

DEPARTMENT OF HEALTH AND HUMAN SERVICES**CFDA 93.268 IMMUNIZATION GRANTS****I. PROGRAM OBJECTIVES**

The objective of the immunization grant program is to reduce and ultimately eliminate vaccine preventable diseases (VPDs) by increasing and maintaining high immunization coverage. Emphasis is placed on populations at highest risk for under-immunization and disease, including children eligible under the Vaccines for Children (VFC) program.

II. PROGRAM PROCEDURES

The Immunization Grants program consists of two parts: discretionary Section 317 immunization grants and VFC financed with mandatory Medicaid (CFDA 93.778) funding.

The objective of the discretionary Section 317 immunization grant program is to reduce and ultimately eliminate VPDs by increasing and maintaining high immunization coverage. Emphasis is placed on populations at highest risk for under-immunization and disease, which includes VFC-eligible children. The statute refers to development of programs for all individuals for whom vaccines are recommended, including infants, children, adolescents and adults. The intent of the discretionary Section 317 immunization grant program is to supplement, not supplant, each grantee's immunization effort at the State/local level. The Centers for Disease Control and Prevention (CDC), through its grant guidance, has identified the following areas of activity for programmatic emphasis and funding prioritization: reduce the number of indigenous cases of vaccine-preventable diseases; ensure that two-year olds are appropriately vaccinated; improve vaccine safety surveillance; increase routine vaccination coverage levels for adolescents; and increase the proportion of adults who are vaccinated annually against influenza and who have ever been vaccinated against pneumococcal disease.

VFC, which is authorized by and financed through Title XIX of the Social Security Act (Medicaid), is activity-based financial assistance and direct assistance in the form of vaccine-purchase funds and program operations funds to support implementation of the VFC program. VFC is administered by CDC and is funded entirely by the Federal government. VFC funds are provided to eligible grantees to develop and operate programs designed to ensure effective delivery of vaccination services to eligible children through enrolled providers of medical care. Grantees are required to encourage a variety of providers to participate in the VFC program and to administer vaccines in an appropriate cultural context. Other criteria, detailed in annual grant application guidance documents, may also apply.

Under VFC, children from birth through 18 years of age are eligible for VFC-purchased vaccine if they are Medicaid-eligible, American Indian/Alaskan Native, or without health insurance. Children who are insured but whose insurance does not cover vaccination also are eligible to receive VFC vaccine at Federally Qualified Health Centers or Rural Health Clinics. The intent of the VFC program is to ensure adequate funding for vaccine purchases and to promote comprehensive health care in a medical setting for all eligible children and reduce the number of children that are referred to the public sector because they cannot afford the vaccine costs. The VFC program authorizes participating immunization providers in all States to receive publicly

purchased vaccine for administration to VFC-eligible children. The goal is to ensure that no child contracts a VPD because his or her parent cannot afford to pay for the vaccine or its administration.

VFC and Section 317 financial assistance (FA) is provided/obligated directly to immunization grantees for administrative and operations costs. Similarly, Section 317 FA is obligated to grantees for the purchase of vaccines not available through federal contracts. Funds for direct assistance (DA) vaccines are maintained at CDC, and are periodically obligated to manufacturer contracts. Grantees are given estimated target budgets for their DA vaccine purchase needs. CDC uses these budgets as a control mechanism for vaccine orders.

Vaccines will be maintained by a federally contracted third-party distributor that receives orders from and ships vaccine to providers. Periodically, when the federal distributors' inventory reaches certain minimum thresholds, the distributor makes a request to CDC for replenishment vaccines. CDC reviews these requests and assigns funding sources to them (VFC or 317) based on the aggregate of grantee submitted spend plans. Orders for the vaccines are processed and sent to the appropriate manufacturer(s), referencing funds that were previously obligated to the manufacturer contracts. The manufacturer fulfills the order and ships the vaccines to the federally contracted distributor.

Source of Governing Requirements

These programs are authorized under 42 USC 247b, 42 USC 243, 42 USC 300aa-3, 300aa-25 and 300aa-26 and 42 USC 1396s. Regulations specific to discretionary Section 317 grants may be found at 42 CFR part 51b.

III. COMPLIANCE REQUIREMENTS

In developing the audit procedures to test compliance with the requirements for a Federal program, the auditor should first look to Part 2, Matrix of Compliance Requirements, to identify which of the 14 types of compliance requirements described in Part 3 are applicable and then look to Parts 3 and 4 for the details of the requirements.

A. Activities Allowed or Unallowed

1. Discretionary Section 317 grant funds may be used to establish and maintain a preventive health service program, including:
 - a. Research into the prevention and control of diseases that may be prevented through vaccination;
 - b. Demonstration projects for the prevention and control of such diseases;
 - c. Public information and education programs for the prevention and control of such diseases;
 - d. Education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals; and

- e. Operational activities associated with the conduct of a successful immunization program (42 USC 247b(k)(1)).
2. The VFC program is intended primarily as a vaccine purchase and supply program for eligible children. VFC funds may be expended to support costs associated with:
 - a. VFC vaccine ordering;
 - b. VFC vaccine distribution for grantees that have not transitioned to a federally contracted vaccine distributor; and
 - c. Direct VFC program operations, such as provider recruitment and enrollment, overall VFC program coordination, vaccine management and accountability, VFC provider accountability and site visit assessments, and VFC program evaluation (42 USC 1396s).

J. Program Income

Grantees providing direct immunization services may generate program income from fees or donations. Fees charged under VFC, however, may not exceed the maximum reimbursement schedule established by the Centers for Medicare and Medicaid Services, the delegated authority. This cap does not apply to discretionary Section 317 grants. However, no one may be denied immunization services due to the inability to pay a fee or donation (42 USC 1396s(c)(2)(C)).

L. Reporting

1. Financial Reporting

- a. SF-269, *Financial Status Report* - Applicable
- b. SF-270, *Request for Advance or Reimbursement* - Not Applicable
- c. SF-271, *Outlay Report and Request for Reimbursement for Construction Programs* - Not Applicable
- d. SF-272, *Federal Cash Transactions Report* - Payments under this program are made by the HHS Payment Management System (PMS). Reporting equivalent to the SF-272 is accomplished through the PMS and is evidenced by the PSC-272 series of reports-.

2. Performance Reporting - Not Applicable

3. Special Reporting - Not Applicable

N. Special Tests and Provisions

1. Control, Accountability, and Safeguarding of Vaccine

Compliance Requirement - Effective control and accountability must be maintained for all vaccine under the VFC program. Vaccine must be adequately safeguarded and used solely for authorized purposes (42 USC 1396s). This includes administration only to VFC program-eligible children, as defined in 42 USC 1396s(b)(2)(A)(i) through (A)(iv), regardless of the child's parent's ability to pay (42 USC 1396s(c)(2)(C)(iii)).

Audit Objective - Determine whether the grantee provides oversight of vaccinating providers to ensure that proper control and accountability is maintained for vaccine, vaccine is properly safeguarded (based on guidance provided by CDC), and VFC-eligibility screening is conducted.

Suggested Audit Procedures

- a. Determine if the grantee has a written procedure for overseeing vaccinating providers that provides for sampling of provider's inventory records and assessment of storage procedures.
- b. Determine if the grantee sampled the provider's inventory records to ensure proper recording of receipt, transfer, and usage of vaccine.
- c. Determine if the grantee reviewed the provider's storage of vaccine for proper safeguarding, including risks of loss from theft, expiration, or improper storage temperature.
- d. Determine if the grantee reviewed a sample of provider medical records for documentation of eligibility screening.
- e. Determine if necessary follow-up procedures were followed if any deficiencies were identified.

2. Record of Immunization

Compliance Requirement - A record of vaccine administered shall be made in each person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) (42 USC 300aa-25) which includes:

- a. Date of administration of the vaccine;
- b. Vaccine manufacturer and lot number of the vaccine; and
- c. Name and address and, if appropriate, the title of the health care provider administering the vaccine.

Audit Objective - Determine whether the grantee provides oversight of vaccinating providers to ensure that the required information has been recorded for vaccine recipients.

Suggested Audit Procedures

- a. Determine if the grantee has a written procedure for ensuring that the required information has been recorded for vaccine recipients.
- b. Determine if the grantee tested a sample of vaccination records to ascertain if the required information was maintained
- c. Determine if the grantee took any follow-up action if the required records and information were not maintained.

IV. OTHER INFORMATION

After the end of each month and after the end of each Federal fiscal year, CDC advises each grantee of the value of all federally funded vaccine that was distributed, in lieu of cash, directly to the grantee and/or on behalf of the grantee to vaccinating providers located in the grantee's geographical area. The annual dollar value of federally funded vaccine should be treated by the grantee as a grant expenditure for purposes of determining audit coverage and reporting on the Schedule of Expenditures of Federal Awards. Vaccinating providers and vaccinated individuals are not considered subrecipients; therefore, the value of vaccine received is not a grant expenditure for purposes of determining audit coverage and reporting for those entities.