

*Excerpts from CDC's 2015*  
**The Vaccines for Children  
Operations Guide**



**VFC**

National Center for Immunization and Respiratory Diseases  
Immunization Services Division



## ***Important Note from the Alaska Immunization Program***

*The purpose of CDC's VFC Operations Guide is to communicate VFC programmatic information to state, local, and territorial immunization programs (a.k.a. "awardees"). This document contains excerpts from CDC's 2015 VFC Operations Guide. It does **not** replace the Alaska Vaccine Distribution Program Handbook which includes all state and federal VFC requirements. The purpose of this document is to provide additional information to assist providers in their efforts to comply with VFC requirements.*

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# VFC Program At-A-Glance

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

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

## VFC FAST FACTS

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

## HOW VFC WORKS

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

## HOW CDC AND AWARDEES MANAGE VFC

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

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

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

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

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

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

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

Major functions of the ACIP are as follows:

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

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

## ACIP'S ROLE IN THE VFC PROGRAM

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

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

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

## COLLABORATING AGENCIES

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

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

## MEDICAID AND THE VFC PROGRAM

Title XIX of the Social Security Act is a federal/state entitlement program that pays for medical assistance for certain individuals and families with low incomes and limited resources. This program, known as Medicaid, became law in 1965 as a cooperative venture jointly funded by the federal and state governments (including the District of Columbia and the territories) to assist states in furnishing medical assistance to eligible persons. Medicaid is the largest source of funding for medical and health-related services for America's 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, awardees will find that those providers who serve the Medicaid population represent the largest provider pool for VFC recruitment. It is important for the immunization programs and state Medicaid agencies to collaborate on policies that affect the VFC program. Both programs should discuss policy changes that affect participating children and providers well in advance of any program changes. State government is ultimately

responsible for ensuring that its agencies comply with Medicaid requirements.

## MEDICAID REQUIREMENTS

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

## FEE CAPS ON VACCINE ADMINISTRATION

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

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

Charge data were used rather than cost data, because accurate, useable nationwide cost data were not available, nor could CMS obtain them by October 1, 1994. Recognizing the importance of using cost data in developing the regional maximum charges, CMS published the interim maximum charges based on charge data with the intention 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.

A final rule was published on November 6<sup>th</sup>, 2012. The final rule updated the interim regional maximum fees that providers may charge for the administration of pediatric vaccines to federally vaccine-eligible children. The state Medicaid agencies have the discretion to pay an administration fee up to the regional maximum amount.

### CDC Requirement:

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

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

Georgia	\$21.93
Guam	\$23.11
Hawaii	\$23.11
Idaho	\$20.13
Illinois	\$23.87
Indiana	\$20.32
Iowa	\$19.68
Kansas	\$20.26
Kentucky	\$19.93
Louisiana	\$21.30
Maine	\$21.58
Maryland	\$23.28
Massachusetts	\$23.29
Michigan	\$23.03
Minnesota	\$21.22
Mississippi	\$19.79
Missouri	\$21.53
Montana	\$21.32
Nebraska	\$19.82
Nevada	\$22.57
New Hampshire	\$22.02
New Jersey	\$24.23
New Mexico	\$20.80
New York	\$25.10
North Carolina	\$20.45
North Dakota	\$20.99
Ohio	\$21.25
Oklahoma	\$19.58
Oregon	\$21.96
Pennsylvania	\$23.14
Puerto Rico	\$16.80
Rhode Island	\$22.69
South Carolina	\$20.16
South Dakota	\$20.73
Tennessee	\$20.00
Texas	\$22.06
Utah	\$20.72
Vermont	\$21.22
Virginia	\$21.24
Virgin Islands	\$21.81
Washington	\$23.44
West Virginia	\$19.85
Wisconsin	\$20.83
Wyoming	\$21.72

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

## CDC Requirement:

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

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

## VFC Statute 42 U.S.C. § 1396s

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

### (a) Establishment of program

#### (1) In general

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

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

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

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

#### (A) In general

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

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

To the extent that a sufficient quantity of a vaccine is not available for purchase or delivery under subsection (d) of this section, the Secretary shall provide for the purchase and delivery of the

available vaccine in accordance with priorities established by the Secretary, with priority given to federally vaccine-eligible children unless the Secretary finds there are other public health considerations.

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

(i) Payments in lieu of vaccines

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

(ii) Determination of value

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

(b) Vaccine-eligible children For

purposes of this section:

(1) In general

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

(2) Federally vaccine-eligible child

(A) In general

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

(i) A medicaid-eligible child.

(ii) A child who is not insured.

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

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

**(B) Definitions**

In subparagraph (A):

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

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

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

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

(3) State vaccine-eligible child

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

(c) Program-registered providers

(1) Defined

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

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

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

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

(2) Provider agreement

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

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

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

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

(B)(i) Subject to clause (ii), the provider will comply with the schedule, regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines, that is

established and periodically reviewed and, as appropriate, revised by the advisory committee referred to in subsection

(e) of this section, except in such cases as, in the provider's medical judgment subject to accepted medical practice, such compliance is medically inappropriate.

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

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

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

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

### (3) Encouraging involvement of providers

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

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

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

### (4) State requirements

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

### (d) Negotiation of contracts with manufacturers

#### (1) In general

For the purpose of meeting obligations under this section, the Secretary shall negotiate and enter into contracts with manufacturers of pediatric vaccines consistent with the requirements of this subsection and, to the maximum extent practicable, consolidate such contracting with any other contracting activities conducted by the Secretary to purchase vaccines. The Secretary may enter into such contracts under which the Federal Government is obligated to make outlays, the budget

authority for which is not provided for in advance in appropriations Acts, for the purchase and delivery of pediatric vaccines under subsection (a)(2)(A) of this section.

(2) Authority to decline contracts

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

(3) Contract price

(A) In general

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

(B) Negotiation of discounted price for current vaccines

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

(C) Negotiation of discounted price for new vaccines

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

(4) Quantities and terms of delivery

Under such contracts--

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

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

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

(5) Charges for shipping and handling

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

(6) Assuring adequate supply of vaccines

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

(7) Multiple suppliers

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

(e) Use of pediatric vaccines list

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

(f) Requirement of state maintenance of immunization laws

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

(g) Termination

This section, and the requirement of [section 1396a\(a\)\(62\)](#) of this title, shall cease to be in effect beginning

on such date as may be prescribed in Federal law providing for immunization services for all children as part of a broad-based reform of the national health care system.

(h) Definitions

For purposes of this section:

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

CREDIT(S)

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

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/17-appx-1-vfc-statute.pdf>

# Eligibility

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

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

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

### **CDC Requirement:**

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

### **Example:**

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

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

### **Example:**

For an AI/AN child who has no insurance:

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

### **Example:**

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

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

**Example:**

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

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

**QUICK VIEW OF AI/AN ELIGIBILITY CATEGORIES**

Population	Eligibility Status/Scenario	Select the following if provider has the ability to select multiple VFC eligibility categories	Select the following if the provider has the ability to select only one VFC eligibility category
*AI/AN	Has no insurance	AI/AN Uninsured	AI/AN
*AI/AN	Has insurance but does not cover vaccines, limits vaccines covered, or caps vaccine coverage and provider is <b>not</b> an FQHC/RHC	AI/AN	AI/AN
*AI/AN	Has insurance but does not cover vaccines, limits vaccines covered, or caps vaccine coverage and provider <b>is</b> an FQHC/RHC	AI/AN Underinsured	AI/AN
*AI/AN	Has Medicaid	Medicaid AI/AN	Medicaid
Underinsured	Has insurance but does not cover vaccines, limits vaccines covered, or caps vaccine coverage and has Medicaid as a second coverage.	Medicaid Underinsured	Medicaid

\*Refers to child seen outside of an Indian Health Facility

## QUICK VIEW OF VFC ELIGIBILITY AND INSURANCE STATUS

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

\*Provision of VFC vaccine to unaccompanied minors without insurance status in family planning clinics is optional at a awardee's discretion and in compliance with the state's medical consent laws as they pertain to minors.

# INSURED EXCEPTIONS

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

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

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

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

### **Option 1**

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

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

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

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

*Considerations regarding this option:*

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

### **Option 2**

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

- If the primary insurer pays less than the Medicaid amount for the vaccine administration fee, the provider can bill Medicaid for the balance of the vaccine administration fee, up to the amount Medicaid pays for the administration fee.
- If the primary insurer denies payment of vaccine and the administration fee, the provider may replace the privately purchased vaccine with VFC vaccine and bill Medicaid for the administration fee. The provider must document this replacement on the VFC borrowing form.

*Considerations regarding this option:*

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

## **OTHER INSURED SITUATIONS WITH MEDICAID AS SECONDARY**

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

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

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

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

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

## **LOCATION OF SERVICE**

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

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

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

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

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

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

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

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

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

## Deputization to Extend Access to Underinsured Children with VFC Vaccine

Children through 18 years of age who meet at least one of the following criteria are eligible to receive VFC vaccine at any VFC provider site: 1) Medicaid eligible, 2) uninsured, 3) American Indian or Alaska Native. Underinsured children are also eligible for VFC vaccine, but only at an FQHC or RHC. Currently, less than ten percent of VFC provider sites are FQHCs or RHCs, both of which, for reasons of geography, have limited access and capacity to serve this population. In more than 20 states, some FQHCs and RHCs have extended access to VFC vaccines for underinsured children through deputization arrangements (sometimes referred to as "delegation of authority") with local health departments and, in some cases, private-sector VFC-enrolled providers.

The Patient Protection and Affordable Care Act (ACA)<sup>1</sup> requires that non-grandfathered private health plans provide coverage for routine ACIP-recommended immunizations without cost-sharing. However, health plans that currently do not offer vaccinations retain their "grandfathered" status until they make a significant change in coverage. Thus, it is likely to take several years before all grandfathered plans lose this status and this form of underinsurance is completely addressed.

Data from CDC's 2008 National Immunization Survey shows that 11% of young children and 20% of teens are not fully insured for vaccines. Until underinsurance among children is eliminated, extending VFC authority to other VFC providers serves as a safety net ensuring that access to VFC vaccine for eligible underinsured children will not be a barrier to vaccination.

<sup>1</sup> Public Law 111-148]

# Provider Recruitment and Enrollment

## CDC Requirement:

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

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

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

## CDC Requirement:

**Maintain all records related to the VFC program for a minimum of three years, or longer if required by state law, and make these records available upon request for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.**

## CDC Requirement:

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

## CDC Requirement:

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

## CDC Requirement:

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

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

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

# Quality Assurance and Program Accountability

## CDC Requirement:

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

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

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

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

The goals of these visits are to:

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

# Vaccine Management

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

## CDC Requirement:

### **Develop and implement feasible and appropriate plans for routine and emergency vaccine management.**

- VFC providers must develop, maintain and implement plans for routine and emergency vaccine management.
- Both the routine and emergency plans should be feasible, and the processes outlined in the plan should be presented in a clear and concise manner.
- Vaccine storage and handling plans must be easily accessible and should be kept near the vaccine storage units.
- All provider vaccine storage and handling plans must be reviewed and updated annually, or more frequently if changes to any information within the plan occur, such as new staff members who have responsibilities specified in the plan.
- A “review date” and signature of the individual responsible for the content is required on all plans in order to verify that they are current.

# CHECKLIST FOR CERTIFICATE OF CALIBRATION/VALIDATION/TESTING REPORTS

## A

**If Certificate Identifies an Accredited Laboratory:**



- ILAC/MRA Signatory body accredited Laboratory

The Following Table lists the accredited laboratories

<b>A2LA</b>	<b>L-A-B</b>	<b>ACCLASS</b>	<b>IAS</b>	<b>PJLA</b>	<b>NVLAP</b>
					

**AND**

- Name of Device (Optional)
- Model Number
- Serial Number
- Date of Calibration (Report or Issue Date)
- Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F (0.5C))

-----

## B

**If Certificate Does Not Identify an Accredited Laboratory:**

- Name of Device (Optional)
- Model Number
- Serial Number
- Date of Calibration (Report or Issue Date)
- Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F (0.5C))
- Statement that calibration testing conforms to ISO 17025*

**Note from the Alaska Immunization Program:**

*The following are examples of calibration certificates for temperature monitoring devices provided by CDC. The devices you use may not be shown, however, this will provide guidance on how to evaluate your certificates for compliance with CDC requirements.*

# Valid Certificate Examples

## Certificate Of Calibration

Digital Thermometer W Thermistor Probe  
Report No. 0926



Customer: TAGE HOSPITAL  
185 GRAFT RD  
TOWNS, VA 00216

Date Received: 09/26/2012  
Calibration Date: 09/26/2012

Make: TROL COP  
Model: 41CC with P10 PROBE  
Serial #: 8042

Customer Specified Due Date: 09/2013  
PO#: 011513  
Contact: JAY BELCHER  
Temperature: 21.6 TO 21.8 °C / RH% 47 TO 47  
CONDITION RECEIVED : IN SPEC  
Item Returned: IN TOLERANCE  
Equipment Location: LAB

Range: -200 TO 800 °C IN 0.01 °C DIVISIONS  
Accuracy/Tolerance : +/- 0.1 % + 0.2 °C BELOW 200 °C  
Item Received : IN TOLERANCE  
Calibration Location: SCH Temperature Laboratory

Notes : CALIBRATED AT CUSTOMERS SPECIFIED POINTS OF USE ONLY !

Nominal	Actual (STD)	Measured (UUT)	Deviation (UUT)	Units	Tolerance (±)	Uncertainty (±)	Pass/Fail
0	0.028	0.08	0.05	°C	0.20	0.09	PASS
20	20.017	20.15	0.13	°C	0.22	0.09	PASS
35	35.003	35.20	0.20	°C	0.24	0.09	PASS

Deviation rounded to the readability of UUT

The measurement traceability and calibration process used for conformance verification of the above instrument meets or exceeds the requirements of 17025-2005. The reported uncertainties reflect those of type B (Systematic errors associated with the standards and the procedure used), and type A (Random errors of the process). The type A and type B uncertainties were calculated in accordance with NIST technical Note 1297 using the RSS method and are reported at the coverage factor  $k=2$  to approximate a confidence level of 95%. The due date as it appears on this report does not imply that the instrument will maintain its accuracy for any given length of time unless supported with further documentation (e.g. statistical etc.) which affirms such stability and is the responsibility of the end user. Many factors may contribute to instrument in-accuracy over time such as drift, environment, transportation, frequency of use etc. The reported results reflect readings obtained at the time of test only. The reported uncertainties reflect those associated with the calibration process itself and not the instrument under test. If the UUT is a digital electronic measurement instrument add 0.6 of the least significant digit to the above stated uncertainty. The instrument is considered to be in-tolerance based on the observed results (Deviation or departure from nominal value) falling anywhere within its specified tolerance limits without consideration of applied uncertainty. This document shall not be reproduced except in full without the written approval of Q.C. Services, Inc.  
Procedure Used QCS 3015 (ORIG) (QCSTD 030106-3)

### TRACEABLE STANDARDS USED:

Fluke 1522	S/N: A6C265	Cal Due : 10/2012	
ERTCO-EUTECHNICS	S/N : 304526	Cal Due : 01/2013	X
HART SCI 1502	S/N 8B552	Cal Due : 04/2013	X

Certified by: Howard Richard

Date: 09/26/2012

Approved By:

Title: Metrologist Date: 09/26/2012

Example

1

**Good Certificate**

Meets all items under "A" from the Checklist

# Report of Validation Primary Temperature Lab

The PRT was calibrated at the following temperatures with the associated uncertainties. The uncertainty evaluation accounts for all known uncertainties present at the time of calibration including long-term behavior of the calibration system, measurement noise, and any short-term effects of the PRT. The uncertainties are reported at the calibration temperatures only. The uncertainties at intermediate temperatures can be computed from these values and the ITS-90 propagation of error curves. The uncertainties are reported at a coverage factor of 2 (k=2).

CALIBRATION POINT			TEMPERATURE	MEASURED	UNCERTAINTY
(point °C)	(type)	(SN)	t90(°C)	RESISTANCE	(mK)
-197.000	Comp	N/A	-197.000	4.6550	±6.0
-80.000	Comp	N/A	-80.000	17.2473	±10.0
-38.834	Comp	N/A	-38.834	21.5122	±6.0
0.010	Comp	N/A	0.010	25.4843	±4.0
In	FP	44013	156.599	41.0245	±6.0
Sn	FP	S7005	231.928	48.2361	±6.0
Zn	FP	S9007	419.527	65.4660	±9.0
Al	FP	17069	660.323	86.0321	±14.0

The following tables indicate the "As Found" RTPW nominal current, the dRTPW in mK, and dRTPW limit in mK. The dRTPW is the change in RTPW during the calibration, not the difference between the "As Found" and "As Left" RTPW. The value of current used in the calibration was 1.000 mA.

As Found Rtpw	dRtpw Observed	dRtpw Limit
1 mA 25.4848	0 mK	3 mK

The following values were determined for the RTPW and the coefficients of the pertinent deviation functions of ITS-90. For best results, the RTPW value shown should be used as a baseline value for determining the PRT. The user should maintain a record of RTPW values measured as a routine operation and use the computing temperature.

Model:  
**5628**

Serial No.  
**1819**

Report date  
**1/25/13**

**Results for Nominal Current Calibration**  
 RTPW = 25.4843  
 a4 = 3.478321 E-05  
 b4 = 4.228464 E-06  
 a7 = -2.581569 E-05  
 b7 = 1.838235 E-05  
 c7 = -1.226871 E-05

**Good Certificate  
Meets all required  
items under "B"  
from the Checklist**

The attached interpolation table was generated from the coefficients listed above. The table is given in terms of resistance (Rt90) versus temperature (°C) at the nominal current. These tables can be used in cases where the readout instrument does not have the capability of computing temperature directly from the coefficients or as a check that the coefficients have been entered into the readout or computer program correctly. The following steps are used to compute temperature from measured resistances utilizing the table. (1) Determine the resistance at the temperature in question. (2) On the table, locate the two resistance values which surround the measured resistance. (3) Subtract the lower of the two from the measured resistance. (4) Divide the result by the sensitivity (dR/dt) from the adjacent column. (5) Add the product of this computation to the temperature which corresponds to the resistance value used in step (3). The additional uncertainty in the tabulated values is negligible (<=0.01mK) but when these tables are used, an additional uncertainty of approximately 0.1 mK should be assumed as a result of the required linear interpolation operation outlined above.

Nominal	Actual	Measured	Error	Calibration Tolerance	Pass/Fail
0.25	0.249996678	0.249996716	0.000000038	±0.000000250	P
1.0	0.9999107	0.9999104	-0.0000003	±0.0000010	P
4.0	3.9997406	3.9997418	0.0000012	±0.0000040	P

This calibration is traceable to NIST and calibration is compliant to NCSL/ISO/IEC 17025:2005.

**Example  
3**

Performed by:   
Mike Mike  
Calibration Manager

Calibration complies with ISO/IEC  
17025, ANSI/NCSL Z540-1, and 9001

Cert. No.: 404

Certificate of Calibration for Monitoring Thermometer

Cust ID: Dept Public Hlth.  
RMA:972198 )

Instrument Identification:

Model: 51161-2

S/N: 1116649

Manufacturer: ConCon

Standards/Equipment:

Description	Serial Number	Due Date	NIST Traceable Reference
Temperature Calibration Bath TC-231	A79341		
Thermistor Module	A17118	2/01/13	1006311439
Temperature Probe	3039	2/14/13	6-BN9WZ-1-1
Temperature Calibration Bath TC-275	A9A237		
Digital Thermometer	122044330	1/24/13	4000-4146811

Certificate Information:

Technician: 6 Procedure: CAL Cal Date: 9/06/12 Cal Due: 9/06/17  
Test Conditions: 25.5°C 38.0°C

Results

Uncertainty

Calibration Data:

Unit(s)	Nominal	As Found	In Tol	Nominal	As Left	In Tol	Min	Max	±U	TUR
°C Probe		N.A.		0.00	0.6	Y	-1.0	1.0	0.06	>4:1
°C Probe		N.A.		25.00	25.5	Y	24.0	26.0	0.06	>4:1

Pass/Fail or In Tolerance

This instrument was calibrated using instruments traceable to National Institute of Standards and Technology.

A Test Uncertainty Ratio of at least 4:1 is maintained unless otherwise stated and is calculated using the expanded measurement uncertainty of the standards used in the calibration process. The uncertainty of the standards is calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" (GUM). The uncertainty of the standards is expressed as a percentage of the nominal value. The uncertainty of the standards is expressed as a percentage of the nominal value. The uncertainty of the standards is expressed as a percentage of the nominal value. The uncertainty of the standards is expressed as a percentage of the nominal value.

Nominal: Standard's Reading; As Left: Instrument's Reading; In Tol: In Tolerance; Min/Max: Acceptance Range; ±U: Expanded Measurement Uncertainty; TUR: Test Uncertainty Ratio; Accuracy: Max-Min(°C); Min = As Left Nominal(Rounded) - Tolerance; Max = As Left Nominal(Rounded) + Tolerance; Date: MM/DD/YYYY

This certificate indicates calibration for external sensors only.

*[Signature]*  
Rod Walters, Quality

*[Signature]*  
Gary Nic, Technical

Maintaining Accuracy:

In our opinion once calibrated your Monitoring Thermometer should maintain its accuracy. There is no exact way to determine how long calibration will be maintained. Monitoring Thermometers change rate, if any at all, but can be affected by aging, temperature, shock, and contamination.

Recalibration:

For factory calibration and re-certification traceable to National Institute of Standards and Technology contact ConCon Company.

Example  
4

Good Certificate  
Meets all required  
items under "B"  
from the Checklist

# REPO CALIBRATION REPORT

Certificate # 130

Instrument ID 162	<u>Description</u>	
Manufacturer CAR	Model Number 5000T	Serial Number 7620023
Calibrated 3/19/2013	Frequency Annual	Next Cal Date 3/19/2014

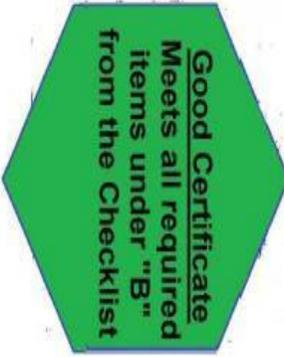
<u>Calibration Specifications</u>										Results	
Group # 1		Group Name 2 PT CAL									
Nom. In. Val / In. Val	In. Type	Std. Accy	Ass. %	±	Tol.	Out. Type	End. As	Lift. As	Dev. %	Pass/Fail	
5.0 / 5.0	C	Plus / Minus	0.000000 / 0.000000	0.5	5.0	C	5.0	5.0	0.00%	Pass	
-15.0 / -15.0	C	Plus / Minus	0.000000 / 0.000000	0.5	-15.0	C	-14.5	-14.5	-3.33%	Pass	

<u>Test Instruments Used During the Calibration</u>							Uncertainty
Test Instrument ID	Description	Manufacturer	Model Number	Serial Number	(As Of Cal. Entry Date)		
					Last Cal. Date	Next Cal. Date	
HART PRECISION RTD		HART-SCIENTIFIC	1502A	A1B599	5/21/2012	5/21/2013	

Notes about this calibration

Company Inc. certifies that the above equipment has been calibrated using instrumentation and standards that are traceable to the National Institute of Standards and Technology (NIST) through certification documents on file. This calibration complies with MIL-STD-45662A and ISO 17025, Test Uncertainty Ratio ≥ 4:1 unless otherwise stated.

**Example 5**



Calibration Result    Calibration Successful  
Who Calibrated        Davis Calvin

Finalized By    Huson  
Date Finalized    3/19/2013

# Invalid Certificate Examples

**Example  
2**

## CERTIFICATE OF CALIBRATION AND TEST

**REF** ILR245      **SN** 2450  
**Date** 12/25/2012

This product was assembled, tested and calibrated in accordance with the product specifications and FDA Quality System Regulations prior to release for shipment on the date indicated above. Product utilizes calibrated instrumentation traceable to NIST standards in the design, manufacturing, and inspection processes. The calibration results for this products chamber temperature monitoring system are recorded below.

NIST Factory Thermometer Reading:	<u>22</u> °C	ID#	<u>010</u>
Product Monitor Probe Reading (Lower):	<u>22</u> °C	NIST Factory Thermometer Reading (Lower):	<u>22</u> °C ID# <u>010</u>



*[Signature]*  
SIGNATURE      DATE 1/2/2013

# INSTRUMENT CALIBRATION REPORT

CDC

Certificate # 4701

Instrument ID 16238	Description	
Manufacturer LASCAR	Model Number V5000T	Serial Number 010023762
Calibrated 3/19/2013	Frequency Annual	Next Cal Date 3/19/2014

<u>Calibration Specifications</u>										
Group # 1										
Group Name 2 PT CAL										
<u>Nom In Val / In Val</u>	<u>In Type</u>	<u>Std Assy</u>	<u>Acc %</u>	<u>±</u>	<u>±</u>	<u>Out Type</u>	<u>Fnd As</u>	<u>Lft As</u>	<u>Dev %</u>	<u>Pass/Fail</u>
5.0 / 5.0	C	Plus / Minus	0.000000 / 0.000000	0.5	5.0	C	5.0	5.0	0.00%	Pass
-15.0 / -15.0	C	Plus / Minus	0.000000 / 0.000000	0.5	-15.0	C	-14.5	-14.5	-3.33%	Pass

<u>Test Instruments Used During the Calibration</u>						
<u>Test Instrument ID</u>	<u>Description</u>	<u>Manufacturer</u>	<u>Model Number</u>	<u>Serial Number</u>	<u>(As Of Cal Entry Date)</u>	
					<u>Last Cal Date</u>	<u>Next Cal Date</u>
HART PRECISION RTD		HART SCIENTIFIC	1502A	A1B599	5/21/2012	5/21/2013

Notes about this calibration

SolConut certifies that the above equipment has been calibrated using instrumentation and standards that are traceable to the National Institute of Standards and Technology (NIST) through certification documents on file. This calibration complies with MIL-STD-4662A and ISO 10012-1 and ANSI/NCSL Z540-1-1994. Test Uncertainty Ratio  $\geq 4:1$  unless otherwise stated.

Example  
6



**SolConut**

Phone: (888) 555-0636  
Fax: (555) 555-5419

Calibration Rest  
Who Calibrat

Finalized By Crav Swin  
Date Finalized 3/19/2013 10:52:24AM



Company

Corporation  
Street  
USA

Certificate Number: 01845      Ambient Temperature(°C): Min: 21.4 Max: 23.8  
Model Number: VL-200      Ambient Humidity(%RH): Min: 30.0 Max: 59.6  
Serial Number: 120521      Method: Calibration by comparison  
Procedures: VCP1009 VCP1010

The calibration(s) on this report are traceable to the United States of America National Institute of Standards and Technology or to other recognized national or international standards or to accepted values of natural physical constants, and are accredited to ISO/IEC 17025. The laboratory meets the requirements of ANSI/NCSL Z540-1. Using methods detailed in the ISO "Guide to the Expression of Uncertainty in Measurement", reported uncertainties represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of k=2. The calibrations were performed equivalently either with minimum test uncertainty ratios of 4:1 using a coverage factor of k = 2, or with the statistical method of guard banding to reduce test limits. The results relate only to the item(s) calibrated.

CALIBRATION REFERENCE EQUIPMENT

	Serial #	Calibration Date	
		Last	Next
Hart Scientific Black Stack Thermistor Scanner Module Model 2564	A39287	27-Nov-11	27-Nov-12
Thunder Scientific Humidity Generator 2500 ST-LT	1007799	28-Jul-11	28-Jul-12
Hart Scientific Thermistor Temperature Probe Model 5610	BOB1519	18-Jan-12	18-Jan-13

CALIBRATION TEST RESULTS

Chan	Test Description	Units	Reference	Measurement	As Left	
				Uncertainty	Result	Diff
1	Temperature	°C	-25.34	0.06	-25.33	0.01
1	Temperature	°C	9.64	0.05	9.65	0.01
1	Temperature	°C	25.01	0.04	25.01	0.00
1	Temperature	°C	44.73	0.06	44.71	0.02
1	Temperature	°C	69.55	0.07	69.55	0.00
2	Relative Humidity at 10°C	%RH	45.00	0.60	45.52	0.52
2	Relative Humidity at 25°C	%RH	11.00	0.60	11.34	0.34
2	Relative Humidity at 25°C	%RH	45.00	0.60	45.26	0.26
2	Relative Humidity at 25°C	%RH	80.00	0.60	80.27	0.27
2	Relative Humidity at 45°C	%RH	45.00	0.60	45.27	0.27



Maintaining Calibration

The electronic components in this data logger are of the highest quality. The unit has been designed to remain within its specifications. The length of in-calibration service can be affected by aging, temperature and shock. For those users with critical needs such as accreditation demands, government specifications, or ISO requirements, we recommend that the unit be calibrated on a periodic basis.

Calibration Technician: Crend P  
  
 Technician: Nuzi Cre

Calibration

Information on calibration services is available at the address below. This data logger was calibrated by:

Sal Inc.  
 100-Pkwy.  
 Richmond, CA 2874  
 Toll Free: 1-800-555-8374, Phone: 555-555-5850, Fax: 555-555-2874  
 Email: support@sal.com

Calibration Date: 19-Jul-2012  
 Next Calibration: 19-Jul-2013





Certificate # 130416

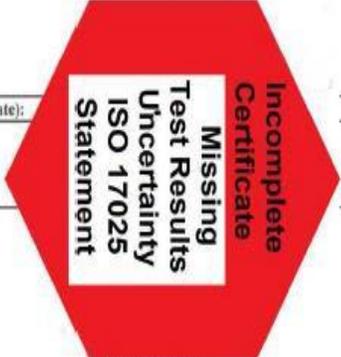
System ID:	Aurora Specialty	Calibration Date/Time:	2013/04/16 07:35 AM
Component ID:	RF1-TE2	Calibrated By:	Pody Wall
Equipment Type:	Temperature Loop	Quality Approval:	Johnn Loo 2013/04/18
Description:	TE-02 Temperature Loop	Next Event Due Date:	2014/04/30
Instrument Location:	Zone East	Next Event Name:	Annual Calibration
Manufacturer:	Precon	Customer Name/Contact:	Phel
Model:	ST-S81E	Customer Location:	34 Fraser ST, CA 11800
Serial Number:	N1800	Calibration Results:	Pass
Instrument Range:	-200 to 800 °C	Out of Tolerance:	Init.
Tolerance:	± 0.5 °C	Ambient Condition:	69 °F / 27 %RH

CALIBRATION DATA

Parameter:	Units:	AS FOUND			AS LEFT		
		Setpoint:	Data:	Deviation:	Setpoint:	Data:	Deviation:
NA	°C	15.91	15.8	-0.11	NP	NP	
NA	°C	1.62	1.7	0.08	NP	NP	
NA	°C	5.05	5.1	0.05	NP	NP	

Example  
8

Reference Standard Used (Mfg, Model #, Serial # or Lot #, and Calibration Due Date): Hart Scientific, 1521, A22097, 2013/07/26 Hart Scientific, 5613, 711917, 2013/04/25	Procedure Used: SOP-4-146-05, 2011/12/16
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Comments:  
Reference Standard was placed as close to the U.U.T. as possible to obtain a stable reading.  
Calibration offset "As Found" 0.0. Calibration offset "As Left" 0.0. KLP 16APR2013

Customer Approval (Optional)-Reviewed By/Date: \_\_\_\_\_ Quality Approval/Date: \_\_\_\_\_

# Glossary

## **Centers for Medicare and Medicaid Services (CMS)**

Agency that provides oversight of the Medicare and Medicaid programs. Funding for VFC program is allocated through this agency.

## **Deputization Agreement**

A formal agreement through a Memorandum of Understanding, whereby Federally Qualified Health Centers (FQHCs) or Rural Health Clinics (RHCs) delegate their VFC authority for vaccinating underinsured children to other VFC-enrolled providers, usually public health department clinics, who then vaccinate underinsured children as agents of the FQHC/RHC.

## **Family Planning Clinic**

Clinic or provider whose main purpose is to prescribe contraceptives. This does not include school-based clinics or any VFC-enrolled provider whose main services are primary or acute care services.

## **Federally Qualified Health Center (FQHC)**

Health center that is designated by the Bureau of Primary Health Care (BPHC) of the Health Services and Resources Administration (HRSA) to provide healthcare 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, as well as “look-alikes,” which meet the qualifications but do not actually receive grant funds. They also include health centers within public housing and Indian Health Service centers.

## **Fully Insured**

Anyone with insurance that covers the cost of vaccine, even if the insurance includes a high deductible or co-pay, or if 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.

## **Maximum Regional Charge**

The amount that a VFC-enrolled provider can charge a non-Medicaid VFC-eligible child for each vaccine administered (also known as the administration fee or “admin fee”). State Medicaid agencies have the authority to reimburse at a lower level. The Centers for Medicare and Medicaid Services (CMS) has the responsibility of setting and adjusting the maximum regional charges.

## **Medicaid-eligible Child**

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 coverage by a state Medicaid program.

## **Section 317 Funds**

Federal funds that support 64 state and local awardees provided through an annual federal appropriation. Although the VFC program is the primary source of federal vaccine purchase funding for pediatric and adolescent vaccines, the vast majority of operations support for state immunization programs comes from the Section 317 immunization grant program. Federal 317 funds also support the purchase of vaccines for certain eligible populations.