

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

(a) Establishment of program

(1) In general

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

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

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

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

(A) In general

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

(B) Special rules where vaccine is unavailable

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

(C) Special rules where State is a manufacturer

(i) Payments in lieu of vaccines

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

(ii) Determination of value

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

(b) Vaccine-eligible children

For purposes of this section:

(1) In general

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

(2) Federally vaccine-eligible child

(A) In general

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

(i) A medicaid-eligible child.

(ii) A child who is not insured.

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

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

(B) Definitions

In subparagraph (A):

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

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

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

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

(3) State vaccine-eligible child

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

(c) Program-registered providers

(1) Defined

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

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

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

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

(2) Provider agreement

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

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

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

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

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

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

(C)(i) In administering a qualified pediatric vaccine to a vaccine-eligible child, the provider will not impose a charge for the cost of the vaccine. A program-registered provider is not required under this section to administer such a vaccine to each child for whom an immunization with the vaccine is sought from the provider.

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

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

(3) Encouraging involvement of providers

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

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

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

(4) State requirements

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

(d) Negotiation of contracts with manufacturers

(1) In general

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

(2) Authority to decline contracts

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

(3) Contract price

(A) In general

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

(B) Negotiation of discounted price for current vaccines

With respect to contracts entered into under this subsection for a pediatric vaccine for which the Centers for Disease Control and Prevention has a contract in effect under [section 247b\(j\)\(1\)](#) of this title as of May 1, 1993, no price for the purchase of such vaccine for vaccine-eligible children shall be agreed to by the Secretary under this subsection if the price per dose of such vaccine (including delivery costs and any applicable excise tax established under [section 4131 of the Internal Revenue Code of 1986](#)) exceeds the price per dose for the vaccine in effect under such a contract as of such date increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from May 1993 to the month before the month in which such contract is entered into.

(C) Negotiation of discounted price for new vaccines

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

(4) Quantities and terms of delivery

Under such contracts--

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

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

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

(5) Charges for shipping and handling

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

(6) Assuring adequate supply of vaccines

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

(7) Multiple suppliers

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

(e) Use of pediatric vaccines list

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

(f) Requirement of state maintenance of immunization laws

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

(g) Termination

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

(h) Definitions

For purposes of this section:

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

CREDIT(S)

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

Provider Profile Vaccines for Children Program

1. Today's Date:
M M D D Y Y Y Y

2. Employer Identification Number: _____

All state or project approved public and private health care providers participating in the Vaccines for Children program (VFC) must complete this form. This document provides shipping information and helps the state determine the amount of vaccine to be supplied through the VFC program. This form may also be used to compare estimated vaccine needs with actual vaccine supply. The state health department must keep this record on file with the "Provider Enrollment" form. The Provider Profile form must be updated annually or more frequently if 1) the number of children being served changes, or 2) the status of the facility changes. One provider may complete the form for the entire practice.

3. Provider's Name: _____

4. Clinic Name: _____

5. Vaccine Delivery Address: _____
Street (No P.O. Boxes)

City State Zip Code

6. Telephone Number: () _____ 7. Fax Number: () _____

7. E-mail: _____

8. Type of Facility:

- | | |
|---|--|
| <input type="checkbox"/> A. Public Health Department
<input type="checkbox"/> C. Private Practice (Individual or Group)
<input type="checkbox"/> E. Federally Qualified Health Center (FQHC)
<input type="checkbox"/> G. Other Public Facility _____
<small>(Specify)</small> | <input type="checkbox"/> B. Public Hospital
<input type="checkbox"/> D. Private Hospital
<input type="checkbox"/> F. Rural Health Clinic (RHC)
<input type="checkbox"/> H. Other Private Facility _____
<small>(Specify)</small> |
|---|--|

Provider Estimates:

Part A. For the 12 mo. period beginning
M M D D Y Y

Report the number of children who will receive vaccinations at your health facility, by age group. Only count a child once in each 12 month period no matter the number of visits.

<1 Year Old	1-6 Years	7-18 Years	Total
a.	b.	c.	d.

Part B. Of the total number for each age group entered above, how many children are expected to be VFC eligible, by category?

	<1 Year	1-6 Years	7-18 Years	Total
Enrolled in Medicaid				
No health insurance				
American Indian/Alaska Native				
Underinsured*				
Total (Note: Totals should equal totals under 8 Part A: A-C)	a.	b.	c.	d.

* To be VFC-eligible, underinsured children must be vaccinated through a FQHC or RHC.

Type of data used to determine profile:

- | | |
|---|--|
| <input type="checkbox"/> A. Benchmarking
<input type="checkbox"/> C. Dose Administered
<input type="checkbox"/> E. Registry | <input type="checkbox"/> B. Medicaid Claims Data
<input type="checkbox"/> D. Provider Encounter Data
<input type="checkbox"/> F. Other _____
<small>(specify)</small> |
|---|--|

Comprehensive Certification Form for Children Who Are Enrolled in Medicaid

This form may be substituted for individual VFC screening records when 100% of the persons to be immunized at this facility are Medicaid enrolled.

Provider enrollment and Provider Profile forms for this practice must be on file with the State Health Department or public health agency of record. Certification must be re-issued annually when provider profile is submitted.

Date: _____

Facility Name: _____

Address: _____
(Street)

_____ City State Zip Code

Telephone:() _____ Fax:() _____

E-mail: _____

Authorizing Official: _____
(Please Print the Authorizing Officials Name) (Signature of Authorizing Official)

Retain a copy of this form at your facility and send the original to the
State Health Department or state public health agency of record.

**Patient Eligibility Screening Record
Vaccines for Children Program in Family Planning Clinics**

1. Initial Screening Date:
M M D D Y Y Y Y

2. Child's Name: _____
Last Name First MI

3. Child's Date of Birth: _____
M M D D Y Y Y Y

4. Parent/Guardian/Individual of Record: _____
Last Name First MI

5. Is your facility a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC)?
 Yes No

6. Primary Provider's Name: _____
Last Name First MI

7. Does this patient qualify for immunization through the VFC program because he/she (check only one box):
- a) Yes, is enrolled in Medicaid
 - b) Yes, does not have health insurance
 - c) Yes, is an American Indian or Alaska Native
 - d) Yes, is underinsured (has health insurance that does not pay for vaccinations)*
 - e) Yes, is an unaccompanied minor without insurance information
 - f) No, this child does not qualify for immunizations through the VFC program because he/she does not meet the eligibility criteria

Eligibility Changes						
Date	Is enrolled in Medicaid	Does not have health insurance	Is an American Indian or Alaska Native	Is underinsured (has health insurance that does not pay for vaccinations)*	Is an unaccompanied minor without insurance information	Does not meet eligibility criteria

A record of all children 18 years of age or younger who receive immunizations must be kept in the health care provider's office. The record may be completed by the parent, guardian, individual of record or by the health care provider. VFC eligibility screening must take place with each immunization visit to ensure the child's eligibility status has not changed. This same record will satisfy the requirements for all subsequent vaccinations, as long as the child's eligibility status has not changed. While verification of responses is not required, it is necessary to retain this or a similar record for each child receiving vaccine.

* To be supported with VFC purchased vaccine, underinsured children must be vaccinated through a FQHC or RHC.

Family Planning Clinic
Unaccompanied Minor without Insurance Information VFC Vaccine Log

Directions: This form must be completed and submitted to the state immunization program on a monthly basis. To prevent duplication of patient count, please record all vaccines administered to one patient on a single line. This report is in addition to other VFC reports required by the state immunization program. In completing this log, document only the administration of any VFC vaccine to unaccompanied minors (through 18 years of age) who present without insurance information. Please keep one copy for your clinic's records and send one to the State Immunization Program at the address below:

State Immunization Program
Mailing Address
City, State ZIP Code
Attention: _____

Clinic name: _____

Person completing this log: _____

Phone number of person completing this log: _____

Log for: Month _____ Year _____

Patient	Date VFC vaccine was administered	List names of VFC vaccines administered	Total number of VFC vaccines administered to this patient
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			

Total number of VFC vaccines, by type, administered this month:

Maximum Regional Charges for Vaccine Administration By State	
State	Regional maximum charge
Alabama	\$14.26
Alaska	\$17.54
Arizona	\$15.43
Arkansas	\$13.30
California	\$17.55
Colorado	\$14.74
Connecticut	\$16.56
Delaware	\$15.13
District of Columbia	\$16.55
Florida	\$16.06
Georgia	\$14.81
Hawaii	\$15.71
Idaho	\$14.34
Illinois	\$16.79
Indiana	\$14.47
Iowa	\$14.58
Kansas	\$14.80
Kentucky	\$14.17
Louisiana	\$15.22
Maine	\$14.37
Maryland	\$15.49
Massachusetts	\$15.78
Michigan	\$16.75
Minnesota	\$14.69
Mississippi	\$13.92
Missouri	\$15.07
Montana	\$14.13
Nebraska	\$13.58
Nevada	\$16.13
New Hampshire	\$14.51
New Jersey	\$16.34
New Mexico	\$14.28
New York	\$17.85
North Carolina	\$13.71
North Dakota	\$13.90
Ohio	\$14.67
Oklahoma	\$13.89
Oregon	\$15.19
Pennsylvania	\$15.76
Puerto Rico	\$12.24

*** MAXIMUM REGIONAL CHARGES for VACCINE ADMINISTRATION**
Source: Federal Register / Vol 59, No. 190 / Monday, October 3, 1994 / Notices 50237

State	Regional maximum charge
Rhode Island	\$14.93
South Carolina	\$13.62
South Dakota	\$13.56
Tennessee	\$13.70
Texas	\$14.85
Utah	\$14.52
Vermont	\$13.86
Virginia	\$14.71
Virgin Islands	\$15.09
Washington	\$15.60
West Virginia	\$14.49
Wisconsin	\$15.02
Wyoming	\$14.31

*** MAXIMUM REGIONAL CHARGES for VACCINE ADMINISTRATION**
Source: Federal Register / Vol 59, No. 190 / Monday, October 3, 1994 / Notices 50237

EMERGENCY RESPONSE PLAN (Sample)

Post on outside of refrigerator for all staff

Practice Name:	
Primary Person Responsible:	Phone:
Secondary Person Responsible:	Phone:
Person with 24-hour access:	Phone:

For a Power Outage: If you do not have a generator, identify at least one location with a generator (hospital, 24-hour store, etc.). Before transporting, call the back-up location site to ensure that their generator is working.

#1. Location & Contact's Name _____ Ph# _____
#2. Location & Contact's Name _____ Ph# _____

How will you be notified of an outage? _____

Vaccines must be transported in an insulated cooler with a barrier separating the vaccines from the ice/cold packs. Varicella, MMRV and zoster **must** be transported with dry ice.

Location where dry ice may be purchased _____ Ph# _____

If your emergency back-up location is more than 30 minutes away and you have a large quantity of vaccine, consider renting a refrigerated truck to transport your vaccine.

Refrigeration Company _____ Ph# _____

OTHER RESOURCES:

Local Health Department: _____ Ph# _____

PREVENT LOSS FROM EXPIRED VACCINES!!

Check and rotate your stock to assure shortest dated vaccine is used first. (Post vaccine expiration date table.)

Notify the state Immunization Program if vaccines are going to expire within 3-6 months.

CHECK AND RECORD REFRIGERATOR AND FREEZER TEMPERATURES TWICE A DAY

- Once in the am when the practice opens.
- Once in the afternoon to allow for adjustments prior to the time the practice closes.

What to do if a power failure occurs, the refrigerator door was left open, the temperature was too cold, the refrigerator plug was pulled, or any other situation which would cause improper storage conditions:

1. Close the door and/or plug in the refrigerator/freezer.
2. Record the current temperature of the refrigerator/freezer.
3. Store the vaccines at appropriate temperatures. Make sure that the refrigerator/freezer is working properly or move the vaccines to a unit that is. Do not automatically throw out the affected vaccine. Mark the vaccine so that the potentially compromised vaccines can be easily identified.
4. Collect essential data on the reverse side of this sheet and notify the state health department.
5. **Call all manufacturers of affected vaccine(s) (see table on the backside).**

Turn over for Emergency Response Worksheet

EMERGENCY RESPONSE WORKSHEET

1. Current temperature of refrigerator: _____ Max/min temperature reached: _____
2. Current temperature of freezer: _____ Max/min temperature reached: _____
3. Amount of time temperature was outside normal range: refrigerator _____ freezer: _____

REFRIGERATOR

Vaccine and Lot #	Expiration Date	Amount of Vaccine

FREEZER

Vaccine and Lot #	Expiration Date	Amount of Vaccine

CALL ALL MANUFACTURER(S) OF AFFECTED VACCINE(S):

Manufacturer	Telephone Number
Sanofi Pasteur	1-800-822-2463
Merck	1-800-609-4618
GlaxoSmithKline	1-888-825-5249
Wyeth	1-800-999-9384
Novartis	1-800-244-7668
MedImmune	1-877-633-4411

Protocol for Assessing VFC Eligibility Screening

1. Before beginning the assessment, each grantee should create a tally sheet for staff to use for manually calculating a provider's VFC-eligibility screening percentages. The necessary elements to collect are outlined in item #4 of this protocol. Before starting the review, the assessor should ask the provider/office staff what method they use for documenting VFC eligibility screening. It is important for the assessor to understand how VFC eligibility screening is done for both VFC eligible and ineligible patients. Remind the provider that VFC-eligibility screening should take place for every child at each immunization visit, although it is only necessary to update the original screening form if the child's status has changed.
2. Ask when the provider first began to receive VFC vaccine, and document this on the tally sheet.
3. Randomly select a sample of 30 patient records. The sample should be drawn from the entire practice, not just the subset of VFC-eligible patients. For newly enrolled providers, the sample should include only patients who made an immunization visit after the office began receiving VFC vaccine.

One of the following methods can be used to select a random sample:

- a. Use a random number table or systematic random sampling method to select the sample. Although the sample may be drawn from all children 0–18 years of age, the assessor may want to narrow the sample to the age range most likely to have received an immunization (e.g., 3–35 months of age) since the provider enrolled in the VFC program.
- b. Divide 30 by the number of shelves holding patient charts. This will determine the number of charts to pull per shelf (i.e., if there are 10 shelves, select 3 charts per shelf). Randomly select a starting point on the shelf and sequentially review each chart until you find the appropriate number of charts from each shelf.
- c. Review the appointment book. Select the first 30 children who visited the practice during the previous week. You may need to extend the time period in order to select the appropriate number of children who received immunizations.
- d. If conducting a combined VFC/AFIX visit, a subset of the sample selected for the AFIX assessment can be used to screen for VFC eligibility documentation. Randomly select 30 charts from the sample selected for the AFIX assessment (≥ 50 charts). The sample will be limited to the age group selected for the purposes of AFIX; however, since these records have already been selected for an assessment, a random numbers table or a systematic random sample can easily be used to select 30 charts from the original AFIX sample. Use these 30 charts to determine eligibility screening using the protocol below.

4. For each patient, document the following on a tally sheet:

- Name or Chart Number
- Date of Birth (*must be between 0 and 18 years old, or in the selected age range*)
- VFC eligibility: mark appropriate category: Medicaid, Uninsured, Underinsured, Native American/Alaska Native, or Not VFC-Eligible
- Did patient visit since office began receiving VFC vaccine*
- Screening documented in chart**

**If a child has not visited since the office began receiving VFC vaccine, the child is not eligible for this assessment. Depending on the method used to obtain the sample, replace this record by selecting either the next eligible patient on the list, the shelf, or in the appointment book.*

***Use the definition from Item #1 to determine if screening was documented in the chart.*

5. Total the column titled "Screening documented in chart."

- If the column totals 30, the practice screens 100% of patients for VFC eligibility.
- If the column totals 29, there is a high probability that the practice screens at least 95% of patients for VFC eligibility.
- If the column totals 28, there is a high probability that the practice screens at least 90% of patients for VFC eligibility.
- If the column totals 27 or lower, there is a high probability that the practice screens fewer than 90% of patients for VFC eligibility.

6. When giving the results to the provider, include a list of children who were found not to have proper screening documentation.

Caution must be used when interpreting the VFC screening results. This methodology is not designed to provide exact point estimates, but instead it will help you determine if a provider is performing above or below a certain level. When you identify a provider who scores low on documenting VFC-eligibility in the chart, you may want to schedule a more in-depth assessment of the provider's screening practices.

Definitions of VFC related Site Visits and Contacts

A VFC site visit is a formal visit to a VFC-enrolled provider site for the purpose of evaluating the provider's compliance with the VFC program requirements. This evaluation relies on the completion of the most current VFC Site Visit Questionnaire. The VFC Site Visit Questionnaire requires the VFC staff to evaluate the following components of vaccine management:

1. Appropriate vaccine handling, storage and ordering procedures. This includes a physical inspection of refrigeration units, temperature measuring devices, daily temperature recording, vaccine accountability, procedures for vaccine retrieval and storage in times of emergencies, and inventory management, including stock rotation to prevent outdating.
2. Proper documentation of children's VFC eligibility status. This involves sampling patient records to ensure appropriate screening (e.g., those in the Medicaid program, uninsured, Alaska Native/American Indian, or underinsured), and the administration of VFC-purchased vaccines only to VFC-eligible children.
3. Compliance with documentation and record retention requirements. This includes distribution of current Vaccine Information Statements and maintaining records in accordance with the National Childhood Vaccine Injury Act.
4. Compliance with other program requirements. This includes not charging for the cost of the vaccine, not charging a vaccine administration fee that is higher than the maximum fee established by the state, and agreeing not to deny vaccinations because of the parent's inability to pay a vaccine administration fee.

A VFC/AFIX combined site visit is a formal visit to a VFC-enrolled provider site which integrates the completion of the site visit questionnaire and vaccine management review to ensure compliance with VFC program with an immunization record assessment and the "FIX" components of AFIX.

***Please Note:** When using CoCASA to document site visits, if the VFC/AFIX staff completes a VFC/AFIX combined site visit and all components of AFIX have been covered, select both an AFIX visit and VFC site visit in CoCASA. If a combined visit occurs but the "FIX" components are completed on a different date than the VFC and assessment components, the date of the "FIX" should be used as the date of visit with the provider because that is the date that all components of "AFIX" were completed.*

A VFC site visit follow-up is defined as any contact made with a VFC-enrolled provider to review progress towards correcting a problem identified during the most recent VFC site visit that was not significant enough to enroll the provider into secondary or tertiary education follow-up.

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A VFC contact is defined as any contact with a provider between VFC site visits (but not related to the most recent VFC site visit) for VFC related issues. For example, if a provider calls because the office has run out of VISs for HPV, the visit made to the office to bring additional VIS copies would be considered a VFC contact.

An educational visit is defined as a special visit to the provider's office to perform an educational in-service (e.g., to discuss recent changes to the immunization schedule). An educational visit is separate from VFC site visits or AFIX visits, which already incorporate an educational component. Select only if educational visit purpose is not related to an identified VFC compliance issue.

A VFC enrollment visit is defined as a visit to the provider's office to enroll a provider into the VFC program.

A VFC Secondary Educational Follow-up is defined as a contact with a provider who was identified with VFC compliance issues and enrolled in Secondary Education program and this follow-up is part of the Secondary Education program. The follow-up contact may be in form of a site visit or other contact like phone, e-mail or fax . .

A VFC Tertiary Educational Follow-up is defined as a contact with a provider who was identified with VFC compliance issues and enrolled in Tertiary Education program and this follow-up is part of the Tertiary Education program. The follow-up contact may be in the form of a site visit or other contacts like phone, e-mail or fax .

Sample VFC Provider Feedback Survey

We'd love to hear what you think about the Vaccines for Children program. Please take a minute to complete the following survey. Your answers will help us improve the program to serve both you and our children better.

Provider/Clinic Name: _____ **Type of Practice:** *Private Solo Practice* *Private Group Practice*
 Federally Qualified Health Center/Rural Health Center
 Health Department Clinic *Other:* _____

Practice Specialty Type: *Pediatrics* *Family practice* *Internal Medicine* *Multispecialty* *Health Department Clinic* *Other:* _____

Address: _____
Street
City
County
Zip Code

Telephone Number: _____ **E-Mail:** _____

Person Completing the Survey: _____ **Title:** _____

***WE WANT TO KNOW WHAT YOU THINK ABOUT THE VFC PROGRAM.
PLEASE RATE YOUR EXPERIENCE FOR QUESTIONS 1 - 9 USING THE SCALE FROM 1 TO 5.***

		Very Satisfied				Very Dissatisfied	
1. The support, information and materials provided by state/local VFC program staff.	1	2	3	4	5	NA	
2. The ease of screening patients for VFC-eligibility.	1	2	3	4	5	NA	
3. The ease of VFC record keeping.	1	2	3	4	5	NA	
4. The ease of using the VFC vaccine ordering system.	1	2	3	4	5	NA	
5. The timeliness of VFC supplied vaccine delivery.	1	2	3	4	5	NA	
6. The condition of VFC supplied vaccine at delivery.	1	2	3	4	5	NA	
7. The decreased need to refer children to public clinics for immunizations.	1	2	3	4	5	NA	

8. The merit of the VFC vaccine accountability system (reporting the number of doses administered, benchmarking, etc.) 1 2 3 4 5 NA
9. Overall satisfaction with the VFC program 1 2 3 4 5 NA
10. The range of vaccine brand choice available for VFC vaccines 1 2 3 4 5 NA
11. Which vaccines are routinely recommended in this practice/clinic? (Please check all that apply)
- | | |
|--|---------------------------------------|
| <input type="checkbox"/> DTaP | <input type="checkbox"/> MMR |
| <input type="checkbox"/> Hepatitis A | <input type="checkbox"/> Pneumococcal |
| <input type="checkbox"/> Hepatitis B | <input type="checkbox"/> Polio |
| <input type="checkbox"/> Hib | <input type="checkbox"/> Varicella |
| <input type="checkbox"/> HPV | <input type="checkbox"/> Influenza |
| <input type="checkbox"/> Meningococcal | <input type="checkbox"/> Rotavirus |
| <input type="checkbox"/> Others: _____ | |
- 12a. Does this practice/clinic have a systematic way to identify and recall children in need of vaccinations? Yes No
- 12b. If yes, what kinds of system do you use? recall system, computerized
 recall system, tickler file
 registry
 periodic chart reviews
 other: _____
- 13a. Have immunization coverage levels been assessed in your practice within the last year? Yes No
- 13b. If yes, by whom? Own practice/clinic staff State health department staff
 Local health department staff MCO staff
- 13c. If yes to 13a., what assessment tool was used? CoCASA Other: _____ Do not know
- 13d. If yes to 13a., what age & series was assessed? _____
- 13e. If yes to 13a, what was the coverage level _____%
14. Does this practice/clinic participate in a state/local immunization registry? Yes No

15. What recommendations do you have for improving the VFC program in (specify state)? _____

Please fax or mail your completed form to:

Your Health Department's Name

Attn: VFC Program

Street Address

City, State, Zip

Telephone: () _____

Fax: () _____

CMS Policy Letter to State Medicaid Officials

May 11, 1998

Dear State Health Official:

The Balanced Budget Act of 1997 established the Children's Health Insurance Program (CHIP) under Title XXI of the Social Security Act (the Act). This new Title enables States to expand health insurance coverage for uninsured children through separate State health insurance program (S-CHIP), through Medicaid, or a combination of the two. Title XXI requires States to submit plans for approval by the Secretary of the Department of Health and Human Services in order to receive funds for providing health care coverage. The Department of Health and Human Services has issued several letters to provide policy and State plan guidance on the implementation of Title XXI.

This letter is intended to provide detailed guidance regarding coverage of immunization under Title XXI and the Vaccines for Children (VFC) program. Ensuring that all children receive appropriate immunizations is a priority for the President, the First Lady and Secretary Shalala. The unique nature of funding for vaccines create special challenges and options for covering vaccines for CHIP-covered children, as described below.

States must ensure coverage for childhood vaccinations under CHIP. Section 2102(a)(7) of the Children's Health Insurance Program requires States to "assure the quality and appropriateness of care, particularly with respect to ... immunizations" provided under the State child health plan. The standard for appropriate care with respect to childhood immunizations, used in the Medicaid and the VFC programs, is the schedule of immunizations recommended by the Federal Advisory Committee on Immunization Practices (ACIP). All State CHIP plans must provide coverage for all ACIP-recommended vaccines to enrollees. The Department expects that children will be immunized with vaccines purchased using funds provided through their Title XXI plans.

The VFC program was established in 1993 to serve children defined as "federally vaccine eligible" under section 1928(b)(2), which includes both "uninsured" and "Medicaid eligible" children. American Indian, Alaskan Native children and children whose insurance does not cover immunizations are also eligible for VFC. States will continue to receive federal funding for reduced-price vaccines under this program.

Children who are newly eligible for Medicaid under Title XXI are federally vaccine eligible, as are all other children eligible for Medicaid. However, because of Title XIX restrictions on eligibility for VFC, States that have designed a separate State health insurance program under CHIP (S-CHIP) may not treat children enrolled in such a program as federally vaccine eligible.

Children enrolled in a separate State insurance program are neither Medicaid eligible nor uninsured as required under Title XIX and, therefore, they are not federally vaccine eligible. However, to ensure that States choosing to expand through S-CHIP have the same opportunity for reduced-price vaccines as States expanding through Medicaid, State have two options for funding.

First, States may define these children as "State vaccine eligible" under Section 1928(b)(3) and purchase vaccine at the federal contract price for these children without these expenditures being subject to the 10 percent cap on expenditures for other child health assistance, health services initiative, outreach, and administration. To do this, States must retain responsibility for the provision of benefits to Title XXI children and sub-contract portions of the benefit package to insurers, except the purchase of vaccine. States must distribute vaccine purchased through the federal contract to their Title XXI providers so that they may administer the vaccine to children. Because the State is

paying for the vaccine, contracts with insurers must not include payment for vaccine costs, although any fees or costs associated with the actual vaccination of children may be included in the sub-contract.

Second, States may choose to contract with insurers for the provision of vaccine as they do for other services. States electing this approach will have to pay private sector market prices for vaccine. Under both options, State expenditures are matched at the CHIP enhanced matching rate.

States are encouraged to work through their State Health Departments and their State Immunization Programs to determine the most effective manner in which to purchase vaccines for S-CHIP children. Also, as part of the State's program evaluation strategy, States are strongly encouraged to track the percentage of children in Title XXI who are receiving age-appropriate vaccinations and how those vaccinations are being delivered.

I hope this guidance will be helpful. If you have any questions regarding coverage of immunization under Title XXI, please contact your HCFA regional office staff.

Sincerely yours,

Sally K. Richardson
Director, Center for Medicaid and State Operations

cc: State Immunization Program Managers

Sample Immunization/SCHIP Interagency Agreement

This agreement is between the State of _____ acting by and through (Agency Administering SCHIP), hereinafter called "SCHIP" and the State Immunization Program hereinafter called "STATE."

I. TERM

This agreement shall be effective on (month/day/year), and shall expire on (month/day/year), unless otherwise terminated or extended.

II. PURPOSE

The (SCHIP) and (STATE) are working in partnership to: 1) improve age-appropriate immunization rates among Medicaid children to 90% by two years of age; and 2) implement a plan to improve adolescent immunizations. These long-term plans will be partially addressed by the following methods:

- A. Purchasing vaccine off current federal and state contracts to provide vaccine coverage to children enrolled in (STATE)'s State Children's Health Insurance Plan.
- B. Providing vaccine purchased for eligible children to public and private medical providers enrolled in the Vaccines for Children (VFC) program using the established VFC distribution system.

III. PROCEDURE

(STATE) will directly and/or through subcontractors coordinate and oversee activities necessary to carry out the purpose of this agreement.

IV. STATEMENT OF WORK

(STATE) AGREES TO:

- A. Purchase vaccines off current federal and state contracts. Vaccines purchased will include all antigens recommended by the Advisory Committee on Immunization Practices for children ages birth through 18 years.
- B. Distribute vaccines to public and private medical providers enrolled in the VFC program. Vaccines purchased for the benefit of SCHIP enrolled children will be distributed to private medical providers through our subcontracted vaccine distributor. Vaccines will be distributed to public providers directly from (STATE).
- C. Providers will continue to screen for VFC eligibility.

(SCHIP) AGREES TO:

- A. Report to (STATE) quarterly the number of SCHIP enrolled children. This information will be reported in four age cohorts; birth through 11 months, 12 months through five years, six years through eleven years, and twelve years through eighteen years.
- B. Report to (STATE) quarterly the proportion of SCHIP enrolled children to total enrolled children. This information will be used to calculate what percentage of vaccines sent to providers will be purchased with Vaccines for Children and State Children's Health Insurance Program funds.

- C. Assist (*STATE*) in the review and approval of sub-agreements to carry out this agreement.
- D. Identify (*STATE*) reporting needs.

V. CONSIDERATION

- A. (*SCHIP*) agrees to pay (*STATE*) an amount not to exceed the sum of (\$ _____) for vaccine purchase and accomplishment of work, as stated in Section IV.
- B. (*STATE*) shall bill (*SCHIP*) quarterly in arrears.
- C. (*STATE*) shall not submit billing and (*SCHIP*) will not pay, any amount in excess of the compensation set forth above.
- D. Billing will be based on the current federal vaccine contract established by the Centers for Disease Control and Prevention and state vaccine contracts established by Department of Administrative Services plus a shipping fee of (\$ _____) per dose. Vaccine prices and shipping charges are subject to change during the contract period.

VACCINE = \$ _____
 SHIPPING = \$ _____
 CONTINGENCY = \$ _____
 TOTAL \$ _____

- E. Billings will be sent to:
 C/O Billing Contact Person
 (Address)

VI. GENERAL PROVISIONS

- A. Funds Available and Authorized
 (*SCHIP*) has sufficient funds currently available and authorized for expenditure to finance the costs of this agreement. (*STATE*) understands and agrees that (*SCHIP*)’s payment of amounts under this agreement attributable to work performed after the last day of the current biennium is contingent on (*SCHIP*) receiving from the Legislative Assembly appropriations, limitations, or other expenditure authority sufficient to allow (*SCHIP*), in the exercise of its reasonable administrative discretion, to continue to make payments under this agreement. In the event the Legislative Assembly fails to approve sufficient appropriations, limitations, or other expenditure authority, (*SCHIP*) may terminate this agreement without penalty or liability to (*SCHIP*), effective upon written notice to (*STATE*), with no further liability to (*STATE*).
- B. Amendment
 The terms of this agreement may not be waived, altered, modified, supplemented or amended, in any manner whatsoever, except by written agreement signed by the parties.
- C. Termination
 - 1. This agreement may be terminated by consent of either party upon 30 days notice in writing delivered by certified mail or in person.
 - 2. In addition, (*SCHIP*) may terminate or modify this agreement, in whole or in part, effective upon delivery of written notice to (*STATE*), or at such later date as may be established by (*SCHIP*), under any of the following conditions.
 - a) If (*SCHIP*) funding from federal, state, or other sources is not

obtained and continued at levels sufficient to allow for purchase of the indicated quantity of service.

- b) If federal or state regulations or guidelines are modified, changed, or interpreted in such a way that the services are not longer allowable or appropriate for purchase under this agreement or are no longer eligible for the funding proposed for payments authorized by this agreement; or
 - c) If any license or certification required by law or regulation to be held by *(STATE)* to provide the services required by this agreement is for any reason denied, revoked, suspended, or not renewed.
3. Time is of the essence of *(STATE)*'s performance of each and every obligation and duty under this agreement. *(SCHIP)*, by written notice to *(STATE)*, may at any time terminate the whole or any part of this agreement if:
- a) *(STATE)* fails to provide services called for in this agreement within the time frame specified herein or any extension thereof; or
 - b) *(STATE)* fails to perform any of the other provisions of this agreement, or so fails to pursue the work as to end anger performance of this agreement. In accordance with its terms, and after receipt of written notice from *(SCHIP)*, fails to correct such failures within 30 calendar days or such other period as *(SCHIP)* may authorize or require.
4. The rights and remedies of *(SCHIP)* are provided in subsection c, above are not exclusive and are in addition to any other rights and remedies provided by law or under this agreement.
5. Termination or modification of this agreement pursuant to subsections a or b, above, shall be without prejudice to any obligations or liabilities of either party, already accrued prior to such termination or modification. However, upon receiving a notice of termination (regardless of whether such notice is given pursuant to subsections, a, b, or c of this section), *(STATE)* shall immediately cease all activities under this agreement, unless expressly directed otherwise by *(SCHIP)* in the notice of termination. Further, upon termination, *(STATE)* shall deliver to *(SCHIP)* all agreement documents, information, works-in-progress and other property that are or would be deliverable had the agreement been completed.

D. Records Maintenance; Access

(STATE) shall maintain all fiscal records relating to this agreement in accordance with generally accepted accounting principles. In addition, *(STATE)* shall maintain any other records pertinent to this agreement in such a manner as to clearly document *(STATE)*'s performance hereunder. *(STATE)* acknowledges and agrees that *(SCHIP)* and not withstanding section 3, above, the Secretary of State's Office, the Federal Government and their duly authorized representatives shall have access to such fiscal records and all other books, documents, papers, plans and writings of *(STATE)* that are pertinent to this agreement for the purpose of performing examinations and audits, and making excerpts and transcripts. All such fiscal records, books, documents, papers, plans and writing shall be retained by *(STATE)* and kept accessible for a minimum of three years, except as required longer by law,

following final payment and termination of this agreement, or until conclusion of any audit, controversy or litigation arising out of or related to this agreement, whichever date is later. All subcontracts shall also comply with these provisions.

E. Written Notice

All notices regarding this agreement should be sent to the following liaisons:

TO: (SCHIP PROGRAM):

**Designee
(Address)
(Phone Number)**

TO: (STATE IMMUNIZATION PROGRAM):

**Designee
(Address)
(Phone)**

F. Indemnification

1. The Agencies understand that each is insured with respect to tort liability by the State of _____, a statutory system of self-insurance established by _____ and subject to _____. Each Agency agrees to accept that coverage as adequate insurance of the other party with respect to personal injury and property damage.
2. Self-Insurance Loss Allocation: The Agencies agree that any tort liability claim, suit or loss resulting from or arising out of the parties' performance of and activities under this contract shall be allocated, as between the state agencies, in accordance with law by the Risk Management Division of the Department of Administrative Services for purposes of their respective loss experiences and subsequent allocation for self-Insurance assessments under _____. Each party agrees to notify Risk management Division and the agency in the event it receives notice or knowledge of any claim arising out of the performance of, or the agencies' activities under this contract.

G. Merger Clause

This contract and attached exhibits constitute the entire agreement between the parties on the subject matter hereof. There are no understandings, agreements, or representations, oral or written, not specified herein regarding this contract. No waiver, consent, modification or change of terms of this contract shall bind either party unless in writing and signed by both parties and all necessary State approvals have been obtained. Such waiver, consent, modification or change, if made, shall be effective only in the specific instance and for the specific purpose given. The failure of Division to enforce any provision of this contract shall not constitute a waiver by Division of that or any other provision.