>Regional Maximum Charge</b>
Alabama	\$19.79
Alaska	\$27.44
Arizona	\$21.33
Arkansas	\$19.54
California	\$26.03
Colorado	\$21.68
Connecticut	\$23.41
Delaware	\$22.07
District of Columbia	\$24.48
Florida	\$24.01
Georgia	\$21.93

Guam	\$23.11
Hawaii	\$23.11
Idaho	\$20.13
Illinois	\$23.87
Indiana	\$20.32
Iowa	\$19.68
Kansas	\$20.26
Kentucky	\$19.93
Louisiana	\$21.30
Maine	\$21.58
Maryland	\$23.28
Massachusetts	\$23.29
Michigan	\$23.03
Minnesota	\$21.22
Mississippi	\$19.79
Missouri	\$21.53
Montana	\$21.32
Nebraska	\$19.82
Nevada	\$22.57
New Hampshire	\$22.02
New Jersey	\$24.23
New Mexico	\$20.80
New York	\$25.10
North Carolina	\$20.45
North Dakota	\$20.99
Ohio	\$21.25
Oklahoma	\$19.58
Oregon	\$21.96
Pennsylvania	\$23.14
Puerto Rico	\$16.80
Rhode Island	\$22.69
South Carolina	\$20.16
South Dakota	\$20.73
Tennessee	\$20.00
Texas	\$22.06
Utah	\$20.72
Vermont	\$21.22
Virginia	\$21.24
Virgin Islands	\$21.81
Washington	\$23.44
West Virginia	\$19.85
Wisconsin	\$20.83
Wyoming	\$21.72

\* MAXIMUM REGIONAL CHARGES for VACCINE ADMINISTRATION effective January 1, 2013;  
Source: Federal Register / CMS-2370-F; Filed: 11/01/12 at 4:15pm; Publication Date: 11/6/2012

**CDC Requirement:**

A provider must not deny administration of a federally purchased vaccine to an established patient whose parent/guardian/individual of record is unable to pay the administration fee.

**CDC Requirement:**

Immunize VFC-eligible children with VFC-supplied vaccine at no charge to the patient for the vaccine.

# Eligibility

VFC is an entitlement program that requires screening and documentation of eligibility status (by category) for all patients from birth through 18 years of age.

## WHEN A CHILD QUALIFIES FOR MORE THAN ONE VFC ELIGIBILITY CATEGORY

Occasionally, children may be VFC-eligible for more than one eligibility category.

### **CDC Requirement:**

**A provider must select and document the eligibility category that will require the least amount of out-of-pocket expenses to the parent/guardian for the child to receive necessary immunizations.**

### **Example:**

For a child who is AI/AN, uninsured, underinsured (if receiving vaccine at a FQHC or RHC), or on Medicaid:

- If the child is AI/AN and is on Medicaid, and if the screening system will allow the provider to select multiple categories, the provider should select both AI/AN and Medicaid as the VFC eligibility categories and then bill the Medicaid agency for the administration fee.
- If the provider's screening system allows for the selection of only one eligibility category, Medicaid should be selected because the administration fee will be billed to Medicaid.

### **Example:**

For an AI/AN child who has no insurance:

- If the screening system will allow the provider to select multiple categories, select both AI/AN and uninsured as the VFC eligibility categories.
- If the provider's screening system allows for the selection of only one eligibility category, the provider should select AI/AN because that is the more permanent VFC eligibility category.
- The parent would be responsible for the administration fee for any VFC vaccine administered to their child. The administration fee must be waived if the parent cannot afford to pay it.

### **Example:**

For an AI/AN child who has health insurance but the insurance does not cover vaccines, limits vaccines covered, or caps vaccine coverage, and if the provider is not an FQHC/RHC:

- The screening record for the child should be documented as AI/AN since underinsured children are eligible to receive VFC vaccine only through a FQHC/RHC.
- If the provider is an FQHC/RHC and the screening system allows selection of multiple categories, select both AI/AN and underinsured as the VFC eligibility categories.
- If the provider's screening system allows for the selection of only one eligibility category, the provider should select AI/AN because that is the more permanent VFC eligibility category.
- The parent would be responsible for the administration fee for any VFC vaccine administered to their child. The administration fee must be waived if the parent cannot afford to pay it.

### **Example:**

For children whose primary health insurance does not cover immunizations, limits the types of vaccines, or caps immunization coverage to a certain financial amount AND who have Medicaid as secondary coverage:

- All providers should select Medicaid as the VFC-eligibility category, use VFC vaccine, and bill Medicaid for the administration fee.
- Even though the child meets the VFC definition for underinsured, it should not be selected because the child would be VFC-eligible only through an FQHC/RHC, and the parent would be responsible for the VFC vaccine administration fee.
- By selecting Medicaid, the child is VFC-eligible in all VFC provider settings, and Medicaid is responsible for the reimbursement of the administration fee.
- The parent would never be billed the administration fee since the child is enrolled in Medicaid.

## QUICK VIEW OF AI/AN ELIGIBILITY CATEGORIES

This chart refers to a child seen outside of an Indian Health Services (IHS) facility.

POPULATION	ELIGIBILITY STATUS/ SCENARIO	SELECT THE FOLLOWING IF PROVIDER HAS THE ABILITY TO SELECT MULTIPLE VFC ELIGIBILITY CATEGORIES	SELECT THE FOLLOWING IF THE PROVIDER HAS THE ABILITY TO SELECT ONLY ONE VFC ELIGIBILITY CATEGORY
AI/AN	Has no insurance	AI/AN Uninsured	AI/AN
AI/AN	Has insurance but does not cover vaccines, limits vaccines covered, or caps vaccine coverage and provider is <b>not</b> an FQHC/RHC	AI/AN	AI/AN
AI/AN	Has insurance but does not cover vaccines, limits vaccines covered, or caps vaccine coverage and provider <b>is</b> an FQHC/RHC	AI/AN Underinsured	AI/AN
AI/AN	Has Medicaid	Medicaid AI/AN	Medicaid

## QUICK VIEW OF VFC ELIGIBILITY AND INSURANCE STATUS

VFC ELIGIBILITY SCENARIO: CHILD IS INSURED AND...	INSURANCE STATUS	IS CHILD VFC-ELIGIBLE?
Has not yet met plan's deductible	Insured	No
Plan covers all ACIP-recommended vaccines but excludes certain products/combination vaccines	Insured	No
Plan covers only a portion of the vaccine cost and <b>does not have Medicaid as secondary insurance</b>	Insured	No
Has insurance, but plan limits coverage to a specific number of provider visits annually	Underinsured (once the limited number of allowable visits are reached during the year)	Yes, once the limited number of visits has been reached AND only administered by a FQHC, RHC or approved deputized provider
Seeking contraceptive or sexually-transmitted disease (STD) services at school-based clinic or facility whose main services are primary or acute care, and wants to be immunized but does not want to access insurance	Insured	No
Seeking contraceptive or STD services at family planning clinic or STD clinic and wants to be immunized but does not want to access insurance or doesn't know status*	Uninsured	*Yes
Has Medicaid as secondary insurance	Medicaid eligible	Yes
Plan covers only a portion of the vaccine cost <b>and has Medicaid as secondary insurance</b>	Medicaid eligible	Yes
Has not yet met plan's deductible <b>and has Medicaid as secondary insurance</b>	Medicaid eligible	Yes
Has exceeded plan's annually allowed number of provider visits	Underinsured only through FQHC/RHC	Yes
Cannot access health insurance due to being incarcerated	Uninsured	Yes
Enrolled in separate Children's Health Insurance Program (CHIP)	Insured	No
Enrolled in Medicaid-expansion Children's Health Insurance programs	Medicaid eligible	Yes

\*Provision of VFC vaccine to unaccompanied minors without insurance status in family planning clinics is optional at an awardee's discretion and in compliance with the state's medical consent laws as they pertain to minors. See definition of "family planning clinic" on page 13.

## INSURED EXCEPTIONS

### **AI/AN with Health Insurance that Covers Immunizations:**

AI/AN children are always VFC-eligible. VFC is an entitlement program and participation is not mandatory for an eligible child. For AI/AN children that have full immunization benefits through a primary private insurer, the decision to participate in the VFC program should be made based on what is most cost beneficial to the child and family.

### **Insured and Medicaid as Secondary Insurance:**

Situations occur where children may have private health insurance and Medicaid as secondary insurance. These children will be VFC-eligible as long as they are enrolled in Medicaid. However, the parent is not required to participate in the VFC program. There are options for the parent and provider. These options are described below:

#### **Option 1**

##### **A provider can administer VFC vaccine to these children and bill the Medicaid agency for the administration fee.**

In most healthcare situations, Medicaid is considered the “payer of last resort.” This means that claims must be filed to and rejected by all other insurers before the Medicaid agency will consider payment for the service. This is not true of the VFC vaccine administration fee for Medicaid-eligible children.

The Medicaid program must pay the VFC administration fee because immunizations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. However, once the claim is submitted to Medicaid, the state Medicaid agency does have the option to seek reimbursement for the administration fee from the primary insurer.

Please note: If the state Medicaid agency rejects a claim for a vaccine administration fee for a child with Medicaid as secondary insurance, stating the claim must first be submitted to the primary insurer for payment, the provider should notify the awardee. The awardee should notify their CDC project officer so that CDC can work with CMS to educate the state Medicaid agency and correct the situation.

##### **Considerations regarding this option:**

- This is the easiest way for a provider to use VFC vaccine and bill Medicaid for the administration fee.
- There are no out-of-pocket costs to the parent or guardian for the vaccine or the administration fee.

#### **Option 2**

##### **A provider can administer private stock vaccine and bill the primary insurance carrier for both the cost of the vaccine and the administration fee.**

- If the primary insurer pays less than the Medicaid amount for the vaccine administration fee, the provider can bill Medicaid for the balance of the vaccine administration fee, up to the amount Medicaid pays for the administration fee.

##### **Considerations regarding this option:**

- The provider may be reimbursed a higher amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer.
- The provider should choose from the vaccine inventory that is most cost-effective for the family.
- The parent/guardian of a child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

## OTHER INSURED SITUATIONS WITH MEDICAID AS SECONDARY

A child should be screened for VFC eligibility as having Medicaid if the child is covered by a high-deductible insurance plan requiring the parent to pay out-of-pocket for vaccines until the deductible has been reached, AND the child has Medicaid as secondary insurance:

- The child should be considered VFC-eligible if the family has not reached its deductible yet. VFC vaccine should be administered, and the administration fee billed to Medicaid until the deductible is reached.

If a child has health insurance that covers only a portion of the cost of the vaccine, AND the child has Medicaid as secondary insurance:

- The child should be screened as having Medicaid and be considered VFC-eligible. VFC vaccine should be administered and the administration fee billed to Medicaid.

Please note: These children are only VFC-eligible because they have Medicaid as secondary insurance coverage. If the child was enrolled in a high-deductible insurance plan, the family had not met the deductible yet, and the child had no secondary Medicaid coverage, the child would be considered insured and not eligible for the VFC program. The same would apply to children who are covered by insurance that covers only a portion of the vaccine cost, and who have no secondary Medicaid; these children would be considered insured and not eligible for the VFC program.

## LOCATION OF SERVICE

In general, *where* vaccine services are delivered is not a factor in determining VFC-eligibility.

- **School-Based and Mass Vaccination Clinics:**

Children who receive vaccines in a school-based or mass vaccination clinic must not automatically be considered VFC-eligible; all children must be screened for eligibility, and VFC vaccine can be administered only to VFC-eligible children.

- **Sexually-Transmitted Disease (STD) Clinics, Family Planning Clinics, and Juvenile Detention Facilities:**

CDC defines a family planning clinic as a clinic or provider whose purpose is to prescribe contraceptives and/or treat sexually transmitted diseases. School-based clinics or any VFC-enrolled provider whose main services are primary or acute care services do not meet CDC's definition of a family planning clinic and cannot use this VFC eligibility category.

Guidance on children under 19 years of age presenting at family planning clinics and juvenile detention centers is provided in the table below.

### ***STD Clinics, Family Planning Clinics, and Juvenile Detention Facilities***

POPULATION	INSURANCE STATUS	VFC ELIGIBILITY
Minors under 19 years of age	Do not know their insurance status and who present at family planning clinics for contraceptive services or STD treatment	Considered <i>uninsured</i> for the purposes of the VFC program
A person under 19 years of age	May have insurance, but because of the confidential circumstances of seeking services in a family planning clinic, does not have access to that insurance coverage	Considered uninsured for the purposes of the VFC program
Juveniles under the age of 19 years who are incarcerated in detention facilities	Loses access to his or her health insurance because of the incarceration	Considered uninsured and VFC-eligible

Please note: Provision of VFC vaccine to unaccompanied minors without insurance status in Family planning clinics is an awardee's choice and in compliance with the state's medical consent laws as they relate to minors.

# Provider Enrollment

## Specialty Providers

For the purposes of the VFC program, specialty providers are providers that do not provide general healthcare services, but instead offer limited care in a specialized environment or provide healthcare in a focused specialty area. Local health departments, pediatricians, and general practitioners are not considered specialty providers.

**A “specialty provider” is defined as a provider that only serves:**

1. A population defined by the practice specialty (e.g., OB/GYN, STD clinic, family planning), or
2. A specific age group within the general population of children ages 0–18 years.

**Please note: Awardees have the option to allow specialty providers to administer only the specific vaccines recommended for the populations that the provider serves.**

## CDC Requirement:

**The vaccines identified and agreed upon in the Provider Profile must comply with immunization schedules, dosages, and contraindications established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program, unless:**

1. In the provider’s medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;
2. The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

VFC providers must offer vaccines for the population they serve. These vaccines are identified and agreed upon during the new enrollment and annual re-enrollment process. Awardees are responsible for ensuring non-specialty providers offer all ACIP-approved vaccines and specialty providers offer all awardee-approved vaccines.

Vaccines with limited use (such as PPV23 and pediatric Td) may be ordered in single dose increments and made available to VFC-eligible children at provider practices serving age groups eligible for these vaccines.

## CDC Requirement:

**The awardee or provider may terminate this agreement at any time or if there is failure to comply with these requirements. If the agreement is terminated, the provider agrees to properly return any unused VFC vaccine.**

## CDC Requirement:

**Comply with awardee immunization information systems (IIS) requirements.**

## CDC Requirement:

**Providers with a signed deputization Memorandum of Understanding (MOU) between a FQHC or RHC and the state/local immunization program to serve underinsured VFC-eligible children must agree to:**

- Include “underinsured” as a VFC eligibility category during the screening for VFC eligibility at every visit.
- Vaccinate “walk-in” VFC-eligible underinsured children.
- Report required usage data.

**Please note:** “Walk-in” in this context refers to any underinsured child who presents requesting a vaccine, not just established patients. “Walk-in” does not mean that a provider must serve underinsured patients without an appointment. If a provider’s office policy is for all patients to make an appointment to receive immunizations then the policy would apply to underinsured patients as well.

## Quality Assurance and Program Accountability

In addition to the VFC operations budget provided for by Congress, the VFC vaccine budget has steadily increased to approximately \$4 billion since the establishment of the program in 1994. The increase in the cost of vaccine and the 2012 Office of Inspector General report has brought a renewed emphasis on program accountability. CDC and awardees have an ongoing responsibility for ensuring program integrity and serving as stewards of the resources provided by this expansive entitlement program.

### **CDC Requirement:**

**To ensure the integrity of the vaccine and the VFC program, all immunization awardees are required to conduct:**

- Enrollment Site Visits
- Compliance Site Visits
- Unannounced Storage and Handling Site Visits
- VFC contacts, as needed
- Annual Provider Training

VFC visits help determine a provider's compliance with VFC program requirements. This includes identifying potential issues with VFC vaccine accountability and determining whether VFC vaccines are being handled, stored, and administered in accordance with the laws and policies governing the VFC program.

The review and evaluation of VFC provider practices involves assessing verbal, written, and visual evidence encountered during the visit to determine if provider sites are following the requirements of the VFC program.

The goals of these visits are to:

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

### **CDC Requirement:**

**Providers must agree to participate in VFC program compliance site visits including unannounced visits and other educational opportunities associated with VFC program requirements.**

# Vaccine Management

The management of publicly purchased vaccine is one of the most important activities for which immunization awardees have oversight responsibility. It is essential for awardees to educate and support providers with proper vaccine ordering, inventory maintenance, and storage and handling practices. Performing proper vaccine storage and handling procedures will ensure the cold chain is maintained at the provider office. Sound vaccine management practices will minimize vaccine loss and waste, and the potential need to revaccinate that could result from administering compromised vaccine.

## **CDC Requirement:**

### **Provider staffing requirements:**

- Each facility must designate one staff member to be the primary vaccine coordinator. This person is responsible for providing oversight for all vaccine management within the office and ensuring all vaccines are stored and handled correctly.
- Each facility must also designate at least one back-up or alternate vaccine coordinator who can assume oversight responsibilities in the absence of the primary vaccine coordinator.
- VFC providers are required to notify the immunization program when there are changes in key vaccine staff (e.g., the vaccine coordinator or back-up vaccine coordinator).

## **CDC Requirement:**

**VFC providers must have at least one backup thermometer with a valid and current certificate of calibration readily available to ensure that temperature assessment and recordings can be performed twice a day.**

## **CDC Requirement:**

### **Comply with the requirements for vaccine management, including:**

- Ordering vaccine and maintaining appropriate vaccine inventories.
- Not storing vaccine in dormitory-style units at any time.
- Storing vaccine under proper conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet state/local/territorial immunization program storage and handling requirements.

# Fraud and Abuse

Federal fraud and abuse laws apply to the entire VFC program. In addition, for those portions of the VFC program involving state funds, state fraud and abuse/consumer protection/medical licensure laws may also apply.

## **CDC Requirement:**

**Providers must agree to operate within the VFC program in a manner intended to avoid fraud and abuse.**

Consistent with “fraud” and “abuse” as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program:

**Fraud:** An intentional deception or misrepresentation made with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

**Abuse:** Provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program (including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient), or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for healthcare. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

Please note: For the purposes of this document, “VFC program” (unless otherwise noted) is defined as an awardee’s VFC program. An awardee may be a state, local, territorial, or other political jurisdiction health department that implements the VFC program.

## **EXAMPLES OF FRAUD AND ABUSE**

Fraud or abuse can occur in many ways. Some types of fraud and abuse are easier for the VFC program to prevent or detect than others. Some examples of potential fraud and abuse that VFC staff might encounter are:

- Providing VFC vaccine to non-VFC-eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC-funded vaccine
- Charging more than the established maximum regional charge for administration of a VFC-funded vaccine to a federally vaccine-eligible child
- Denying VFC-eligible children VFC-funded vaccine because of parents’ inability to pay for the administration fee
- Failing to implement provider enrollment requirements of the VFC program
- Failing to screen for and document eligibility status at every visit
- Failing to maintain VFC records and comply with other requirements of the VFC program
- Failing to fully account for VFC-funded vaccine
- Failing to properly store and handle VFC vaccine
- Ordering VFC vaccine in quantities or patterns that do not match the provider’s profile or otherwise over-ordering VFC doses of vaccine
- Waste of VFC vaccine

## **CDC Requirement:**

When providers enroll in the VFC program, they agree to comply with all the requirements of the program. Lack of adherence to the VFC program requirements by an enrolled provider could lead to

fraud and abuse of the VFC program by that provider.

Failure to comply with VFC requirements is defined as:

- Any VFC-enrolled provider who is identified as not maintaining any of the federal requirements

**If the non-compliance appears intentional and the provider has received financial benefits from the behavior, the situation would require immediate referral to an outside agency for investigation of suspected VFC fraud and abuse.**

## VFC Statute 42 U.S.C. § 1396s

42 U.S.C. § 1396s. Program for distribution of pediatric vaccines (parallel cite – Section 1928 of the Social Security Act)

### (a) Establishment of program

#### (1) In general

In order to meet the requirement of [section 1396a\(a\)\(62\)](#) of this title, each State shall establish a pediatric vaccine distribution program (which may be administered by the State department of health), consistent with the requirements of this section, under which--

**(A)** each vaccine-eligible child (as defined in subsection (b) of this section), in receiving an immunization with a qualified pediatric vaccine (as defined in subsection (h)(8) of this section) from a program-registered provider (as defined in subsection (c) of this section) on or after October 1, 1994, is entitled to receive the immunization without charge for the cost of such vaccine; and

**(B) (i)** each program-registered provider who administers such a pediatric vaccine to a vaccine-eligible child on or after such date is entitled to receive such vaccine under the program without charge either for the vaccine or its delivery to the provider, and **(ii)** no vaccine is distributed under the program to a provider unless the provider is a program-registered provider.

#### (2) Delivery of sufficient quantities of pediatric vaccines to immunize federally vaccine-eligible children

##### (A) In general

The Secretary shall provide under subsection (d) of this section for the purchase and delivery on behalf of each State meeting the requirement of [section 1396a\(a\)\(62\)](#) of this title (or, with respect to vaccines administered by an Indian tribe or tribal organization to Indian children, directly to the tribe or organization), without charge to the State, of such quantities of qualified pediatric vaccines as may be necessary for the administration of such vaccines to all federally vaccine-eligible children in the State on or after October 1, 1994. This paragraph constitutes budget authority in advance of appropriations Acts, and represents the obligation of the Federal Government to provide for the purchase and delivery to States of the vaccines (or payment under subparagraph (C)) in accordance with this paragraph.

##### (B) Special rules where vaccine is unavailable

To the extent that a sufficient quantity of a vaccine is not available for purchase or delivery under subsection (d) of this section, the Secretary shall provide for the purchase and delivery of the available vaccine in accordance with priorities established by the Secretary, with priority given to federally vaccine-eligible children unless the Secretary finds there are other public health considerations.

##### (C) Special rules where State is a manufacturer

###### (i) Payments in lieu of vaccines

In the case of a State that manufactures a pediatric vaccine the Secretary, instead of providing the vaccine on behalf of a State under subparagraph (A), shall provide to the State an amount equal to the value of the quantity of such vaccine that otherwise would have been delivered on behalf of the State under such subparagraph, but only if the State agrees that such payments will only be used for purposes relating to pediatric immunizations.

(ii) Determination of value

In determining the amount to pay a State under clause (i) with respect to a pediatric vaccine, the value of the quantity of vaccine shall be determined on the basis of the price in effect for the qualified pediatric vaccine under contracts under subsection (d) of this section. If more than 1 such contract is in effect, the Secretary shall determine such value on the basis of the average of the prices under the contracts, after weighting each such price in relation to the quantity of vaccine under the contract involved.

(b) Vaccine-eligible children For

purposes of this section:

(1) In general

The term "vaccine-eligible child" means a child who is a federally vaccine-eligible child (as defined in paragraph (2)) or a State vaccine-eligible child (as defined in paragraph (3)).

(2) Federally vaccine-eligible child

(A) In general

The term "federally vaccine-eligible child" means any of the following children:

(i) A medicaid-eligible child.

(ii) A child who is not insured.

(iii) A child who (I) is administered a qualified pediatric vaccine by a federally-qualified health center (as defined in [section 1396d\(l\)\(2\)\(B\)](#) of this title) or a rural health clinic (as defined in [section 1396d\(l\)\(1\)](#) of this title), and (II) is not insured with respect to the vaccine.

(iv) A child who is an Indian (as defined in subsection (h)(3) of this section).

(B) Definitions

In subparagraph (A):

(i) The term "medicaid-eligible" means, with respect to a child, a child who is entitled to medical assistance under a state plan approved under this subchapter.

(ii) The term "insured" means, with respect to a child--

(I) for purposes of subparagraph (A)(ii), that the child is enrolled under, and entitled to benefits under, a health insurance policy or plan, including a group health plan, a prepaid health plan, or an employee welfare benefit plan under the Employee Retirement Income Security Act of 1974 [[29 U.S.C.A. § 1001](#) et seq.]; and

(II) for purposes of subparagraph (A)(iii)(II) with respect to a pediatric vaccine, that the child is entitled to benefits under such a health insurance policy or plan, but such benefits are not available with respect to the cost of the pediatric vaccine.

(3) State vaccine-eligible child

The term "State vaccine-eligible child" means, with respect to a State and a qualified pediatric vaccine, a child who is within a class of children for which the State is purchasing the vaccine pursuant to subsection (d)(4)(B) of this section.

(c) Program-registered providers

(1) Defined

In this section, except as otherwise provided, the term "program-registered provider" means, with respect to a State, any health care provider that--

**(A)** is licensed or otherwise authorized for administration of pediatric vaccines under the law of the State in which the administration occurs (subject to [section 254f\(e\)](#) of this title), without regard to whether or not the provider participates in the plan under this subchapter;

**(B)** submits to the State an executed provider agreement described in paragraph (2); and

**(C)** has not been found, by the Secretary or the State, to have violated such agreement or other applicable requirements established by the Secretary or the State consistent with this section.

(2) Provider agreement

A provider agreement for a provider under this paragraph is an agreement (in such form and manner as the Secretary may require) that the provider agrees as follows:

**(A)(i)** Before administering a qualified pediatric vaccine to a child, the provider will ask a parent of the child such questions as are necessary to determine whether the child is a vaccine-eligible child, but the provider need not independently verify the answers to such questions.

**(ii)** The provider will, for a period of time specified by the Secretary, maintain records of responses made to the questions.

**(iii)** The provider will, upon request, make such records available to the State and to the Secretary, subject to [section 1396a\(a\)\(7\)](#) of this title.

**(B)(i)** Subject to clause (ii), the provider will comply with the schedule, regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines, that is established and periodically reviewed and, as appropriate, revised by the advisory committee referred to in subsection (e) of this section, except in such cases as, in the provider's medical judgment subject to accepted medical practice, such compliance is medically inappropriate.

**(ii)** The provider will provide pediatric vaccines in compliance with applicable State law, including any such law relating to any religious or other exemption.

**(C)(i)** In administering a qualified pediatric vaccine to a vaccine-eligible child, the provider will not impose a charge for the cost of the vaccine. 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.

**(ii)** The provider may impose a fee for the administration of a qualified pediatric vaccine so long as the fee in the case of a federally vaccine-eligible child does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administration).

(iii) The provider will not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parent to pay an administration fee.

(3) Encouraging involvement of providers

Each program under this section shall provide, in accordance with criteria established by the Secretary-

(A) for encouraging the following to become program-registered providers: private health care providers, the Indian Health Service, health care providers that receive funds under title V of the Indian Health Care Improvement Act [[25 U.S.C.A. § 1651](#) et seq.], and health programs or facilities operated by Indian tribes or tribal organizations; and

(B) for identifying, with respect to any population of vaccine-eligible children a substantial portion of whose parents have a limited ability to speak the English language, those program-registered providers who are able to communicate with the population involved in the language and cultural context that is most appropriate.

(4) State requirements

Except as the Secretary may permit in order to prevent fraud and abuse and for related purposes, a State may not impose additional qualifications or conditions, in addition to the requirements of paragraph (1), in order that a provider qualify as a program-registered provider under this section. This subsection does not limit the exercise of State authority under [section 1396n\(b\)](#) of this title.

(d) Negotiation of contracts with manufacturers

(1) In general

For the purpose of meeting obligations under this section, the Secretary shall negotiate and enter into contracts with manufacturers of pediatric vaccines consistent with the requirements of this subsection and, to the maximum extent practicable, consolidate such contracting with any other contracting activities conducted by the Secretary to purchase vaccines. The Secretary may enter into such contracts under which the Federal Government is obligated to make outlays, the budget authority for which is not provided for in advance in appropriations Acts, for the purchase and delivery of pediatric vaccines under subsection (a)(2)(A) of this section.

(2) Authority to decline contracts

The Secretary may decline to enter into such contracts and may modify or extend such contracts.

(3) Contract price

(A) In general

The Secretary, in negotiating the prices at which pediatric vaccines will be purchased and delivered from a manufacturer under this subsection, shall take into account quantities of vaccines to be purchased by States under the option under paragraph (4)(B).

(B) Negotiation of discounted price for current vaccines

With respect to contracts entered into under this subsection for a pediatric vaccine for which the Centers for Disease Control and Prevention has a contract in effect under [section 247b\(j\)\(1\)](#) of this title as of May 1, 1993, no price for the purchase of such vaccine for vaccine-eligible children shall be agreed to by the Secretary under this subsection if the price per dose of such vaccine (including delivery

costs and any applicable excise tax established under [section 4131 of the Internal Revenue Code of 1986](#)) exceeds the price per dose for the vaccine in effect under such a contract as of such date increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from May 1993 to the month before the month in which such contract is entered into.

(C) Negotiation of discounted price for new vaccines

With respect to contracts entered into for a pediatric vaccine not described in subparagraph (B), the price for the purchase of such vaccine shall be a discounted price negotiated by the Secretary that may be established without regard to such subparagraph.

(4) Quantities and terms of delivery

Under such contracts--

(A) the Secretary shall provide, consistent with paragraph (6), for the purchase and delivery on behalf of States (and tribes and tribal organizations) of quantities of pediatric vaccines for federally vaccine- eligible children; and

(B) each State, at the option of the State, shall be permitted to obtain additional quantities of pediatric vaccines (subject to amounts specified to the Secretary by the State in advance of negotiations) through purchasing the vaccines from the manufacturers at the applicable price negotiated by the Secretary consistent with paragraph (3), if (i) the State agrees that the vaccines will be used to provide immunizations only for children who are not federally vaccine-eligible children and (ii) the State provides to the Secretary such information (at a time and manner specified by the Secretary, including in advance of negotiations under paragraph (1)) as the Secretary determines to be necessary, to provide for quantities of pediatric vaccines for the State to purchase pursuant to this subsection and to determine annually the percentage of the vaccine market that is purchased pursuant to this section and this subparagraph.

The Secretary shall enter into the initial negotiations under the preceding sentence not later than 180 days after August 10, 1993.

(5) Charges for shipping and handling

The Secretary may enter into a contract referred to in paragraph (1) only if the manufacturer involved agrees to submit to the Secretary such reports as the Secretary determines to be appropriate to assure compliance with the contract and if, with respect to a State program under this section that does not provide for the direct delivery of qualified pediatric vaccines, the manufacturer involved agrees that the manufacturer will provide for the delivery of the vaccines on behalf of the State in accordance with such program and will not impose any charges for the costs of such delivery (except to the extent such costs are provided for in the price established under paragraph (3)).

(6) Assuring adequate supply of vaccines

The Secretary, in negotiations under paragraph (1), shall negotiate for quantities of pediatric vaccines such that an adequate supply of such vaccines will be maintained to meet unanticipated needs for the vaccines. For purposes of the preceding sentence, the Secretary shall negotiate for a 6- month supply of vaccines in addition to the quantity that the Secretary otherwise would provide for in such negotiations. In carrying out this paragraph, the Secretary shall consider the potential for outbreaks of the diseases with respect to which the vaccines have been developed.

(7) Multiple suppliers

In the case of the pediatric vaccine involved, the Secretary shall, as appropriate, enter into a contract referred to in paragraph (1) with each manufacturer of the vaccine that meets the terms and conditions of the Secretary for an award of such a contract (including terms and conditions regarding safety and quality). With respect to multiple contracts entered into pursuant to this paragraph, the Secretary may have in effect different prices under each of such contracts and, with respect to a purchase by States pursuant to paragraph (4)(B), the Secretary shall determine which of such contracts will be applicable to the purchase.

(e) Use of pediatric vaccines list

The Secretary shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention).

(f) Requirement of state maintenance of immunization laws

In the case of a State that had in effect as of May 1, 1993, a law that requires some or all health insurance policies or plans to provide some coverage with respect to a pediatric vaccine, a State program under this section does not comply with the requirements of this section unless the State certifies to the Secretary that the State has not modified or repealed such law in a manner that reduces the amount of coverage so required.

(g) Termination

This section, and the requirement of [section 1396a\(a\)\(62\)](#) of this title, shall cease to be in effect beginning on such date as may be prescribed in Federal law providing for immunization services for all children as part of a broad-based reform of the national health care system.

(h) Definitions

For purposes of this section:

- (1) The term "child" means an individual 18 years of age or younger.
- (2) The term "immunization" means an immunization against a vaccine-preventable disease.
- (3) The terms "Indian", "Indian tribe" and "tribal organization" have the meanings given such terms in section 4 of the Indian Health Care Improvement Act [[25 U.S.C.A. § 1603](#)].
- (4) The term "manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any pediatric vaccine. The term "manufacture" means to manufacture, import, process, or distribute a vaccine.
- (5) The term "parent" includes, with respect to a child, an individual who qualifies as a legal guardian under State law.
- (6) The term "pediatric vaccine" means a vaccine included on the list under subsection (e) of this section.
- (7) The term "program-registered provider" has the meaning given such term in subsection (c) of this

section.

(8) The term "qualified pediatric vaccine" means a pediatric vaccine with respect to which a contract is in effect under subsection (d) of this section.

(9) The terms "vaccine-eligible child", "federally vaccine-eligible child", and "State vaccine-eligible

child" have the meaning given such terms in subsection (b) of this section. CREDIT(S)

(Aug. 14, 1935, c. 531, Title XIX, § 1928, as added Aug. 10, 1993, [Pub.L. 103-66, Title XIII, § 13631\(b\)\(2\)](#), 107 Stat. 637.)