Vaccines for Children Operations Guide

Atlanta, Georgia
Centers for Disease Control and Prevention

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Publication Date: August 2007
Revision Date: None

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Revision Date: None

Executive Summary

This *Vaccines for Children (VFC) Program Operations Guide* is the first update of the guide since 2002. Since the VFC program became operational in 1994, the budget for this program has risen steadily, and in the year 2007 it is nearing $3 billion. As program costs rise, so does the need to ensure that all aspects of the program are being implemented appropriately. The content of the guide has been updated and significant changes have been made in many areas of the VFC program, including provider enrollment, vaccine management and fraud and abuse. This executive summary outlines new material added or significant changes made to key modules in the *VFC Program 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 Program Operations Guide* for a comprehensive discussion of these issues.

Provider Recruitment and Enrollment

The number of requirements for provider enrollment has been decreased to nine items. CDC has removed the provider enrollment form template from this version of the *VFC Program Operations Guide* because most grantees have created their own provider enrollment forms. All nine required items must be used, with modifications only to the items specified in Module 3, "Provider Recruitment and Enrollment."

Beginning in 2008, 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 **even if approval has been received in the past.** The formal process for requesting approval of additional provider enrollment requirements is outlined in Module 3. **In addition, all grantees must submit their 2008 Provider Enrollment forms to CDC for review no later than October 1, 2007. All forms must be submitted even if the grantee only includes the nine federal requirements on their enrollment form.**

Module 3 also contains a new section on special populations, including eligibility screening options for patient populations that are 100% American Indian/Alaska Native or 100% enrolled in Medicaid. The section also discusses requirements for use of VFC vaccine for unaccompanied minors who present at family planning clinics without insurance information. CDC will begin gathering data on unaccompanied minors receiving VFC vaccines in family planning clinics starting in 2007 through the VFC Management Survey.

Vaccine Management

Module 6, "Vaccine Management," identifies grantee vaccine management requirements both before and after transition to centralized distribution. A key requirement is to provide initial and periodic training to VFC providers and staff, focusing on critical

aspects of proper vaccine management. Grantees will need to 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. Each VFC-enrolled provider must have a designated vaccine coordinator and a backup person. These individuals will be points of contact for the VFC program within that office and are responsible for implementing all VFC storage and handling requirements.

Module 6 outlines the minimum storage and handling equipment a provider must have to participate in the VFC program. A grantee can include additional storage and handling equipment 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

PLACEHOLDER: Publication of Module 8, "Vaccine Accountability," is pending revision by CDC's Accountability Workgroup.

Fraud and Abuse

Grantees are required to develop and implement a written fraud and abuse policy. The required components for this policy are outlined in Module 10, "Fraud and Abuse." **Each grantee will be required to submit a copy of its fraud and abuse policy annually to CDC. The first submission is due no later than December 31, 2007, and should be sent to the VFC policy coordinator.**

Developing a realistic fraud and abuse policy will require grantees to work in close collaboration with the state Medicaid Agency and other agencies to develop a workable process for referring potential cases of fraud and abuse. The fraud and abuse policy will require grantees to develop internal processes for identifying fraud and abuse, a referral process to external agencies for further investigation, or an internal process for education on needed practice changes. The policy requires grantees to designate an individual position (and at least two back-ups) as the Fraud and Abuse Coordinator. Two important responsibilities of this position are to determine if the case requires referral and to notify both CDC and the Centers for Medicare & Medicaid Services (CMS) in the time frame specified in Module 10.

Publication Date: August 2007
Revision Date: None

Important Vaccines for Children (VFC) Requirements Due Dates at a Glance 2007–2008

Requirement	Due Date (no later than)
Submission of 2008 Provider Enrollment Form	October 1, 2007
Submission of Fraud and Abuse Policies	December 31, 2007
First Submission of Family Planning Clinic VFC Logs	March 1, 2008 in the VFC Management Survey

Date of Publication: August 2007
Revision Date: None

Question and Answers about The New *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 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 AFIX/VFC 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 AFIX/VFC quarterly conference calls?

Answer:
It is the responsibility of each grantee to ensure that all staff working in the VFC program have 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.

Date of Publication: August 2007
Revision Date: None

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 Nancy Fenlon, the VFC Policy Coordinator, directly:

Nancy Fenlon, RN, MS
ncf1@cdc.gov
404-639-8810

Publication Date: August 2007
Revision Date: None

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 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. As the program enters its second decade, it is becoming increasingly recognized for its successes in raising immunization coverage rates among high-risk children and reducing disparities in access to health care. The VFC Program has also helped reduce physician referrals for immunizations to public clinics.

Publication Date: August 2007
Revision Date: None

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 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.

Guiding Principles

The policies and procedures in this *Operations Guide* are based on the premise that the VFC program should...

- keep provider enrollment, patient access and administrative accountability procedures simple while maintaining necessary requirements for vaccine accountability and program evaluation;

- integrate VFC activities into existing immunization programs and systems;

- promote maximum participation by private providers and cooperation between the public and private healthcare sectors;

- promote close coordination among public agencies, including state health departments and state Medicaid programs, and programs serving families and children.

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.

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 states and 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, and 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.

Publication Date: August 2007
Revision Date: None

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).**

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 had not been met.

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

enrolled in a separate SCHIP. The Medicaid-eligible children are entitled to VFC program benefits, and the children enrolled in the separate SCHIP program are considered insured and are not entitled to VFC program benefits.

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. Patient eligibility screening records should be maintained on file for a minimum of 3 years after service to the patient has been completed unless state law/policy establishes a longer archival period. VFC eligibility screening is discussed in more detail in Module 3.

Publication Date: August 2007
Revision Date: None

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, 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, relevant vaccines.

Recruitment efforts should also be targeted to providers who may have initially declined enrollment, 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 fully insured and are not VFC eligible.

Grantees should have written policies, protocols, and procedures to recruit and enroll providers into the VFC program. These guidance 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 over providers who have declined to participate in VFC in the past.
- Scheduling recruitment appointments with providers based on the priority criteria.
- Documenting results of recruitment efforts and following up as needed with all 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 should begin during the recruitment and enrollment process and continue with every provider contact. Education regarding the VFC program should be structured according to the requirements for provider enrollment. These are explained below.

Two forms must be completed by each VFC provider at enrollment, and be kept up-to-date thereafter:

1. **Provider Profile form** (see Appendix 2). The Provider Profile form requests information on the VFC-eligible children in the practice. It is used to evaluate vaccine orders and ensure that VFC-funded vaccine is being administered only to VFC-eligible children. 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 providers enrolled for more than 1 year, 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 indicates 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 with many providers should sign the Provider Enrollment form for the entire group. All other providers within the practice must be listed on the enrollment form. CDC defines the compliance requirements of the VFC program. Grantees should create their own forms, but the form must contain all the 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.

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 beneath 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 all immunization encounters for 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**
        (1) Are an American Indian or Alaska Native
        (2) Are enrolled in Medicaid
        (3) Have no health insurance
        (4) Are underinsured: Children who have commercial (private) health insurance but the coverage does not include 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 vaccine purchased with Section 317 or other state funds.**

Provider Education Goals *for this requirement:*
By the end of the enrollment or education session the provider and staff will understand

- The eligibility requirements for the VFC program;
- Where to refer underinsured children to obtain VFC vaccine;
- How and when to document the initial screening on the appropriate screening form and retain in the child's medical record;
- That after the initial VFC screening form is completed, the child should, at a minimum, be verbally screened at each subsequent immunization visit for continued eligibility;
- That the initial screening form must be updated when eligibility changes (see Appendix 3). A new screening form may be completed or the initial screening form may be updated with the following information:

    -Date of screening
    -Reason for change in eligibility

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 education session the provider and staff will understand

- The current ACIP recommendations and how to locate these recommendations and the VFC resolutions;
- 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 3 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.**

Provider Education Goals *for this requirement:*
By the end of the enrollment or education session 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 education session the provider and staff will understand

- Patients or Medicaid agencies cannot be billed for the cost of VFC vaccine or state-supplied vaccine;
- VFC vaccine cannot be given to non–VFC-eligible children;
- Providers are prohibited from borrowing VFC vaccine for administration to non–VFC-eligible children.

5. **Not charge a vaccine administration fee to the non-Medicaid VFC-eligible children that exceeds the administration fee cap of $____ per vaccine dose (state to fill in amount for 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 education session 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;
- How to bill for the administration fee for VFC-eligible children enrolled in Medicaid.

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.**

Please note: *The term "established patient" applies only to private providers enrolled in the VFC program. FQHCs/RHCs must administer VFC vaccine to any VFC-eligible children who present for immunization services at their facilities.*

Provider Education Goals *for this requirement:*
By the end of the enrollment or education session the provider and staff will understand

- This requirement applies to VFC as well as any other vaccines purchased through the CDC federal contract when the 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 (NCVICA), 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 education session 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 NCVICA or purchased through federal contracts;
- The recordkeeping requirements for the NCVICA;
- How to report adverse reactions to VAERS.

8. **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 Education Goals *for this requirement:*
By the end of the enrollment or education session the provider and staff will understand

- The vaccine management practices required for participation in the VFC program;
- The grantee's policy regarding replacing vaccine lost due to mismanagement;
- How to order vaccine and which documents must be submitted with vaccine orders;

Please note: *Grantees must include all required vaccine management responsibilities listed under "Provider Vaccine Management Requirements" in Module 6, "Vaccine Management" of this* VFC Operations Guide.
Other items that grantees may include under this requirement without prior approval from CDC include:

-Any grantee 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).

-Any requirement to replace, dose-for-dose, all VFC vaccine lost due to mismanagement within the provider's practice.

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

9. **The grantee or the provider may terminate this agreement at any time for personal reasons or failure to comply with these requirements. If the provider chooses to terminate the agreement, he or she agrees to properly return any unused VFC vaccine.**

Provider Education Goals *for this requirement:*
By the end of the enrollment or education session 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.

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 going through the CDC approval process. **States may not impose additional requirements for enrollment without prior approval from CDC (see below)**.

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 acceptable and 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.

Please note for 2007: *All grantees must submit a copy of their 2008 Provider Enrollment forms to the VFC Policy Coordinator no later than October 1, 2007. All grantees must submit their forms even if the grantee's form contains only the nine federal requirements. All grantees will receive written confirmation that their enrollment forms were received and approved.*

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 aged 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 or 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 optional 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 a specialized VFC screening form is minors under 19 years of age without insurance status presenting at family planning clinics. A person under 19 years of age who may have insurance but because of the confidential circumstances for seeking services 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: titled "**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 optional 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. CDC will begin collecting this information through a new question in the 2007 VFC Management Survey that is due March 1, 2008.*

Please note: *Grantees can develop their own system to collect the information required on the Family Planning Clinic Unaccompanied Minor without Insurance Information VFC Vaccine Log (see Appendix 3). The template form is provided as an example, but use of the template form is not required.*

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.

Publication Date: August 2007
Revision Date: None

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 for 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.

Publication Date: August 2007
Revision Date: None

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 upon 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

Publication Date: August 2007
Revision Date: None

MODULE 5 – Expanding the Reach of VFC and AFIX through Marketing and Collaboration

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

Marketing and Collaboration

The purpose of this module is to provide immunization programs at both the state and local level with basic information and ideas on how to market VFC and AFIX and establish collaborations with other organizations to expand participation in VFC and AFIX activities. Effective marketing and collaborations for both VFC and AFIX programs can improve the quality of immunization services at the provider level. Marketing, when applied to provider education on proper storage and handling practices and VFC program requirements, will ensure that all VFC vaccines that reach eligible children are viable and wastage is eliminated. Collaboration with other organizations with similar immunization-related goals and objectives can assist immunization programs in reaching more eligible providers and improving the quality of both organizations' programs.

AFIX Standards

The Program Operations component of the Level I AFIX Standards (which grantees are required to achieve by 2008) requires all AFIX programs to develop measurable long- and short-term objectives for their programs. Standard #9 requires development of clearly defined methods for contacting outside agencies and exploring the possibility of collaborating on quality improvement activities and/or marketing AFIX. (http://www.cdc.gov/vaccines/programs/afix/stds-guide.htm)

A project might develop an AFIX program objective that focuses on a marketing plan to reach VFC providers who are not participating in AFIX. One method for accomplishing this objective is through collaboration with insurers, which would also aid in achieving several of the nine AFIX Level I Program Operation Standards.

The VFC program might focus its marketing and collaboration activities on a specific effort, such increasing the number of VFC-enrolled providers that meet all VFC storage and handling requirements.

What is Marketing?

"Marketing" means all the activities associated with identifying the particular wants or needs of a target customer and then satisfying those wants or needs of the customer better than the competitors. While the VFC and AFIX programs do not have competition for the services offered, their customers (the providers) have many competitors for their time. For the VFC and AFIX programs to secure office time, the programs must be able to market themselves successfully. This involves doing research on your customers, and then making strategic decisions about product, price, promotion and distribution.

In the case of the VFC and AFIX programs, **the product** marketed is improved immunization coverage levels and reduction in vaccine-preventable diseases (VPD) through participation in both programs. Optimal provider participation in the VFC program ensures that viable vaccines are administered correctly to VFC-eligible children. Optimal provider participation in the AFIX program ensures that systems are in place in the practice so eligible children receive all necessary vaccines on schedule. Ultimately, the product being marketed is the health of children within a community through prevention of morbidity and mortality related to VPDs.

The price of participation in the VFC and AFIX programs is the cost to a provider to change some behavior. This might be stopping an existing practice, such as inappropriate storage or handling of a vaccine, or adopting a new practice, such as agreeing to the requirements of the VFC program. A key selling point of both the VFC and AFIX programs is that participation is free. The VFC program has an added bonus of providing vaccine at no cost to the enrolled provider. This key component now makes it easier for VFC-eligible children to remain in their medical homes for all medical services and not receive fragmented care based on ability to pay or insurance coverage. A key selling point of AFIX participation is the availability of the knowledge and experience of the AFIX staff to assist the provider in making behavioral changes to improve immunization coverage levels.

Promotion is the most recognizable component of the marketing process. This is the advertising of the product. Promotion does not require an elaborate or costly media campaign. Effective word of mouth and one-on-one conversation can be more effective than a flashy and expensive media campaign. The development and effective use of an "immunization champion" in the eXchange of Information component of the AFIX process provides an excellent forum for promoting Continuous Quality Improvement (CQI). First-person testimonials from a recognizable professional from the community whose practice has gone or is going through the AFIX process to improve immunization coverage levels will have far greater impact than a mass mailing or media spot. Promotion of the VFC program should focus on the benefits of participation in the program. The approach should be multifaceted to include the financial benefits to the provider, benefits to the provider's patients, creating a medical home, and staff development benefits related to receiving education on all aspects of immunizations.

Distribution is the process of actually delivering the goods and services to your customer. The distribution of the VFC and AFIX programs should be twofold, with special focus on the needs of enrolled providers and their staff and on recruiting new providers to participate in the programs. Distribution requires that immunization programs are able to give providers what was promoted during the marketing of VFC and AFIX. This aspect of marketing focuses on providing good customer service and following up on the needs of the enrolled providers.

What is Collaboration?

Collaboration has been defined as the process of various individuals, groups, or systems working together but at a significantly higher level than through coordination or cooperation. Collaboration typically involves joint planning, shared resources, and joint resource management.
(Reference source: http://www.nccev.org/resources/terms.html#Collaboration)
Collaboration on VFC or AFIX issues requires research by immunization programs on what organizations in their geographic location have similar or common goals or objectives. The research can be conducted formally or informally. If VFC or AFIX coordinators have extensive professional experience in the community, their research may involve telephoning or sending an e-mail to a long-standing colleague to schedule a meeting over lunch to discuss immunization objectives for the coming year. For new project staff, or staff without a strong established network, more formalized research on possible collaboration partners might be required. One way to do this is to list all organizations you are aware of that have an interest in improving immunization delivery to pediatric populations in your geographic area. Once you have made a list, conduct research on each organization. A good place to start is the organization's website. Review mission statements, goals and objectives and look at sub-sites such as quality improvement, studies and statistics, and clinical indicators. If the organization has compatible goals, find the name of an individual to contact. Target those organizations for collaboration that have the most focus on improving immunizations.

Who is the Target?

The target for marketing and collaboration may be one population or multiple populations depending on the project's objectives for the VFC and AFIX programs. Examples for marketing might be new providers in the community or institutions such as juvenile detention centers. For collaboration, targets might be chapters of national professional organizations of pediatric physicians or nurses.

How Do We Get Started?

Often with marketing and collaboration activities the first step is the most difficult. Without breaking down marketing and collaboration into smaller steps, the tasks may seem too overwhelming to implement. The following steps are the same for marketing

and collaboration. The steps will assist you in developing and implementing a marketing and/or collaboration plan for your VFC and/or AFIX programs:

Step 1 Determine your objective and your target audience. For example, your objective for the year may be "Increase the number VFC-enrolled providers who receive an initial AFIX evaluation by 20 providers by December 31 20__."

Step 2 Select and research which providers you want to target to receive an initial AFIX visit during the year. It is a good idea to select a larger number of providers than stated in the objective so there is a better chance of achieving the stated objective. Determine if the targeted providers have ever been offered AFIX visits in the past, and if they have declined, what was the reason for declining the AFIX visit? Determine if the reasons given for declining the AFIX visit can be adequately addressed and resolved. If so, incorporate the solutions into the marketing plan. If not, work on ways to communicate the advantages of participating in the AFIX program and how they surpass the inconvenience to the practice.

For collaboration activities, make a list of potential partners. Focus on both well-known partners such as the state Medicaid agency, and lesser known potential partners, such as commercial insurers, professional organizations (state chapters of AAP, AAFP and the state nurses' association) and all types of academic institutions with medically related programs (e.g., schools of nursing and technical schools that train medical assistants). Be prepared to communicate how collaboration activities would mutually benefit both the AFIX programs and the potential partner organizations.

Step 3 Develop a written plan for marketing AFIX or plan to recruit other organizations for potential collaboration activities. When developing a marketing plan, focus on addressing each of the components of marketing: product, price, promotion and distribution. When developing collaboration plans, include identifiable common goals, benefits of collaboration, the cost of collaboration in terms of commitment of time and resources, and highlight the expected outcomes focusing on the return on investment.

Step 4 Begin to implement marketing plan and/or collaboration plan to target audience or organization.

Step 5 Review and revise the marketing and/or collaboration plan as necessary based on successful recruitment of providers or partners. It is important to document any changes made to the plans in writing to maintain an accurate record of how the plan evolves and the impact of the changes to the success of the plan.

Step 6 Schedule selected providers for AFIX visits. For collaboration partners, schedule meeting to discuss further steps for implementation of collaboration activities.

Step 7 Repeat Steps 1–6 at least on an annual basis.

Resources to Assist with Marketing and Collaboration

- The Community Tool Box: University of Kansas- Lawrence, Kansas
  Website: http://ctb.ku.edu/
- Immunization Action Coalition
  Website: http://www.immunize.org/
- Assessment Feedback Incentives and eXchange of Information (AFIX) Strategy
  Website: http://www.cdc.gov/vaccines/programs/afix/default.htm
- Vaccines For Children (VFC) Program
  Website: http://www.cdc.gov/vaccines/programs/vfc/default.htm

Publication Date: August 2007
Revision Date: None

MODULE 6 – Vaccine Management

http://www2a.cdc.gov/nip/isd/shtoolkit/splash.html

Overview

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 distribution 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 the *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
- Vaccine Transfers

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. 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.

Vaccine Distribution

Historically, the management, distribution and ordering of federally purchased vaccines was handled individually by each of the 64 immunization grantees. Grantees had their own storage facilities and developed processes or systems to support distribution of vaccines from the manufacturer to providers. Some grantees outsourced the ordering and/or distribution of vaccines to a third-party distributor, and others used in-house resources for these functions.

In order to improve efficiencies and achieve cost savings, CDC initiated the Vaccine Management Business Improvement Project (VMBIP). This initiative recommended several changes designed to enhance operating efficiency, improve vaccine inventory visibility and reduce operating expenses.

One of these significant program changes calls for the implementation of a new model for distribution and funds management. In the early stages of the new centralized distribution process, ordering at the provider level will occur largely as it does today, with providers ordering their vaccines directly from the grantees. Orders will then be shipped directly from a CDC-contracted distributor to providers.

The implementation of centralized vaccine distribution is occurring in three phases: 1) pilot sites, 2) grantees with existing third-party distribution, and 3) grantees with existing in-house distribution. The first phase of centralized distribution was a focused pilot of four grantees. Lessons learned from the early phases will help make the transition to overall centralized distribution smoother for the grantees that follow.

There are some differences in vaccine management responsibilities between grantees that have transitioned to centralized vaccine distribution and those grantees that have not yet transitioned. The most significant of these differences are shown in Table 1 below.

Table 1. Responsibilities of grantees before and after centralized vaccine distribution

Responsibility	Pre-Centralized Vaccine Distribution	Centralized Vaccine Distribution
Distribution System Management	Managed by grantee (in-house, third-party contract)	Managed by CDC
Grantee Vaccine Inventory Management	Managed by grantee	CDC manages inventory for federal contract vaccines; grantee manages inventory of any non-federal contract vaccines
Bulk Orders	Placed with VFC, 317, and grantee funds	CDC places VFC and 317 orders, grantees will only place order using grantee funds
VACMAN	VACMAN 3.1 – transmits bulk orders and direct-ship orders only	VACMAN 4.1 – transmits bulk orders and all provider orders (direct-ship and non-direct-ship)

Elements of Vaccine Management

The management of publicly purchased vaccine is one of the most important activities conducted by an immunization grantee. 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 CDC's *Vaccine Storage and Handling Toolkit*, available on the Vaccines website at http://www.cdc.gov/vaccines/ for detailed procedures, and to access other CDC resources

regarding vaccine storage and handling at
http://www.cdc.gov/vaccines/recs/storage/default.htm

The Cold Chain

Storage and handling errors in which vaccines are compromised 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:

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

All three components are needed to ensure safe vaccine transport and storage.

The cold chain begins with the refrigerator or freezer 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.

If there is suspicion of a cold chain failure or evidence that vaccine has been exposed to temperatures outside the recommended temperature range, providers should immediately notify the state, city or territorial immunization program. Vaccine should be marked "DO NOT USE" so that the vaccine is not used until a response indicating that the vaccine is still potent has been received. Providers should not discard any vaccine unless directed to do so by the immunization program.

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. Grantees should 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 wastage is both costly and preventable. There are many reasons for vaccine wastage including heat exposure, freezing, breakage of 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 wastage are attributed to poor vaccine management, i.e., loss due to expiration and loss due to cold chain failures.

Vaccine loss due to expiration is frequently a consequence of over ordering and/or poor inventory management. To reduce the risk of expiration loss, avoid stockpiling vaccine or building up more inventory than can be used before the expiration date. Grantees should advise providers against stockpiling vaccine and review provider orders to prevent excessive inventory build-up.

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. In preparation for the transition to the new Vaccine Ordering and Distribution System software (VODS), CDC recommends that grantees implement tiered-ordering practices that link order frequency to provider size and usage. In general, the largest providers would be expected to order monthly. Medium-size providers would order every 2 months, and small providers would order quarterly. Storage capacity may also be a consideration in order frequency.

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

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

When providers do have excess inventory, steps may be taken to prevent vaccine loss. Providers should be required to review their inventories regularly for short-dated vaccine and to report short-dated vaccine to the immunization program. 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.

In addition to loss or wastage due to mismanagement, vaccine can be lost because it is unaccounted for. If grantees observe that unaccounted for vaccine is becoming a problem, they should begin to look at their accountability policies and provider reporting requirements to determine if data are available to identify providers with large volumes of unaccounted for vaccine. Optimally, inventory, wastage reports, and doses administered reports can be used to determine the number of unaccounted for doses for each provider. The following formula should be used:

(Vaccine inventory at start of month + doses received) - (doses administered + wastage + vaccine transferred to another location) = expected ending inventory.
Expected ending inventory - actual ending inventory = unaccounted for vaccine.

If grantees decide to monitor for unaccounted vaccine, the process must be reflected in their accountability policies.

Grantee Vaccine Management Requirements

Before Transition to Centralized Distribution

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

- Provide training on appropriate vaccine ordering, handling, storage, accounting and wastage reporting to enrolled VFC providers and their staff involved in the public vaccine distribution system. The initial training should occur at time of enrollment into the VFC program. The training should include offering providers a simple generic storage and handling plan that they may implement to meet the storage and handling plan requirements. 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.
- Maintain an efficient system to distribute public vaccines.
- Ensure that vaccines are delivered to providers in a timely manner.
- Ensure vaccine is available to fulfill provider orders.
- Ensure that vaccines within the distribution system are handled, stored and shipped so as to preserve vaccine viability.
- Provide guidance to providers on vaccine storage and handling issues.
- Review, approve and process orders from VFC-enrolled providers in a timely manner.
- Order vaccine in accordance with the annual vaccine spending plan that outlines population-based vaccine needs, funding sources and purchase schedules for each antigen.
- Ensure that vaccines remain effective (potent) by developing, reviewing regularly, and, as necessary, updating written standard operating procedures (SOPs) for vaccine ordering, receiving, storage, handling, shipping, tracking and disposal.
- Review vaccine storage and handling practices to 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.

- Document expired and wasted doses of publicly provided vaccine by developing and implementing written procedures for providers to report and respond to losses resulting from vaccine expiration, wastage, and compromised cold chain.
- Require providers to return wasted and expired vaccines to facilitate collection of excise tax credit.
- Request federal excise tax credit from manufacturers for outdated or unusable vaccine. Policies and procedures for returning vaccine and requesting credit for federal excise tax can be found on the Vaccines web site: http://www.cdc.gov/vaccines/programs/vfc/downloads/nip_tax_policy.doc
- Track grantee vaccine inventory and reorder vaccine as providers deplete inventory.
- Ensure vaccine purchase amounts are in line with the grantee-submitted spending plans.
  - -Apportion costs for bulk orders
  - -Apportion costs for direct-ship vaccine orders
- Forward orders to CDC via VACMAN

After Transition to Centralized Distribution

All grantee staff working on VFC activities should 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 should be documented and kept as part of the staff member's training /orientation record. All staff should have a copy of the responsibilities and should know how to do the following:

- Provide training on appropriate vaccine ordering, handling, storage accounting and wastage reporting to enrolled VFC providers and their staff involved in the public vaccine distribution system. The initial training should occur at time of enrollment into the VFC program. The training should include offering providers a simple generic storage and handling plan that they may implement to meet the storage and handling plan requirements. 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.
- Review, approve and process orders from VFC-enrolled providers in a timely manner.
- Order grantee-funded vaccine in accordance with the annual vaccine spending plan that outlines population-based vaccine needs, funding sources and purchase schedules for each antigen.
- Ensure that vaccines remain effective (potent) by developing, reviewing regularly, and, as necessary, updating written standard operating procedures (SOPs) for vaccine ordering, receiving, storage, handling, tracking and disposal.
- Urban grantees and local health departments must develop written SOPs for storage and handling.
- Review vaccine storage and handling practices to 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.

- Document expired and wasted doses of publicly provided vaccine by developing and implementing written procedures for providers to report and respond to losses resulting from vaccine expiration, wastage, and compromised cold chain.
- Require providers to return wasted and expired vaccines to the distributor to facilitate collection of excise tax credit.
- Track inventory and reorder vaccine as providers deplete inventory of non-federal contract vaccines.
- Ensure vaccine purchase amounts are in line with the grantee-submitted spending plans.
  - Apportion costs for bulk orders
  - Apportion costs for direct-ship vaccine orders
- Forward orders to CDC via VACMAN or VODS when it becomes available (bulk and all provider orders—non-direct ship and direct ship).

Provider Vaccine Management Requirements

All VFC-enrolled providers do not have the same level of expertise regarding vaccine management. An important responsibility of the grantee to the VFC program is to work with providers to develop and implement accurate but simple plans for routine and emergency vaccine management. Grantees must be able to provide templates to providers on key vaccine management requirements. Please see Appendix 5 for a sample emergency storage and handling plan. All providers must be able to meet the following requirements in order to participate in the VFC program:

Vaccine Personnel

- 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 some key requirements and will provide oversight for all vaccine management within the office.
- The designated vaccine coordinator and backup must be responsible for the following vaccine management activities:
  - -Adjusting the temperature of a vaccine storage unit;
  - -Documenting the temperature on the temperature logs for each storage unit;
  - -The primary vaccine coordinator should review temperature logs weekly if daily monitoring is being conducted by a backup person to ensure proper temperature recording. The backup staff should monitor the temperature logs if the primary coordinator is recording the daily temperatures.
- The primary and backup vaccine coordinators are responsible for training 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 should be kept as documentation.

- Unless otherwise noted, the vaccine coordinator and/or backup should be the VFC contacts for the office.

Storage and Handling Plans

Providers may develop their own written routine and emergency storage and handling plans or use the grantee-supplied storage and handling templates and customize the 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 the following aspects of routine vaccine management:
  - -ordering vaccines
  - -controlling inventory
  - -storing vaccines and monitoring storage conditions
  - -minimizing vaccine wastage
  - -vaccine shipping, including receiving, packing and transporting
- The emergency vaccine storage and handling plan should 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 The emergency plan should include the following:
  - -person(s) responsible for preparing and transporting vaccine, including contact information
  - -how this person will be notified that vaccine needs to be moved
  - -location that will receive vaccine
  - -how receiving location will be notified of transport
  - -how to pack vaccine for transport
  - -worksheet to document vaccine involved in power or equipment failure

  At a minimum the emergency plan must be reviewed and updated annually (or as necessary) or when there is a change in staff who have responsibilities specified in the emergency plan.

Vaccine Storage Equipment

Providers must have appropriate equipment that can store vaccine and maintain proper conditions. If a provider does not have the appropriate storage units, the grantee must work with the provider to obtain storage units that are acceptable.

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 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 certified 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;
- 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.)

Vaccine Storage Practices

The vaccine storage practices listed below can be the responsibility of the vaccine coordinator or can be delegated to another staff member. If the practices are delegated, the vaccine coordinator should monitor the activity periodically.

- 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 immunization program of any vaccine doses that will expire before they can be administered. Only with the approval and direct guidance of the 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.
- Space stored vaccine to allow for cold air circulation around the vaccine.
- Do not store vaccines in the door of the storage unit.

Temperature Monitoring

Temperature monitoring should be the primary responsibility of the 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 place.
- 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). The freezer temperature should be 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).

Vaccine Shipments

- Immediately check vaccine cold chain monitors[1] and document the temperature inside the transport unit when vaccine arrives at office or clinic.
- Take proper action if cold chain monitor was activated.
- Develop a policy, complete with protocols and procedures, for maintaining the vaccine cold chain during transport to off-site clinics or emergency storage locations. See guidelines: *Maintaining the Cold Chain During Transport* (http://www.immunize.org/catg.d/p3049.pdf).

Vaccine Wastage

- Notify the immunization program of vaccine cold chain failure/wastage incidents involving publicly funded vaccines promptly after discovery of the incident. Follow the guidance of the grantee on how to document and report the incident.
- Implement written procedures 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 spoiled or expired publicly purchased vaccines for excise tax credit.

***Please note*:** *Prior to transition to centralized distribution, providers should return spoiled/expired vaccine to the grantee.*
Following transition to centralized distribution, providers should return vaccine to the centralized distributor.

Vaccine Preparation

It is not acceptable clinical practice to pre-draw vaccines into syringes. Providers should draw vaccine only at the time of administration to ensure that the cold chain is maintained and the vaccine is not inappropriately exposed to light.

Vaccine Ordering and Inventory Management

- Order vaccine in accordance with actual vaccine need; avoid stockpiling or build-up of excess vaccine inventory.
- Develop and maintain complete, accurate and separate stock records for both public and private 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

Post warning notices at both the electrical outlet and the circuit breaker to prevent power from being disconnected.

[1] Cold Chain Monitors (CCMs) - These single-use devices come in three basic types: those that indicate whether packages have reached temperatures that are too warm, those that indicate whether packages have reached temperatures that are too cold, and those that continuously record the temperature. These types of monitors are designed to be irreversible indicators of inappropriate temperatures.

Additional Recommendations for Providers

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. Place opened vials of vaccine in a tray, so that they are readily identifiable. Indicate on the label of each vaccine vial the date and time it was reconstituted or first opened.
- Open only one vial, or box, of a particular vaccine at a time to control vaccine usage and allow easier inventory control.
- Store vaccine products that have similar packaging in different locations 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.
- Follow manufacturer's recommended schedule for recalibration of the certified thermometers.

Vaccine Inventory Management

Until transition to centralized distribution, conduct a monthly inventory to monitor vaccine use, anticipate needs and remove expired vaccines.

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 (generators) and a security system to alert appropriate personnel in the event of a power outage.
- If applicable, test backup generators quarterly and maintain backup generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).

Vaccine Transfers

Vaccine transfers between providers can occur only after receiving approval from the grantee. The grantee must actively coordinate the transfer of vaccine between providers.

Publication Date: August 2007
Revision Date: None

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, distribute, 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. Reports available in both VACMAN 3.0.11 and VACMAN 4.1.2 assist the immunization programs with vaccine order tracking.

The recent implementation of a centralized vaccine distribution system has resulted in the creation of three different vaccine order management systems:

- **VACMAN 3.0.11:** Current system used by grantees to place vaccine orders, manage inventory and distribute vaccine.
- **VACMAN 4.1.2:** Transitional system used by grantees that have transitioned to centralized distribution to place individual provider vaccine orders but has no functionality to distribute vaccine.
- **VaxNet:** Final system designed to incorporate all features of VACMAN, NIPVAC and the Vaccine Ordering Forecasting Application (VOFA) into a single centralized system used by CDC and grantees for placing vaccine orders and managing funds.

VACMAN Help Desk

The VACMAN Help Desk answers questions and assists with problems concerning a vaccine order, placing an order, and federal vaccine contracts. The Help Desk can be reached at:

Voice: **(404) 639-8303**
FAX: **(404) 639-8171**
E-mail: ccidinformatics@cdc.gov

The Help Desk's hours are Monday through Friday 8:00 a.m. to 6:00 p.m. Eastern time.

Transition Plan

CDC is currently supporting two versions of VACMAN: VACMAN 3.0.11 for grantees not using the centralized distributor, and VACMAN 4.1.2 for grantees that have transitioned to centralized distribution. Support of the two VACMAN systems will continue until all grantees have transitioned to centralized distribution. Grantees ordering vaccine in bulk using VFC, 317 and grantee state or local funds will transition to using grantee funds only (replenishment under centralized distribution) when they transition to centralized distribution. After transition to centralized distribution, grantees will continue to use VACMAN 4.1.2 until the development and testing of VaxNet are complete.

The Vaccine Ordering and Distribution System (VaxNet) 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. VaxNet will provide data to support vaccine distribution that will be made available to CDC and grantees for analysis and program management.

A timeline has been established to bring each grantee onto the new ordering system. The designated project officer for each grantee will provide support throughout the grantee transition period.

Publication Date:
Revision Date: None

MODULE 8 – Vaccine Accountability

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

Placeholder

Publication Date: August 2007
Revision Date: None

MODULE 9 – Quality Assurance

http://www.cdc.gov/vaccines/programs/vfc/default.htm
http://www.cdc.gov/vaccines/programs/afix/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. Quality assurance (QA) involves review and evaluation of VFC provider practices and is a legal requirement of the VFC program. Quality assurance is implemented through site visits to VFC providers. Outcomes of provider site visits help program staff determine how well the VFC program is being implemented at the individual provider site level, and individual evaluations also assist with improving the overall VFC program at the state level.

Quality assurance takes place during two types of site visits:

- VFC provider site visits
- Assessment, Feedback, Incentives, and eXchange (AFIX) visits

VFC provider site visits help to determine if VFC vaccines are being distributed, handled, and administered in accordance with the laws and policies that govern the VFC program.

AFIX (Assessment, Feedback, Incentives, and eXchange) is a Continuous Quality Improvement strategy that consists of 1) assessment of the healthcare provider's vaccination coverage levels and immunization practices, 2) feedback of the results to the provider along with recommended strategies to improve coverage levels, 3) motivating the provider through incentives to improve vaccination coverage levels, and 4) exchanging healthcare information and resources necessary to facilitate improvement.

VFC Provider Site Visits

All immunization grantees are required to conduct site visits to VFC providers in both the public and private healthcare sectors. The purpose of the 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 the requirements of the VFC program. Appendix 6 contains instructions on how to conduct VFC eligibility screening by selecting a random sample of children within a practice. Persons conducting VFC provider site visits must complete all the questions in Section I

of the VFC Site Visit Questionnaire. These are the required questions that must be asked to assess the provider's compliance with the VFC requirements. Questions identified with a red exclamation point (!) are considered high priority. Corrective actions must be developed if the provider is not in compliance with any of these questions. Section II of the questionnaire includes optional questions related to the Standards of Pediatric and Adolescent Immunization Practices. Section III of the questionnaire allows grantees to create custom questions specific to their programs (Section III is only available in the CoCASA software application).

The VFC site visit questionnaire is reviewed and updated annually and is available in the Comprehensive Clinic Assessment Software Application (CoCASA). Every grantee should develop a written protocol for provider site visits that outlines procedures for selecting provider sites for QA visits, conducting site visits—including instruction on how to administer the VFC Site Visit Questionnaire—and reporting results from completed site visits. All immunization grantees are required to conduct VFC provider site visits to enrolled VFC provider sites annually. Please refer to the annual grant guidance for specific information.

VFC Site Visit Objectives

The main VFC site visit objectives are

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

The ABCs of Conducting Site Visits

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

A. Training staff and required equipment

In order to achieve the objectives, 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 notifying the provider of the time and date of the visit and what working space and materials the visitor will need.

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

- The purpose and importance of the visit;
- How to correctly administer the VFC Site Visit Questionnaire (if applicable);
- Objectives of the visit (preplanning);
- 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.

B. Selecting provider sites

Grantees must develop a protocol for determining how VFC provider sites are selected for a visit. The following situations necessitate that a VFC site visit be conducted more frequently:

- High-volume vaccine usage
- Unusual ordering patterns
- Healthcare providers who are outliers with respect to vaccine ordering
- Reports of vaccine abuse or fraud
- Medicaid billing inconsistencies
- Unacceptable storage and handling practices

Additional provider sites should be visited according to a process of random selection. All staff should be made aware of the process used to select provider sites for QA visits and follow it accordingly. Grantees that conduct separate AFIX visits must develop protocols for determining how providers are selected for AFIX visits.

C. Scheduling site visits

A scheduling policy should include the following key points on how to schedule a site visit:

- 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 and any criteria necessary to select charts)
  - -VFC-related materials for VFC visits (such as VIS statements used, temperature logs)
- Send a confirmation letter or fax to contact with date, time, materials needed and summary of visit process;
- Confirm the visit with the provider 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 that provider site. 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 to 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.

Staff should also have on hand a selection of VFC-related forms and educational brochures available to distribute to provider site staff as needed.

E. Site Visit Questionnaire

Staff conducting VFC site visits are required to ask all questions in Section I of the VFC Site Visit Questionnaire developed by CDC. The questions contained in this questionnaire are essential to evaluating a provider's compliance with the requirements of the VFC program. All grantees must include CDC's required questions (Section I) as part of their VFC provider site visit data collection instruments. Some questions are designated as "high priority" and are identified by a red exclamation point (!). If answered inappropriately, the high-priority questions require a written corrective action. The inappropriate answer must be discussed with the provider and a corrective action agreed upon. Some inappropriate findings on the high-priority questions require that corrective actions be implemented immediately upon identification. Findings that place the viability of vaccine at risk, such as no working thermometers or no temperature log on the storage units, would need immediate attention.

Additional optional and custom questions can also be included in the VFC Site Visit Questionnaire at the discretion of the grantee. If the program decides to include optional and/or custom questions, these questions must be used consistently at all VFC site visits. Without consistent data collection, data cannot be used for meaningful analysis. All grantees are sent an electronic version of the VFC questionnaire in Microsoft Word annually before the start of the new calendar year.

Please Note: *For programs using the CoCASA software, the VFC Site Visit Questionnaire is programmed into the software. Staff can enter responses to questions electronically and print out a copy of the completed questionnaire to share with the provider. Questions designated as "high-priority" are marked with a red exclamation point* (!) *icon. If noncompliant responses are given for any of these high-priority questions, the person entering the questionnaire will be required to enter a corrective action for each noncompliant response given. This function is programmed into the software to ensure that the areas of highest importance are being appropriately addressed. Staff members are not limited to entering corrective actions for these high-priority questions; they can enter recommendations for any issue identified during the site visit. Further information on how to use CoCASA and the current version of CoCASA can be found at* http://www.cdc.gov/vaccines/programs/cocasa/default.htm .

F. Preparing for the site visit

The site visit policy 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 that use CoCASA to enter VFC Site Visit Questionnaire responses
- Certified 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 or vaccine accountability reports)
- Blank forms as necessary (provider profile, VFC questionnaire)
- Handouts/resources, such as
  - -Immunization brochures and other educational materials
  - -Latest 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 (Make sure the VISs are current.)
  - -Monthly temperature log for refrigerator and freezer recordings
  - -Stickers for refrigerators/freezers/electrical outlets
  - -VFC labels for labeling public vaccine
  - -Refrigerator plug locks and signs
  - -State Children's Health Insurance Program (SCHIP) information
  - -Other information about upcoming CDC satellite courses, copies of any recent mailings from the grantee to providers about VFC or specific vaccine-preventable diseases

G. Conducting the site visit

The main focus of the site visit will depend on the type of site visit being conducted. The VFC Site Visit Questionnaire guides the reviewer through a VFC provider 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 on how to conduct site visits, but these policies and procedures will vary depending on the type of site visit. Training staff on how to conduct site visits is an essential component of provider quality improvement activities. Certain interpersonal skills and behaviors can be helpful in making the site visit a success, and these skills should be emphasized:

- Be organized;
  - -Know where to go, what time to arrive, and whom to talk to
  - -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.

H. Reviewing the findings

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 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 the both office staff and immunization program. All details of the follow-up plan should be documented electronically. Please refer to the AFIX Standards for specific content requirements regarding the AFIX feedback session. (See AFIX section below.)

I. 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 would be a valuable tool for identifying potential problems within that provider's office. Other reporting options are available through CoCASA and could be used to assist with the review of data at the program level.*

Combined VFC/AFIX visits

Every effort should be made to combine the VFC site visit with an AFIX visit to reduce disruption to provider offices.

Assessment, Feedback, Incentives and eXchange (AFIX)

One of the most effective strategies for improving immunization coverage levels and standards of practice at the provider level is use of the continuous quality improvement process known as AFIX. As described in the introduction, AFIX stands for Assessment of immunization levels, Feedback of immunization information to key staff, Incentives to motivate and/or recognize outstanding performance, and eXchange of information on best practices to improve immunization coverage levels.

The "A" or Assessment component of AFIX assists providers in identifying opportunities for improvement. Once an opportunity is identified, an improvement goal is created. A plan is then developed, implemented and evaluated to determine if the goal was achieved. This process continues with revisions to the plan until the goal is met. The "F-I-X"

components of AFIX are used during this process to develop, implement and evaluate the continuous quality improvement process.

The goal of AFIX is to ensure that viable vaccines reach all children served by the provider site in accordance with the ACIP schedule. A successful AFIX process requires implementation of all four components and repeated contacts with to a provider site. It requires that the immunization staff and the provider site become partners in improving immunization coverage levels. CDC encourages grantees to develop programs that merge the content of both VFC and AFIX programs into a single site visit. By combining visits, grantee resources can be used more efficiently to reach VFC providers, particularly in the private sector where the majority of vaccinations are delivered.

CoCASA, the software tool described above, may be used to conduct the assessment component of AFIX. The assessment component is the foundation of the AFIX program. The other components build on the findings from the assessment. Grantees must be mindful that all the components of AFIX interact and must be included when working with both public and private providers.

The benefits of AFIX have been demonstrated in public clinic settings and private provider offices. CDC offers technical assistance and documentation to assist grantees with implementing their VFC and AFIX site visits, including guidance for meeting all the grant requirements for AFIX and VFC programs. The information described above is available on the AFIX and VFC websites located at http://www.cdc.gov/vaccines/programs/afix/default.htm and http://www.cdc.gov/vaccines/programs/vfc/default.htm, respectively.

The following sections describe elements of a successful AFIX quality improvement program.

AFIX Standards

Funding for implementing AFIX activities in VFC provider sites is made available to grantees through the immunization grant. To assist grantee program staff in implementing, managing, and evaluating an AFIX program, AFIX Standards have been developed. These standards contain the essential elements of all AFIX programs and are organized into three levels, each one building on the components of the previous level. The AFIX standards are specific enough so grantees can design their programs to fulfill the CDC grant requirements, yet they offer flexibility so grantees can individualize their programs for the specific conditions in their area.

Standards for a Level I program focus primarily on the development and implementation of written protocols and procedures and represent the basic components of the grant requirements. A Level II program builds upon Level I written protocols and procedures. Level II standards focus on improving protocols and procedures and increasing activities and objectives. A Level III program builds upon Levels I and II and focuses on developing innovative strategies for improving the AFIX process.

The key concepts for AFIX Standard Level I are summarized below. This summary does not include all Level I Standards, only the major concepts from each of the six components contained in each level. Grantees should be actively working toward achieving all Level I Standards by developing written policies and procedures. The complete AFIX Standards document is available on the AFIX website at http://www.cdc.gov/vaccines/programs/afix/stds-guide.htm#what

Level I Program Operations Component

- Clearly defined measurable short- and long-term objectives and methods to evaluate achievement of each objective;
- Written protocol and procedures for daily program activities, including
  - -Provider selection
  - -Staff development (written job descriptions, orientation process for new staff, ongoing staff training, supervision, monitoring and evaluation of job performance)
- Explore possible collaborations with external organizations.

Level I Assessment Component

- Written assessment parameters
  - -Assessment methodology
  - -Age range of sample
  - -Number of records to assess
  - -Active patient definition
  - -Immunizations to assess
  - -Demographic fields to be collected
  - -Moved or gone elsewhere (MOGE) definitions
- Method for generating the sample
- Method for monitoring and evaluating performance of staff conducting assessment component of the AFIX process

Level I Feedback Component

- Coordination of feedback session
  - -Timing (on day of assessment or within 2 weeks of assessment)
  - -Logistics (face-to-face discussion)
  - -Participants (what staff are required to attend the feedback session)
- Content of session
  - -Prioritize opportunities for improvement and discuss two
  - -Identify office's strengths related to immunization delivery
- Discussion and development of quality improvement plan
  - -Agree upon follow-up plan with provider office
- Method to evaluate feedback session, including joint visits with supervisor

Level I Incentives Component

- Development of guidelines and options to include two informal incentives during the feedback session

- Development of formal incentive program for providers with improved or sustained high immunization coverage
- Documentation of process for implementing formal incentives

Level I eXchange Component

- List of specific information to exchange with provider/staff during feedback session and how to use the information to improve immunization coverage levels;
- Promoting VFC and AFIX participation through health professional meetings or conferences.

Level I Program Evaluation Component

- Utilize an electronic database to monitor site visit activities. At a minimum, the database must be able to generate the summary information required in the annual VFC Management Survey.
- Develop written protocol for the utilization of the database.
- Submit VFC Management Survey in appropriate format by the due date.
- Develop and implement a procedure for conducting a process evaluation.

Training Plan

A successful quality improvement program requires certain technical and interpersonal skills. Grantees should develop a training plan for AFIX/VFC staff that provides the following:

- New employee orientation, on-the-job training, and formal training on conducting AFIX visits. This activity is a Level I Program Operations Standard. CDC no longer provides grantee-based training on AFIX or CoCASA. CDC staff are available for technical assistance in developing the training curriculum and training plan for grantee staff to implement, and CoCASA has a training module located under the "Help" function on the main toolbar of the software.

- Periodic staff development meetings that include updates and refresher courses for experienced staff on the latest developments.

- Development of state or local training resources, particularly a "CoCASA expert" to provide assistance to field staff implementing AFIX using CoCASA. The CoCASA expert will be the liaison to CDC if he/she is unable to resolve problems experienced by staff.

The Core Elements for AFIX Training and Implementation are available on the AFIX website at http://www.cdc.gov/vaccines/programs/afix/downloads/coreelements.pdf. This document can be a helpful resource when developing training materials at the grantee level.

Partnerships and Collaboration

Grantees should have a plan to involve state and local organizations to help promote, educate, and collaborate with their constituencies on VFC and AFIX programs. Please refer to Module 5 of this manual for more information on how to market and develop collaborations around the VFC and AFIX programs. Some potential partners or collaborators are listed below:

- Local chapters of the American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), American Nurses Association (ANA), National Medical Association (NMA), medical societies, or similar organizations (these organizations can help market the program through meetings and in newsletters and bulletins)
- Health insurance organizations such as Medicaid and commercial insurers in the grantee's region
- Academic settings for allied health professionals, including but not limited to:
  - -Colleges of nursing (registered nurses and advanced practice nurses)
  - -Technical or vocational nursing schools (licensed practical nurses or licensed vocational nurses (LVNs)
  - -Medical assistant schools

Successful partnerships and collaborations can be helpful in implementing the "I" and the "X" components of AFIX by having partners publicize successful strategies and information about AFIX and VFC to their target audiences. It may be possible to work with partners to recognize and reward high achievers or outstanding accomplishments through sponsorship of an annual award ceremony. Partners can facilitate exchanges of information on AFIX and VFC at local, regional and state levels.

Reporting Requirements

Grantees should have written plans and procedures 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 in Appendix 6.)

Responses to the VFC Site Visit Questionnaire are reported in aggregate form. The AFIX outcome measure, immunization coverage levels, is also reported as the number of providers with coverage levels within a specific percentile. For assessment visits that employ the hybrid method, the number of providers meeting the predetermined threshold should be reported. In addition, information regarding repeat assessment visits and outcomes should be documented. The VFC Site Visit Questionnaire and the VFC and AFIX reporting templates are located in the CoCASA program.

If the VFC/AFIX Evaluation module of CoCASA is used, the software will generate the VFC/AFIX activities information to be documented in the VFC Program Management Survey.

The VFC Activity section of the VFC Management Survey asks the user to record providers' answers to a subset of questions from the VFC Site Visit Questionnaire administered during every VFC site visit. If information is entered into the VFC/AFIX module of CoCASA, the software will 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.

Publication Date: August 2007
Revision Date: None

MODULE 10 – Fraud and Abuse

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

Overview

As the cost of childhood vaccines increases and the complexity of immunization programs grows, 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 the VFC program.

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.

It is important for state immunization programs and the state Medicaid agencies to collaborate on the development of policies and procedures regarding VFC program fraud and abuse. In addition to using the services of state Medicaid agencies and CMS, state immunization programs, in collaboration with their state Medicaid agencies, should also use the fraud and abuse–related services of other state agencies that are responsible for investigating and prosecuting fraudulent healthcare activities and misuse of government funds.

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

Fraud

Fraud is defined as **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

Abuse is defined as **provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, [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 vaccine;
- Charging more than the established maximum regional charge for administration of a VFC vaccine to a federally vaccine-eligible child;
- Not providing VFC-eligible children VFC vaccine because of parents' inability to pay for the administration fee;
- Not implementing provider enrollment requirements of the VFC program;
- Failing to screen patients for VFC eligibility;
- Failing to maintain VFC records and comply with other requirements of the VFC program;
- Failing to fully account for VFC vaccine;
- Failing to properly store and handle VFC vaccine;
- Ordering VFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC doses;
- Wastage of VFC vaccine.

On rare occasions after further assessment of an alleged fraud or abuse incident, and in conformance with the requirements of 42 CFR §455.15, if the grantee determines that there was no intentional deception, misrepresentation or negligent deception or misrepresentation of the VFC program by the provider or office staff, the situation may be corrected through an educational referral process within the VFC program. The grantee should have clear written criteria indicating when an incident may be appropriate for an educational referral. The criteria should include both objective and subjective factors such as the amount of money lost by the VFC program; inadvertent financial gain of the provider; how the incident was identified; length of time the situation was occurring; provider's willingness to replace dose for dose lost VFC vaccine with privately purchased vaccine; and the provider's willingness to participate in the educational referral and post-education follow-up.

Determining if the alleged abuse situation is unintentional due to a clearly excusable lack of knowledge should be based on observations of the VFC staff and other appropriate investigative authorities. It should be noted that unintentional abuse or error is nevertheless still unacceptable. The response to instances of unintentional abuse or error may vary depending on the circumstances and whether other instances of fraud or abuse (either intentional or unintentional) have occurred. In appropriate circumstances, education may be the proper response in lieu of criminal enforcement. The investigative/enforcement referral requirements of 42 CFR §455.15 must be followed to determine whether an educational intervention is adequate.

Fraud and Abuse Program Requirements

Written Policy

All grantees are required to develop and implement a comprehensive written fraud and abuse policy for the VFC program that addresses prevention, detection, investigation and resolution of fraud and abuse allegations. The fraud and abuse policy must be submitted to CDC annually. **The first submission is due no later than December 31, 2007, and should be sent to the VFC policy coordinator by that date.**

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

1. Identify one primary position and at least two back-up positions that have the authority to 1) make decisions about where identified potential fraud/abuse situations are to be referred; 2) make the referral; and 3)notify appropriate governmental agencies (CDC, state Medicaid and others as appropriate).
2. Identify enforcement agencies that will receive referrals of potential fraud or abuse cases and the process for referral. The referral process should include

   a. How coordination occurs with the Medicaid Integrity Program within the state Medicaid agency;
   b. If appropriate, memoranda of understanding (MOU) between the grantee and each investigative/enforcement agency that detail the role of each entity and the processes to be followed in responding to allegations of fraud or abuse.

3. Describe the process for implementing activities to detect and monitor for fraud and abuse in the daily operations of the VFC program. Documentation of the following activities is required:
   a. List examples of actions that might constitute potential fraud or abuse situations for staff to use as a training and resource document.
   b. List the types of potential fraud and abuse situations to be referred to each investigative/enforcement agency.
   c. Based on items a and b above, develop an algorithm or action steps describing how to respond to particular allegations of fraud or abuse in conformance with the Medicaid investigation and referral requirements of 42 CFR §455.15 (refer to end of module for information on 42 CFR §455 .15), including when educational interventions are an appropriate response versus when referral for enforcement is necessary and including which enforcement agencies have jurisdiction over the particular allegation.
   d. Describe the process for responding to potential fraud or abuse situations identified by the VFC program staff as well as those referred to the VFC program by outside individuals. The process should include the data to be collected regarding the situation and a maximum acceptable time frame not to exceed 5 working days from identification to referral to external agency and/or to VFC educational resource staff and the documentation process.
   e. Describe the educational process, including use of corrective action plans that will be used when a provider is referred to educational resource staff for excusable lack of knowledge related to the VFC program.
   f. Describe how staff members are educated about the fraud and abuse policy, including frequency of updates. At a minimum, staff should receive education as part of new employee orientation and updates annually after completion of orientation.
   g. Develop and implement a plan for continual evaluation and enhancement of the fraud and abuse policy.
4. Describe the process for incorporating provider accountability measures and responsibilities into the daily operations of the VFC program to detect and monitor for fraud and abuse activities.
5. Make available and disseminate a VFC fraud and abuse phone line for reports of suspected cases of fraud and abuse.
6. Describe how the excluded provider list is used for identifying potential situations of fraud and abuse. Information about parties who are excluded by the HHS Office of Inspector General is found on their website

(http://www.oig.hhs.gov/fraud/exclusions.html) under "List of Excluded Individuals and Entities."

7. Describe the process for notification of CDC and CMS, as appropriate, regarding fraud and abuse activities, including mandatory reporting as described in the last section below.

Coordination of Policy Development between Urban and State Grantees

In areas with both city and state grantees (Texas, Illinois, New York and Pennsylvania), the grantees must work together to develop identical policies and procedures for the following required policy components: items #2, #3, #4, #6 and #7.
Each grantee must develop items #1 and #5 separately.

Defining the Referral Process

Each grantee must, in its policy and procedures, outline a procedure for handling potential fraud or abuse situations, including to which investigative/enforcement entities particular allegations should be referred. The policy should provide guidance to persons making referral decisions in differentiating between situations that may be corrected through educational resolution and situations that must be referred for formal investigation consistent with 42 CFR Part 455, Subpart A. Further information on each type of referral is provided below.

Educational Resolution Referral

Certain situations may initially appear to be potential cases of fraud or abuse, but when assessed further, there may be no purposeful intent to misrepresent or defraud the VFC program and no negligence regarding VFC responsibilities. The situation can be attributed to an excusable lack of knowledge or understanding of the VFC program. The first intervention in these situations can be education regarding the requirements of the VFC program, consistent with the requirements of 42 CFR Part 455, Subpart A. The grantee's fraud and abuse policy should provide guidance on what types of situations would qualify for this type of referral and how to properly document the referral and the corrective action plan as well as the outcome of the educational process. Grantees are responsible for ensuring that VFC-enrolled providers and their staff have the information they need to participate in the program and fully comply with program requirements.

Formal Investigation/Referral

Situations identified by VFC staff or reported by the public that are not related to excusable lack of knowledge or understanding of the VFC program must be referred in conformance with 42 CFR §455.15 to the appropriate agencies for further investigation and potential enforcement of relevant laws, including fraud and abuse, consumer protection and professional licensure. The grantee's fraud and abuse policy must provide guidance on what types of situations require this type of referral, how to properly document the referral, and what follow-up is required for this type of referral.

Investigation and Reporting of Fraud and Abuse Cases

If the VFC program determines from the information available that the situation requires referral for further investigation by an outside agency, the VFC program should make these referrals in a timely manner (i.e., within 5 working days). To accomplish this, the grantee must identify the appropriate referral agencies within its geographic area and develop a working relationship with each agency. State agencies and their responsibilities related to fraud and abuse vary by state, so the appropriate referral agency in one state may not be an appropriate agency in another state. Below is a list of potentially relevant state and federal agencies. In developing its fraud and abuse policy, each grantee must, at a minimum, consult with each entity to determine relevant laws and potential investigative and enforcement capabilities.

State Medicaid Agency

Each state Medicaid agency has a process in place to meet requirements for detecting, investigating, pursuing, and referring suspected cases of fraud and abuse to law enforcement officials. The state Medicaid agency's Program Integrity Unit and/or its Surveillance and Utilization Review Unit usually perform these functions. These units identify questionable provider practices and conduct preliminary investigations into complaints of Medicaid fraud and abuse. If there is sufficient reason to believe that an incident of fraud or abuse has occurred, a full investigation may be conducted and the case referred to the Medicaid Fraud Control Unit (MFCU) or appropriate law enforcement agency.

Medicaid Fraud Control Unit

The Medicaid Fraud Control Unit is responsible for investigating and prosecuting (or referring for prosecution) violations of all applicable state laws pertaining to fraud in the administration of the Medicaid program, including the VFC Program. The MFCU is often located in the Office of the State Attorney General or another part of state government that has statewide authority to prosecute individuals for violations of criminal laws with respect to fraud in the Medicaid program.

Office of the State Attorney General

The Office of the state Attorney General generally advises and represents state agencies that protect the rights of state consumers and may also represent other relevant state agencies.

State Consumer Protection Agency

State consumer protection agencies offer a variety of important services. They might mediate complaints, conduct investigations, prosecute offenders of consumer laws, license and regulate professional service providers, provide educational materials and advocate for consumer rights.

Department of Insurance or State Insurance Commissioner
The Department of Insurance (DOI) or the State Insurance Commissioner is responsible for enforcing insurance-related laws of the state. A link to each state's DOI or Insurance Commissioner can be found at http://www.naic.org/state_web_map.htm

State Secretary of State/State Medical Licensing Board/State Department of Education
Each state licenses medical providers to practice medicine within state boundaries. The agency that issues licenses and that has regulatory responsibility over healthcare providers may vary from state to state. In general, these responsibilities are implemented by the state's Secretary of State, the state medical licensing board or the state department of education. It is necessary for each grantee to determine which agency in its state has this responsibility.

Federal Agencies

CDC
All suspected cases of VFC fraud and abuse that are referred to an external agency for further follow-up must be reported to the grantee's Program Operations Branch (POB) project officer within 2 working days of the referral to the external agency. The grantee must submit to the VFC policy coordinator a copy of the information supplied to the external agency where the case was referred.

CMS and the Department of Health and Human Services Office of Inspector General
All suspected cases of VFC fraud and abuse that are referred to an external agency for further follow-up must be reported to CMS' Medicaid Integrity Group and, as appropriate, to the DHHS Office of Inspector General, within 2 working days of the referral to the external agency. An example of a case that should be reported to the Office of Inspector General would be discovery of a provider that has not disclosed information regarding conviction of a crime under the Medicare, Medicaid or Title XX programs. The grantee must submit to the Medicaid Integrity Group a copy of the information supplied to the external agency to which the case was referred **by fax to 410-786-0711.** Questions regarding this requirement may be directed by e-mail to Medicaid_Integrity_Program@cms.hhs.gov. No HIPAA-sensitive information should be e-mailed to the Medicaid Integrity Group.

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 provider 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.

42 CFR § 455.15 Medicaid Program Integrity

PART 455--PROGRAM INTEGRITY: MEDICAID
Subpart A--Medicaid Agency Fraud Detection and Investigation Program
Sec. 455.15 Full investigation.

If the findings of a preliminary investigation give the agency reason to believe that an incident of fraud or abuse has occurred in the Medicaid program, the agency must take the following action, as appropriate:

1. If a provider is suspected of fraud or abuse, the agency must:
    a. In States with a State Medicaid fraud control unit certified under subpart C of part 1002 of this title, refer the case to the unit under the terms of its agreement with the unit entered into under Sec. 1002.309 of this title; or
    b. In States with no certified Medicaid fraud control unit, or in cases where no referral to the state Medicaid fraud control unit is required under paragraph (a)(1) of this section, conduct a full investigation or refer the case to the appropriate law enforcement agency.
2. If there is reason to believe that a recipient has defrauded the Medicaid program, the agency must refer the case to an appropriate law enforcement agency.
3. If there is reason to believe that a recipient has abused the Medicaid program, the agency must conduct a full investigation of the abuse.

[48 FR 3756, Jan. 27, 1983, as amended at 51 FR 34788, Sept. 30, 1986]

Publication Date: August 2007
Revision Date: None

MODULE 11 – Evaluation

NCIRD Website: http://www.cdc.gov/vaccines/default.htm
CDC Evaluation Workgroup: http://www.cdc.gov/eval/index.htm
CDC Framework for Program Evaluation: http://www.cdc.gov/eval/framework.htm
CDC Evaluation Self Study Guide: http://www.cdc.gov/eval/evalguide.pdf
Community Tool Box: http://ctb.ku.edu

Overview: Why Evaluate Your VFC and AFIX Programs

Given the amount of funding and considerable resources that are invested in implementing and managing programs such as VFC and AFIX at both the federal and grantee levels, it is important to ensure that these programs are managed appropriately and are achieving their desired outcomes. Program evaluation is an essential organizational practice in public health and is a grantee requirement as stated in the 2008 Program Announcement and the *2008–2012 Immunization Program Operations Manual*. Evaluation is also an integral component of VFC and AFIX programs. This module is intended to provide guidance to grantees about program evaluation.

Evaluation provides objective insight into a program and identifies opportunities to assess its impact, make improvements, or build program capacity. Evaluation enables programs to identify components that are achieving their desired effect as well as those that are not functioning adequately. In addition, program evaluation provides documentation for funding agencies such as state legislatures or the federal government that funds are being used appropriately and the desired effect or outcomes are being achieved.

For the VFC program, it is important to evaluate program processes and outcomes. Program processes that should be evaluated periodically include provider recruitment, enrollment, communications, provider satisfaction with the VFC program, provider storage and handling practices, site visits, and building collaborations with other organizations. The desired outcome of the VFC program is viable vaccine administered to eligible children.

The Assessment, Feedback, Incentive and eXchange of information (AFIX) program must be evaluated on a regular basis as well. AFIX is a natural companion to VFC. The desired outcome of the AFIX program is that viable vaccine is administered to children according to the recommended immunization schedule. The process to achieve this

desired outcome is based on a Continuous Quality Improvement (CQI) strategy that identifies clinical and behavioral practices that are affecting immunization coverage levels among patients served by the office, providing feedback regarding the identified practices, and working with the staff to develop a realistic plan to change practices or behaviors. An important but frequently overlooked informal step is supporting the staff in making changes that will improve immunization coverage levels. This step requires the AFIX staff to make contact and follow up with the provider or clinic staff between AFIX visits.

Steps Involved in the Evaluation Process

Determine the focus of the evaluation

The evaluation should be specific and focused on questions that are most relevant and important. You will achieve the best evaluation focus by understanding where the questions fit into the overall program. A program evaluation can focus on the program implementation/process and/or effectiveness/outcome. The type of evaluation selected should be based in part on the maturity of the program that is being evaluated. A process/implementation evaluation focuses on answering questions regarding program planning and implementation. (For example, what resources were required to implement the program? What program activities were accomplished and implemented as planned?) Effectiveness/outcome evaluation measures the program's success in producing the desired outcomes or measures progress toward the program's objectives and goals, which may include short-term, intermediate, and long-term outcomes. As a program matures, outcome evaluation must be added to process measures.

Determine who should be involved in the evaluation process

Stakeholders need to be part of the design, implementation and evaluation of any program for it to make a difference. Stakeholders are individuals or agencies that have a vested interest in the success of your programs. They may include those involved in program operations, those who participate in the program, or anyone with a particular interest or expertise in the program activity being evaluated. Stakeholders are much more likely to support the evaluation and act on the results and recommendations if they are involved in the evaluation process. Conversely, without stakeholder support, your evaluation may be ignored, criticized, or resisted.

Staff from within the immunization program, both field and management staff, should be included in the entire process to obtain a complete picture of the program. External stakeholders should include staff from the state Medicaid agency and other collaborating agencies or organizations. Planners should think comprehensively and identify partners at the outset in order to build momentum and assess willingness. It is important to monitor communications and relationships throughout the evaluation process because it is fluid.

Apply Evaluation Framework

CDC has developed a framework to assist programs in the evaluation process. An immunization program may decide to use the following steps to conduct an evaluation of the VFC and AFIX programs or as part of their overall programmatic evaluation efforts.

1. Establish the workgroup, its objectives, and timeframe to achieve the objectives.
2. Describe the program to the workgroup. Present a complete picture of the program to the workgroup members. A comprehensive program description clarifies all the components and intended outcomes of the program, which helps focus the evaluation on the most central and important questions. A comprehensive description includes the following components: need, targets, outcomes, activities, outputs, resources/inputs, and relationship of activities and outcomes. One way of developing this description is by using a logic model. This method draws a "soup-to-nuts" picture of the program. Every activity and outcome related to the program is written on an individual piece of paper, note card or adhesive note. Once all activities and outcomes are identified and documented, the activities and outcomes are arranged in a way that depicts a causal relationship between activities and their intended outcomes. By using this method to describe the program, each workgroup member can visualize the complete program. The logic model can be created by working backwards from the intended outcomes, or forward by asking, “What happens next as a result of this activity?”
3. Focus the evaluation. What are the desired outcomes and did the intended outcomes occur? At what cost were the activities implemented and outcomes achieved? Identify and list all possible evaluation questions that could be asked and then determine the key essential questions to be evaluated. If the list is long, reduce this list to only one or two questions so that the evaluation process will be manageable.
4. Determine what information is needed to answer the questions.
5. Gather credible information for the evaluation. Determine how to collect the information and implement data collection.
6. Justify conclusions. Review and interpret data/evidence to determine successes or failures of the program.
7. Use the lessons learned from the evaluation**.** Use results in a meaningful way to improve program areas that need to be strengthened. As appropriate, promote and distribute the findings that show intended outcomes are being met and/or how changes were made to the program based on the evaluation. Evaluation results should be shared with all interested stakeholders and appropriate CDC staff.
8. Repeat the process on regular basis. Evaluation is an ongoing process. Depending upon the results of the initial evaluation, there may be a need to evaluate changes that are made to the program. Future evaluation activities might focus on aspects of the program that were not initially evaluated.

Data Sources for Use in Evaluation

CDC requires grantees to gather information from each enrolled provider visited regarding various aspects of both the VFC and AFIX programs. Specific data from individual providers are aggregated and used to complete the VFC Management Survey that is submitted to CDC annually. Data from VFC and AFIX provider site visits as well as the aggregated information in the VFC Management Survey are excellent sources of evaluation data for a grantee. These and other sources of data, and their use in evaluating VFC and AFIX programs, are described below.

VFC Provider Site Visit Questionnaire

The VFC Provider Site Visit Questionnaire is completed during the VFC site visit. The information collected provides the grantee with a measurement of how successfully the VFC program is being implemented at an individual provider's office. Information from the VFC Provider Site Visit Questionnaire should be used to provide feedback to the office on how well it is meeting the requirements for participation in the VFC program. The high-priority questions in the questionnaire are easily identified with a red exclamation mark (!) in front of the question. If a provider's response to one of these questions is unacceptable, a corrective action plan must be developed and implemented to correct the situation. (For more information about the VFC Site Visit Questionnaire, see Module 9 of this manual.) CDC requires grantees to aggregate the responses of selected high-priority questions and report the results annually in the VFC Management Survey.

At the grantee level, the aggregated information on the high-priority questions can be analyzed to determine the strengths and weakness of a grantee's VFC program. The high-priority questions are categorized into those focusing on administrative practices and those having to do with vaccine storage and handling. The questions related to administrative practices include maintaining administrative fees within the maximum regional charge, conducting VFC eligibility screening, using most current VISs, maintaining written policies on vaccine management, and conducting monthly physical inventories of VFC vaccine. The other high-priority questions focus on vaccine storage and handling practices. Areas of weakness can become the focus of quality improvement projects for the grantee. For example, if the aggregate data indicate that a significant portion of the providers who received a VFC site visit in a given year did not rotate their vaccine stock, specific educational interventions could be developed for providers regarding how to incorporate rotating vaccine stock into everyday office practices. Repeat site visits could be done at predetermined times after the intervention to evaluate its success.

VFC Management Survey

The VFC Management Survey is a web-based questionnaire that grantees are required to complete and submit annually by March 1 for the previous calendar year's activities. The survey has several different sections. The first section requires information on the number of enrolled providers and how the VFC program operates within the grantee's geographic area. The second section of the Survey covers VFC/AFIX activities from the previous year, and the final section requires grantees to report on VFC accountability activities

conducted in the previous calendar year. The aggregated information collected on the high-priority questions in the VFC questionnaire is reported in this section of the Survey. Thoughtful review of the answers to the questions in the first section can assist grantees with identifying program activities that would benefit from intervention and evaluation.

Grantee Progress Reports

Each grantee is mandated by the grant requirements to submit progress reports on a routine basis to CDC. The notice of award provides specific information about the due date for these progress reports. These progress reports can identify program areas that could benefit from more in-depth evaluation to determine why the objective was or was not successful.

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 is in Appendix 7. If a survey is done, the grantee will need to determine the specifics regarding which VFC providers to include, what questions to ask in the survey, how to conduct the survey and how to analyze the results. In addition to evaluating operational components, provider surveys can be used to gather information on the educational needs of enrolled providers or their response to education provided. Findings can determine what quality improvement projects are 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.

Several grantees have submitted to CDC copies of provider satisfaction surveys that they have created and conducted in the past. These surveys are posted on CDC's VFC website at http://www.cdc.gov/vaccines/programs/vfc/projects/surveys/provider-examples.htm. These surveys are examples and should not be interpreted as approved by CDC.

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 or AFIX programs.

CDC has a website to assist programs and individuals in learning more about program evaluation. The website includes tools to assist with the evaluation process as well as links to other evaluation websites. The website is located at:
http://www.cdc.gov/eval/resources.htm

Publication Date: August 2007
Revision Date: None

MODULE 12 - Medicaid and State Children's Health Insurance Plan

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 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 needy 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 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 61% of Medicaid beneficiaries are covered under some type of managed care plan, and about 56% 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 VFC provider who is not a plan provider provides an immunization to that child.

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 the 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 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 (see Appendix 4).

State Children's Health Insurance Plan

The State Children's Health Insurance Program (SCHIP) 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, Virgin Islands, American Samoa, and the Commonwealth of the Northern Mariana Islands have approved SCHIP 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 SCHIP covers immunizations within the program and the child is considered insured. If the SCHIP 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 SCHIP 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 SCHIP plans. It also discusses how vaccines for the SCHIP program can be purchased and utilized off the federal contract. A sample interagency agreement between SCHIP and a state immunization program is in Appendix 9.