

Vaccines for Children Operations Guide



**Atlanta, Georgia
Centers for Disease Control
and Prevention**



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VFC Operations Guide

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This document can be found on the CDC website at:
<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/01-toc.pdf>

Executive Summary

Since the VFC program became operational in 1994, the budget for this program has risen steadily, and at the time of this revision is approaching \$4 billion. As program costs rise, so does the need to ensure that all aspects of the program are being implemented appropriately. The White House, by Executive Order, has challenged the entire federal government to reduce the risk of fraud, waste, and abuse. Secretary Sebelius has launched a new *Program Integrity Initiative* to ensure the integrity of operations in all HHS programs. Program integrity seeks to make certain that intended recipients are provided the proper payments, services, and benefits while ensuring quality, safety, and access. Assuring program integrity should be a key element of all programmatic work and business conducted by the CDC. The VFC program must work with our partners (e.g., grantees and enrolled providers) so that everyone understands the importance of program integrity and their role to make sure the integrity of the VFC program is not compromised.

Many modules in the guide have been updated to reflect the changes that have been made in many areas of the VFC program since the last revision, including provider enrollment, vaccine management, accountability, and fraud and abuse. This executive summary outlines new material added or significant changes made to key modules in the *VFC Operations Guide*. This summary does not outline all changes within the *Operations Guide* or even in the modules discussed below, so it should not be considered an all-inclusive summary of changes or new requirements. The user is referred to the full text of the *VFC Operations Guide* for a comprehensive discussion of these issues.

Eligibility

The Eligibility Module has been significantly revised. This module now includes information on how to determine which eligibility category to select as primary eligibility if a child is VFC eligible in multiple categories. The module has new information on insured children, Medicaid as secondary, and other frequently asked VFC eligibility questions. It has an expanded section that discusses the provider's responsibility for screening for VFC-eligibility.

Provider Recruitment and Enrollment

The number of requirements for provider enrollment has increased to eleven items. The new requirements reflect specific requirements related to the implementation of VTrckS. All eleven required items must be used as written. Limited modifications can be made to certain requirements, and those modifications are outlined in Module 3. Any additional items that grantees wish to include as requirements for provider enrollment in the VFC program must be submitted to CDC for documentation and formal approval. The formal process for requesting approval of additional provider enrollment requirements is outlined in Module 3.

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Please remember that providers are required to sign and submit an updated provider enrollment form annually. Provider profiles must be updated based on accurate data and submitted annually.

Module 3 contains expanded guidance related to the educational goals for the federal requirements. This additional guidance is a result of incorporating many of the frequently asked questions regarding provider enrollment from the VFC Frequently Asked Question and Answers document into Module 3. It is important that all staff who conduct VFC compliance site visits to providers have access to Module 3 as well as the entire *VFC Operations Guide*. As the first line of contact with enrolled providers, it is critical that these individuals are well versed on the VFC program and its requirements and have CDC's requirements available to them at all times for reference.

Site Visit Basics

This is a new a module. It replaces the former Module 5, "Expanding the Reach of VFC and AFIX through Marketing and Collaboration." This new module discusses important skill sets that those conducting site visits should have to be able to make quality VFC compliance site visits and outlines how staff should prepare for site visits. The module also outlines CDC training requirements for staff that conduct VFC compliance site visits.

Vaccine Management

Module 6, "Vaccine Management," identifies grantee vaccine management requirements. Key grantee requirements include providing initial and periodic training to VFC providers and staff and focusing on critical aspects of proper vaccine management. Grantees must develop simple storage and handling plan templates that VFC providers can adapt and implement in their practices.

This module also outlines the minimum vaccine management requirements for enrolled VFC providers. A grantee can include additional vaccine management requirements in its provider enrollment form by submitting a request to CDC. The process for requesting approval of additional provider enrollment requirements is addressed in Module 3, "Provider Recruitment and Enrollment."

Accountability

Module 8 identifies grantee and provider level accountability requirements. Provider level requirements include requiring new signed provider enrollment forms annually, completing a provider profile annually and screening for VFC eligibility at every immunization encounter. Grantees have the discretion to require providers to document the screening results at every immunization encounter. Grantees must have written accountability policies that address how provider profiles are used to monitor provider vaccine orders, how wasted and lost vaccine is monitored at the provider level that includes waste/loss thresholds that will trigger follow-up and education. The policies should include how provider vaccine inventory records are monitored to ensure the

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provider has the appropriate amount of public and private vaccine for each population served. Grantees should have a standardized methodology to determine how providers are selected to have their vaccine inventory records reviewed.

Quality Assurance

This module discusses the requirement that increases the number of VFC Compliance site visit to be conducted annually to 50% beginning on January 1, 2011. This change means that least half of a grantee's enrolled and active providers are visited each year and the other 50% of providers are visited the next year. The module discusses how VFC staff that conduct site visits should prepare for a site visit. The module contains tips on how to administer some key high priority questions from Section One of CDC's Site Visit Questionnaire and how to address issues that are identified during the site visit. The module briefly discusses the reporting requirements related to VFC site visit activities.

Fraud and Abuse

The major change to the fraud and abuse module is how referrals are made for investigation. Beginning on January 1, 2011, all suspected cases of VFC fraud and abuse that grantees decide to refer for further investigation will be referred to the Medicaid Integrity Group Field Office (MIG). The MIG Field Office will direct the referral to the most appropriate agency for follow-up. The module outlines what information to include in the referral to the MIG Field Office and how to make the referral. The module also clarifies the requirements for grantees' written fraud and abuse policies.

Evaluation

The focus of the Evaluation module has changed from describing the evaluation process and applying CDC's evaluation framework to discussing the importance of accurately completing the VFC Management Survey. The module discusses how the VFC Management Survey results should be used at the program level to evaluate and make changes (as needed) to VFC programmatic activities. The module provides instructions on how to use the Program Annual Progress Assessments (PAPA) website to compare grantee outcomes in specific VFC program areas.

Glossary

A glossary is included to assist staff new to the VFC program understand the many different acronyms used in the program.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/02-exec-sum.pdf>

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Question and Answers about *The VFC Operations Guide*

Question:

Why is there no date on this edition of the *VFC Operations Guide*?

Answer:

This edition of the *VFC Operations Guide* is designed to accommodate revisions of individual modules so that the user will not have to wait for publication of an entire new edition in order to receive the most current information. Rather than a date of publication being assigned to the manual as a whole, each individual module will carry the date of publication and the date of the latest revision on every page. Since some modules will be updated more frequently, the revision dates may eventually vary throughout the text. In the table of contents, the most current date will be listed next to each entry.

Question:

How will grantees be notified when modules are updated?

Answer:

As modules are revised and replaced, the new module will be placed on the VFC website and sent out electronically through the all-grantee message system. The table of contents page will be updated to reflect the date the module was revised, and the new table of contents will be posted on the website and sent electronically with the revised module. Additionally, revisions will be announced during the quarterly VFC/AFIX conference calls; participants will be instructed regarding how to access the newly revised module.

Question:

What if I do not get the all-grantee messages or participate in the VFC/AFIX quarterly conference calls?

Answer:

It is the responsibility of each grantee to ensure that each staff working in the VFC program has access to the most up-to-date VFC Operations Guide. This could be accomplished by forwarding the all-grantee message to all VFC staff and instructing the staff to print the module and table of contents and replace the old versions with the new versions in their hard copy of the VFC Operations Guide.

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Question:

When a new version of a Module is released that contains new requirements, when will those requirements become effective?

Answer:

Unless otherwise noted in the Module, the effective date of any new requirements will be 90 days after the release of the Module. The 90 day clock will start the day after the all-grantee message is sent.

Question:

Whom should I contact if I have any questions about the content of the *VFC Operations Guide*?

Answer:

It is always best to start by contacting your Project Officer. If that person is unable to assist you, he or she will refer your question to the VFC Policy Coordinator. If the Project Officer is unavailable, please feel free to contact the VFC Policy Coordinator, directly.

This document can be found on the CDC website at:
<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/04-q-and-a.pdf>

MODULE 1 – Overview



<http://www.cdc.gov/vaccines/programs/vfc/default.htm>

Background

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 inability to pay. 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 (see Appendix 1). The program was officially implemented in October 1994 as part of the President's Childhood Immunization Initiative. Funding for the VFC program is approved by the Office of Management and Budget and allocated through the Centers for Medicare & Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC). CDC buys vaccines at a discount from the manufacturers and distributes them to grantees — i.e., state health departments and certain local and territorial public health agencies — which in turn distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers. Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices through passage of VFC resolutions.

It is important to understand that the VFC program is a component of each state's medical assistance plan and is considered a Title XIX Medicaid program. 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 Section 317 grant funds). VFC-eligible children include both "federally vaccine-eligible children" and "state vaccine-eligible children" (i.e., those children for whom states purchase vaccine although purchases may be limited to particular vaccines). The VFC program is a unique component of the federal Medicaid program. In addition to having different eligibility criteria, the VFC program provides services not only to Medicaid-eligible children but also to VFC-eligible children who are not otherwise eligible for Medicaid. Similarly, the VFC program enrolls providers who are not Medicaid providers but who provide immunizations to federally vaccine-eligible or state vaccine-eligible children. 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.

Highlights

The VFC Program...

- provides public-purchased vaccine for eligible children at no charge to VFC-enrolled public and private providers in all states, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands;
- covers vaccines recommended by the Advisory Committee on Immunization Practices through passage of VFC resolutions;
- saves parents and enrolled providers out-of-pocket expenses for vaccine;
- provides cost savings to states through bulk purchase of vaccine at lower prices using CDC's contracts and eliminates state-to-state variations in price;
- eliminates or reduces vaccine cost as a barrier to vaccinating eligible children;
- reduces the practice of referring children from the private sector to the public sector for vaccination.

Collaborating Agencies

CDC has the lead responsibility for policy development, operational oversight, and provision of technical assistance to immunization program grantees (states and certain local and territorial health departments) for the VFC program. Grantees, in turn, manage and implement the VFC program at the state and local levels. In addition, successful implementation of this program requires close collaboration and participation by the following programs and agencies:

- Centers for Disease Control and Prevention
- Centers for Medicare & 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

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

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About This Guide and Other Resources

The *VFC Operations Guide* is intended as a resource for the management and operation of the VFC program. The requirements and procedures are applicable to all immunization grantees that receive VFC-funded vaccines. This *VFC Operations Guide* serves as a companion to the *Immunization Program Operations Manual* and provides further guidance on grant requirements.

In addition to this *Operations Guide*, located on the VFC website at <http://www.cdc.gov/vaccines/programs/vfc/projects/default.htm> is a series of frequently asked questions (FAQs) about various aspects of the VFC program. This website is updated periodically to reflect new questions and should be used as a companion to the *VFC Operations Guide* to assist grantees in improving the integrity of the VFC program.

As changes occur to this guide, an individual module or section will be revised, and the date of the latest revision will be put at the top of each page in the module. The new information will be posted on the VFC website, and the immunization program manager and VFC coordinator for each grantee will be notified. The program managers are encouraged to routinely share this information with representatives of state Medicaid agencies and other partners such as other public health department agencies and state and local AAP and AAFP chapters.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/05-module-1.pdf>

MODULE 2 – Eligibility



<http://www.cdc.gov/vaccines/programs/vfc/default.htm>

Eligibility Criteria

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

- ◆ **Medicaid eligible:** A child who is eligible for the Medicaid program. (For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who have health insurance covered by a state Medicaid program)
- ◆ **Uninsured:** A child who has no health insurance coverage
- ◆ **American Indian or Alaska Native:** As defined by the Indian Health Care Improvement Act (**25 U.S.C. 1603**)
- ◆ **Underinsured:** A child who has commercial (private) health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only); or a child whose insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured. **Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC).**

VFC Eligibility Hierarchy

Occasionally children may have VFC-eligibility in two eligibility categories. This could occur with American Indian/Alaska Native populations (AI/AN) or children that have Medicaid as secondary coverage and the child's primary insurance does not cover immunizations, covers only selected vaccines or caps coverage at a certain financial amount. In this case, the child would meet the VFC definition of underinsured.

If a provider is providing care for a child who is AI/AN, that child could also be VFC-eligible because the child is uninsured, underinsured (if receiving vaccine at a FQHC or RHC) or on Medicaid. The provider should select 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. So, 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. This action would require no out-of-pocket cost to the parent for the administration fee since the fee would be billed to Medicaid. 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.

For an AI/AN child that 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. Please remember that the administration fee must be waived if the parent cannot afford to pay it.

For an AI/AN child that 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 only VFC eligible who are vaccinated at an 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. Please remember that the administration fee must be waived if the parent cannot afford to pay it.

Providers may also see children whose primary health insurance does not cover immunizations, limits immunizations 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. The parent would never be billed the administration fee since the child is enrolled in Medicaid. 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 following chart summarizes VFC Eligibility Hierarchy:

VFC Eligibility Hierarchy

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 not 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 is an FQHC/RHC	AI/AN Underinsured	AI/AN
AI/AN*	Has Medicaid	Medicaid AI/AN	Medicaid
Underinsured	Has insurance but does not cover vaccines, limits vaccines covered, or caps vaccine coverage and has Medicaid as a second coverage.	Medicaid Underinsured	Medicaid

*These scenarios refer to AI/AN populations seen at VFC provider sites other than IHS facilities.

Insured Children

Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible (high deductible plan) had not been met.

The Children's Health Insurance Program (CHIP), also known as Title XXI, enables states to expand health insurance coverage for uninsured children. Title XXI children enrolled in a **separate** Children's Health Insurance Program are not VFC-eligible because these children are considered insured. Title XXI children who are enrolled in a Medicaid-expansion CHIP program are Medicaid-eligible and entitled to VFC program benefits. Some states have implemented their CHIP programs as a combination plan with some children becoming Medicaid-eligible through an expansion plan and some children enrolled in a separate CHIP. The Medicaid-eligible children are entitled to VFC program

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benefits, and the children enrolled in the separate CHIP program are considered insured and are not entitled to VFC program benefits.

Some insurance plans may cover all ACIP-recommended childhood vaccines but exclude certain combination vaccines or certain products. A child with this type of coverage would be considered insured and not eligible for VFC because all recommended vaccines are covered. Some insurance plans may cover a portion of the cost of the vaccine; even though it may be only a small portion of the cost of the vaccine, this child is considered insured for the purposes of the VFC program.

Exceptions

The VFC Program does have a few exceptions based on circumstance when a child who has insurance that covers vaccine may be considered underinsured or uninsured. The exceptions are described by eligibility category:

Underinsured Exception

Some insurance plans limit the coverage to a specific number of provider visits annually. If a child's insurance will not cover the cost of the vaccine after the child has exceeded the number of provider visits, the child can be considered underinsured for the purposes of the VFC program since the insurance would not cover the vaccine. The child would be VFC-eligible only through FQHC/RHC.

Insured Exceptions

Minors under 19 years of age who do not know their insurance status and who present at family planning clinics for contraceptive services or STD treatment can be considered uninsured for the purposes of the VFC program. 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. A person under 19 years of age who may have insurance but because of the confidential circumstances for seeking services in a family planning clinic does not have access to that insurance coverage is considered uninsured for the purposes of the VFC program. Provision of VFC vaccine to unaccompanied minors without insurance status in family planning clinics is optional at a grantee's discretion and in compliance with the state's medical consent laws as they pertain to minors.

Another special population that the VFC program may serve is juveniles under the age of 19 years who are incarcerated in detention facilities. If a child under age 19 years loses access to his or her health insurance because of the incarceration, the child is considered uninsured and VFC-eligible. Please refer to Module 3 for additional information and requirements on these special populations.

In general, where vaccines services are delivered is not a factor in determining VFC-eligibility except as discussed above. Children who receive vaccines in a school-based clinic cannot automatically be considered VFC- eligible; the children must be screened for eligibility, and VFC vaccine can be administered only to VFC-eligible children.

Fully Insured Children Who Are Also VFC-Eligible

Situations can occur where children have private health insurance that includes full immunization benefits and be VFC-eligible as well. VFC is an entitlement program, and participation is not mandatory for an eligible child. **For children that have full immunization benefits through a primary private insurance, the decision to participate in the VFC program should be made based on what is financially most cost effective to the child and his/her family.**

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. Immunizations are a component of the Early Periodic Screening, Diagnosis and Treatment (EPSDT) program, and the Medicaid program must pay the VFC administration fee; the state Medicaid agency has the option to seek reimbursement for the administration fee from the primary insurer. In most circumstances, 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 for the VFC vaccine administration fee for Medicaid-eligible children. If a provider notifies the VFC program that the state Medicaid agency has rejected a claim for a vaccine administration fee for a VFC vaccine administered to a child with Medicaid as secondary coverage with the rationale that the claim must first be submitted to the primary insurance for payment, this situation should be addressed. The VFC Policy Coordinator at CDC should be contacted when these issues arise. CDC will work with CMS to educate the state Medicaid agency and correct the situation.

Consideration regarding this option:

- This is the easiest option for a provider to use VFC vaccine and bill Medicaid for the administration fee. There are no out of pocket costs for 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 insurance 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. If the primary insurance denies payment of vaccine and the administration fee, the provider may replace the private-purchased vaccine with VFC vaccine and bill Medicaid for the administration fee. The provider must document this replacement on the VFC borrowing form (see Module #3).

Considerations regarding this option:

- 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 insurance.
- The deciding factor on which vaccine inventory to use should be based on what will be 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 for an administration fee.

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 insurance, the decision to participate in the VFC program should be made based on what is financially most cost advantageous to the child and family.**

Other Insured Situations with Medicaid As Secondary

There are many different levels of coverage provided through health insurers. A child who is covered by a high-deductible insurance plan that requires the parent to pay out-of-pocket for vaccines until the deductible has been reached and who has Medicaid as secondary insurance should be screened as having Medicaid and 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 Medicaid as secondary, 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 remember that 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 had no secondary Medicaid, 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.

What is an FQHC?

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

What is an RHC?

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

Provider Responsibility to Screen for VFC Eligibility

Screening to determine a child's eligibility to receive vaccines through the VFC Program must take place with each immunization visit, although the screening form need be replaced or updated only if the status of the patient changes. The patient eligibility screening record provides a means of recording parent responses to VFC eligibility questions. The parent, guardian or provider may complete this form (see Appendix 3). Verification of parent/guardian responses is not required. To maximize efficiency, providers may elect to incorporate these screening questions into an existing form; however, any revision must include the core screening information listed on the CDC-developed form and be approved by the state Immunization Program. The state Immunization Program may require providers to document the results of VFC screening at every immunization visit. Please remember that screening and documentation must be

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done on all patients from birth through 18 years of age. The only factors that can be considered when screening for VFC-eligibility are age and whether the child meets the definition of at least one of the following categories: uninsured, underinsured, American Indian/Alaska Native or Medicaid enrolled. Patient eligibility screening records should be maintained on file for a minimum of three years after service to the patient has been completed unless state law/policy establishes a longer retention period. VFC eligibility screening is discussed in more detail in Module 3.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/06-module-2.pdf>

MODULE 3 – Provider Recruitment and Enrollment



<http://www.cdc.gov/vaccines/programs/vfc/default.htm>

Overview

The success of the VFC Program is due in large part to the participation of private providers in the program. The VFC Program was created to increase access to immunizations outside of public health department clinics in order to allow eligible children to remain in their medical homes for immunizations to the extent possible. Therefore, maintaining participation of private immunization providers is critical to ensuring that VFC-eligible children have access to vaccines in their medical homes.

Please note: The "FAQs for State/Territory VFC Projects" section on the VFC website contains additional guidance on provider enrollment not contained in this module. Please refer to

<http://www.cdc.gov/vaccines/programs/vfc/projects/default.htm#faq>

Provider Recruitment

State and local immunization programs should continue to enroll healthcare providers into the VFC program by identifying and recruiting new providers, including nontraditional providers who serve adolescents—e.g., long-term juvenile correctional facilities, pharmacies, family planning and STD clinics, adolescent medicine practices, and OB/GYN practices. Particularly relevant for these nontraditional providers, grantees have the discretion to allow specialty providers to limit their VFC participation to specific vaccines recommended for the populations that these providers serve.

Recruitment efforts should be targeted to providers who have not been previously recruited or who are newly licensed or newly established within the grantee's area. It is understood that not all providers who serve children will be enrolled in the VFC program because some serve only children who are not VFC eligible.

Grantees should have written policies, protocols, and procedures to recruit and enroll providers into the VFC program. These documents should include methods for accomplishing the following:

- Identifying practicing providers. This can be done through collaboration with medical societies, state licensing boards and the state Medicaid agency. With assistance from these organizations, grantees can better identify the subset of

providers who may be immunizing children and who are not enrolled in the VFC program.

- Prioritizing potential VFC providers for contact. Prioritization criteria may include practice size, age of patients, location of practice, or previous contact with the provider regarding VFC enrollment. Newly licensed providers and providers located in “pockets of need” or who have large panels of Medicaid children should be given priority.
- Scheduling enrollment visits with interested providers based on the priority criteria.
- Documenting results of recruitment efforts and enrollment visits to new VFC providers.

Provider Enrollment

A provider's understanding of how the VFC program works is critical to maintaining the integrity of the VFC program. ("Provider" includes all appropriate office staff.) Therefore, it is essential that VFC grantees have a strong and ongoing provider education component. Provider education must begin during the recruitment and enrollment process and continue with every provider contact. All providers enrolling in the VFC program must have an initial VFC enrollment site visit. The purpose of this visit is to ensure that the provider and office staff are educated on the VFC program requirements and have the appropriate resources to implement those requirements. Education regarding the VFC program should be structured according to the requirements for provider enrollment. The federal requirements are explained later in this module. For the purposes of reporting activities to CDC, all enrollment visits must be documented as enrollment visits in CoCASA or the grantee's alternative database. For more information on CDC's visit definitions, see Appendix 6.

VFC site visit questionnaires must **not** be administered during the enrollment visit because many of the questions cannot not be answered accurately before a provider has begun to participate in the program. To accurately administer and assess how well a provider is maintaining the VFC program requirements, the provider must have actively participated in the program for at least 3-6 months. CDC considers active participation in the VFC program to mean that the provider has ordered and received VFC vaccine and administered VFC vaccine to patients. This timeframe allows the provider to implement the VFC program within the practice and allows the VFC program to evaluate how well the practice is maintaining the program requirements.

Two forms must be completed by each VFC provider at enrollment; thereafter the forms must be completed and be submitted annually to the VFC program:

1. **Provider Profile form** (see Appendix 2). The Provider Profile form requires information on the number of VFC-eligible children and non-VFC eligible children seen in the practice. It is used to evaluate vaccine orders and ensure that the amount of VFC-funded vaccine being provided is appropriate to the number of VFC-eligible children that receives care from that specific provider office.

States may collect this information on a different form as long as the required information is included. Each grantee is responsible for the accuracy and reliability of the Provider Profiles submitted by VFC-enrolled practitioners. For all VFC-enrolled providers, enrollment figures must be based on actual data. The Provider Profile must be updated annually. For further information on determining VFC eligibility, please refer to Module 2.

2. **Provider Enrollment form.** The Provider Enrollment form is the provider's agreement to comply with all the conditions of the VFC program. This form must be signed annually. The medical director or equivalent in a group practice must sign the Provider Enrollment form for the entire group. All other providers within the practice must be listed on the enrollment form. The provider enrollment form must include the professional license numbers for listed providers in the practice. CDC defines the federal compliance requirements of the VFC program. Grantees must create their own forms. The form must contain all the federal requirements listed below. A grantee may not mandate additional requirements for provider enrollment in the VFC program without formal approval from CDC. The process to request additional requirements for participation in the VFC program is outlined later in this module.

Submission of signed Provider Enrollment forms and completed Provider Profile forms must occur annually, and the timing of the submissions is at the grantees' discretion. The date for provider submissions must occur at the same time each year and should be considered valid for 12 months. If an unexpected situation occurs necessitating a delay in the reenrollment process and collection of the required documents (provider enrollment form and provider profile), the grantee must notify their project officer within the Program Operations Branch of CDC in advance of the change and provide the following information in writing:

1. Reason for the date change
2. The new submission date
3. Previous submission date
4. Will the new submission date be permanent?
5. If not when will the submission revert back to the original date?

Submission of Provider Enrollment and Provider Profile Forms

Grantees have the discretion to require their enrolled provider sites to complete, sign and submit a hard copy of the Provider Enrollment form to the grantee's VFC program by mail, fax or in person.

VFC enrollment and renewal paperwork may also be completed electronically through the grantee's website. If this method is used, the grantee's system must meet all program-specific electronic security requirements. In addition, a grantee that has a web-based VFC enrollment and renewal process must have an electronic signature as acknowledgement of understanding and agreement to maintain the requirements of the

VFC program. In addition, the agreement must include wording that receipt and acceptance of vaccine from the VFC program after the date of the electronic signature is additional acknowledgement and acceptance of the terms outlined in the provider enrollment form.

Pharmacists as VFC Providers

Historically, VFC-enrolled providers have been physicians or advanced practice nurses providing primary care services to children birth through age 18 years. Over the last several years, new types of providers have become eligible and are enrolling in the VFC program; this includes specialty providers (e.g., OB/GYNs), residential facilities, and pharmacists (in areas that have expanded pharmacy practice acts to include prescribing and administration of vaccines). Many of these new VFC-enrolled providers offer a limited number of VFC vaccines and some may offer only seasonal influenza vaccine. While these non-traditional providers have expanded the access to VFC vaccine for VFC-eligible children, current program guidance would require that these providers receive the same amount of oversight as VFC providers who offer all VFC vaccines and receive large amounts of publicly purchased vaccine throughout the year. Pharmacists that offer only VFC seasonal influenza vaccine may be eligible of a streamlined oversight process.

Eligibility for Streamlined Oversight

VFC-enrolled pharmacists who are currently enrolled and active in the VFC program and meet the following criteria:

- Offer only seasonal influenza vaccines
- Are currently enrolled and active in the VFC program (have a current signed enrollment form and have ordered/received VFC vaccine within the current calendar year)
- Received and have a documented enrollment visit on file

At the discretion of the grantee, these providers may be excluded from site visits if the following documentation is provided to VFC program at the time intervals indicated and the grantee has written records that certify that the documentation has been reviewed by program staff. Streamlined oversight does not relieve the VFC pharmacist from implementing and maintaining all VFC program requirements.

Required Documentation

Monthly submission of the following documentation will be required:

- Temperature logs
- Inventory report that includes:
 - Doses on hand by vaccine at beginning of reporting period
 - Doses received by vaccine during reporting period
 - Doses of vaccine administered by eligibility category
 - Doses of vaccine wasted/lost due to mishandling by vaccine for reporting period

- Doses on hand by vaccine at the end of reporting period
- A signed statement certifying that no change in VFC Coordinator or storage units has occurred since last report submission. The statement must be signed and dated by the individual who signed the enrollment form.

Grantee Follow-up

Grantee must review submitted documentation within 10 working days of receipt from the provider. If the documentation shows wasted/lost or unaccounted for vaccine of greater than 5%, temperature excursions, or a statement that there has been a change in the VFC coordinator or change in storage units used, grantee must follow-up with provider. If provider does not submit all required documentation, orders must be held until the required documentation is submitted and reviewed.

Provider Enrollment Requirements

Each provider must agree to the following requirements to participate in the VFC program. To help with communication of these requirements to the provider, educational goals are listed after each requirement. These educational goals must be communicated to providers at the time of initial enrollment and during the renewal process. It is the responsibility of the grantee's VFC staff to educate the provider and office staff on how to implement each requirement.

- 1) **Screen patients at each immunization encounter for VFC eligibility and administer VFC-purchased vaccine only to children who are 18 years of age or younger who meet one or more of the following categories:**
 - a) Are federally vaccine-eligible
 - i) are an American Indian or Alaska Native
 - ii) are enrolled in Medicaid
 - iii) have no health insurance
 - iv) are underinsured (children who have commercial [private] health insurance that does not include coverage for vaccines, children whose insurance covers only selected vaccines [VFC-eligible for non-covered vaccines only], or children whose insurance caps vaccine coverage at a certain amount [once that coverage amount is reached, these children are categorized as underinsured]. Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC).
 - b) Are considered state vaccine-eligible under criteria determined by each grantee (e.g., underinsured children not served through an FQHC or RHC) for administration of pediatric vaccines purchased with Section 317 or state funds.

Please Note: When developing the provider enrollment form, grantees that have any purchase policy other than VFC-only must outline which children are state vaccine-eligible to receive publicly purchased vaccines from VFC-enrolled providers.

Provider Education Goals for this requirement:

By the end of the enrollment or VFC compliance site visit, the provider and staff will understand

- The eligibility requirements for the VFC program
 - The eligibility requirements for children who are state vaccine-eligible
 - The VFC maximum regional charge does not apply to vaccine administration fees for state vaccine-eligible children. The VFC program does not have any authority over administration fees charged to state-vaccine-eligible children or privately insured children.
 - The grantee will monitor the screening for eligibility requirement during the VFC site visit by conducting a random sample of children 0-18 yrs.
 - For children that have Medicaid as secondary insurance are VFC-eligible, providers will understand the options of administering VFC vaccine and billing Medicaid for the administration fee or if the child's primary insurance includes full immunization benefits and no out-of-pocket expense for the parent, the provider may opt to use private stock vaccine and bill the private/primary insurance for the cost of the vaccine and the administration fee. The provider **MUST NOT** administer VFC vaccine and bill the private/primary insurance for the cost of the VFC vaccine. For more information on VFC and Medicaid as secondary, please see the VFC Frequently Asked Question and Answers document.
 - Where to refer underinsured children to obtain VFC vaccine if the child is not state-eligible in that practice
 - How and when to document the initial VFC screening appropriately. For more information on eligibility screening, please see Modules 2 and 9.
 - How to conduct VFC screening and document screening results (if required by the grantee) at subsequent immunization visits for all children birth – 18 years of age;
 - How to document changes to VFC eligibility status.
- 2) **Comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:**
- a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate;
 - b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

Provider Education Goals for this requirement:

By the end of the enrollment or VFC compliance site visit the provider and staff will understand

- The current ACIP recommendations and how to locate these recommendations and the VFC resolutions;

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- The process the grantee uses to notify VFC-enrolled providers about changes to the VFC program;
- The state laws related to vaccination requirements and acceptable vaccine exemptions;
- The true contraindications for each VFC vaccine.

3) Maintain all records related to the VFC program for a minimum of three years, or longer if required by state law, and make these records available to public health officials, including the state or Department of Health and Human Services, (DHHS) upon request.

Please Note: The grantee must check with legal counsel, medical licensing board, or Secretary of State to determine if the state requirement for record retention by a provider is longer or shorter than three years. If the state requirement is less than the three-year federal requirement, the state should use the federal requirement and delete the portion of the requirement that states, “or longer if required by state law.” If the state requires providers to maintain records for longer than three years, this requirement should be edited to state the amount of time the records must be maintained according to the state law.

Provider Education Goals for this requirement:

By the end of the enrollment or VFC compliance site visit the provider and staff will understand

- All records related to the VFC program must be maintained for the required time period. These records include (but are not limited to) patient screening forms, temperature logs, and any other reports or documents required by the grantee.

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

Provider Education Goals for this requirement:

By the end of the enrollment or VFC compliance site visit the provider and staff will understand

- Patients or Medicaid agencies cannot be billed for the cost of VFC vaccine or state-supplied vaccine.
- ***For grantees that allow borrowing, grantees must educate enrolled providers on CDC’s borrowing guidance. Providers must use the CDC borrowing form and follow the grantee requirements located at the end of this module. Grantees will be required to monitor the borrowing activities of VFC-enrolled providers during VFC compliance site visits and document findings in the VFC Site Visit Questionnaire.***
- Borrowing VFC vaccine to administer to a non-VFC eligible patient can occur only in rare, unplanned situations.

- VFC-enrolled providers are expected to maintain an adequate inventory of vaccine for their non-VFC-eligible patients.
- VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory.
- The provider's VFC vaccine supply must be adequate to meet the needs of the provider's VFC-eligible patients, and borrowing VFC vaccine must not prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child.
- Borrowing can occur only when there is lack of private-stock vaccine due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly.
- Every time a VFC vaccine is borrowed, the provider must complete the VFC Vaccine Borrowing Report form (borrowing forms are located at the end of this module). Once the borrowed VFC vaccine is replaced with private stock vaccine, that date should be entered on the form and the completed form saved and made available to VFC staff for review during the VFC compliance site visit.
 - If a provider borrows privately purchased vaccine to administer to a VFC-eligible child because no VFC vaccine is available, the provider must document that borrowing and replacement on the VFC borrowing form. This action is to ensure that the private-stock vaccine is replaced and the private inventory is made whole.

5) Not charge a vaccine administration fee to non-Medicaid VFC-eligible children that exceeds the administration fee cap of \$____ per vaccine dose (state to fill in amount for its administration fee. See Appendix 4 for maximum regional charges). For Medicaid VFC-eligible children, accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.

Provider Education Goals for this requirement:

By the end of the enrollment or VFC compliance site visit the provider and staff will understand

- The maximum amount that can be charged for administration of each VFC vaccine to non-Medicaid VFC-eligible children; the non-Medicaid VFC-eligible categories of children are Uninsured, Underinsured, and American Indian/Alaska Native.
- How to bill for the administration fee for VFC-eligible children enrolled in Medicaid.
- The administration fee is per vaccine and **not per antigen in vaccine.**

6) Not deny administration of a federally purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.

Provider Education Goals for this requirement:

By the end of the enrollment or VFC compliance site visit the provider and staff will understand

- This requirement applies to VFC vaccines as well as any other vaccines purchased through the CDC federal contracts when the VFC-eligible or state- eligible child's family/guardian is unable to pay the administration fee;
- The only fee that must be waived is the administration fee. Other visit or office fees may be charged as applicable.

7) Distribute the most current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

Provider Education Goals for this requirement:

By the end of the enrollment or VFC compliance site visit the provider and staff will understand

- How to obtain the most current VIS forms;
- The use of VIS forms applies to all vaccines included in the NCVIA or purchased through federal contracts;
- The recordkeeping requirements for the NCVIA;
- How to report adverse reactions to VAERS.

8) Comply with the requirements for vaccine ordering, vaccine accountability, and vaccine management. Agree to operate within the VFC program in a manner intended to avoid fraud and abuse.

Provider Education Goals for this requirement:

By the end of the enrollment or VFC compliance site visit the provider and staff will understand

- The vaccine management practices required for participation in the VFC program;
- At a minimum comply with all provider requirements outlined in Module 6 of this *VFC Operations Guide*;
- The grantee's policy regarding replacing vaccine lost due to mismanagement;
- The grantee may require the provider to replace vaccine lost due to mismanagement by one of the following methods:
 - Dose-for-dose replacement of all VFC vaccine lost due to mismanagement
 - Reimbursement to State: This is acceptable if grantee has mechanism in place to accept payment for cost of all VFC vaccine lost due to mismanagement and the entire amount paid by a provider is returned to

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the immunization program and used to purchase additional pediatric vaccine for administration to VFC or state eligible children.

- Reimburse CDC for VFC vaccine lost due to mismanagement. Payment(s) should be made payable to CDC with documentation that the payment is reimbursement for cost of VFC vaccine lost due to mismanagement. Payments should be mailed to the following address:

CDC/FMO

P O Box 15580

Atlanta, GA 30333

- How to order vaccine and which documents must be submitted with vaccine orders.

***Please note:** When developing their requirements for vaccine ordering, accountability and management, grantees must include all required vaccine management responsibilities listed under “Provider Vaccine Management Requirements” in Module 6 “Vaccine Management” of this VFC Operations Guide.*

Grantees may include requirements related to the process for ordering VFC vaccine, including timing and amount of order as well as submission of any documents to demonstrate that VFC vaccine was provided only to VFC-eligible children within the provider's practice (accountability) without prior approval from CDC.

Beginning in 2011 the following requirements must be incorporated into all provider enrollment agreements in preparation for the implementation of VTrckS vaccine ordering system.

- 9) **Should my staff, representative, or I access VTrckS, I agree to be bound by CDC’s terms of use for interacting with the online ordering system. I further agree to be bound by any applicable federal laws, regulations or guidelines related to accessing a CDC system and ordering publically funded vaccines.**

- 10) **In advance of any VTrckS access by my staff, representative or myself, I will identify each member of my staff or representative who is authorized to order vaccines on my behalf. In addition, I will maintain a record of each staff member who is authorized to order vaccines on my behalf. If changes occur, I will inform CDC within 24 hours of any change in status of current staff members or representatives who are no longer authorized to order vaccines, or the addition of any new staff authorized to order on my behalf. I certify that my identification is represented correctly on this provider enrollment form.**

Provider Education Goals for this requirement:

By the end of the enrollment or VFC compliance site visit the provider and staff will understand

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- The provider should contact the Vaccine Order Management Contact Center at 877/878-6247 within 24 hours of a change in staffing related to vaccine ordering;
- The provider must keep a copy of the Identity Voucher available for review;
- The provider and grantee must keep a listing (paper-based or electronic) of all users who are authorized to use VTrckS and order vaccine on behalf of a specific provider;
- The provider must be able to use the VTrckS Access guide to assist in determining acceptable methods to verify the identification of staff who are authorized to order vaccines on the provider's behalf;
- The documents that discuss the regulations related to the federal CDC systems on the National Institute of Standards and Technology website at: <http://csrc.nist.gov/publications/PubsSPs.html>.

11) The grantee or the provider may terminate this agreement at any time for personal reasons or failure to comply with these requirements. If providers choose to terminate the agreement, they agree to properly return any unused VFC vaccine.

Provider Education Goals for this requirement:

By the end of the enrollment or VFC compliance site visit the provider and staff will understand

- Situations that would terminate their participation in the VFC program.
- How to return unused VFC vaccine.
- How to discontinue enrollment from the VFC program if the practice's situation changes.
- If a provider terminates their VFC enrollment, they must return all unused VFC vaccine within 30 days of termination date.

Please Note: All Provider Enrollment Forms must include the professional license numbers of all providers in the practice that are authorized to prescribe vaccines under state law.

Additional activities require prior approval from CDC (see next section on how to submit additional requirements for approval).

CDC no longer provides a template for the Provider Enrollment form; grantees must create their own Provider Enrollment forms using the nine requirements outlined above. The only requirements that grantees may customize are #1, #5 and #8. Items #1 and #5 allow the grantee to select the most appropriate wording, and requirement #8 allows grantees to select a limited number of additional accountability requirements without submitting to CDC for approval. **States may not impose additional requirements for enrollment without prior approval from CDC (see below for process to request additional provider requirements).**

Process for Requesting and Approving Additional Provider Requirements for VFC Participation

1. Immunization program manager submits written request to the Program Operations Branch VFC policy coordinator (electronic submission is preferred) for adding a new requirement to the VFC provider enrollment agreement. The written request must include the following information:
 - a. New requirement as it would appear on the enrollment form
 - b. Rationale for the new requirement, including why it would strengthen or enhance the grantee's VFC program
 - c. Proposed start date for the new requirement together with a written plan for implementing the new requirement for both new and existing VFC providers
 - d. Any potential negative impact to VFC program.
2. On a regular basis, the VFC policy coordinator will review the pending requirement requests with the Director or Deputy Director of the Immunization Services Division, CDC legal counsel, and other officials as necessary to approve, disapprove or request further information before making a decision on the request and will communicate the decision to the project officer.
3. The approval or disapproval will be communicated to the grantee by the project officer and/or the VFC policy coordinator.

VFC Eligibility in Special Populations

The VFC program recognizes several situations in which the use of special VFC eligibility screening forms may improve the efficiency of the provider's or clinic's implementation of the VFC program or are necessary because of the individual's situation. If a provider exclusively serves patients from birth through 18 years who are American Indian or Alaska Native or serves only Medicaid-enrolled patients, he/she may use the appropriate Comprehensive Certification Form (see Appendix 3). **Please remember that these Comprehensive Certifications are acceptable substitutes for individual VFC screening forms only if that provider's patient population is 100% American Indian, Alaska Native, or Medicaid enrolled. This certificate must be signed annually and verified against the most current provider profile.**

Please Note: Use of comprehensive certification forms is at a grantee's discretion. A grantee may require providers to screen all children individually for VFC eligibility even if the provider's population is 100% American Indian/Alaska Native, or Medicaid enrolled.

Another population that requires specialized VFC screening is minors under 19 years of age without insurance status presenting at family planning clinics. CDC defines a family planning clinic as a clinic or provider whose main purpose is to prescribe contraceptives

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and/or treat sexually transmitted diseases. School-based clinics or any VFC-enrolled provider whose main services are primary or acute care services are not defined by CDC as family planning clinics. A person under 19 years of age who may have insurance but because of the confidential circumstances for seeking services in a family planning clinic does not have access to that insurance coverage is considered uninsured for the purposes of the VFC program. The family planning clinic must screen these adolescents for VFC eligibility using the form "**Patient Eligibility Screening Record Vaccines for Children Program in Family Planning Clinics**" (see Appendix 3). In addition, each family planning clinic must document all VFC vaccines administered to unaccompanied minors without insurance information on the administration log titled: **Family Planning Clinic Unaccompanied Minor without Insurance Information VFC Vaccine Log** (see Appendix 3). The completed logs should be submitted to the immunization program on a monthly basis. Please note that the VFC program does not in any way regulate the issue of medical consent for the provision of medical care to minors. It is assumed that the clinic provides any such care in conformance with the state's medical consent laws as they pertain to minors. Provision of VFC vaccine to unaccompanied minors without insurance status in family planning clinics is at a grantee's discretion and in compliance with the state's medical consent laws as they pertain to minors.

***Please note:** In addition, to reviewing a family planning clinic's monthly Family Planning Clinic Unaccompanied Minor without Insurance Information VFC Vaccine Log, each grantee must provide aggregate information annually on the number of children without insurance status who are provided VFC vaccine in family planning clinics, including the type and number of VFC vaccines administered to these children in the VFC Management Survey that is due annually on March 1.*

***Please note:** Grantees can develop their own systems to collect the information required on the Family Planning Clinic Unaccompanied Minor without Insurance Information VFC Vaccine Log (see Appendix 3). The template is provided as an example, and use of the template is not required. If a grantee develops its own system, the grantee must collect all information shown on template.*

Another special population that the VFC program may serve is juveniles under the age of 19 years of age who are incarcerated in detention facilities. If a child under age 19 years loses access to their health insurance because of the incarceration, the child is considered uninsured and VFC-eligible.

At times VFC-eligible children receive their health care in a bordering state instead of their state of residency. This usually occurs due to access to health care issues. Grantees should have Memoranda of Understanding (MOUs) in place with neighboring states to ensure VFC-eligible children have access to VFC vaccine within their medical homes. Providers must be educated that if the provider administers VFC vaccine to a Medicaid VFC-eligible child from a neighboring state, the provider must be a Medicaid enrolled provider for the state where the Medicaid VFC-eligible child resides in order to receive reimbursement for the administration fee from the neighboring state's Medicaid program. Please refer to Appendix 3 for a sample "border states" MOU.

Grantee Requirements for Monitoring and Reporting Borrowing Vaccine between Private and VFC/Public Stocks

Providers that care for VFC-eligible and privately insured children in non-universal purchase states must maintain two separate inventories of vaccines, one inventory of privately purchased vaccine for the provider's privately insured children and the inventory of publicly purchased vaccine supplied to the provider for administration to VFC and state vaccine-eligible children. At the grantee's discretion borrowing between the two inventories of vaccines may occur but must be a rare occurrence. **Please Note: The only vaccine not eligible for borrowing is the seasonal influenza vaccine since there is no guarantee that the influenza vaccine can be replaced within the same season.**

CDC's expectation is that VFC-enrolled providers maintain adequate inventories of vaccine to administer to both privately insured and VFC-eligible children. The borrowing of vaccine must be due to unforeseen delay or circumstance surrounding the vaccine that was ordered. Scheduling of a mass immunization clinic without having appropriate amounts of both public and privately purchased vaccine available on-hand for the expected participants would not be considered an unexpected circumstance. Expecting 5,000 VFC-eligible children and 2,000 privately insured children to attend a mass immunization clinic and having 7,000 VFC-eligible children and 1,000 privately insured children present at the clinic would be an unexpected circumstance. Borrowing forms must be completed in all settings for all vaccine borrowed. When a situation occurs that vaccine must be borrowed from VFC stock to administer to a non-VFC-eligible child or when private stock is borrowed to administer to a VFC-eligible child. The VFC borrowing report must be completed. The borrowing report must be completed when either privately purchased vaccine is administered to a VFC-eligible child or VFC vaccine is administered to a privately insured child. The provider must document why the vaccine was borrowed and must document the date the vaccine was replaced and the inventory was made whole.

Borrowing activities must be monitored as part of the VFC compliance site visit, and questions regarding borrowing are included in CDC's VFC Site Visit Questionnaire. Follow-up and/ or corrective actions must be taken when excessive or inappropriate borrowing activities are noted.

- Documentation must occur when any vaccine is borrowed regardless of inventory origin.
- Two-way borrowing can be used by a VFC-enrolled provider with a patient population that is mostly VFC-eligible and has only a small number of privately insured children in order to prevent loss of privately purchased vaccine due to expiring vaccine. Privately purchased vaccine that is short dated may be "borrowed" and administered to a VFC-eligible child and the borrowed dose replaced with a longer-dated VFC dose. This borrowing may occur to prevent vaccine loss due to the vaccine reaching the expiration date. Please remember that this type of "borrowing" must be documented on the VFC borrowing report.

- If requested by CDC, grantees must be able to provide data on reasons for borrowing and average length of time to replace borrowed stock
- Borrowing of vaccine between the two vaccine inventories must be a rare occurrence. Grantees must follow-up with providers that have multiple episodes of borrowing of vaccine in a single year (the exception is for providers who are borrowing short-dated vaccine to prevent loss of vaccine), and the follow-up should include assessment of the immunization delivery system within the practice or VFC program to determine if changes must be implemented to eliminate the need for frequent borrowing of vaccine. Providers should be notified that the state may ask for information validating that borrowed VFC vaccine was replaced by asking for a copy of the invoice for the privately purchased vaccine used to replenish the borrowed VFC vaccine; the invoice date should correspond with the replacement date on the borrowing report.

VFC Enrollment and VFC Compliance Visits

As noted on page 2 of this module, all providers enrolling in the VFC program must receive an enrollment visit prior to receiving any vaccine through the VFC program. The visit must include the following content:

- Review and confirmation of that provider and staff understand and can implement the VFC requirements
- Confirm that provider has the proper equipment to maintain VFC vaccine and staff understand how to properly store, handle, and monitor VFC vaccine and who to contact if problems arise
- Each grantee must develop a standardized method for documenting these visits.
- CoCASA can be used to document the date of the visit and a small amount of information in text form on the content of the enrollment visit.

VFC compliance site visits are defined as visits that include the administration of Section One of CDC's VFC Site Visit Questionnaire (see Module 9). Beginning in 2011, grantees are required to conduct VFC compliance site visits to a minimum of 50% of their enrolled and active public and private VFC providers annually. The goal is to ensure that all enrolled and active providers receive a VFC compliance site visit with the administration of Section One of CDC's Site Visit Questionnaire at least every other year. Grantees may wish to conduct VFC compliance site visits to more than 50% of their enrolled and active providers annually, and CDC fully supports these additional activities. For the purposes of determining a provider's status for receiving a VFC compliance site visit, the definition of enrolled and active VFC provider is a provider that has a current signed provider enrollment form on file and has ordered vaccine in the current reporting year. If a provider receives a VFC compliance site visit in January, it is acceptable to use the previous year's activity to define enrolled and active. Enrolled and active providers are defined within Table One of the VFC Management Survey.

Who Should Sign the VFC Provider Enrollment Form?

Section 1928 (c) (1) (A) of the Social Security Act (42 U.S.C. 1396s (c) (1) (A) states that the following providers qualify to be VFC program-registered providers: those healthcare providers "licensed or otherwise authorized for administration of pediatric vaccines under the law of the State in which the administration occurs" (subject to section 333 (e) of the Public Health Service Act, which authorizes members of the Commissioned Corps to practice).

The VFC statute follows state law in qualifying practitioners as VFC providers. The term "authorized for administration of pediatric vaccines" is intended to mean authorized to "prescribe" vaccines. Therefore, only providers authorized to prescribe vaccines under state law should be the official VFC program-registered providers. However, other providers authorized to administer vaccines can operate under the supervision of a prescribing VFC provider and should be listed on the Provider Enrollment Form.

SAMPLE COMPLETED VFC Vaccine Borrowing Report

Guidance:

VFC-enrolled providers are expected to maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. VFC vaccine cannot be used as a replacement system for a provider’s privately purchased vaccine inventory. The provider must assure that borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child. Borrowing would occur only when there is lack of appropriate stock vaccine (VFC or provider-purchased) due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly. The reason cannot be provider planned borrowing from either the private stock or the VFC stock.

Directions for use of this form:

When a provider has borrowed vaccine from one stock to administer to a child who is only eligible to receive vaccine from the other stock, this form must be COMPLETELY FILLED OUT for each borrowing occurrence. **Each vaccine a child receives must be listed on a separate row.** As soon as the borrowed doses of vaccine are replaced to the appropriate vaccine stock that date must be entered on this form. These borrowing reports must be kept as part of the VFC program records and be made available to the VFC staff during the VFC Site Visit.

Vaccine Borrowed	Patient Name/Patient Identifier/ Insurance status (VFC or private)	DOB	Date Borrowed	Reason no appropriate stock vaccine was available (circle one)	Date vaccine returned to appropriate stock
DTaP	Shirley Temple VFC	08/01/2010	10/19/2010	1. Private stock order delayed 3. <u>VFC order delayed</u> 5. other (specify)	2. Private stock non-viable on arrival 4. VFC order non-viable on arrival 10/21/2010
IPV	“ “	“ “	“ “	1. Private stock order delayed 3. VFC order delayed 5. other (specify)	2. Private stock non-viable on arrival 4. VFC order non-viable on arrival 10/21/2010
DTaP	Mickey Rooney private	08/15/2010	10/19/2010	1. Private stock order delayed 3. VFC order delayed 5. other (specify)	2. <u>Private stock non-viable on arrival</u> 4. VFC order non-viable on arrival 10/21/2010
IPV	Mickey Rooney private	08/15/2010	10/19/2010	1. Private stock order delayed 3. VFC order delayed 5. other (specify)	2. <u>Private stock non-viable on arrival</u> 4. VFC order non-viable on arrival 10/21/2010
				1. Private stock order delayed 3. VFC order delayed 5. other (specify)	2. Private stock non-viable on arrival 4. VFC order non-viable on arrival

"I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.

"Provider Name: Dr. Sam Who Provider Signature: Dr. Sam Who Date: 02/21/2011

VFC Vaccine Borrowing Report

Guidance:

VFC-enrolled providers are expected to maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. VFC vaccine cannot be used as a replacement system for a provider’s privately purchased vaccine inventory. The provider must assure that borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC eligible child. Borrowing would occur only when there is lack of appropriate stock vaccine due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly. The reason cannot be provider planned borrowing from either the private stock or the VFC stock.

Directions for use of this form:

When a provider has borrowed vaccine from one stock to administer to a child who is only eligible to receive vaccine from the other stock, this form must be COMPLETELY FILLED OUT for each borrowing occurrence. **Each vaccine a child receives must be listed on a separate row.** As soon as the borrowed doses of vaccine are replaced to the appropriate vaccine stock that date must be entered on this form. These borrowing reports must be kept as part of the VFC program records and be made available to the VFC staff during the VFC Site Visit.

Vaccine Borrowed	Patient Name/Patient Identifier/ Insurance status (VFC or private)	DOB	Date Borrowed	Reason no appropriate stock vaccine was available (circle one)	Date vaccine returned to appropriate stock
				1. Private stock order delayed 2. Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	
				1. Private stock order delayed 2. Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	
				1. Private stock order delayed 2. Private stock non-viable on arrival 3. VFC order delayed 4.VFC order non-viable on arrival 5. other (specify)	
				1. Private stock order delayed 2. Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	
				1. Private stock order delayed 2. Private stock non-viable on arrival 3. VFC order delayed 4. VFC order non-viable on arrival 5. other (specify)	

"I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form."

Provider Name: _____ Provider Signature: _____ Date: _____

This document can be found on the CDC website at: <http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/07-module-3.pdf>

MODULE 4 – ACIP and VFC Vaccines



<http://www.cdc.gov/vaccines/recs/default.htm>

ACIP and its Responsibilities

The Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee that was established in 1964 to provide advice and guidance on the most effective means to prevent vaccine-preventable diseases. In 1993, Congress gave ACIP unique statutory authority to determine recommendations for the routine administration of vaccines to children and adults in the civilian population; these recommendations include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications. The ACIP is the only entity in the federal government that makes such recommendations. 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 associated with immunization and infectious diseases, including the chair. The Committee also includes eight nonvoting ex-officio members and several nonvoting liaison representatives from other health organizations. 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 2 to 5 years prior to licensure of a particular vaccine. Workgroups 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. Final immunization recommendations are published in the *Morbidity and Mortality Weekly Report (MMWR)* when approved by the ACIP and the Director of CDC.

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ACIP's Role in the VFC Program

ACIP's statutory authority includes the authority to determine the vaccines, number of doses, schedule, and contraindications for the VFC program as well as for the general population. ACIP is therefore legislatively linked to the VFC Program. The Committee also approves the specific recommendations for inclusion of a vaccine in the VFC Program, which are 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/acip-vfc-resolutions.htm>) soon after ACIP approval.

ACIP-Approved Vaccines and Biologicals Available through the VFC Program

The most current list of vaccines available through the VFC program can be found at: <http://www.cdc.gov/vaccines/programs/vfc/parents/apprvd-vaccs.htm>.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/08-module-4.pdf>

Module 5 - Site Visit Basics



<http://www.cdc.gov/vaccines/programs/vfc/default.htm>

Overview

The purpose of this module is to provide immunization programs at both the state and local level with basic information on the skills and resources necessary to make high-quality site visits. Site visits can focus on quality assurance, quality improvement or contain components of both quality assurance (VFC) and quality improvement (AFIX). Certain skills are necessary to be able to successfully conduct both types of site visits. Preparation and knowledge are key attributes that will assist staff to become successful in conducting site visits. It is important to remember that the main purpose of a site visit is **not** to complete a specific task, such as answer all the questions in the VFC Site Visit Questionnaire in 90 minutes or data enter 50 immunization records into the Comprehensive Clinic Assessment Software Application (CoCASA), run the reports for the office, and leave by 4 p.m. While all site visits have a time-sensitive component and reviewers must be mindful of the time, the visit should be viewed as an educational opportunity. The purpose of the VFC site visit is to assure that the enrolled provider is in compliance with all VFC program requirements. This module will outline the skills, knowledge, and preparation that will assist staff who make site visits become more effective and efficient.

Skill Sets for Site Visits

Being successful at conducting provider site visits requires more than just the ability to enter data, ask questions, run reports and give the office the information. Both VFC and AFIX visits require the staff conducting the visit to engage the office and develop an on-going relationship with the office staff. Certain skills and abilities can assist the staff conducting site visits to become an immunization resource for the provider and office staff. The good news is that all the skills needed to become a welcomed resource in a provider's office can be learned. Remember, it takes both time and practice to master developing new skills. So, the more time that is spent incorporating these skills into daily activities, the better staff will become at helping the providers they visit.

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Knowledge

Knowledge about immunizations and the willingness to share knowledge are critical when conducting site visits. It is important that the staff making the site visit have a clear and accurate understanding of the different types of immunizations, current recommended schedule, and proper storage and handling practices. The VFC staff must be able to share this knowledge with providers and office staff as needed during VFC site visits.

Staff members who make site visits should develop a resource binder or folder of up-to-date immunization related materials that can be left with the provider as necessary. This is important for both VFC and AFIX site visits.

Understanding the program

An important skill for any staff making provider site visits is to understand why the site visit is being conducted. For staff members that conduct VFC compliance visits, it is critical that they understand all aspects of the VFC program ranging from the state's vaccine purchase policy to the VFC Site Visit Questionnaire. In-depth knowledge of the program is essential for field staff to have since they are the individuals that will be responding to program questions and concerns. At a minimum, each staff member should understand why each question in the VFC Site Visit Questionnaire is being asked, and what to do if any high-priority questions are answered incorrectly. Staff conducting AFIX visits must have a clear understanding of the assessment methodology. For assessments using chart reviews, this includes what charts to include or exclude in the assessment, the number of charts to review, age range to include, active patient definition, and immunization series to be assessed.

In addition to understanding the key elements of the program, implementation of the visit policy/protocol as written by the grantee is extremely important. If the protocol calls for review of 30 charts for VFC eligibility, it is important to review all 30 charts. If the protocol instructs staff to review 50 charts but the office pulls fewer than the requested 50 and the number pulled does not represent the office's entire population of the selected age group, then the staff making the site visit must ask the clinic to pull additional charts for that age group to equal the number requested. The staff must review all the charts for all the required data elements. This consistency allows the results to be compared in a standardized fashion for providers visited by that grantee's staff. Understanding the rationale for why questions are asked, why reviews are conducted in a certain manner, and how the results are used at the local and national level will help assure that visits are conducted following the established protocol.

Staff training and joint compliance visits

Conducting staff trainings and monitoring the quality of VFC site visits are critical components to assuring the quality of the VFC program. Reviewers conducting compliance visits are required to participate in annual trainings held by the grantee to educate them on VFC program policies and other practices aimed at improving the quality of the VFC compliance visit. VFC Coordinators are also encouraged to

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participate in joint visits with each site visit reviewer annually, if feasible, to assess how the reviewer conducts site visits. Additional information on staff training and joint compliance visits can be found in Module 9 of this *VFC Operations Guide*.

Critical Thinking and Common Sense

Staff conducting VFC compliance visits must use their critical thinking skills throughout the visit. Many different skills are required to be able to think critically about a certain situation and how to resolve it. Knowledge of the VFC program is essential; if staff do not understand the rationale behind a requirement, it is doubtful that they can facilitate change in that situation. The responses provided to questions in Section One of CDC's Site Visit Questionnaire may not provide the whole picture to answer the question, "How well is this practice meeting the intent and requirements of the VFC program?" Critical thinking includes asking follow-up questions on answers or observations that do not make sense, are incomplete, or are vague. Critical thinking can be aided by keenly observing what is seen in the office, listening to what is being said to patients and colleagues about immunizations, and thinking about whether what is seen and heard fits with answers to the VFC Site Visit Questionnaire (Section One) provided by the office.

The Power of Observation

Staff members making provider site visits need to become skilled observers because what they see can be more important than what is said to them. Being aware of surroundings and developing questions based on observations can be used as teaching tools with the office. The following questions can be answered by looking around the office during a site visit and listening to what's being said: What printed immunization material is displayed for patients and staff? Are the materials current? When patients arrive for their appointment, does the staff ask for their immunization records? When scheduling an appointment, does the staff remind the patient to bring their immunization records with them? What information is posted on the clinic's storage units? How can these observations be used to assist the office in improving the implementation of the VFC and/or AFIX programs? The answers may lead to teachable moments that VFC/AFIX staff can use to comment positively on office strengths or opportunities for improvement related to immunization practices. For example, an outdated memo regarding VFC storage and handling posted on a storage unit can be replaced with the most current version, and the benefits of keeping important information in a key location can be reinforced with the office staff.

Effective Listening

Effective listening skills are important for staff members that make site visits. Staff must actively listen to what the provider and office staff say during a site visit. This means connecting with the other person and showing interest in what the person is saying. This can be accomplished through body language, making eye contact with the other person, addressing the other person by name, and taking notes about what the other person tells you.

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Of course, reviewers must respond to what was said. That response may involve confirming their understanding of what was said before responding. Confirmation may involve restating and clarifying what was heard or summarizing critical points and asking if the reviewer's understanding is accurate.

Before responding, it's important to think about what was said and the context of the conversation. A pause or simply stating, "Let me think about that for a minute," allows time to formulate a response to what was said. If someone from the practice or clinic asks a question that will require gathering more information, it is important to indicate that the information will be provided within a specific time frame and to follow up as promised. It is always better to research the question or concern and provide an accurate response at a later time than to respond immediately with incorrect information.

Asking Questions

It is important to not only understand why a question in the VFC Site Visit Questionnaire is being asked but how to ask the question. Staff administering the VFC site visit questionnaire should not ask the questions in a manner that would lead the respondent to answer the question correctly but allow them to describe what the practice is for that office. Outlined below are two ways to ask the same question:

What is the vaccine administration fee charged to non-Medicaid VFC eligible patients (uninsured, American Indian/Alaska Native, under-insured if vaccinated at FQHC/RHC)?

Do you charge more than (insert your state's maximum regional charge) as the vaccine administration fee to non-Medicaid VFC eligible patients (uninsured, American Indians/Alaska Native, underinsured if vaccinated at FQHC/RHC)?

The first question is asked exactly as it is written in VFC Site Visit Questionnaire (2011) and does not lead the office to the appropriate answer. The second question may suggest to the respondent what the correct answer is. Many of the questions in CDC's VFC site visit questionnaire are multiple choice and, depending on the situation, the administration of the questionnaire may flow more smoothly if the reviewer does not immediately read the choices to the office but waits to see if the office responds or if a prompt is needed to answer the question.

Note Taking

Note taking during a site visit can be helpful for remembering names or remembering to check on something for the provider; it can help improve organizational skills as well. Good organizational skills will help staff meet commitments and deadlines in a timely fashion. Providers and their employees will appreciate receiving correct information about the program within the agreed upon timeframe. The act of note taking allows the reviewer to document areas of concern and areas of strength identified during the site visit that may be used when developing an action plan to correct areas of VFC non-compliance or when developing strategies to improve immunization coverage levels. By

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following up and providing information to providers over time, providers will come to view VFC/AFIX staff as resources and not as reviewers, auditors, or evaluators.

Poise in Uncomfortable Situations

While most people dislike being or putting other individuals in uncomfortable situations, at some time while making site visits, a reviewer will be faced with addressing some potentially uncomfortable issues. Reviewers must be able to share and address negative information. For example, a provider may be found to be non-compliant with regard to a number of VFC requirements or the assessment may reveal a low coverage level. The reviewer must be able to present the information in a non-judgmental manner and help the provider and office staff understand their responsibilities (if the issue is VFC non-compliance) and what they can (for AFIX) or must (for VFC) do to improve or correct the situation. The discomfort in the situation may be lessened if the VFC staff can identify at least one strength of the practice and, if possible, suggest how the strength could be used to address or correct the non-compliant behavior. A good rule to follow is to begin and end the visit on a positive note. In these types of situations reviewers must rely on their knowledge and understanding of the program, their observations, and effective listening and communication skills to turn an uncomfortable situation into a positive interaction.

Reporting the Findings and Developing Follow-up Plans

An important aspect of the site visit is to share the findings with the provider and staff. For VFC site visits, any high-priority questions (designated by “!” in front of the question) answered incorrectly must be discussed and actions developed to correct the situation. Some high-priority questions that were answered incorrectly may be corrected through technical assistance at the time of the site visit, and no further follow-up is necessary.

Examples of high-priority questions that can be corrected at the time of the site visit are outdated VIS forms and absence of “Do Not Unplug” signs on electrical outlets or circuit breakers. If time permits, the reviewer could assist the office staff with reorganizing the storage units so short-dated vaccine is stored in front of longer-dated vaccine and all vaccine is stored centrally in the unit with space between vaccines for air to circulate. Once these activities are completed the provider would be in compliance with those high-priority questions and no further follow-up would be necessary. If technical assistance is provided, and no further follow-up is required because the non-compliant issue has been corrected, please remember that the original answer in the site visit questionnaire is **NOT** to be changed to the correct answer. The original answer to the questionnaire should never be changed after technical assistance or further follow-up is conducted that changes the situation from non-compliance to compliance. If the situation was corrected by technical assistance during the site visit, the technical assistance provided must be documented in the VFC site visit questionnaire under the question, “What corrective actions were recommended to this VFC-enrolled site?”

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For high-priority questions that require some type of follow-up to assure that the behavior has changed and the provider is in compliance, the plan should be documented in the VFC site visit questionnaire under the question, “What corrective actions were recommended to this VFC-enrolled site?” When the follow-up is completed, the grantee should document the appropriate type of VFC follow-up (VFC follow-up, secondary or tertiary educational follow-up). If the grantee uses CoCASA, this information should be documented on the visit information screen. Documenting VFC site visit follow-up activities in CoCASA allows the grantee to use CoCASA to run the necessary reports to complete the VFC Management Survey.

Be a Resource and be Resourceful

Networking

While it is critical to have knowledge about immunizations, ACIP-recommended schedules and the grantee’s program, it is not necessary to memorize every detail. It is important to be able to respond correctly to basic questions during the site visit, but it is equally important to know where to go to find the correct answer to more difficult questions. As provider offices develop on-going relationships with program staff members, they will rely on these staff members to answer more difficult questions. It is important for staff to have the knowledge base to know where or who to go to find the correct answer to difficult questions. This is as important to successful site visits as having a solid foundation of basic immunization and program knowledge.

Programs should promote networking among staff who conduct site visit so issues may be discussed and solutions identified. Equally as important is for grantees to have processes and procedures in place to assist new staff learn how and where to locate resources to help them answer difficult questions. Staff meetings present an ideal networking opportunity during which those who conduct site visits could discuss problematic situations and other program staff could offer ideas or help identify where written guidance is located to address the situation. The next section of Module 5 will discuss the preparation and logistics to conduct a site visit.

By developing the skills and habits discussed above, reviewers representing the VFC and/or AFIX program will be able to comfortably and effectively implement the goals of both programs and assure that the VFC program requirements are being implemented properly in provider offices.

Resource Materials

VFC staff that conduct site visits should develop a resource binder or folder of up-to-date immunization materials that can be copied or left with providers and office staff. It is important to have available a list of reputable immunization resources to share with providers and office staff. These resources should include, but are not limited to:

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Websites

- **Immunization Action Coalition**
<http://www.immunize.org/>
- **CDC**
<http://www.cdc.gov/vaccines/programs/vfc/default.htm>
<http://www.cdc.gov/vaccines/pubs/vis/default.htm>
<http://www.cdc.gov/vaccines/programs/afix/default.htm>
<http://www.cdc.gov/parents/>
<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>
- **State Health Department or Grantee Website Address**
(If applicable)

Print Materials

Current Vaccine Information Statements for all ACIP-recommended vaccines

Current Immunization Schedule

Storage & Handling Information

VFC-related materials including, but not limited to:

- Copy of the current Provider Enrollment Form to use as an aid for discussing program requirements
- Screening forms
- Temperature Logs
- Provider Profile forms (blank)
- Accountability forms (state specified)
- Any other additional materials

Since the field staff is the face of the VFC program to the provider, they must have immediate access to the most current version of CDC's VFC Operations Guide. This means that all field staff must have a hard copy of the most up-to-date VFC Operations Guide or know how to access the Operations Guide on CDC's VFC website.

Preparing for Site Visits

The ABCs of Conducting Site Visits

Grantees must develop written policies and protocols on how to schedule, prepare, implement, and document both VFC and AFIX provider site visits. The protocols should be as specific as possible. A good rule to follow is to provide enough detail in the protocol so that a person with appropriate skills and training could conduct a site visit with minimal supervision or clarification of expectations.

Grantees must have a formal training plan to educate staff about why site visits are important and how to conduct site visits. The outline below can be used to assist grantees

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in developing procedures for separate VFC and AFIX site visits or combined VFC/AFIX visits.

A. Staff training and required equipment

Staff responsible for conducting VFC and AFIX site visits must be able to schedule, conduct and appropriately document the site visits (following the grantee-developed site visit protocol). Scheduling site visits includes identifying a mutually convenient time for the visit, letting the provider know what working space and materials the VFC staff will need and approximately how long the visit will take, and reminding the provider of the time and date prior to the visit.

Training

Staff conducting the site visits must have received training on and must understand the following concepts:

- The purpose and importance of the visit and questionnaire;
- How to correctly administer the VFC Site Visit Questionnaire;
- Communication skills required to effectively schedule, conduct, report feedback findings and document the content of the visit;
- Documentation required after completing site visit;
- Follow-up with provider following the visit.

Required Material/Equipment

CDC requires all grantees to provide staff that conducts VFC or AFIX visits with the following:

- Copy of most current CDC VFC Operations Guide
- Copies of the current VFC Site Visit Questionnaire (Section One is required)
- Thermometer that has a certificate of calibration to check temperatures of storage units

B. Selecting provider sites

Grantees must develop a protocol for determining how VFC provider sites are selected for a visit. At a minimum, CDC requires that grantees conduct VFC visits to at least 50% of its VFC-enrolled and active providers each year. This means that half of the VFC-enrolled and active public and private providers are visited one year and the other half of the VFC-enrolled and active providers are visited the next year. VFC site visits may be done separately or combined with an AFIX visit. The composition of the providers visited should be split between both public and private providers so that, at a minimum, grantees are conducting VFC compliance visits to half of their public providers and half of their private providers annually. The compliance visits to 50% of enrolled and active VFC providers is the minimum-level requirement, and grantees that wish to conduct more compliance visits are encouraged to do so.

The following situations may necessitate an unscheduled VFC site visit:

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- High-volume vaccine usage/unusual ordering patterns
- Reports of suspected misuse or abuse of VFC vaccine
- Unacceptable storage and handling practices

All staff should be aware of the process used to select provider sites for VFC visits and follow it accordingly. Grantees that conduct separate AFIX visits must develop protocols for determining how providers are selected for AFIX visits.

C. Site visit scheduling protocols

A scheduling protocol should include the following key points:

- Identify a contact person in the office to discuss site visit requirements;
- Arrange the date and time for the visit;
- Confirm contact name, job title and phone number;
- Confirm office address and location;
- Discuss with the office manager how much time you estimate the visit will take and whom you need to talk to during the visit;
- Request to have the following materials ready for your review on the day of the visit:
 - Charts (number needed and any criteria to be used to select charts)
 - VFC-related materials for VFC visits (such as VIS statements and temperature logs)
- Send a confirmation letter, e-mail, or fax to office contact with date, time, materials needed and summary of visit process;
- Confirm the visit with the office contact 1 to 2 working days before the scheduled appointment.

D. Reviewing previous site visit information

Before making a site visit, staff should review all available information related to the provider site to be visited. Relevant documents to review may vary by grantee and type of visit but may include doses-distributed and doses-administered reports, enrollment data, provider profiles, past VFC site visit questionnaires, and AFIX findings. A thorough review of these documents will help staff be more aware of the past performance of the provider site as well as provide insight into questions that should be asked during the site visit. The provider profile should be carefully examined before every site visit; staff should be prepared to discuss necessary updates to the profile. In addition, staff should be prepared to review the VFC eligibility screening procedure with the provider.

E. Preparing for the site visit

The site visit protocol should provide the staff with information on what equipment and resources to bring with them to the site visit. Some essential items to bring include:

- Laptop computer for staff who use CoCASA to enter VFC Site Visit Questionnaire responses

- Calibrated thermometer to check temperature of storage units (**required for completion of VFC Site Visit Questionnaire**)
- Previous reports as applicable (i.e., previous VFC questionnaire results, provider profile, vaccine accountability reports)
- Blank forms as necessary (Provider Profile, VFC Site Visit Questionnaire)
- Handouts/resources, such as:
 - Immunization brochures and other educational materials
 - Current list of vaccines available through the VFC program
 - VFC Eligibility Screening Form
 - Standards for Pediatric Immunization Practice
 - Vaccine Information Statements (VIS) and instructions for their use (ensure that each VIS is current)
 - Monthly temperature logs for refrigerator and freezer recordings
 - “Do Not Unplug” stickers for refrigerator/freezer/electrical outlets and circuit breakers
 - Children's Health Insurance Program (CHIP) information
 - Information about upcoming CDC satellite courses, copies of any recent mailings from the grantee to providers about VFC or specific vaccine-preventable diseases

F. Conducting the site visit

The main focus of the site visit will depend on the type of visit being conducted. The VFC Site Visit Questionnaire guides the reviewer through a VFC compliance site visit with the primary focus on adherence to VFC program requirements and correct vaccine storage and handling practices. The AFIX process requires the reviewer to identify strengths and opportunities for improvement related to administration of appropriate vaccines to eligible patients according to the recommended schedule. In a VFC/AFIX combined visit, the reviewer must focus on the entire immunization process from how the vaccine is handled and stored to ensuring that the appropriate vaccine is given to an eligible patient on schedule. Each grantee must provide written policies and protocols on how to conduct site visits, but these policies and protocols will vary depending on the type of site visit. Training staff on how to conduct site visits is an essential component of provider quality assurance and improvement activities. Certain interpersonal skills and behaviors help to make the site visits a success, and these skills should be emphasized:

- Be well organized;
 - Know where to go, what time to arrive, and name of contact
 - Have identification and provide business cards
- Expect the unexpected and try to be flexible in addressing unexpected situations;
- Be a good observer and listener; use observations to back up findings of office's strengths and opportunities for improvement;
- Be an immunization resource and a partner to the provider and office staff.

G. Reviewing the findings

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Upon completion of the site visit, staff should discuss the outcomes in a face-to-face meeting with appropriate staff, either at the conclusion of the site visit or soon thereafter. This discussion should include a review of the visit findings and should address any recommended corrective actions (for VFC compliance visits) for the provider site. A follow-up plan for addressing any issues of noncompliance or opportunities for improvement should be agreed upon between the immunization program staff and the provider site staff and should be documented in writing for both office staff and immunization program. All details of the follow-up plan should be documented electronically. Please refer to the AFIX website and AFIX Standards for specific content requirements regarding the AFIX feedback session.

H. Analysis of provider site visits

In addition to sharing site visit results with the provider, the VFC/AFIX coordinator and/or immunization program manager should regularly review summary data from completed site visits. Reviewing summary data will help to track staff activities as well as identify any trends across multiple provider sites. Identified issues should be carefully reviewed with staff, and follow-up plans should be made to address staff and/or provider needs.

Please Note: Use of CoCASA will allow users to print out past VFC site visit results (at the provider level), which is a valuable tool for identifying potential problems within that provider's office. Other reporting options are available through CoCASA and can be used to assist with the review of provider data at the program level.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/09-module-5.pdf>

MODULE 6 – Vaccine Management



<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>

Overview

Throughout this module, CDC's Vaccine Storage and Handling Toolkit is referenced frequently. This toolkit will always be the most current source of information regarding vaccine storage and handling and should be the primary resource for vaccine storage and handling questions. Readers are urged to bookmark the website provided above for easy access when questions arise.

This module consolidates and standardizes information on all elements of vaccine management to help immunization grantees and their VFC providers improve the quality of their vaccine management from receipt to administration. It specifies the responsibilities at the various levels of vaccine management and provides general guidelines for effective vaccine management and correct vaccine storage and handling.

The module describes the required policies of the VFC program, which are based on guidance from CDC's *Vaccine Storage and Handling Toolkit* (referenced above) and other relevant resource materials developed for proper vaccine management. Specific topics covered are:

- Vaccine Distribution
- Elements of Vaccine Management
- Grantee Vaccine Management Requirements
- Provider Vaccine Management Requirements
- Provider Vaccine Management Recommendations
- Project Points of Contact (PPOC) Users Guide

Specific recommendations for vaccine storage and handling procedures may vary among grantee immunization programs. This module outlines the minimum vaccine management requirements for the VFC program and includes recommendations for improving vaccine management practices. These recommendations may be implemented at the grantees' discretion. Grantees may add additional vaccine management requirements to their provider enrollment requirements; however, the process to add additional requirements described in Module 3 must be followed.

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Vaccine Distribution

All vaccines purchased off the federal contract, with the exception of those that must be shipped frozen, are managed by CDC and distributed to end users through a third-party distributor (currently McKesson Specialty). Vaccines that must be kept frozen are shipped directly from the manufacturer to the end user in order to ensure maintenance of the cold chain.

Elements of Vaccine Management

The management of publicly purchased vaccine is one of the most important activities for which immunization grantees have oversight responsibility. Vaccines must be maintained properly to protect their viability prior to administration. Adhering to proper storage and handling procedures will minimize vaccine loss and wastage. The following paragraphs describe the key elements of vaccine management for immunization programs. Grantees are advised to consult the following resources for detailed information related to vaccine storage and handling:

CDC's Vaccine Storage and Handling Toolkit

(<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>)

CDC's recommendations and guidelines for vaccine storage and handling

(<http://www.cdc.gov/vaccines/recs/storage/default.htm>)

Project Points of Contact (PPOC) Users Guide

(<http://www.cdc.gov/vaccines/programs/vmbip/agm-documents-ppoc.htm>)

The Cold Chain

Primary resource:

CDC's Vaccine Storage and Handling Toolkit

(<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>)

Storage and handling that compromise vaccine viability can be costly in money and time. Vaccines must be stored properly from the time they are manufactured until the time they are administered. Excess heat or cold will reduce their potency and increase the risk that recipients will not be protected. The system used to maintain and distribute vaccines in optimal condition is called the "cold chain." The cold chain has three main components to ensure safe vaccine transport and storage:

- Transport and storage equipment
- Trained personnel
- Efficient management procedures

Vaccine manufacturers set vaccine temperature requirements for storage. It is important to follow manufacturers' vaccine product specifications found in the package insert. Contact the manufacturer directly for questions about a specific vaccine storage

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temperature or temperature excursion. Alternatively, specific questions on vaccine storage issues can also be sent to nipinfo@cdc.gov.

The cold chain begins with the cold storage unit at the vaccine manufacturing plant, extends through the transfer of vaccine to the distributor and then to the provider's office, and ends with the administration of the vaccine to the patient. Proper storage temperatures must be maintained at every link in the chain. At the transport link (from manufacturer to distributor to provider), vaccine is transported in a refrigerated or frozen state, as appropriate (refrigerator 35°–46°F [2°–8°C]; freezer 5°F [-15°C] or colder), using an insulated container or a refrigerated truck. During storage, vaccines must also be appropriately stored at the recommended temperature ranges shown above. As noted in the *Storage and Handling Toolkit*, the desired average temperature is 40°F/5°C for refrigerated vaccines.

If a cold chain failure is suspected or there is evidence that vaccine has been exposed to temperatures outside the recommended temperature range or inappropriately exposed to light, providers should immediately notify the state, city, territorial, or other responsible immunization program. Vaccine should be marked "DO NOT USE" so that the vaccine is not administered until a response indicating that the vaccine is acceptable for use has been received. Providers should not discard any vaccine unless directed to do so by the immunization program. Providers should follow the instructions in the CDC *Vaccine Storage and Handling Toolkit* for handling inappropriate vaccine storage conditions.

CDC's *Vaccine Storage and Handling Toolkit*

<http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/troubleshooting.htm>

The manufacturer's package insert describes the required storage conditions for a vaccine. Manufacturers also have access to internal (unpublished) thermostability data concerning the impact of exposures to inappropriate temperatures or light. Providers that experience or suspect that the cold chain has been compromised should contact the grantee immunization program which will contact manufacturers for guidance in the event of such exposure.

Prevention of Vaccine Loss and Wastage

Immunization program staff and healthcare providers and staff are responsible for maintaining vaccine quality from the time a shipment arrives until the moment a dose is administered. Maintaining the quality of vaccines and other biological products is the shared responsibility of manufacturers, vaccine handlers, and all healthcare professionals involved in immunization delivery.

Vaccine waste is both costly and preventable. There are many reasons for vaccine waste including heat and/or light exposure, inappropriate freezing, broken vials and syringes, poor reconstitution practices, contamination and suspected contamination, discarding doses at the conclusion of outreach sessions, missing inventory, and theft. However, the most significant causes of vaccine waste are attributed to poor vaccine management, i.e., loss due to expiration and loss due to cold chain failures.

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Vaccine loss due to expiration is frequently a consequence of over ordering and/or poor inventory management. Grantees should educate providers about proper vaccine management, including how to determine appropriate order sizes and rotate vaccine doses in inventory to avoid loss because of expiration and excess ordering. Grantees also need to review provider orders to monitor any issues pertaining to the provider's inventory management (e.g., wastage, excessive inventory).

Inventory Management

Public and private providers enrolled in the VFC program are responsible for the proper maintenance of their vaccine inventories and for ordering vaccine in the appropriate amounts. Providers are expected to maintain a five-week inventory and order vaccines in a manner that enables them to support that inventory.

Providers should order all vaccines at one time. To avoid shortages, providers should place replenishment vaccine orders at least 15 days in advance of their actual need.

Grantees should require providers to submit vaccine inventory with each order. This provides a check against possible stockpiling or inventory build-up and can serve to prompt the provider to order all vaccines at the same time.

Where practical, and as long as the cold chain can be maintained, short-dated vaccine may be transferred to another provider so that it may be used prior to expiration. The grantee must actively coordinate the transfer of vaccine between the providers.

Temperature Monitoring – Using Calibrated Thermometers

Providers enrolled in the VFC Program are required to have calibrated thermometers in all refrigerator and freezer compartments used for VFC vaccine storage in order to monitor temperatures. Reviewers conducting VFC compliance site visits must also use a separate calibrated thermometer during the visit to independently assess storage unit temperatures. Each device is to be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are traceable to an ISO/IEC 17025 accredited testing laboratory, to NIST, or to another internationally recognized standards agency. A certificate of calibration accompanies thermometers that have undergone this calibration against a reference standard. If there is not a calibrated thermometer with valid documentation (i.e., certificate) at the time of the VFC compliance site visit in any of the vaccine storage units, then corrective action must be taken by the office to correct the situation, and the corrective action steps must be monitored by the grantee.

Additional information about thermometers is available in the *Vaccine Storage and Handling Toolkit* located at: <http://www2d.cdc.gov/nip/vsh/ToolkitWeb/splash.html>.

Grantees must establish their own policies regarding which types of thermometers are acceptable and their recalibration requirements when the thermometer calibration expires.

Recalibration requirements should take into account manufacturer specifications and guidelines. Grantees should consider the following when developing requirements:

1. Manufacturer specifications for recalibration of thermometers: the manufacturer-specified frequency of recalibration varies by make and model, with recalibration every 1-2 years being typical. This should be considered as part of the overall cost when purchasing thermometers.
2. The recalibration of reviewer thermometers: reviewer thermometers are used to assess storage unit temperatures during compliance visits to compare against the provider site's thermometer temperature reading. It is important to recalibrate the thermometers used by reviewers according to the manufacturer's recommended schedule.
3. The relative accuracy of thermometers: nearly all thermometers will have some variance in accuracy (generally +/- 1° C and +/- 2° F). The grantee should define the acceptable variance before recalibration or replacement is required.

Grantee Vaccine Management Requirements

All grantee staff working on VFC activities must receive initial training and periodic review in a formal setting on the grantee's responsibilities for VFC vaccine management. The content and date of the training for each staff member must be documented and kept as part of the staff member's training/orientation record. All staff should have a copy of the responsibilities and must know how to do the following as appropriate to their role:

- Provide training on appropriate vaccine ordering, handling, and storage, as well as reporting requirements about wastage to VFC-enrolled providers and their staff. The initial training should occur at the time of enrollment into the VFC program. The training should include giving providers a simple generic vaccine management plan that they can modify or use as is to meet the vaccine management plan requirement. Follow-up training should occur in any of the following situations: provider request, site visit findings, or program changes. Maintain records of training of VFC providers and other attendees responsible for storage and handling of vaccine who participate in such training. Please refer to the *Vaccine Storage and Handling Toolkit* section on *Storage and Handling Plans* (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>) and Appendix 5 for resources to assist in the development of vaccine management plans.
- Review, approve, and process orders from VFC-enrolled providers in a timely manner.
- Review orders for appropriateness based on provider profile, doses administered and inventory data.

- Order grantee-funded vaccine in accordance with the vaccine spending plan that is established annually and updated monthly which outlines population-based vaccine needs, funding sources and purchase schedules for each NDC.
- Ensure that vaccines remain effective (potent) by developing, reviewing regularly, and, as necessary, updating written standard operating procedures (SOPs) for providers that cover vaccine ordering, receiving, storage, handling, inventory management and disposal.
- Annually review vaccine storage and handling practices and update all VFC providers on the latest storage and handling policies.
- Request that VFC providers notify the program of any vaccine doses that will expire before they will be able to administer them. When feasible and if the cold chain can be ensured, redistribute short-dated vaccines to high-volume providers who are able to administer them before they expire.
- Develop and implement written procedures for providers to report and respond to losses resulting from vaccine expiration, waste, and compromised cold chain.
- Document expired and wasted doses of publicly purchased vaccine.
- Require providers to return wasted and expired vaccines to the distributor to facilitate collection of excise tax credit.
- Actively coordinate and document the transfer of vaccine between providers. Vaccine transfers between providers can occur only after receiving approval from the grantee.

Provider Vaccine Management Requirements

An important VFC program responsibility of the grantee is to work with providers to develop and implement simple but accurate plans for routine and emergency vaccine management. Grantees must provide templates to providers on key vaccine management requirements. Please see the *Vaccine Storage and Handling Toolkit* (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>) sections on *Storage and Handling Plans* and *Vaccine Personnel*, as well as Appendix 5 for resources to assist in the development of plans. All providers must be able to meet the following requirements in order to participate in the VFC program:

Vaccine Personnel

Each VFC provider must:

- Designate one staff member to be the primary vaccine coordinator and at least one back-up vaccine coordinator who is able to perform the same responsibilities as the primary vaccine coordinator in the event that the primary person is unavailable. These positions will be responsible for key requirements and will provide oversight for all vaccine management within the office.
- The designated vaccine coordinator and backup must be responsible for reviewing vaccine storage unit temperatures to ensure they are within the recommended

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- ranges and documenting the temperature on the temperature logs for each storage unit twice a day.
- Train other staff who are responsible for administering vaccines or who may be required to transport vaccine in an emergency situation, following the office's vaccine storage and handling plan. A simple log sheet with the staff member's name and date of training must be kept and displayed as documentation.
- Unless otherwise noted, the vaccine coordinator and/or backup should be the VFC contact for the office.

Storage and Handling Plans

Providers must have written routine and emergency storage and handling plans. They may develop their own or customize grantee-supplied storage and handling templates to reflect their office practice. Both the routine and the emergency plans should be simple, and the processes outlined in the plan should be presented in a clear and concise manner. Both plans should be reviewed and updated as necessary.

- The routine vaccine storage and handling plan should include guidance on routine vaccine management process/practices. Please refer to “Routine Vaccine Storage and Handling Plan Worksheet in the *Vaccine Storage and Handling Toolkit* (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>).
- The emergency vaccine storage and handling plan must include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. Please refer to “Emergency Vaccine Retrieval and Storage Plan Worksheet” found in the *Vaccine Storage and Handling Toolkit* (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>).
- In any type of power outage:
 - Freezers and refrigerators should not be opened until power is restored, except to transport vaccine to an alternative storage location.
 - Temperatures and duration of power outage must be monitored; vaccine should not be discarded or administered until the situation has been discussed with public health authorities.
- At a minimum, the emergency plan must be reviewed and updated annually (or as necessary) or when there is a change in staff that have responsibilities specified in the emergency plan.

Vaccine Storage Equipment

Providers must have appropriate equipment that can store vaccine and maintain proper conditions. For detailed information on refrigerators and freezers, grantees and providers should refer to CDC’s *Vaccine Storage and Handling Toolkit* (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>). Two types of storage units are acceptable:

- 1) A refrigerator that has a separate freezer compartment with a separate exterior door, or

2) Stand-alone, single-purpose refrigerators and freezers.

Refrigerators or freezers used for vaccine storage must comply with the following requirements:

- Be able to maintain required vaccine storage temperatures year-round;
- Be large enough to hold the year's largest inventory;
- Have a working thermometer calibrated with certificate in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards placed in a central area inside each storage compartment; follow manufacturer's recommended schedule for recalibration.
- Be dedicated to the storage of vaccines. (Food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.)

A dormitory-style refrigerator (a small combination refrigerator-freezer unit outfitted with a single external door) is **never acceptable for permanent storage** of VFC vaccines. Permanent storage is defined as having the vaccine supply maintained in the unit 24 hours a day/7 days a week. Dormitory-style refrigerators are not adequate for long-term storage of biological products; they cannot be used to store vaccine on a permanent basis due to their inability to reliably maintain temperatures needed to keep vaccine within required ranges to prevent vaccine loss caused by inappropriate temperature excursions. The primary concern with dormitory-style units is the presence of the freezer compartment co-located inside the refrigerator compartment, which creates an environment that places refrigerated vaccine at high risk for freezing.

At the grantee's discretion, providers may use dormitory-style refrigerators to **temporarily** store a clinic's single-day supply of **refrigerated** vaccines. The freezer portion of the dormitory-style refrigerator must never be used to store any vaccine. Temporary storage is defined as storing a clinic's single-day supply of refrigerated vaccines and returning unused vaccine to the main (permanent) refrigerator storage unit at the end of each clinic day. Visually monitoring temperatures twice daily and recording temperatures in a log are required for any unit storing VFC vaccine, permanent and temporary.

Grantees have the discretion to ban the use of dormitory style refrigerator among providers altogether, even for temporary storage. However, for grantees choosing to allow the use of dormitory-style refrigerators under limited conditions for short-term (temporary) storage of select VFC vaccines, the following conditions listed below must apply:

1. The purpose of using these units is for temporary storage when it is not reasonable for the staff administering the vaccine to go to the main storage unit to obtain vaccine for each and every patient.
2. **The unit is never used for storing varicella-containing vaccines**

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3. Only small amounts of inactivated vaccines are maintained in these units. The amount of inactivated vaccines stored in the unit must never exceed the amount used in the clinic in one day.
4. The vaccine is returned to the main storage unit at the end of each clinic business day and vaccine is never stored in these units overnight or during periods of time when the practice is not open for business.
5. Each unit has a dedicated calibrated thermometer in place.
6. **Temperatures are visually monitored and documented twice a day on temperature log specifically for that unit.** Appropriate action is immediately taken when the temperatures are outside the appropriate range.
7. These units must be included and examined during the VFC compliance visit and corrective actions taken and documented by the grantee if any of the above conditions are not met.

It is essential for the integrity and continuation of the VFC program to ensure that VFC vaccine is stored under conditions which decrease the chance of vaccine loss due to inappropriate storage conditions. Sharing with the provider the monetary amount that the VFC vaccine represents in that specific practice can help to further illustrate the need to store and manage the vaccine appropriately. Grantees are encouraged to develop a protocol to have reviewers discuss the monetary value of vaccine stored at the provider site. The directions for reviewers can be outlined in the grantee's site visit protocols.

Vaccine Storage Practices

The vaccine storage practices listed below are the responsibility of the provider/clinic vaccine coordinator or the vaccine coordinator's back-up. If delegated to the back-up, the designated vaccine coordinator must monitor these activities regularly.

- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine.
- Notify the grantee immunization program of any vaccine doses that will expire before they can be administered. Only with the approval and direct guidance of the grantee immunization program and only if the cold chain can be ensured, redistribute short-dated vaccines to high-volume providers who are able to administer it before it expires.
- Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent.
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils, and peripheral areas.
- Store vaccine with enough space to allow for cold air circulation around the vaccine.
- Never store vaccines in the door of the storage unit.
- Never store food or drink in the storage unit.

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Temperature Monitoring

Please see “Temperature Monitoring” section in CDC’s *Vaccine Storage and Handling Toolkit* (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>).

Temperature monitoring should be the primary responsibility of the provider/clinic vaccine coordinator and backup. If other staff must monitor temperatures, those persons must be trained on how to respond to and document actions taken when temperatures are outside the appropriate range.

- Post a temperature log on the vaccine storage unit door or nearby in a readily accessible and visible location.
- Record refrigerator and freezer temperatures twice each day (beginning and end) ensuring that refrigerator temperatures are between 35° and 46° F (2° and 8°C) and the freezer temperatures are 5°F or lower (-15°C or lower). Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used.
- Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage temperatures outside the recommended ranges. Document actions taken on the temperature log.
- Maintain an ongoing file of temperature logs, and store completed logs for 3 years (unless state statutes or rules require retention for a longer period).

Receiving Vaccine Shipments

Primary resource:

“Vaccine Shipments” section of CDC *Vaccine Storage and Handling Toolkit* (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>)

- VFC vaccine shipments received from the distributor contain heat and freeze exposure indicators. VFC direct shipments of frozen vaccine from manufacturers are shipped in specialized boxes and do not contain heat indicators.
- Immediately upon delivery of vaccine, check the vaccine cold chain monitors, if included, and store vaccine according to manufacturers’ product specifications.
- Take proper action if either the freeze or heat cold chain monitor was activated. Instructions for reading the monitors are printed on the monitor cards.
- Document heat or freeze monitor readings if indicative of out-of-range temperature exposure, and contact the state immunization program for further guidance. Document action taken based on state immunization program instructions.
- If the provider believes that a vaccine shipment is compromised, temperature monitors are out-of-range, or a heat monitor is not activated (i.e., turned on), the provider should also contact McKesson Customer Service within 2 hours of vaccine shipment delivery time at 1-877 836-7123.
- Develop policies and protocols for maintaining the vaccine cold chain during transport to off-site clinics or emergency storage locations. See guidelines:

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Maintaining the Cold Chain During Transport
(<http://www.immunize.org/catg.d/p3049.pdf>).

Vaccine Wastage

Primary resource:

“Preparation and Disposal” section of CDC’s *Vaccine Storage and Handling Toolkit*
(<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>)

- Notify immediately the immunization program of vaccine cold chain failure/wastage incidents involving publicly funded vaccines after discovery of the incident. Follow the guidance of the grantee on how to document and report the incident.
 - Wasted vaccine: a vaccine that cannot be used; includes expired, spoiled, drawn-up but not administered, dropped vial, broken vial, lost vial.
 - Expiration date: the last date on which the vaccine may be used; expired vaccine includes vaccine that is past the manufacturer expiration date on the vial or expiration date after reconstitution depending on the vaccine and according to manufacturer instructions.
- Implement written protocols for reporting and responding to losses resulting from vaccine expiration, wastage, and compromised cold chain.
- Remove wasted/expired vaccine from storage containers with viable vaccine to prevent inadvertent administration.
- Return, as directed by the grantee, all wasted or expired publicly purchased vaccines for excise tax credit.

Please note: Providers should return vaccine to the centralized distributor.

Vaccine Preparation

The National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention, strongly recommends that providers draw vaccine only at the time of administration to ensure that the cold chain is maintained and that vaccine is not inappropriately exposed to light. **Do not** pre-draw doses before they are needed.

Vaccine Ordering and Inventory Management

- Order vaccine in accordance with actual vaccine need
- Develop and maintain complete, accurate and separate stock records for both publicly and privately purchased vaccines. The requirement to keep separate records does not necessitate having separate storage units for public and private vaccines. Providers must be able to distinguish between their public and private vaccine stock.

Vaccine Security and Equipment Maintenance

Primary resources:

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“Storage Equipment” section of CDC’s *Vaccine Storage and Handling Toolkit*
(<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>)

Post “DO NOT DISCONNECT” notices at both the electrical outlet and the circuit breaker to prevent power from being disconnected.

Provider Vaccine Management Recommendations

Grantees may encourage providers to implement all or some of the following vaccine management activities, as applicable to the individual practice.

Vaccine Personnel

The primary and backup vaccine coordinators should train other staff to be responsible for vaccine storage and handling requirements in case of emergency.

Vaccine Storage Practices

- Remove vegetable bins from the refrigerator; replace with cold water bottles.
- Store all opened and unopened vials of vaccine in their boxes inside the appropriate storage unit so that their contents and expiration dates are easily visible.
- Stabilize refrigerator and freezer temperatures with proper placement and use of water bottles and frozen packs.
- Keep vaccines organized.
- Open only one vial, or box, of a particular vaccine at a time to control vaccine use and allow easier inventory control. On each opened vaccine vial indicate on the label the date and time it was reconstituted or first opened.
- Store vaccine products that have similar packaging in different locations in the storage unit to avoid confusion and medication errors.

Temperature Monitoring

- Monitor vaccine storage temperatures by using a minimum/maximum thermometer or continuous recording thermometer in the refrigerator and freezer.

Vaccine Security and Equipment Maintenance

- Limit access to the vaccine supply to authorized personnel only.
- Install locks on refrigerators and, if possible, the electrical plug.
- Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
- In larger clinics, provide a source of backup power (generator) and a security system to alert appropriate personnel in the event of a power outage.

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- If applicable, test backup generators quarterly and maintain backup generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).

Project Points of Contact (PPOC) Users Guide

The PPOC Users Guide is a resource for grantees that provides guidance on vaccine ordering, vaccine shipping, vaccine inventory management, and wasted/expired vaccine returns. This guidance is based on federal contracting rules and procedures, including those outlined in the federal vaccine distribution contract and the Federal Acquisition Regulations (FAR). For additional information, Grantees should refer directly to the PPOC guide located at the following link:

<http://www.cdc.gov/vaccines/programs/vmbip/agm-documents-ppoc.htm>.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/10-module-6.pdf>

MODULE 7 – Vaccine Order Management System



<http://www.cdc.gov/vaccines/programs/vacman/default.htm>

Overview

CDC's vaccine management software application (VACMAN) is used by immunization grantees to order, track and record information concerning publicly funded (VFC, 317 and state) vaccine purchases. VACMAN communicates with an in-house system (NIPVAC) at CDC, which approves and processes orders for vaccine shipment and payment.

Version 4.x refers to any VACMAN version starting with 4. (For example, it includes 4.0, 4.1.2, 4.1.3, 4.1.3.1.) Reports are available in VACMAN 4.x to assist the immunization programs with vaccine order tracking. Information about VACMAN is available online at: <http://www.cdc.gov/vaccines/programs/vacman/default.htm>

Note:

VACMAN Help Desk

Grantees needing assistance with orders or ordering sent to CDC using VACMAN should use the contact information below.

- Voice: TOLL FREE 1-877-878-6247 (Select Option 3 for VACMAN)
- FAX: 1-866-958-6247
- TTY/TDD: 1-800-232-0038
- vaccineordermgmt@CDC.GOV

Alternatively, grantees may use the current VACMAN Help Desk number (404-639-8303) or the VACMAN e-mail box vacman@cdc.gov.

Transition Plan

The Vaccine Tracking System (VTrckS), a critical component of the Vaccine Management Business Improvement Project (VMBIP), is an information technology system that will integrate the entire publicly-funded vaccine supply chain from bulk purchasing and provider ordering to distribution of the vaccine.

VTrckS will allow health care providers to input their vaccine requests (orders) directly online thereby improving efficiency and accountability of public dollars. The system will

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evaluate vaccine orders against specific guidelines set by grantees (i.e., state, local, and territorial health departments) and the Centers for Disease Control and Prevention. VTrckS will replace existing systems, both external and internal to CDC, that are currently used for vaccine management. These systems include VACMAN, NIPVAC and other internal CDC systems used for managing vaccine funding. VTrckS will provide data to support vaccine distribution that will be made available to CDC and grantees for analysis and program management.

VTrckS is being developed by teams with a variety of expertise and in consultation with key stakeholders including grantees and immunization providers. A Grantee Advisory Committee helped to ensure that VTrckS will meet the needs of the grantee community, and a Provider Advisory Committee is working to ensure that VTrckS will meet the needs of the health care provider community.

For current information on the VTrckS implementation, please visit the link below:

<http://www.cdc.gov/vaccines/programs/vtrcks/index.html>

<http://www.cdc.gov/vaccines/programs/vmbip/default.htm>

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/11-module-7.pdf>

MODULE 8 – Vaccine Accountability



<http://www.cdc.gov/vaccines/programs/vfc/default.htm>

Overview

Vaccine accountability is a cornerstone of the VFC program and one of CDC's highest priorities. Immunization grantees have the primary responsibility for developing and maintaining vaccine accountability systems that ensure:

1. Vaccines purchased with VFC funds are administered only to VFC-eligible children;
2. Vaccine loss and waste are minimized and measured;
3. The VFC program is protected against fraud and abuse;
4. VFC and other federally purchased vaccines are ordered appropriately based on a provider's VFC-eligible population and state-eligible population.

The vaccine budget for the VFC program has steadily increased since the establishment of the VFC program in 1994. In 2011, the vaccine budget will be nearly \$4 billion. The rise in the vaccine budget is primarily due to the increase in the number of ACIP-recommended childhood vaccines and the increased cost of these new vaccines. The increase in the cost of VFC vaccine has placed renewed emphasis on program accountability at all levels – federal, grantee and provider.

Background

Structuring an effective VFC accountability program requires knowledge and understanding of each grantee's vaccine finance policy. The finance policy determines what funding sources are used to purchase vaccine through the federal vaccine contracts, how these vaccines are distributed to VFC-enrolled providers and what groups of children and adults can receive the vaccine. Key terms to understand are:

Vaccine funding sources

How grantees use VFC, 317, and state/local funding sources to purchase vaccines:

- VFC funds: Federal entitlement funds used to purchase vaccines for administration only to VFC-eligible children;
- 317 funds: Federal discretionary funds that can be used to purchase vaccine for non-VFC eligible populations (children and adults);
- State funds: State-contributed funds used to purchase vaccines for individuals who are not VFC-eligible (children and adults).

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Vaccine-eligible children

Vaccine purchased through federal contracts with VFC, 317 or state funds can be used for:

- Federally-vaccine eligible children (a child who is eligible to receive VFC vaccine);
- State-vaccine eligible children (a child with characteristics defined by the state who is eligible to receive vaccine purchased by the state using state and/or 317 funds).

Public- vs. private-purchased vaccine

- **Public vaccine** is vaccine purchased with 317, VFC or State funds and provided at no cost to providers to be administered at no cost for the vaccine to eligible persons.
- **Private vaccine** is vaccine purchased by a health care provider to administer to individuals who are not federally-vaccine eligible or state-vaccine eligible.

Grantee Finance Policies

A grantee's finance policy determines which vaccines a grantee will purchase, which funding sources will be used, and which populations and provider facility types will be eligible to receive the vaccines.

Accountability Requirements

Since the beginning of the VFC program, every VFC provider has been required to submit a Provider Enrollment form and a Provider Profile form at the time of enrollment and annually thereafter. By signing the Provider Enrollment form, VFC providers agree to certain requirements as a condition of participation in the VFC program. The requirements include:

- Screen patients at all immunization encounters for eligibility and administer VFC-funded vaccine only to VFC-eligible children. Children should be screened for VFC eligibility and, where appropriate, screened for state vaccine eligibility (criteria determined by each grantee; vaccines for this category are purchased with Section 317 or other state funds)
- Comply with the requirements for ordering, vaccine accountability, and vaccine management.
- Agree to operate within the VFC program in a manner intended to avoid fraud and abuse.

Provider Enrollment Forms

Provider Enrollment forms must be signed annually by all enrolled and active VFC providers. Annual reenrollment in the VFC program is a federal requirement. The requirement for annual reenrollment affords grantees the opportunity to reinforce the VFC program requirements and answer any questions providers might have regarding the

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requirements. Grantees must develop their own Provider Enrollment forms that include all required federal requirements as outlined in Module 3.

If a grantee has a finance policy that uses 317 and/or state funds to purchase vaccines to support vaccination of children who are not VFC eligible, these populations are defined as “state-eligible” and must be defined as such on the enrollment form or on an attachment to the enrollment form. Providers must have a clear understanding of VFC-eligible and state-eligible populations in order to appropriately order and administer publicly purchased vaccine.

Screening for Eligibility

CDC requires all providers to document the VFC-eligibility status of all children in the practice. The screening process determines if a child is eligible to receive a publicly purchased vaccine. After the initial documentation of VFC screening, CDC requires verbal screening at all future immunization encounters. Whenever a child’s eligibility changes, CDC requires documentation of the child’s new eligibility status; this includes documenting if the child is no longer VFC-eligible because the child is fully insured. Accurate and timely screening of all children who present for immunization screening is an essential accountability activity. Grantees are responsible for ensuring and verifying that all children are screened for eligibility at every immunization encounter. Grantees have the discretion to require enrolled providers to document the VFC screening results at every immunization encounter even if the eligibility status is unchanged.

Provider Profiles

VFC program guidance requires that all providers complete a provider profile based on actual data, and update and submit a provider profile with new data annually. Since data from a provider’s profile should be used to evaluate the provider’s vaccine orders, the accuracy of the data is very important. Currently, each grantee determines how the information should be collected and how it should be used for ensuring that VFC-funded vaccine is being administered only to VFC-eligible children. Please see Appendix 2 for a sample provider profile form.

VFC Compliance Site Visits

Beginning in 2011, all grantees must conduct VFC compliance site visits to at least 50% of the program’s enrolled and active providers annually. This means that half of the VFC-enrolled and active public and private providers are visited one year and the other half are visited the following year. A VFC compliance site visit is defined as a site visit that includes the administration and completion of Section One of CDC’s most current VFC Site Visit Questionnaire. Information gathered during the site visit can be used to identify accountability and compliance issues at the individual provider level. Follow-up activities will be needed to address any non-compliance issues identified. Please refer to Modules 3, 5, 9, and 10 of the *VFC Operations Guide* for additional information about VFC Compliance Site Visit Requirements.

Additional Requirements

Written Accountability Policies

All grantees must develop, implement, maintain and, when requested, submit to CDC written vaccine accountability policies. These written policies must address:

- How provider profiles are used to monitor provider orders.
- How wasted and lost vaccines are monitored at the provider level. At a minimum, grantees should have thresholds that will prompt follow-up and education.
- How provider vaccine inventory records are monitored to ensure that providers have adequate supplies of public and privately purchased vaccine for the population size that the provider serves. Grantees should have a standardized methodology to determine how providers are selected to have their vaccine inventory records reviewed.
- How fraud and abuse is prevented or identified; specifically, how VFC staff members are educated on and use the *CDC Non-compliance with VFC Provider Requirements Protocol* (algorithm) is used to address providers who are not maintaining VFC program requirements.
- How providers return expired and wasted VFC vaccine for excise tax credit.

Vaccine Loss and Waste

Beginning on January 1, 2011, CDC will require grantees to monitor and report the volume (e.g. number of doses by vaccine type) of publicly purchased (VFC, 317, and state/city/territory) vaccine wasted by the sum total of VFC-enrolled providers due to expiration and improper storage and handling. All grantees will be required to report in the VFC Management Survey due March 1, 2012, the total number of doses of publicly purchased vaccine wasted due to expiration and improper storage and handling and the cost of that vaccine for the reporting period. The cost of the lost/wasted vaccine should be based on the CDC's price list as of December 31st of the reporting year. CDC will analyze data submitted and develop goals for vaccine wastage/loss. Grantees have the flexibility to determine how to monitor providers for vaccine loss and wastage.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/12-module-8.pdf>

MODULE 9 – Quality Assurance



<http://www.cdc.gov/vaccines/programs/vfc/default.htm>
<http://www.cdc.gov/vaccines/programs/cocasa/default.htm>

Introduction

The purpose of this module is to provide immunization programs at both the state and local level with information on the quality assurance requirements for the VFC program. All immunization grantees are required to conduct compliance site visits to all enrolled and active VFC providers in both public and private healthcare sectors. The review and evaluation of VFC provider practices involves the assessment of the verbal, written, and visual evidence encountered during the visit to determine if provider sites are following the requirements of the VFC program.

Compliance site visits help program staff determine the extent to which a provider site is in compliance with the requirements of the VFC program, including identifying potential issues with VFC accountability and determining whether VFC vaccines are being handled, stored, and administered in accordance with the laws and policies that govern the VFC program. Aggregated provider site visit results provide grantees with information on areas where providers are doing well or areas of non-compliance needing additional attention (e.g., policy change, training, education, etc.).

VFC Compliance Site Visits

The purpose of the VFC compliance site visit is to review records of children who are immunized through the VFC program and to evaluate the provider's recordkeeping, vaccine handling and storage procedures, and compliance with requirements of the VFC program. All immunization grantees are required to conduct compliance site visits to all enrolled and active VFC providers in both public and private healthcare sectors. VFC compliance site visits must include the administration of all questions in Section One of CDC's VFC Site Visit Questionnaire. During a VFC compliance site visit, the provider's compliance with requirements of the VFC program are evaluated by reviewing a sample of the records of children who are immunized through the VFC program, evaluating the provider's recordkeeping, vaccine handling and storage procedures, and responses to Section One of CDC's VFC Site Visit Questionnaire; to be considered a VFC compliance site visit, the visit must include the administration of all questions in Section One of CDC's VFC Site Visit Questionnaire.

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VFC compliance site visits must include:

- Administration of the VFC Site Visit Questionnaire;
- Reviewing VFC eligibility screening procedures;
- Verifying the information in the provider profile;
- Monitoring VFC vaccine administration, storage and handling;
- Ensuring VFC program policies are being properly implemented;
- Providing feedback and, as necessary, implementing corrective actions and follow-up of identified problems.

Site visit minimums and selecting provider sites

As of January 2011, grantees are required to conduct VFC compliance site visits to at least 50% of their enrolled and active VFC providers annually, so that at least half of enrolled and active VFC providers are visited in one year and the remaining half the following year. The composition of the providers visited should be split between both public and private providers so that, at a minimum, grantees are conducting VFC compliance site visits to half of their public providers and half of their private providers annually. The compliance site visits to 50% of enrolled and active VFC providers is the minimum-level requirement and grantees that wish to conduct more compliance site visits are encouraged to do so.

Selecting the order in which to see providers in a given year is at the discretion of the grantee. Factors such as volume of vaccine orders, past non-compliance issues, reports of waste, complaints, or geographic location may influence decisions to prioritize the order of the visits made during the year.

Staff training and joint compliance site visits

Conducting quality compliance site visits begins with well-trained and competent reviewers. Reviewers conducting site visits are, at a minimum, required to participate in annual trainings sponsored by the grantee. The training should provide updates on program policies and additional education that prepares reviewers to conduct effective site visits and provide current and accurate information to clinic staff. Newly hired reviewers are required to shadow an experienced site visit reviewer on a VFC compliance site visit as part of their training. The experienced reviewer must have a thorough understanding of VFC program requirements and knowledge on conducting VFC compliance site visits in provider office settings. The VFC Coordinator (or qualified designee) is also required to accompany new reviewers on at least one VFC compliance site visit when the new reviewer begins conducting independent site visits. The VFC Coordinator (or qualified designee) should observe the reviewer's practices in conducting the compliance site visit and, if needed, provide guidance and suggestions to improve the quality of the visit conducted. A record or notes from the joint visit should be documented in the reviewer's training file.

VFC Coordinators are encouraged to conduct at least one joint VFC compliance site visit with each reviewer annually and document the joint visit in the reviewer's training file.

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Joining reviewers on VFC compliance site visits is one means to observe reviewer practices and behaviors during a compliance site visit in order to assess site visit skills, make suggestions or corrective actions for improvement, and learn of techniques the reviewer may be using that could be valuable for others. The goal of the joint site visit is to make observations and recommendations that will ultimately improve the quality of the visits conducted by assessing a site visit reviewer's behaviors and practices. A sample supervisory site visit tool shared by a grantee is located in Appendix 6.

Preparing for the site visit

Reviewing previous site visits

Prior to conducting a compliance site visit, reviewers should prepare by reviewing past site visit data, if available. Information on past site visits, planned or conducted follow-up, or other contacts made with the provider site can provide the reviewer a basis to help identify areas in which to focus attention during the visit. Particular attention should be paid to past non-compliance resulting in corrective actions in order to note whether behavior changes or compliance to other requirements were sustained. Vaccine wastage or expired vaccine reports should also be reviewed to detect unusual patterns or problems that need to be addressed during the site visit.

Reviewing the fraud and abuse database and excluded provider list

Fraud and abuse database

Grantees are required to maintain a database to monitor fraud and abuse allegations that include the date of the allegation, source of allegation, actions taken, and outcomes. Additional information regarding the development and maintenance of the database can be found in Module 10 of this *VFC Operations Guide*. In preparation for the compliance site visit, the grantee maintained fraud and abuse database must be checked to see if the provider to be visited was involved in past allegations and the outcomes of any allegations. The reviewer can use the information found on past allegations to help inform or focus the site visit and must address any re-lapses of non-compliance found during the site visit.

Excluded provider list

The Department of Health and Human Services (HHS), Office of Inspector General (OIG) established a program to exclude certain providers from participating in Federally-funded health care programs and maintains a list of those excluded on the "*List of Excluded Individuals/Entities*." The basis for exclusion includes program-related fraud, patient abuse, licensing board actions, and default on Health Education Assistance Loans. The list can be accessed at: <http://oig.hhs.gov/fraud/exclusions.asp>.

The list must be reviewed at the provider site's initial enrollment into the VFC program and subsequently reviewed on a monthly basis for all provider sites. Grantees may check a state database for excluded providers in addition to the HHS OIG list, but not in place of the list. Persons on the "*List of Excluded Individuals/Entities*" are not allowed to participate in the VFC program; a VFC-enrolled provider site that has a person employed

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on the excluded provider list must be terminated from the VFC program. The state Medicaid Agency must be notified of the termination. Additionally, excluded providers cannot participate in the program indirectly, such as providing services under a non-excluded VFC provider. A non-excluded VFC provider that employs or contracts with a provider who is an excluded provider cannot seek payment on behalf of the excluded provider. In such circumstances, the non-excluded provider employing or contracting with the excluded provider is not able to participate in the VFC program. Additional information is available in the *Special Advisory Bulletin on the Effect of an Exclusion* located at: http://oig.hhs.gov/fraud/alerts/effect_of_exclusion.asp. Please refer to Module 10, Fraud and Abuse, of this *VFC Operations Guide* for further guidance.

Preparing the provider site

Just as grantees prepare for the compliance site visit, it is useful for providers to be informed about their upcoming visit and what to expect. Preparing the office in advance will improve the efficiency of the site visit by making the most of the limited time available during the visit. Provider sites should be provided with general information about the upcoming compliance site visit in order to help them understand what to expect and the items they will need to have available for the reviewer. Provider site staff involved in the site visit should be prepared to accurately answer and demonstrate behaviors assessed in the questionnaire. Grantees may wish to send Section One questions 1-8 to the provider prior to the visit and ask that the responses be completed prior to the site visit. However, the complete questionnaire (Section One) in its entirety should not be provided to the clinic/practice in advance of the compliance site visit. The compliance site visit should give the reviewer a realistic picture of how the provider site is implementing the VFC program on a daily basis, and not one that is changed specifically for the site visit.

It is also critical to communicate to the provider site the items and locations the reviewer will need to access in order to efficiently conduct the site visit. In advance of the site visit, the provider site should be notified the reviewer will need access to:

- A space to work (and a power source if a laptop is used)
- Patient medical records to screen for patient eligibility. The provider site should be informed of the number of records to select and the protocol for selecting the records if the reviewer does not complete this task for the provider site.
- Current and past temperature logs and vaccine borrowing reports for the last 3 months or longer if issues are found.
- Clear access to the circuit breaker. The provider site should be informed that maintenance staff may need to be available during the site visit to gain access to the circuit breaker, if needed.
- Access to admitting and billing personnel to clarify screening and billing processes, if needed.
- Access to all vaccine storage units where VFC vaccine is maintained, both permanent and temporary storage units.
- Other items deemed necessary to review by the grantee.

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Having provider site staff who will be involved in the site visit understand the needs and expectations of the site visit will increase the reviewer's ability to conduct an effective and successful visit in a timely manner.

The VFC Site Visit Questionnaire

The CDC VFC Site Visit Questionnaire is a tool used to determine a provider site's compliance with the federal requirements of the VFC program. The Questionnaire is reviewed and updated annually and is available in the Comprehensive Clinic Assessment Software Application (CoCASA). CDC requires all grantees to administer all high priority questions in Section One of the CDC VFC Site Visit Questionnaire as written. The Questionnaire and answer key to the high priority questions may also be found at: <http://www.cdc.gov/vaccines/programs/vfc/psv-questionnaire.htm>.

Persons conducting VFC compliance site visits must complete all the questions in Section One of the CDC VFC Site Visit Questionnaire. Questions identified with a red exclamation point (!) are considered high priority and corrective actions must be developed if the provider is not in compliance with any of these questions. Only Section One of the VFC Site Visit Questionnaire is required to be completed during a site visit; all other additional questions asked during the site visit are optional and at the discretion of the grantee. Section Two of the questionnaire includes optional questions related to the Standards of Pediatric and Adolescent Immunization Practices. Section Three of the questionnaire allows grantees to create custom questions specific to their programs (Section Three is only available in the CoCASA software application). Grantees choosing to ask additional optional questions beyond the required Section One questions must make sure the questions asked and information gained are used to improve the quality of the VFC program or provider site practices. If asked by CDC, the grantee must be able to demonstrate how this information is being collected and used in a standardized manner across the grantee's jurisdictional area.

Every grantee must develop a written protocol for provider compliance site visits that outlines procedures for:

- Selecting provider sites
- Conducting compliance site visits (including instruction on how to administer the VFC Site Visit Questionnaire)
- Reporting results from completed compliance site visits and post compliance site visit actions (follow-up activities).

All immunization grantees are required to conduct VFC compliance site visits to 50% of enrolled and active VFC provider sites annually.

Administering the Questionnaire

Understanding the intent of each question (and the associated federal requirement) in Section One of the questionnaire and successfully using interview and observation skills to complete the questionnaire are key elements to conducting quality site visits. Administering the questionnaire is more than reading the questions verbatim and

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collecting the provider's responses. A successful visit involves assessing the verbal, written, and visual cues encountered during the visit to complete the questionnaire. The reviewer should engage in dialogue with provider staff to gain a full understanding of how VFC requirements are being met and to what degree; the reviewer should provide education and corrective actions when the provider site is not compliant with the high priority questions.

Each question in Section One of the CDC VFC Site Visit Questionnaire is linked to a federal requirement for the program. It is important for reviewers to understand all questions asked in Section One of the questionnaire and be comfortable in providing the correct guidance when provider sites are noncompliant with a question, especially for the high priority questions designated by the red "!".

Verifying the Provider Profile

Providers are required to submit an updated provider profile with the provider enrollment agreement annually to the grantee. The provider is required to estimate the number of children who will receive vaccinations at the provider site and the number of children expected to be VFC eligible. A copy of the provider profile is located in Appendix 2.

Grantees are required to assess if the patient population estimate reported in the provider profile is a reasonable estimate that coincides with the provider site's vaccine ordering patterns. This requirement is reflected in the first high-priority question on the CDC Site Visit Questionnaire, "Are vaccine orders consistent with the most current provider profile?" Assessing the reasonableness of the population estimate reported on the provider profile could involve comparing the estimate to the birth cohort for your state or jurisdiction to see if the percentage of patients estimated to be seen relative to the birth cohort is an amount that appears to make sense for the community that the provider serves. Grantees can also assess the provider site's vaccine orders to determine if the ordering pattern is an appropriate amount for the estimated VFC-eligible patient population. For example, if the provider profile indicates the provider site estimates serving 100 eligible patients under one year of age over a twelve month period, the grantee could review the amount of DTaP doses ordered during the same period to see if it greatly exceeds or falls short of what a child under one would expect to receive over the course a year (3 doses per eligible child, 300 doses over a year, or 75 doses over a quarter). If the quantity of doses greatly exceeded or falls short of the expected number of doses to be used for the estimated population, the provider site should be queried to better understand the reasons for the differences or if the provider profile needs to be updated and/or the source of the estimate.

Another method to verify the provider profile could involve using doses administered data reported through a registry system. A comparison between the amount of vaccine ordered and the doses that provider site administered to eligible patients could help show whether doses ordered are being correctly administered to eligible populations, and whether the quantities ordered are appropriate amounts for the eligible populations estimated on the provider profile.

Screening for VFC Eligibility

The purpose of assessing provider site procedures for eligibility screening is to monitor whether providers are appropriately identifying eligible populations to receive VFC vaccine. Screening for VFC eligibility is the foundation of provider-level accountability. Screening children for eligibility at every visit is the only way to ensure that VFC vaccine is used only for VFC eligible patients. Consequently, provider sites must screen all children at every immunization visit. During a child's initial visit to the provider site, documentation of the child's eligibility category must be collected and then maintained on future visits. Verbal screening is sufficient for subsequent visits after initial documentation as long as the child's eligibility status has not changed; if the child's eligibility status changes, it must be documented. However, grantees have the discretion to require enrolled providers to document the VFC screening results at every immunization encounter even when the eligibility status is unchanged.

To assess provider sites screening practices, the grantee must have a written standardized protocol that all field staff follows that includes sample size, random records/charts selection, reviewing the records/charts and compiling results. CDC recommends a sequential-based review, which involves using the appointment schedule and selecting the last X (sample size) patients who were 0 through 18 years of age and were seen for immunizations. At a minimum, CDC requires at least 10 records/charts be reviewed for documentation of screening for VFC eligibility unless the provider has fewer than 10 patients from birth through 18 years of age. If a provider has 10 or fewer patients from birth through 18 years (both VFC and non-VFC eligible), charts for all 10 (or fewer) of those patients must be reviewed for documentation of screening for VFC eligibility. If a provider has 11 or more patients from birth through 18 years (both VFC and non-VFC eligible), the grantee has the option of determining the sample size. The number of records/charts reviewed can be based on the volume of patients seen from birth through 18 years by a provider. Appendix 6 contains sample instructions on how to conduct VFC eligibility screening by selecting a random sample of children within a practice. The protocol and methodology uses a sample size of 30 records/charts and discusses different methods for selecting the screening sample. The methods for pulling the sample can be used with different sample sizes (e.g., 10 records).

If a combination visit (VFC/AFIX) is being conducted, the records from the AFIX sample can be used to assess eligibility screening. If the AFIX sample does not contain at least 10 records, use the AFIX sample and systematically select additional records from the 0-18 years age group until the needed number of records for the eligibility screening sample is reached. Reviewing more than the minimum 10 records is at the grantees' discretion. Grantees must establish a standard number of charts to be reviewed for eligibility screening during all VFC compliance site visits. The sample must include both VFC and non-VFC eligible children. If a provider does not have the necessary number of records for children in the 0-18 years of age group, review all available charts.

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The grantee may require the provider to use the CDC screening form (see Appendix 3), a grantee developed screening form that contains all data elements on the CDC form or a provider-specific method. If a grantee approves a provider-specific method, the screening documentation must include **all data** elements listed on the CDC screening form. The screening documentation must be standardized regardless of type of health record used (paper or electronic).

Since the VFC requirement is to screen children at all immunization encounters (Module 3, *VFC Operations Guide*), anything less than full compliance (that is, identifying any chart that does not have documentation of screening) must be discussed with the provider and office staff and may require additional follow-up. If a provider site is not documenting the initial screening of all pediatric patients for VFC eligibility correctly, CDC's *Non-Compliance with VFC Provider Requirements Protocol* must be followed. After the initial documentation of VFC screening, CDC requires, at a minimum, verbal screening at all future immunization encounters; if a child's eligibility status changes, CDC requires documentation of the child's new eligibility status. Grantees have the discretion to require enrolled providers to physically document the VFC screening results at every immunization encounter even if the status is unchanged. Further discussion on screening practices and accountability is located in Modules 3 and 8 of this *VFC Operations Guide*.

Tips to understanding the Site Visit Questionnaire

The following are tips to understand select high-priority questions contained in Section One of the CDC VFC Site Visit Questionnaire:

A. “Are vaccine orders consistent with most current provider profile?”

- The purpose of this question is to verify the population estimates reported on the provider profile by confirming that the quantities of vaccine ordered are in the appropriate range to serve the VFC-eligible population the clinic reported on its provider profile. This cross-check will need to be conducted prior to the visit, and by staff at the grantee level with access to ordering information and the provider profiles. If this activity is done centrally and apart from the site visit questionnaire, responses to this question will need to be compiled and entered into the site visit questionnaire or compiled and reported in the annual VFC Management Survey.

B. “What is the vaccine administration fee charged to non-Medicaid VFC eligible patients (uninsured, American Indian/Alaska Native, under-insured if vaccinated at FQHC/RHC)?”

- Providers cannot charge more than the maximum regional charge for their state or territory for the non-Medicaid VFC-eligible patient. During the site visit, the provider site must be able to explain or demonstrate how much the practice charges for the administration fee for non-Medicaid VFC eligible patients.

C. “Which of the following vaccines are NOT routinely administered in this clinic/practice?”

- All VFC enrolled primary care providers should offer all ACIP-recommended vaccines. Specialty care providers (such as OB/GYNs, family planning clinics, pharmacies, and birthing hospitals) may be an exception and are allowed to offer select vaccines appropriate for the setting.

D. “When does this clinic/practice provide patients with copies of the Vaccine Information Statements (VIS) to keep?”

- Vaccine Information Statements should be offered at every immunization encounter prior to administration.

E. “When does the clinic/practice screen patients for VFC eligibility?”

- Screening of all children must occur at every immunization visit. Documentation of initial screening must be present in the patient record and the provider must document when change of eligibility occurs. Verbal screening is acceptable after the initial documentation. However, grantees have the discretion to require providers to document screening at all immunization encounters.

F. “Does this clinic/practice always notify the Immunization Program when publicly purchased vaccine has been involved in a cold chain failure, has expired or been wasted?”

- This question helps to identify sites with problem storage and handling practices. If expired vaccine is found in the storage unit and there was no indication the provider had notified the immunization program, this question must be documented as being noncompliant with a “No” response.

G. “Does the clinic/practice “borrow vaccine” between public stock and private stock?”

- Providers that care for VFC-eligible and privately insured children in non-universal purchase states must maintain two separate stocks of vaccines, one for privately insured children and another for VFC and/or state vaccine-eligible children. Borrowing between public and private stocks of vaccines is allowed, but must be a rare occurrence. CDC’s expectation is that VFC-enrolled providers maintain adequate stocks of vaccine to administer to both privately insured and VFC-eligible children. When a situation occurs which necessitates the borrowing of vaccine from VFC stock to administer to a non-VFC-eligible child or from private stock to administer to a VFC-eligible child, the VFC borrowing report must be completed.

Similar to temperature log forms, the bi-directional borrowing form must be maintained by the provider site and must be reviewed during VFC site visits. Grantees will review the borrowing report during site visits and use it to respond to the borrowing questions located in the VFC Site Visit Questionnaire.

A completed sample of the borrowing report and a blank borrowing report are located at the end of Module 3. Immunization grantees are required to report the incidence of borrowing in aggregate to CDC in the VFC Management Survey.

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Please refer to Module 3 for additional guidance related to the borrowing of vaccine between public and private stocks.

H. “Does the clinic/practice have a written plan for vaccine management including the following (review for accurate content)...”

- Providers must have written documentation for all eight required policies listed and the documentation must contain proper content. For the required content, please refer to Module 6 in this Guide. Grantees are strongly encouraged to develop policy templates for each of the eight areas that providers may customize by completing appropriate sections and dates. Please see the *Vaccine Storage and Handling Toolkit* (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>) section on *Storage and Handling Plans* and Appendix 5 for resources.

I. “Please identify the publication date for each of the VIS currently being used in this clinic/practice and check the appropriate status for each VIS.”

- During the year, updates to VIS forms periodically occur. Providers should have a process to frequently check for updated VIS forms on the CDC website (<http://www.cdc.gov/vaccines/pubs/vis>). The site visit questionnaire in CoCASA has a feature to allow users to change the dates of the VIS as needed.

J. “What type of storage units does this clinic/practice use to store varicella-containing vaccines and all other vaccines?”

- Dorm-style units and combined units with single doors are not acceptable as permanent vaccine storage units. Dorm-style units may be used on a limited basis to store VFC vaccine (but **never** varicella-containing vaccine) during clinic hours only.

K. “For each type of thermometer used by the clinic/practice, indicate if the thermometer is calibrated with certificate.”

- Units storing VFC vaccine must have a working calibrated thermometer inside each storage compartment. Each device is to be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are traceable to an ISO/IEC 17025 accredited testing laboratory, to NIST, or to another internationally recognized standards agency. A certificate of calibration accompanies thermometers that have undergone this calibration against a reference standard. If the program does not provide a calibrated thermometer with certificate of traceability and calibration to enrolled providers, the clinic/practice must be able to show the reviewer the appropriate documentation for the thermometer used by the clinic/practice.

A corrective action plan must be developed even if only one unit does not have a thermometer with a certificate of traceability and calibration. If any storage units contain multiple thermometers with and without required documentation, the clinic/practice staff must be instructed to use only the thermometer with proper

documentation of traceability and calibration to record the temperature on the log sheets.

L. “For each refrigerator and freezer, indicate how often temperatures are recorded.”

- Temperatures must be visually inspected and documented twice a day during clinic hours (a.m. & p.m.) on temperature logs and provider sites must document actions taken if the temperatures fall outside guidelines. Corrective actions must be developed if provider sites are documenting the temperature fewer than two times a day or if no documentation of action is provided for any temperature excursions outside allowable limits. If there is any period of time for which no temperatures are documented, additional research must be done by reviewers, including contacting utility companies to determine if any outages occurred during the time period.

Use of temperature monitoring systems that employ continuously recording data loggers with alarm systems are not a substitute for visually inspecting and documenting temperatures twice daily. Built in, automatic, alarmed thermometers have not proven to be error proof and in several cases have either not triggered the alarm, the alarm has been ignored by staff, the calibration was not current or the monitoring devices have proven inaccurate. A continuous data logger system can be a helpful tool to assess temperature ranges at past points in time, such as providing temperature information during past power outages to help determine the length of time vaccine may have been exposed to inappropriate temperatures. However, these systems cannot be a substitute for the visual inspection of temperature readings assessed with a calibrated thermometer twice daily and manual documentation of the temperature in a log.

M. “Are current temperatures within the guidelines according to the reviewer’s thermometer?”

- Reviewers are required to bring working calibrated thermometer to the provider site to assess the temperatures of storage units containing VFC vaccine.

N. “Is there a ‘Do Not Disconnect’ sign on the circuit breaker?”

- In advance of the site visit, provider sites should be informed the reviewer will need clear access to the circuit breaker. The reviewer needs to check that proper signage is posted to minimize the possibility the circuit breaker will be inadvertently switched off. The provider site may need to have facility management staff available to open the room where the circuit breaker is located and assure, in advance, that there is a clear path available to access the box.

If the reviewer encounters situations where the circuit breaker is not accessible due to debris or materials that may be blocking the circuit breaker or that would make it unsafe for staff to enter the room, the reviewer will need to provide corrective actions for the provider site to require that clear access to the circuit breaker is established. It is also incumbent upon the reviewer to determine

whether conditions to enter the room or to get to the circuit breaker are safe, especially if there is concern over an unusual location for the circuit breaker or debris that may be blocking the area. If a power failure were to occur, the provider site would likely need access to the circuit breaker to assess the problem. Circuit breakers that are not accessible or are unsafe to access are problems that providers are required to correct.

O. “Can the clinic/practice physically differentiate privately purchased vaccine from publicly purchased vaccine? To answer yes, clinic/practice must be able to demonstrate how this is done.”

- If providers see privately insured children, the clinic must have private stock vaccine. The only exception will be for universal states where the grantee supplies all vaccine for children in its jurisdiction.

P. “Upon checking the clinic/practice’s vaccine supply, did the reviewer find any unreported expired vaccine?”

- All VFC vaccine inventory in each storage unit must be checked for unreported expired vaccine. Random sampling of one or two containers of vaccine is not an acceptable method to answer this question.

Grantees are required to report the volume of publicly purchased (VFC, 317, and state) vaccine wasted by VFC-enrolled providers due to expiration and improper storage and handling. For additional information, please refer to Module 8, Vaccine Accountability, of this *VFC Operations Guide*.

A subset of the storage and handling questions require completing responses for storage units listed from one to five for each the refrigerator and freezer. Please note that if the provider site uses temporary storage units to store VFC vaccine during business hours, these temporary units must be assessed during the VFC compliance site visit as well as the permanent storage units. If the provider site has more than five total storage units for the refrigerator and/or freezer each (both temporary and permanent combined), reviewers need to use the tables to first document the non-compliant units for all the storage and handling questions containing tables. Notes and comments for all remaining units in excess of five are to be documented in the final corrective actions section, under the storage and handling area.

Feedback, Corrective Actions and Site Visit Follow-up

During or at the end of the VFC compliance site visit, reviewers should provide education to the provider site staff when non-compliant behaviors or practices are observed or encountered, in order to correct the situations. If the provider is found to be non-compliant with a high priority question (identified by a red “!”), corrective actions need to be documented at the end of Section One of the VFC Site Visit Questionnaire, along with next steps for follow-up and a timeframe. The *Non-compliance with VFC Provider Requirements Protocol (VFC Operations Guide, Module 10)* must be used when any high-priority question is answered incorrectly during a VFC compliance site visit.

Some issues of non-compliance can be corrected on-site with technical assistance and may not require further action. For example, during a site visit, a reviewer may have encountered an outdated VIS and lack of “Do not disconnect” signs next to the storage outlets. The reviewer can provide technical assistance during the visit to educate site staff on the importance and purpose of both requirements, and subsequently observe the provider site staff correct the problems during the review. In situations where education and corrective actions can be implemented during the site visit and the reviewer is confident the provider staff can maintain compliance with the requirement moving forward, no further action is needed. Other non-compliant issues encountered during the site visit for which further education and monitoring of behavior change or a referral of the case to an external agency is needed will require the use of the *Non-compliance with VFC Provider Requirements Protocol*. Please refer to Module 10 of this *VFC Operations Guide* for further guidance on use of the *Non-compliance with VFC Provider Requirements Protocol*.

Reporting Requirements

Grantees must have written plans and protocols for meeting CDC's annual reporting requirements. Detailed summary reports of provider site visits are submitted in the VFC Management Survey and should include findings from VFC-only visits, AFIX-only visits, and combined VFC/AFIX visits. Site visit definitions are located in Appendix 6.

If the VFC/AFIX Evaluation module of CoCASA is used, the software can be used to generate reports on VFC/AFIX core activities and responses to the Site Visit Questionnaire; these reports are used to complete the annual VFC Program Management Survey. For example, the VFC activity section of the VFC Management Survey asks the user to record the number of providers that answered each high-priority question incorrectly from the VFC Site Visit Questionnaire administered during every VFC compliance site visit. If information is entered into the VFC/AFIX module of CoCASA, the software can be used to produce a summary report that will aggregate the responses to the selected questions that grantees are required to report to CDC.

The VFC/AFIX Evaluation module of CoCASA is a helpful tool for organizing the VFC/AFIX site visit information and producing aggregate results. Use of this software is not required; however, if this software is not used, grantees must create their own system for collecting the data elements required to complete the VFC Management Survey.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/13-module-9.pdf>

MODULE 10 – Fraud and Abuse



<http://www.cms.hhs.gov/apps/mfs/statecontacts.asp>
http://www.consumeraction.gov/caw_state_resources.shtml

Overview

As childhood vaccines become more expensive and immunization programs more complex, the VFC program becomes more vulnerable to fraud and abuse. It is important that grantees' VFC programs have well-defined processes for prevention, identification, investigation and resolution of suspected cases of fraud and abuse within their VFC programs.

The VFC program, as a component of each state's medical assistance plan, is considered a Title XIX Medicaid program. Section 1928 of the Social Security Act (42 U.S.C. §1396s) provides for purchase of vaccine for administration to VFC-eligible children—"federally vaccine-eligible children" and "state vaccine-eligible children" (i.e., those children for whom states purchase vaccine; may be limited to particular vaccines)—using federal Medicaid funds and state funds (including 317 grant funds), respectively. 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. However, the VFC program is different from the Medicaid medical assistance program. It also includes other VFC program-enrolled providers and the other VFC-eligible children who qualify as federally vaccine-eligible or state vaccine-eligible and who do not participate or are not eligible for the Medicaid medical assistance program. 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.

A working understanding of what constitutes fraud and abuse is critical for all persons working in the VFC program. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of this *VFC Operations Guide*, the following definitions will be used:

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

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

Examples of Fraud and Abuse

Fraud or abuse can occur in many ways, and some types of fraud and abuse are easier for the VFC program to prevent or detect than others, depending on how the VFC program is implemented. The VFC program should try to differentiate between intentional fraud and abuse and unintentional abuse or error due to excusable lack of knowledge. 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 patients for VFC eligibility 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 of VFC doses of vaccine
- Waste of VFC vaccine

Failure to Comply with VFC Requirements

Fraud and abuse by VFC-enrolled providers is a result of the VFC-enrolled provider failing to comply with the VFC program requirements outlined in each grantee's provider enrollment form. As discussed in Module 3, there are 11 federal requirements that all grantees must include in their VFC-provider enrollment forms. Failure to comply with VFC requirements is defined as any VFC-enrolled provider who is identified as not maintaining any of the federal requirements listed and discussed in Module 3 of this Operations Guide. Failure to comply may be identified by VFC program staff, the enrolled provider's staff, or a third party. For the purposes of this document "VFC program," (unless otherwise noted) is defined as a grantee's VFC program. A grantee

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may be a state, urban, territorial or other political jurisdiction health department that implements the VFC program.

Addressing Provider Non-compliance with VFC Requirements

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. Non-compliance with program requirements may occur due to an unintentional lack of understanding of the VFC program requirements, or the behavior may be intentional. 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. CDC's *Non-compliance with VFC Provider Requirements Protocol* (provided at the end of this module) must be used to determine how to deal with provider non-compliance in the VFC program. The *Non-compliance with VFC Provider Requirements Protocol* is not designed to tell the user how to correct the identified non-compliant behavior, but rather is designed to direct the user through a series of steps to determine the most appropriate level of intervention.

The *Non-compliance with VFC Provider Requirements Protocol* must be used when an allegation is made against a provider or when any high-priority question is answered incorrectly during a VFC compliance site visit. The high-priority questions located in Section One of CDC's VFC Site Visit Questionnaire are proxy measures for compliance with the 11 federal requirements that providers agree to maintain as participants in the VFC program. If a VFC program has knowledgeable staff and provider educational programs in place, it is likely that the majority of high-priority questions that are answered incorrectly can be corrected and the provider brought into compliance by providing technical assistance during the site visit or conducting some short-term individualized follow-up that would be designated as "VFC Follow-up" in CoCASA or the grantee's alternate database. If a provider has a history of non-compliance with the same issue or the issue has serious consequences, the provider must be enrolled into a formal educational process. The *Non-compliance with VFC Provider Requirements Protocol* has two levels of formal education – secondary and tertiary. Each level requires a minimum amount of educational intervention and follow-up. The protocol allows the grantee the flexibility to determine how the educational intervention will occur and **does not** dictate that the educational intervention/follow-up must be face to face.

When a focused VFC compliance site visit is conducted following secondary education, it should focus only on the areas of non-compliance addressed with the educational intervention. The full Section One of CDC's VFC Site Visit Questionnaire does not have to be administered in these situations. For a provider to successfully complete the Secondary Education process, the provider must have corrected the situation. Tertiary Education does require a full VFC compliance site visit, and the compliance issue must be resolved for the provider to be released from the educational intervention.

Grantee Fraud and Abuse Requirements

Written Policy

All grantees are required to implement a comprehensive written fraud and abuse policy for the VFC program that addresses prevention, detection, investigation and resolution of fraud and abuse allegations.

Each grantee's written fraud and abuse policy must address, at a minimum, the following components and describe how the components are integrated into the daily activities of the immunization program:

1. **Oversight Personnel:** Identify one primary position and at least two back-up positions that have the authority to:
 - a. Determine if situation requires immediate referral or if educational intervention following CDC's *Non-compliance with VFC Program Requirement Protocol* should be used.
 - b. Make decisions to refer case to the Medicaid Integrity Group and any other state agencies that the grantee is required by law to refer case.
 - c. Make the referral(s).
 - d. Notify CDC of referral to Medicaid Integrity Group and any other agencies.

2. **Fraud and Abuse Referral Procedure:** Refer all suspected cases of VFC fraud and abuse to the Centers for Medicare & Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office. CMS/MIG will refer the suspected case to the appropriate state Medicaid agency. The state Medicaid Agency will conduct preliminary investigations and, as warranted, refer appropriate cases to the state's Medicaid Fraud Control Unit following the Federal Regulatory scheme at 42 CFR section 455.15. The referral must be sent electronically to: MIG_Fraud_Referrals@cms.hhs.gov .

3. **Allegation and Referral Database:** Develop and maintain a database to monitor and document all actions taken on allegations related to fraud and abuse of the VFC program requirements, including actions taken to address identified situations. As requested, database must be made available to CDC. At a minimum, the following data elements must be collected:
 - a. Subject's name (Medicaid ID if known)
 - b. Address
 - c. Source of allegation
 - d. Date allegation reported to program
 - e. Description of suspected misconduct
 - f. Specific VFC requirements violated
 - g. Value of vaccine involved if available

- h. Success of educational intervention
 - i. Disposition (closed, referred, entered into educational process) of case and date of disposition
4. **Monitoring of VFC program:** Develop procedures on:
- a. How to use VFC program information to identify failure to comply and potential fraud and abuse patterns. Program information that must be monitored includes provider profiles, ordering patterns, VFC compliance site visit results, and any grantee-specific accountability reports.
 - b. How to analyze above information to determine if possible VFC fraud and abuse is occurring within individual provider sites.
 - c. How to follow-up on information that suggests occurrence of VFC fraud and abuse within individual provider sites.
5. **Personnel Training:** Grantee must have written procedures and training documents that demonstrate that all VFC staff that have interaction with VFC-enrolled providers understand how, based on their job responsibilities, to:
- a. Prevent situations that involve suspected VFC fraud and abuse or non-compliance with VFC program requirements.
 - b. Identify situations that involve suspected VFC fraud and abuse or non-compliance with VFC program requirements.
 - c. Follow-up on situations that involve suspected VFC fraud and abuse or non-compliance with VFC program requirements.
- The VFC staff training must include how to use CDC's *Non-compliance with VFC Provider Requirements Protocol*.
6. **Enrollment & Exclusion Checking Procedure:** Develop procedures for:
- a. Mandatory review of the "List of Excluded Individuals and Entities" administered and published by the Department of Health and Human Services (HHS), Office of the Inspector General (OIG) (<http://oig.hhs.gov/fraud/exclusions.asp>) for all providers initially enrolling in the VFC program and on a monthly basis thereafter. Grantees may check a state database for excluded providers in addition to HHS OIG list but not in place of the list.
 - b. Termination of any VFC-enrolled provider site that has a person employed that is on the excluded provider list. Grantees must educate and urge enrolled providers to check the OIG list of excluded Individuals/Entities on the OIG web site (www.hhs.gov/oig) prior to hiring or contracting with any individuals or entities. This procedure must include notification of the state Medicaid agency and, within five working days of the notification of the state Medicaid agency, notification of the Medicaid Integrity Group at MIG_Fraud_Referrals@cms.hhs.gov.
 - c. Monthly obtain the names of any Medicaid providers that appear on the excluded provider list from the state Medicaid agency. Review the excluded list monthly for VFC-enrolled providers who are not also Medicaid providers.

7. **Reporting VFC Provider Terminations:** Develop procedures with the state Medicaid agency on how to report providers that are terminated from the VFC program (both voluntary and involuntary) to the state Medicaid agency.
8. **Annual Review of Fraud and Abuse Policy:** Develop a protocol to review and, as necessary, update policy annually based on CDC guidance and any grantee-specific factors.

While not required as part of the fraud and abuse policy, grantees should consider addressing the following activities in their written policies:

1. **Coordination with Private Insurers:** Develop protocols to work with private insurance entities within grantee's jurisdiction that may be affected by VFC fraud and abuse.
2. **Fraud and Abuse Hotline:** Establish a VFC fraud and abuse phone line that is promoted and made available to the general public to report suspected cases of VFC fraud and abuse.

Using the Non-compliance with VFC Provider Requirements Protocol

This section of Module 10 will illustrate how to use the *Non-compliance with VFC Provider Requirements Protocol* (also known as the non-compliance algorithm) with a situation identified during a routine VFC compliance site visit. This illustration will not outline corrective actions to take but only how to navigate the non-compliance algorithm to determine what level of intervention/follow-up should be taken. A copy of the *Non-compliance with VFC Provider Requirements Protocol* is located at the end of this module.

Situation: On a routine VFC compliance site visit to a pediatric provider, the following information was found during the administration of the 2011 VFC Site Visit Questionnaire, observation, and discussion with the office staff:

1. Failure to screen children for VFC eligibility: On review of 30 charts of children 0-18 years, documentation of VFC screening could be found in only six charts even though the office manager reported that VFC screening occurs at every visit. The screening forms located in the six charts were completed on children between 3 and 18 years of age. No screening documentation could be found on any of the infants.
2. Lack of private stock vaccine: Upon inspection of the storage unit only VFC vaccine was found. The nurse who has worked in the office for less than a year reported to you that she was told to order vaccine from the VFC program. She seems unaware of the need to screen patients or keep private stock for insured patients.
3. Lack of documentation of borrowing: The clinic reported that they do not borrow between public and private stock vaccine.

- 4 Additional information about the provider site: The last VFC compliance site visit was in 2007. The provider had a written document of screening on 28/30 records reviewed (93%) at that visit. The previous reviewer had documented both public and private stock. CDC's borrowing policy was not released until after the 2007 visit. The new nurse had been employed with the clinic since November 2009 and had minimal orientation to vaccine ordering. According to the most recent provider profile from 2009, the office indicated that about 40% of the children they care for are fully insured.

Applying the *Non-compliance with VFC Provider Requirements Protocol*:

Page 1: Provider was non-compliant with screening requirements and using VFC vaccine on non-VFC eligible children (lack of private stock, no borrowing reports). These behaviors fall into the Misuse of VFC Vaccine box on the bottom right of the first page.

Pages 2 and 3:

1. **Decision Point One:** Determine who identified the non-compliance issue. It was identified during a routine VFC compliance site visit, so the reviewer would refer to page 2, "Identified by External Source."
2. **Decision Point Two:** Since the external agency is the VFC program staff and not an enforcement agency, the reviewer would follow the vertical line to the row with the 3 boxes titled, "Previous compliance issue," "Extenuating Circumstances Existed," and "No Previous Compliance issues." The reviewer must decide on the based on their knowledge of the situation and grantee procedures which of the 3 boxes best describes this situation. Based on the above description of the situation, the box titled "Extenuating Circumstances Existed" is the best fit because the new nurse lacked information about program requirements.
3. **Decision Point Three:** Following the vertical line down, the reviewer has four possible intervention options to chose from:
 - a. Correct situation through technical assistance during site visit or VFC site visit follow-up
 - b. Secondary education and follow-up
 - c. Tertiary education and follow-up
 - d. Referral to the Medicaid Integrity Group for further investigation.

Based on individual grantee's written fraud and abuse policy, entry into tertiary education may require discussion with the grantee's primary fraud and abuse coordinator or their back-up. If the situation is serious enough to require immediate referral to the Medicaid Integrity Group without any educational intervention attempts, that referral should be made by the primary fraud and abuse coordinator or back-up. In the situation described above, tertiary education would be the most appropriate because of the seriousness of the situation and because

the staff had a lack of understanding of program requirements. The reviewer would then go **to Page #5** to determine minimum follow-up schedule.

4. **Decision Point Four:** After follow-up activities are conducted and documented appropriately in CoCASA or grantee site visit database and in the grantee's fraud and abuse database, the reviewer, in collaboration with the fraud and abuse coordinator, must decide if the education was effective based on the results of the full VFC compliance site visit (completion of Section One of the VFC Site Visit Questionnaire). If the answer is "Yes," the provider would be returned to routine follow-up.
5. **Decision Point Five:** If the answer is "No," further research must be done to determine next step.
6. **Decision Point Six:** Act on selected next step. Next step options are:
 - a. Repeat tertiary education.
 - b. Refer to Medicaid Integrity Group for further investigation.
 - c. Terminate from VFC program.

If decision is to refer case to the Medicaid Integrity Group, the steps on Page #6 would be followed. If tertiary education is repeated, the steps on Page #5 would be repeated.

Reporting of VFC Fraud and Abuse Cases for further investigation

Federal Agencies

CMS

If the VFC program determines from the assessment of information available that the situation requires referral for further investigation by an outside agency, the VFC program must make these referrals within 10 working days from assessment. Beginning on January 1, 2011, all suspected cases of fraud and abuse that grantees determine should have further investigation must be referred to the Medicaid Integrity Group. All referrals should be sent to the following e-mail address: MIG_Fraud_Referrals@cms.hhs.gov.

The Medicaid Integrity Group will transmit the referral to the appropriate oversight entity and will attempt to monitor the handling of the referral by entity.

CDC

All suspected cases of VFC fraud and abuse that are referred to the Medicaid Integrity Group for further follow-up must be reported to the grantee's Program Operations Branch (POB) project officer within two working days of the referral to the Medicaid Integrity Group. It is acceptable to copy the grantee's project officer on the referral to the Medicaid Integrity Group as the official report to CDC.

Preparing a referral to the Medicaid Integrity Group Field Office

Beginning January 1, 2011, all suspected fraud and abuse cases that merit further investigation must be referred to the Centers for Medicare and Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office. The referral should be sent to the following e-mail address: MIG_Fraud_Referrals@cms.hhs.gov with a copy to the CDC POB project officer. MIG will then refer the case to the appropriate state Medicaid agency. If a state law mandates that the grantee refer any suspected fraud and abuse cases to a specific state agency, the grantee should concurrently make the referral to the specific state agency and MIG. The following information should be included to assist the MIG and the state Medicaid agency in evaluating the case:

- Name, Medicaid provider ID (if known), address, provider type (e.g., private provider).
- Source of complaint (e.g., provider officer, VFC staff, anonymous caller).
- Date on which grantee received information that provider might be engaged in behavior putting the VFC program at risk of loss due to fraud or abuse.
- Description of suspected misconduct with specific details including:
 - Complete description of alleged behavior, persons involved and contact information if available; include actions taken by program to confirm behavior.
 - Specific Medicaid statutes, rules, regulations violated and how conduct of provider violated the rules or regulations.
 - Value of vaccine involved, when available,
- Contact information for VFC Fraud and Abuse Coordinator
- Have available all communication between the VFC program and the provider concerning the suspected misconduct. This includes signed provider enrollment forms, any education given to provider as a result of previous compliance problems and any general communication given to all enrolled providers.

Fraud and Abuse Prevention

The grantee must actively work to prevent fraud and abuse in the VFC program. The best methods to prevent fraud and abuse are strong educational components carried out during the provider enrollment process and during VFC compliance site visits. Both occasions provide the opportunity to prevent situations that may develop into fraud or abuse. Along with education, well-organized and correctly administered VFC accountability programs are the cornerstones for preventing situations from developing into potential fraud and abuse incidents.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/14-module-10.pdf>

Failure to comply with VFC Requirements

Mishandling of VFC Vaccine (examples)

- Improper Storage & Handling of VFC vaccine
- Lost, wasted/expired vaccine

Billing & Office Practices (examples)

- Billing for VFC vaccine (any source)
- Charging above the maximum regional charge for non-Medicaid eligible children
- Failure to maintain VFC records for required time period
- Failure to comply with VFC ordering or site visit requirements

Misuse of VFC Vaccine (examples)

- Refusing to provide VFC-eligible children with VFC vaccine due to inability to pay administration fee
- Using VFC vaccine on non-VFC eligible children (failure to screen)
- Transfer of VFC vaccine without approval of program
- Routine borrowing of VFC vaccine for use on non-VFC eligible patients
- No private purchase vaccine but provider profile indicates privately insured children

Non-compliance with VFC Provider Requirements Protocol

External Source- Any person or agency outside VFC provider's office. This would include patients, general public, former employees, VFC staff, or any outside individual who may witness immunization practices within the provider's office.

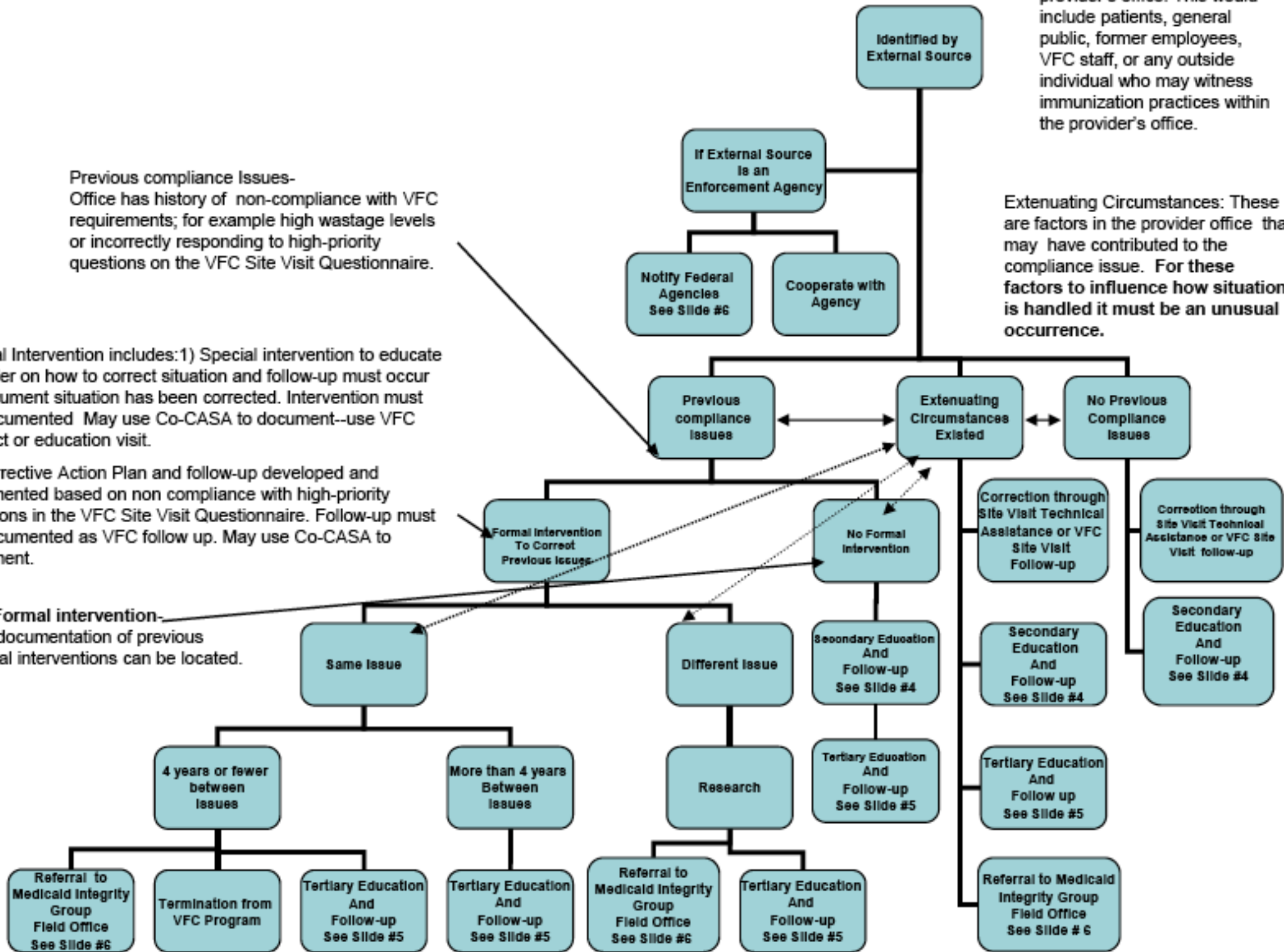
Previous compliance Issues- Office has history of non-compliance with VFC requirements; for example high wastage levels or incorrectly responding to high-priority questions on the VFC Site Visit Questionnaire.

Extenuating Circumstances: These are factors in the provider office that may have contributed to the compliance issue. For these factors to influence how situation is handled it must be an unusual occurrence.

Formal Intervention includes: 1) Special intervention to educate provider on how to correct situation and follow-up must occur to document situation has been corrected. Intervention must be documented May use Co-CASA to document--use VFC contact or education visit.

2) Corrective Action Plan and follow-up developed and documented based on non compliance with high-priority questions in the VFC Site Visit Questionnaire. Follow-up must be documented as VFC follow up. May use Co-CASA to document.

No Formal intervention- No documentation of previous formal interventions can be located.



Hierarchy of VFC Provider Education

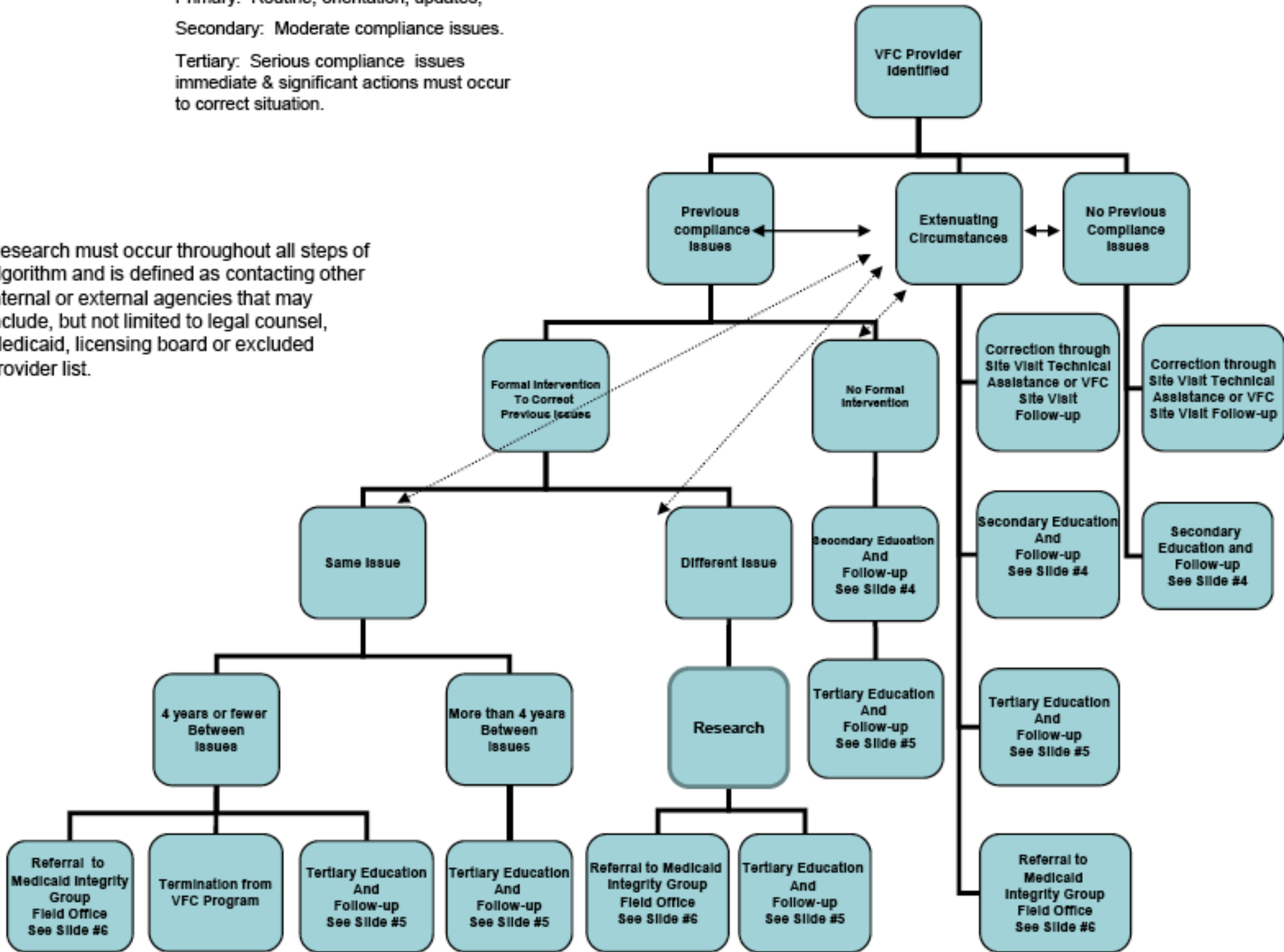
Primary: Routine, orientation, updates,

Secondary: Moderate compliance issues.

Tertiary: Serious compliance issues
immediate & significant actions must occur
to correct situation.

3

Research must occur throughout all steps of algorithm and is defined as contacting other internal or external agencies that may include, but not limited to legal counsel, Medicaid, licensing board or excluded provider list.



Secondary Education and Follow-up

Follow-up (minimum schedule)
Corrective Action Plan when identified;
1-2 Follow ups between post identification; and
Focused VFC Compliance Site Visit 3-12 months
after entry into education

Education Effective?

Yes

Return to routine follow-up

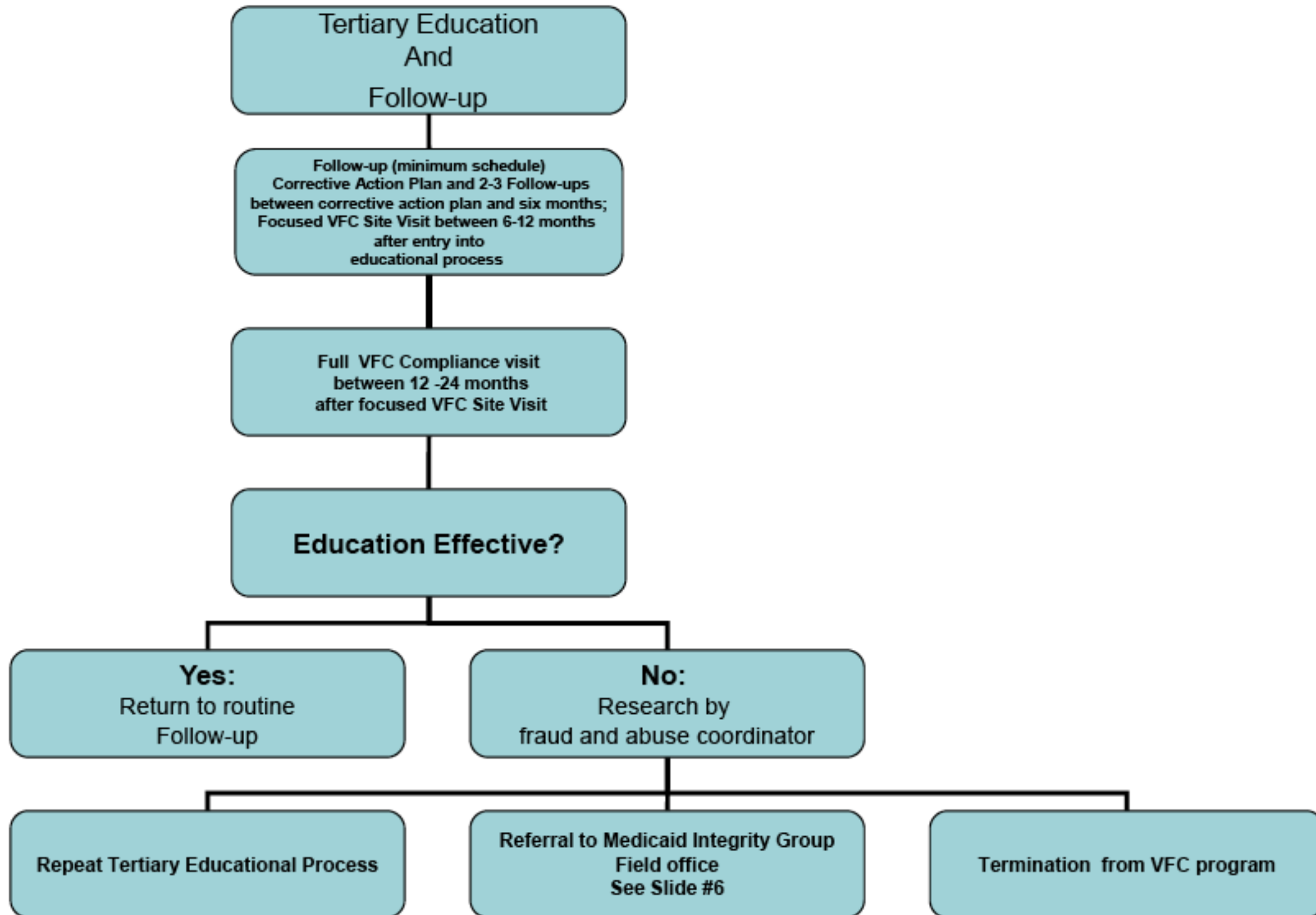
No

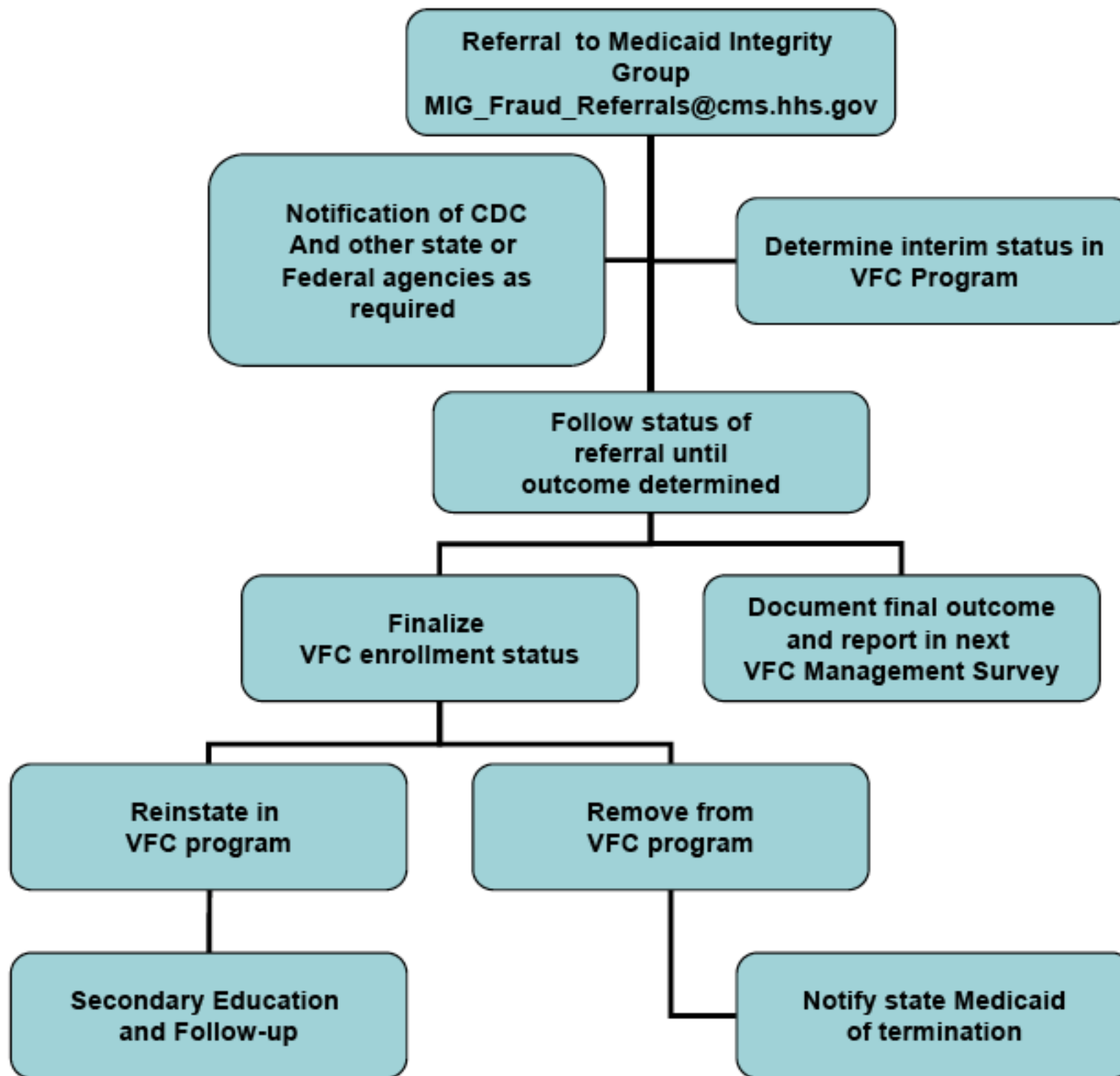
**Research by
Fraud and abuse Coordinator**

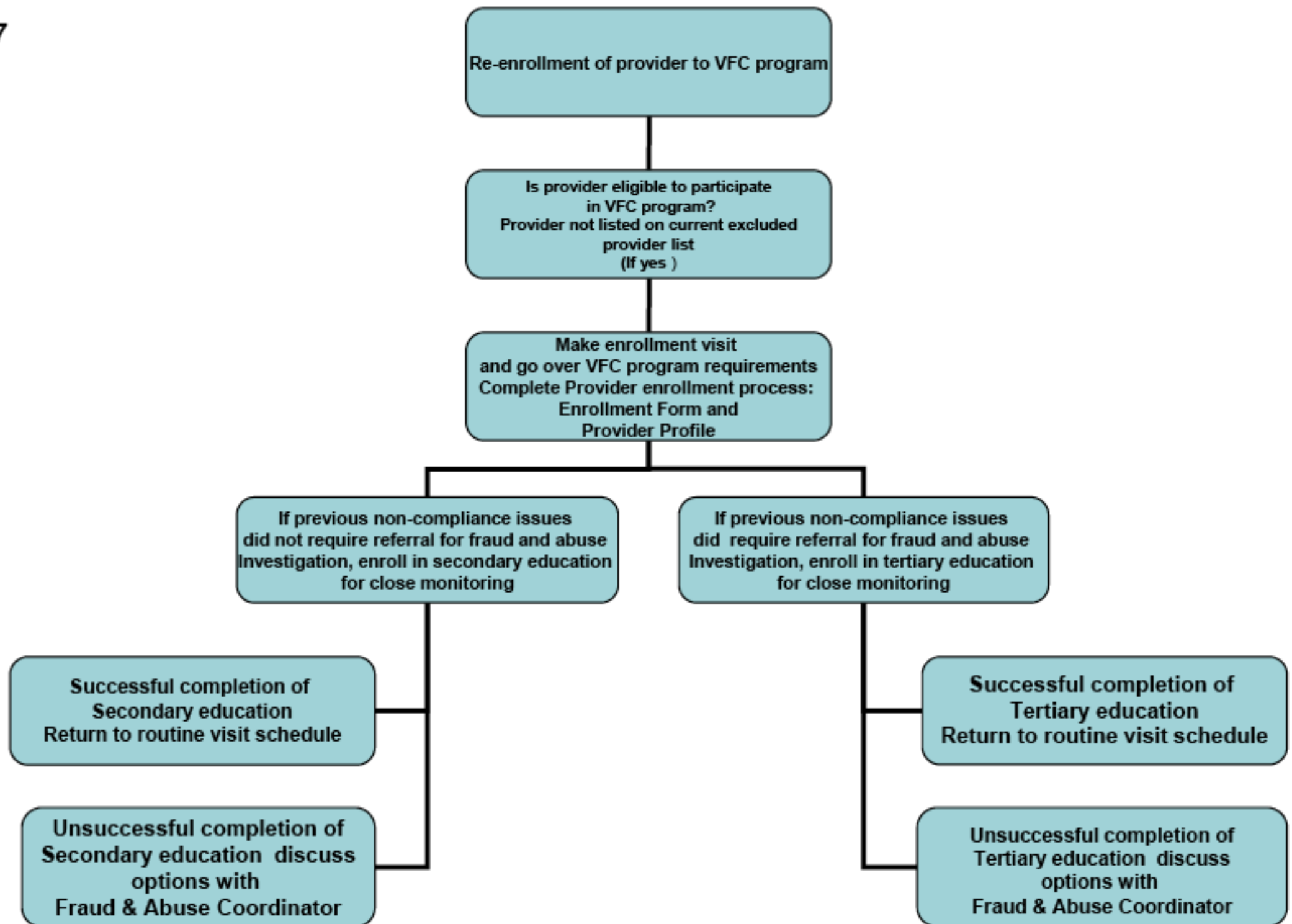
**Tertiary Education
And Follow-up
See Slide #5**

**Referral to
Medicaid Integrity Group
Field Office
See Slide #6**

Termination from program







MODULE 11 – Evaluation of the VFC Program



NCIRD Website: <http://www.cdc.gov/vaccines/default.htm>

IPOM: <http://www.cdc.gov/vaccines/vac-gen/policies/ipom/>

PAPA Website: <http://www2a.cdc.gov/nip/irar/grantee/granteeinfo.asp#grptg>

CDC Evaluation Workgroup: <http://www.cdc.gov/eval/index.htm>

Immunization Program Evaluation Website:

<http://www.cdc.gov/vaccines/programs/progeval/>

Overview: Why Evaluate Your VFC Program?

Evaluation is a critical component of the VFC program. A considerable amount of funding and resources is invested in implementing and managing the VFC program at both the federal and grantee levels every year. It is important to ensure that this investment is managed appropriately and that the program is achieving its desired outcome of administering viable vaccine to eligible children.

This module is intended to provide guidance to grantees on how to use the VFC Management Survey and the Program Annual and Progress Assessment (PAPA) website to evaluate their VFC program's processes and outcomes. VFC program areas that should be regularly evaluated, and that can be assessed through these tools, include: provider recruitment, enrollment, communications, provider satisfaction with the VFC program, provider storage and handling practices, and site visits. General evaluation resources are included and briefly described in the last section of this module.

VFC Management Survey

The VFC Management Survey is a web-based data collection tool that grantees are required to complete and submit to CDC annually by March 1. The survey collects aggregated data from VFC Site Visit Questionnaires and provides an overview of a grantee's immunization policies, program activities, and accountability measures for the previous year.

Completing the VFC Management Survey

The VFC Management Survey is divided into two main sections. The first section requires information on the number of enrolled providers and how the VFC program

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operates within the grantee's geographic area. This section also requires information on discovered, reported and referred fraud and abuse allegations. The second section requires information on staff (FTEs) working on VFC/AFIX activities, VFC provider contacts, VFC provider coverage levels, VFC provider compliance with VFC high-priority questions, and follow-up activities during the previous year.

In order to complete the survey, grantees need to have an understanding of VFC-related policies in their jurisdictions, as well as access to fraud and abuse allegation reports for the year and provider enrollment and vaccine ordering records. Grantees also need access to a system that will allow them to collect and compile the data elements in the second section of the survey. Grantees can choose to use the Comprehensive Clinic Assessment Software Application (CoCASA) or their own database for this purpose. Brief descriptions of both of these options are provided below.

Comprehensive Clinic Assessment Software Application (CoCASA)

CoCASA is a tool for assessing vaccine coverage, VFC/AFIX activities, and provider compliance with high-priority questions from the VFC Site Visit Questionnaire. This software was developed by CDC and can be downloaded from the CDC website free of charge. CoCASA has data entry and import capabilities. After immunization data have been entered into CoCASA, data analysis can be conducted to pinpoint strengths and areas of improvement for an individual immunization provider.

There are two specific reports that grantees can generate from CoCASA to complete the VFC Management Survey: the VFC/AFIX Core Report and the VFC Site Visit Questionnaire Results Report. Both reports must be generated from January 1 to December 31 of the previous year for the completion of the survey. Other CoCASA reports that can serve as valuable evaluation tools for grantees are discussed under the *Other Evaluation Tools* section in this module.

Grantee-developed system

Grantees can use any database, software or system that will allow them to collect, compile and report the data required in the second section of the VFC Management Survey. At a minimum, grantee-developed systems much include:

- Provider sites visited at least once during the year
- Provider contacts by type of visit and type of provider
- AFIX methods used
- Childhood and adolescent coverage levels
- Number of private and public providers that were non-compliant for each of the high-priority administrative and storage and handling questions
- Corrective actions recommended for public and private providers
- Vaccine borrowing practices

The VFC Site Visit Questionnaire and the VFC Management Survey undergo revision every year and any changes are reflected in CoCASA. Grantees are responsible for

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ensuring that their data collection systems are updated to reflect any changes in these documents.

Ensuring Data Reliability and Accuracy

The VFC Management Survey can be a valuable evaluation resource for grantees only if its data are reliable. Given that most of the VFC Management Survey is completed with aggregated data from the VFC Site Visit Questionnaires, it is important for grantees to ensure that their staff is filling out the VFC Site Visit Questionnaires accurately. Staff conducting site visits must have a clear understanding of the questions and why they are asked, answer options and terms used throughout the questionnaire (see Module 9). They should also have a clear understanding of how to complete the questionnaire during a compliance site visit (see Module 5) and be able to do so consistently. Grantees are required to provide ongoing training and periodic observation of site visits to help ensure that data collected through VFC Site Visit Questionnaires are reliable.

Grantees must also ensure that data submitted in the VFC Management Survey are accurate and consistent. It is important for grantees to have a clear understanding of the information that is required in different sections of the survey. Grantees are encouraged to seek guidance from the VFC/AFIX staff in the Program Operations Branch at CDC if they have any questions regarding how to complete specific sections. One table that grantees have had difficulty completing in previous years is the FTE table, Table 2.

Completing Table 2: Number of FTEs Working on VFC and/or AFIX Project

This table requires information on the full-time equivalent (FTE) employees that worked on VFC and/or AFIX during the previous year. In this table, grantees are expected to report only the fraction of a full time employee's time that was spent working on VFC or AFIX activities. Grantees are required to report the amount of staff time being spent on VFC/AFIX and the proportion of that time being spent conducting site visits. Grantees can use this information to evaluate program priorities, modify staff responsibilities, and ensure that staff activities and funding sources are aligned.

In order for a staff person to be counted as 1 FTE in this table, they should be a full-time employee spending 100% of their time in VFC and/or AFIX activities. For example, if a full-time employee spent half of their time conducting VFC site visits and half of their time coordinating a childhood immunization campaign, they would represent .5 FTE in "FTEs that conduct VFC or AFIX site visits." If the childhood immunization campaign is related to the VFC or AFIX program, this person would represent .5 FTE in "All other VFC/AFIX FTEs." If the childhood immunization campaign is not related to the VFC or AFIX program, the time they spent on that activity would not be included in this table.

It is also important for grantees to ensure that data submitted in different sections is consistent. Cross-checking the data in the VFC Management Survey before submitting it to CDC can ensure accuracy and consistency throughout the document. Grantees are strongly encouraged to conduct at least two specific cross-checks before submitting their

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VFC Management Surveys. Each of these cross-checks is briefly described below and involves data from *Table 4: Completed Provider Contacts by Activity*.

- Cross-check #1: The sum of reported “VFC Only” and “VFC/AFIX visits” for public and private providers in Table 4 of Section I. VFC/AFIX Core Activities **must equal** the number of compliance site visits for public and private providers reported at the beginning of Section II.”VFC Accountability.”
- Cross check #2: The sum of reported “VFC Site Visit follow ups,” “Secondary Educational Follow Ups,” and “Tertiary Educational Follow Ups” reported in Table 4 of Section I. VFC/AFIX “Core Activities” **must equal** the sum of reported “Telephone call,” “Site visit,” “Suspended delivery of vaccine,” and “Other” follow-up plans in the VFC Administration Guidelines table at the end of the survey.

Using Collected Data for Program Evaluation

Data collection and data cleaning by themselves do not equal evaluation or lead to the improvement of program processes and outcomes. After ensuring that data is collected accurately and consistently, grantees must carefully look at the data. Collecting data is useless unless the data is analyzed, understood and used to make informed program decisions and help determine priorities. Grantees should have a plan in place to regularly analyze and use any data that they are collecting. This plan should include a timeline for when data will be analyzed, who will be responsible for analyzing the data and which decision-making stakeholders will be informed of the findings.

Carefully looking at data can help grantees identify and address problematic practices, vaccine misuse, fraud and/or abuse, and reporting errors in a timely manner. It is beneficial for grantees to encourage all of their staff to carefully look at the data that they collect and receive. When looking at data, grantees should ask questions such as:

- Does this data reflect the realities of the program as we know them?
- Is this information consistent with what we know about the populations being served in this area, birth cohorts, doses required for specific vaccines, etc.?
- Does this data reflect compliance with program policies?
- Is there anything that seems strange, surprising or does not make sense?
- Does anything look very different from previously reported data? If so, do we know what has caused this change?

Program Evaluation Measures from the VFC Management Survey

A grantee’s VFC Management Survey offers a snapshot of its VFC program for the previous year. Carefully and thoughtfully reviewing the answers to the questions in the VFC Management Survey can assist grantees with identifying program processes and activities that are working adequately, as well as those that are performing poorly. Measures of different program processes and activities, available through data from the survey, are listed and explained below. Grantees must ensure that marked differences

between public and private providers in any of these measures are carefully assessed and addressed. Both public and private providers are critical for the success of the VFC program, and grantees must ensure that they are being enrolled, engaged and supported.

- Proportion of Enrolled Providers that are Active
Ideally 100% of VFC-enrolled providers should be active. Although a number of circumstances might prevent a small group of providers from ordering VFC vaccine in any given year, at least 90% of enrolled providers in any of the categories in *Table 1. VFC Provider Enrollment* should be active. Lower proportions of enrolled providers that are active could be a sign of poor provider education on how to order VFC vaccine, poor provider participation in the VFC program, unaddressed vaccine ordering barriers, and/or enrollment of providers that do not serve VFC-eligible children.
- Proportion of Vaccine Doses Administered in Family Planning Clinics
Unaccompanied minors under the age of 19 without insurance status presenting at family planning clinics are eligible for VFC vaccine. Family planning clinics must screen these minors and report administered vaccine to grantees on a monthly basis (see Module 3). Grantees should review these forms regularly and ensure that any clinic submitting these reports is a family planning clinic according to CDC's definition (see Module 3 of this *VFC Operations Guide*). Grantees should also make sure that the number and types of administered vaccines reported is adequate for the clinic's population. Data reported on the VFC Management Survey can help grantees further ensure that the overall proportion of vaccines being administered in family planning clinics is adequate considering the number of family planning clinics, the population they serve, and the adolescent birth cohorts in the grantee's geographic area. Vaccine doses administered that exceed the needs of the grantee's adolescent birth cohort and/or the proportion of that cohort being served by VFC-enrolled clinics can indicate vaccine misuse, fraud, and/or abuse.
- Proportion of Providers that Received a VFC Compliance Site Visit
Grantees must conduct compliance site visits to at least 50% of their VFC-enrolled and active providers annually (see Module 8). Grantees conducting compliance site visits to less than 50% of their providers must further evaluate their program to identify factors that will enable them to meet this requirement. Some of the program areas that grantees can further evaluate include: time spent on required and non-required VFC program activities, priority and purpose of data collected on Section Two of the VFC Site Visit Questionnaire during compliance site visits, compliance site visit coordination, and compliance site visit follow-up.

Please Note: Grantees are required (at a minimum) to conduct compliance site visits to 50% of their enrolled and active public providers and 50% of their enrolled and active private providers annually. Grantees can look at the proportion of public and private providers that received site visits separately to assess their compliance with this requirement.

- Administrative and Storage and Handling High-Priority Questions with 5% or greater / 10% or greater Non-Compliance Among Providers

Provider compliance with VFC program requirements is measured through high-priority questions. These questions are included in the VFC Site Visit Questionnaire that grantees are required to administer during compliance site visits. The VFC Management Survey reports the aggregate count of providers that answered each one of the high-priority questions incorrectly and are therefore, in non-compliance with the requirement the question monitors. These aggregate results are one of the most valuable sources of data for grantees.

In general, questions with 10% or greater non-compliance among private and/or public providers represent a potentially serious threat to the integrity of the VFC program. There are four key high-priority questions that are considered critical and for which 5% or greater non-compliance level among private and/or public providers is considered a serious threat to the integrity of the VFC program.

These key high-priority questions are:

- When does the clinic/practice screen patients for VFC eligibility?
- What type of storage units does this clinic/practice use as permanent units to store varicella-containing vaccines and all other vaccines?
- Are working thermometers placed in a central area of each refrigerator and freezer?
- When the temperatures were outside the recommended range, what action did the clinic practice take?

These levels of non-compliance among private and/or public providers can indicate: poor provider knowledge of program requirements, high provider staff turn-over, and/or VFC staff who need additional training in order to fully educate VFC-providers on program requirements.

- Proportion of Planned Corrective Actions Implemented

All corrective actions that are recommended after a compliance site visit must be implemented and reported. There might be a few instances in which a planned corrective action might be deemed unnecessary or inappropriate after it has been recommended, but this should not be the norm. High proportions of recommended corrective actions that are not implemented can indicate lack of follow up by staff, lack of structure for the implementation of corrective action activities at the grantee level, and/or under-reporting of corrective actions by staff.

Program Annual Progress Assessments (PAPA) Website

The Program Annual Progress Assessments (PAPA) open website

[<http://www2a.cdc.gov/nip/irar/grantee/granteeinfo.asp#grptg>] provides access to immunization-related annual reports for all grantees dating back to 2001. VFC Management Survey data can be accessed through both the “Grantee Reports” and the “Summary Reports” when “VFC” is selected. These reports can be valuable resources

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for grantees that want to evaluate their program over a period of years, learn about other grantee's programs and/or compare their program with those of other grantees.

VFC Management Survey Reports

VFC Management Survey Reports provide the answers to all VFC Management Survey questions for a specific grantee and year. Grantees can access surveys from previous years to look at time trends for different program areas such as enrollment, site visits conducted, and/or non-compliance with high-priority questions. Grantees can also use these reports to learn more about other grantee's VFC programs and compare their overall program with those of other grantees. It might be particularly valuable for grantees to learn more about the VFC programs of grantees in the same geographical region, with comparable population size, with similar vaccine-purchase policies, and/or with a comparable number of enrolled providers.

To generate a VFC Management Report go to the PAPA open website. The top section of the webpage titled "Grantee Reports" includes information on individual grantee annual reports by topics. In this section, select the grantee and desired year for the report. Select "VFC" from the menu of topics and click on the "Display Report" icon. The VFC Management Survey for the selected grantee and year will be displayed.

VFC Summary Reports

A VFC summary report provides the responses from all grantees that reported on a specific question from the VFC Management Survey for a specific year. Grantees can use these reports to get an idea of how they compare to the overall universe of VFC grantees in specific questions or program areas. These reports can also be used to identify grantees that can serve as examples or resources for reaching desired program objectives. For example, if a grantee wants to increase the percentage of providers that answer all 6 administrative high-priority questions correctly, they can use this report to identify grantees with a high percentage in this question and then contact these grantees to learn more about how they achieved that specific outcome.

To generate a summary report, go to the PAPA open website. The bottom section of the webpage titled "Summary Reports" allows users to create summary reports from annual reports and progress assessments by topics. In this section, select the desired year for the report. Select "VFC" from the menu of topics and click on the "View Menu" icon. The VFC Reporting Menu Screen allows the grantee to select one specific question from the selected year's VFC Management Survey. After selecting the desired question, click on the "Run" icon located in the same section as the question selected. The requested report will be displayed. In some reports the data displayed can be sorted by the variables in blue font.

Other Evaluation Tools

CoCASA Reports

Thoughtful and periodic review of the aggregate data available through CoCASA VFC/AFIX reports can help grantees identify program areas that require immediate intervention as well as monitor changes once interventions are implemented. CoCASA reports can be generated for any time period the grantee wishes to evaluate and can focus on providers' responses to Section One of the VFC Site Visit Questionnaire, Section Two of the VFC Site Visit Questionnaire, or custom questions grantees administer during compliance site visits inputted into CoCASA.

Grantees should become familiar with all of the reports and lists that can be generated through CoCASA. In addition to the VFC/AFIX Core Activities Report and the VFC Site Visit Questionnaire Results Report used to complete the VFC Management Survey, grantees might find the following CoCASA reports and lists helpful:

- Aggregate VFC Non-Compliant Summary Report
This report provides the number and percentage of public and private providers that were non-compliant with administrative and storage and handling high priority questions. Grantees can use this report to assess compliance differences between public and private providers. For example, if 2% of public providers and 15% of private providers are non-compliant in the same question, the grantee might want to assess what is causing a higher percentage of private providers to be non-compliant with this question and tailor specific interventions to them.
- Providers Receiving At Least One Visit
This list can help grantees determine which providers were visited at least once throughout any specific time period. It can be a valuable tool for grantees to coordinate site visits for their providers and ensure that 50% of their enrolled and active providers are visited one year, and the other 50% is visited the next year.
- VFC Non-Compliant Providers
This list can be a valuable resource for grantees that choose to consider previous non-compliance as a factor for prioritizing compliance site visits. This list can also help grantees determine which providers need to be targeted for non-compliance educational interventions and/or out-of-schedule follow ups.

VFC-Enrolled Providers

Providers enrolled in the VFC program can be some of the best sources of information for evaluating what aspects of the VFC program are or are not working optimally. One method for collecting provider opinions is through a provider satisfaction survey. A generic example of a provider satisfaction survey can be found in Appendix 7. If a survey is done, the grantee will need to determine which VFC providers to include, what questions to ask in the survey, how to conduct the survey and how to analyze the results.

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In addition to evaluating operational components, provider surveys can be used to gather information on the educational needs of enrolled providers or their responses to education provided. Findings can determine what quality improvement projects should be undertaken by the grantee. For example, if survey results indicate that a significant portion of the providers who received education on completing a VFC accountability form are not completing the form because it is too complicated, a quality improvement project might be needed to simplify the form.

Evaluation Resources

Several resources are available to grantees requiring assistance or further information on program evaluation. The best place to start is with the CDC project officer assigned to each immunization grantee. The project officer can direct the grantee to specific individuals who can assist in developing, implementing, or interpreting evaluation measures for the VFC program.

The CDC Evaluation Workgroup has a website to assist programs and individuals in learning more about program evaluation. The website is located at:

<http://www.cdc.gov/eval/index.htm>. Specific resources within the website include:

CDC Evaluation Framework: <http://www.cdc.gov/eval/framework.htm>

CDC Evaluation Self Study Guide: <http://www.cdc.gov/eval/evalguide.pdf>

Evaluation Resources: <http://www.cdc.gov/eval/resources.htm>

Immunization specific evaluation resources can be found in the Immunization Program Evaluation website located at: <http://www.cdc.gov/vaccines/programs/progeval/>.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/15-module-11.pdf>

MODULE 12 - Medicaid and Children's Health Insurance Plan



<http://www.cms.hhs.gov>

Medicaid

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 poorest people.

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, grantees 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. Depending on how each state

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administers its program, whether through demonstration waivers, fee for service, or managed care organization (MCO) contracts, each state Medicaid program must file a Medicaid State Plan amendment covering its pediatric immunization program in order to receive federal funds to operate its Medicaid program and to receive vaccines from the VFC program. This is accomplished by submitting a “state plan amendment preprint.”

Managed Care

Medicaid managed care continues to be a preferred model for serving children enrolled in the Medicaid program. Approximately 71% of Medicaid beneficiaries are covered under some type of managed care plan, and about 54% of those are children. Most children who are enrolled in these plans are required to receive care from designated providers.

Otherwise, the federal government will not reimburse the service. This requirement is commonly called a "lock-in" requirement. If lock-in applies, Medicaid and the plan may refuse to pay a vaccine administration fee if a child is immunized by a VFC provider who does not belong to the Medicaid managed care plan.

There are exceptions to the above statement. Some states have written conditions into their contracts with managed care organizations (MCOs) requiring the plan, or the state, to pay immunization administration fees to non-plan providers. The state Medicaid agency should be able to advise if this is the case in a particular situation.

It may also be possible for a public provider to directly negotiate an agreement with an MCO to serve its patients and to bill the MCO for the vaccine administration fee when that MCO's enrollees are immunized at a public health clinic. In this case, the public health clinic is part of the MCO's network, and negotiated services are considered to be in-plan services. Consult your state Medicaid agency to determine whether a VFC participating physician, who is not that child's primary care physician, may bill Medicaid for the vaccine administration fee.

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 to

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conduct 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. While a final rule has not occurred, the current administration fees remain in effect until further notice.

The state Medicaid agencies have the discretion to pay an administration fee up to the regional maximum amount. With only five state Medicaid agencies paying the maximum regional administration fee, the current fee structure has been reviewed and will remain in effect for the time being (see Appendix 4).

Children's Health Insurance Plan

The Children's Health Insurance Program (CHIP) was created through the Balanced Budget Act of 1997 to address the fact that one in seven children (more than 10 million, nationwide) are uninsured and therefore at significantly increased risk for preventable health problems. Many of these children are in working families that earn too little to afford private insurance on their own but too much to be eligible for Medicaid.

All 50 states, the District of Columbia, Puerto Rico, Guam, U.S Virgin Islands, American Samoa, and the Commonwealth of the Northern Mariana Islands have approved CHIP state plans. States can choose to provide child health assistance to low-income, uninsured children through a separate child health program, an expansion of Medicaid or a combination of both types of programs. States may submit amendments to these plans at any time, which could result in revisions to original approved state plans.

If the state has a separate child health program, the child does not qualify for VFC because CHIP covers immunizations within the program, and the child is considered insured. If the CHIP program is an expansion of Medicaid, the child is considered VFC eligible. Under the combination methodology, children who are enrolled in the Medicaid expansion are VFC eligible, and children enrolled in the separate CHIP program are considered to be insured and are not eligible for VFC.

A copy of the state Medicaid director's letter from May 1998 is in Appendix 8. The letter outlines how immunizations are covered for each of the different types of CHIP plans. It also discusses how vaccines for the CHIP program can be purchased and utilized off the federal contract.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/16-module-12.pdf>