

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF DIRECTOR**

ACTION REFERRAL

TO <i>Giese</i>	DATE <i>1-2-13</i>
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DIRECTOR'S USE ONLY		ACTION REQUESTED	
1. LOG NUMBER <i>100204</i>	<input type="checkbox"/> Prepare reply for the Director's signature DATE DUE _____ <input type="checkbox"/> Prepare reply for appropriate signature DATE DUE _____ <input type="checkbox"/> FOIA DATE DUE _____ <input checked="" type="checkbox"/> Necessary Action		
2. DATE SIGNED BY DIRECTOR <i>cc: Mr. Tuck, COS, Depd, CMS file</i>			

APPROVALS <small>(Only when prepared for director's signature)</small>	APPROVE	* DISAPPROVE <small>(Note reason for disapproval and return to preparer.)</small>	COMMENT
1.			
2.			
3.			
4.			

Jan Polatty

To:

Deirdra Singleton

Subject:

FW: VFC Deputization from CMS

Attachments:

Sec Guidance VFC Deputization pdf.pdf

RECEIVED

Deirdra, Did TK share with you and staff? I think we should log

JAN 02 2013

Department of Health & Human Services
OFFICE OF THE DIRECTOR

From: Glaze, Jackie L. (CMS/CMCHO) [mailto:Jackie.Glaze@cms.hhs.gov]
Sent: Monday, December 17, 2012 3:28 PM

To: David.Dzielak@medicaid.ms.gov; Watson, Michael (michael.watson@dhhs.nc.gov); Anthony Keck; Darin J. Gordon (darin.j.gordon@tn.gov); Azar, Stephanie (Stephanie.Azar@medicaid.alabama.gov); Senior, Justin (Justin.Senior@ahca.myflorida.com); Jerry Dubberly (jdubberly@ddch.ga.gov); Kissner, Lawrence (CHFS DMS) (Lawrence.Kissner@ky.gov)

Cc: Roberts, Shantrina D. (CMS/CMCHO); Cartwright, Catherine A. (CMS/CMCHO); Wilkerson, Joyce C. (CMS/CMCHO); patricia.powers@medicaid.ms.gov; Larson, Tara (tara.larson@dhhs.nc.gov); Brinson, Shirley C (shirley.brinson@dhhs.nc.gov); Jan Polatty; Cris McCoy (Cris.McCoy@tn.gov); Hudson, Kathleen (Kathleen.Hudson@medicaid.alabama.gov); Bush, Becky (Becky.Bush@ahca.myflorida.com); Jacqueline Foster (jfoster@ddch.ga.gov); Dunn, Anna M (CHFS DMS) (AnnaM.Dunn@ky.gov)
Subject: VFC Deputization

Dear State Medicaid Directors,

In October 2011, HHS Secretary Kathleen Sebelius signed a decision memo allowing Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to deputize public health clinics, or other Vaccines for Children (VFC) providers in jurisdictions lacking public health clinics, to vaccine VFC-eligible, underinsured children. This was done to enlarge the safety net for the VFC program. Deputization is a special arrangement subject to annual review and renewal.

In partnership with the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA), CMS is providing guidance to implement the Secretary's decision. CDC, in coordination with HRSA and CMS, may authorize FQHC and RHC deputization through Memoranda of Understanding (MOU) of local health department (LHDs) to vaccinate underinsured VFC-eligible children. In VFC awardee locations without LHDs or where LHDs are unable to handle the capacity to serve the underinsured, FQHCs and RHCs may deputize through a MOU particular non-public VFC providers which have been designated by the VFC awardee, with CDC approval and appropriate justification, to serve in place of LHDs to vaccinate underinsure children with VFC vaccines. The MOU specifies the responsibility of all parties to the agreement and is authorized when underinsured children lack sufficient access to FQHCs and RHCs. VFC awardees and CDC are responsible for monitoring the use of VFC vaccines under these deputization arrangements.

In this process, CMS is responsible for communicating the HHS approved guidance on VFC deputization arrangement to FQHCs and RHCs. I've attached a document that provides guidance and detail on the process for the use of VFC Deputization to extend access to underinsured children with VFC vaccines.

Please let me know if you have questions. Thanks, Jackie

Jackie Glaze | Associate Regional Administrator | Division of Medicaid and Children's Health | Centers for Medicare and Medicaid Services | 61 Forsyth St. S.W., Suite 4T90 | Atlanta, GA 30303-8909 | 404-562-7417 | 404-562-7183 |
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

TO:

The Secretary
Through:

DS _____
COS _____
ES _____

FROM:

Director, Centers for Disease Control and Prevention
Administrator, Agency for Toxic Substances and Disease Registry

DATE:

April 16, 2012

SUBJECT:

Guidance for Use of Vaccines for Children (VFC) Deputization to Extend Access
to Underinsured Children with VFC Vaccines.

Issue

The attached document provides guidance on the use of deputationization to extend VFC authority from Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to other children with access to VFC vaccines that would otherwise be unavailable due to limited capacity or absence of an FQHC or RHC in a service area. Deputationization remains a special arrangement subject to annual review and renewal.

Secretarial Action

I recommend that you approve the attached guidance.

BACKGROUND

In October, 2011, HHS Secretary Kathleen Sebelius signed a decision memo allowing FQHC/RHCs to deputize public health clinics (or other VFC providers in jurisdictions lacking public health clinics) to vaccinate VFC-eligible, underinsured children, expanding the safety net for the VFC program.

The Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), and Centers for Medicare and Medicaid Services (CMS) drafted the attached guidance to implement the Secretary's decision. Specifically, the guidance adheres to the following key elements of deputationization:

- The safety-net focus of deputationization.
- The essential role of a state-wide memorandum of understanding among deputizing FQHC/RHCs, deputized VFC providers, and the VFC grantee.
- Requirements of deputized VFC providers to report utilization of deputationization.
- Roles and responsibilities at the federal, VFC grantee, and provider levels.

"Signed Electronically"

Thomas R. Frieden, M.D., M.P.H.

Attachment:

Guidance for Use of Vaccines for Children (VFC) Deputization to Extend Access to Underinsured Children with VFC Vaccine

Decision

Approved: _____

✓

No: _____

Would like to be briefed before signing: _____

Other/Comments:



Kathleen Sebelius
Secretary

Guidance for use of Vaccines for Children (VFC) Deputization to Extend Access to Underinsured Children with VFC Vaccine

Purpose

The purpose of this document is to provide guidance on the use of deputization to extend VFC authority to vaccinate underinsured¹ VFC-eligible children from Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to other VFC providers. Extension of this VFC authority is intended to provide underinsured VFC-eligible children with access to VFC vaccines that would otherwise be unavailable due to limited capacity or absence of an FQHC or RHC in a service area. Deputization is a special arrangement subject to annual review and renewal. This guidance has been approved by the Department of Health and Human Services (DHHS), and the Centers for Disease Control and Prevention (CDC), with input from the Health Resources and Services Administration (HRSA) and the Centers for Medicare & Medicaid Services (CMS).

Background

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)² 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.

¹ See Definitions of Terms, Appendix B

² Public Law 111-148]

There has been some concern expressed that extending access to VFC vaccine through deputization may expose the deputizing FQHC/RHC to liability. The National Vaccine Injury Compensation Program (VICP) greatly reduces the legal liabilities involved in administering most vaccines. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines. Generally, persons with claims of vaccine-related injuries or deaths resulting from covered vaccines must first exhaust their remedies under the VICP before they can pursue alternative legal actions against vaccine administrators. In addition, for certain vaccines to prevent diseases, health conditions, and threats that constitute or threaten a public health emergency and that are not covered by VICP, the Public Readiness and Preparedness Act of 2005 (PREP Act)³ may provide liability protection to providers administering such vaccines, and the Countermeasures Injury Compensation Program established by the PREP Act may provide compensation to eligible individuals who are injured by these vaccines.

CDC, HRSA, and CMS have not previously provided guidance for extending VFC authority through deputization, although CDC currently honors various deputization arrangements by providing VFC vaccine to deputized provider sites. VFC program awardees, FQHCs, and RHCs have requested official guidance on VFC deputization for extending VFC access to underinsured children. This document fulfills that request for guidance.

Guidance Overview

CDC, in coordination with HRSA and CMS, may authorize FQHC and RHC deputization through Memoranda of Understanding (MOU) of local health departments (LHDs) to vaccinate underinsured VFC-eligible children. In VFC awardee locations without LHDs or where LHDs lack capacity to serve the underinsured, FQHCs/RHCs may deputize through MOU particular non-public VFC providers which have been designated by the VFC awardee, with CDC approval and appropriate justification, to serve in place of LHDs to vaccinate underinsured children with VFC vaccine. The purpose of such an MOU is to confer underinsured VFC immunization authority to designated VFC providers by FQHCs/RHCs through deputization and to specify the responsibilities of all parties to the agreement (the VFC awardee, the deputizing FQHC or RHC, and the LHD or other VFC provider). Deputization is authorized when underinsured children lack sufficient access to FQHCs and RHCs. A VFC awardee must justify to CDC the need to use deputization to reach underinsured children and specify the number and type (LHD or non-public) of VFC providers proposed for deputization by FQHCs/RHCs within its jurisdiction. CDC will evaluate the justification and, if approved, notify the VFC awardee that FQHCs/RHCs may deputize approved VFC providers through an MOU. VFC awardees and CDC are responsible for monitoring the use of VFC vaccine under these deputization arrangements.

³ HR 2863, "DEPARTMENT OF DEFENSE APPROPRIATIONS ACT, 2006

Guidance Details

1. Awardee Request for Authorization of Deputization: VFC awardees justify to CDC the need for FQHC/RHC deputation of VFC providers in their jurisdictions. To deputize LHDs, the awardee must provide CDC with the total number of VFC-enrolled LHDs in the awardee's jurisdiction, the number of VFC-enrolled LHDs proposed for deputation, and the number of clinic sites (if different from the number of LHDs) proposed for deputation.

VFC awardees that do not have LHDs or that have LHDs that lack capacity to serve the underinsured will need to demonstrate that extending authority to other non-public VFC providers is necessary to serve a population of underinsured children who face barriers to receiving VFC vaccine because of:

- a. Geographic distance from an FQHC/RHC.
- b. Insufficient capacity of FQHCs/RHCs to serve the needs of the underinsured population.
- c. No LHDs or insufficient capacity of LHDs to be deputized to serve the needs of the underinsured population in their service areas.

VFC awardees may request deputation of no more than the number of non-public VFC provider sites needed to serve in the place of a local health department as a safety net for immunization.

2. CDC Approval: CDC approval of the request must be granted prior to execution of the MOU, and such approval must meet the following requirements:

- a. agreement to vaccinate "walk-in" VFC-eligible underinsured children as defined under subsection 1928(b)(2)(A)(iii) of the Social Security Act;
- b. screening for VFC eligibility, including for underinsured status, at every visit by any child less than 19 years of age;
- c. reporting to the VFC awardee, in manner and time as decided by the awardee, all requirements set forth in the guidance; and
- d. compliance with any additional VFC requirements as the VFC awardee [or name of state] Department of [Public] Health] or CDC may from time to time impose.

Awardees must submit initial requests no later than October 1, 2012, and should allow 60 days from the date of request submission for CDC's response.

3. MOU Elements: CDC will provide an MOU template. The MOU will include three actions:

- a. The conferral of deputation by the signatory FQHCs/RHCs to the identified VFC providers.
- b. The requirements to be met by the deputized sites.

- c. The implementation date of the deputization arrangement by the VFC awardee with consent of the deputized VFC providers.
4. MOU Execution: The VFC awardee, the deputizing FQHCs and RHCs, and qualified additional VFC-enrolled providers must all sign the MOU that conforms to the CDC-provided template.
 - a. The deputizing FQHC/RHC retains all of its authorities as a VFC provider; the MOU does not change the participating FQHC's or RHC's access to vaccine needed to immunize VFC-eligible children, including underinsured children.
 - b. CDC and the awardees retain oversight responsibility of deputized VFC providers in the same manner they do over all other VFC providers.
 - c. All parties retain copies of the fully-executed MOUs.
5. Responsibilities of VFC providers deputized with extended VFC authority:
 - a. Signing the MOU deputizing the VFC provider to immunize underinsured children, retaining a copy of the MOU during the time that the MOU is in effect, and fulfilling the terms of the MOU.
 - b. Annually signing the VFC provider enrollment form that describes the provider's responsibilities under the deputization arrangement.
 - c. Including "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit,
 - d. Ongoing compliance with all other VFC provider responsibilities, and
 - e. Reporting to the VFC awardee and deputizing FQHC/RHC the use of the deputization agreement as described below under Awardee Reporting Requirements.
6. Awardee Reporting Requirements:

The purpose of requiring deputized providers to report utilization of deputization is to determine whether utilization of deputization at the state level decreases over time. As health plans cover ACP-recommended vaccines as required by the Affordable Care Act, CDC anticipates a decrease in utilization of deputization.

In an effort to report the most accurate data possible, each awardee may choose the measure that will best capture utilization from its deputized VFC providers. The option chosen from the following list must be used by all deputized VFC providers throughout the awardee's jurisdiction:

 - a. Report the total number of visits of underinsured children who receive VFC vaccines in deputized clinics, by age category (ages 0-6 and 7-18).
 - b. Report the total number of doses of vaccine administered to underinsured children in deputized clinics, by age category (ages 0-6 and 7-18).

- c. Report the number of individual children who have received VFC vaccine in deputized clinics because they were underinsured at one or more clinic visits, by age category (ages 0-6 and 7-18).

The VFC awardee must report annually to CDC the total number of clinics deputized and the aggregate utilization between January 1 and December 31 of each calendar year, using the utilization measure selected by the awardee. The report must be submitted with the VFC Management Survey by March 1.

7. Current Arrangements: All current deputization agreements (both formal and informal) must be reviewed and updated based on the guidance contained herein and re-executed no later than December 31, 2012. Compliance with this guidance will be a requirement in the 2013-2017 Funding Opportunity Announcement for Immunization and VFC Program.

Attachments

Attachment A: Responsibilities

Attachment B: Definitions of Terms

Attachment A

Responsibilities

- **VFC awardees are responsible for:**
 - Identifying those FQHCs/RHCs willing to deputize other VFC providers to serve as their agents to immunize underinsured children.
 - Identifying and providing to CDC the number of LHDs and qualified non-LHD VFC providers proposed for deputization **no later than October 1, 2012.**
 - Modifying the annual VFC enrollment form to include specific responsibilities for deputized VFC sites including the requirements to screen for underinsured status, serve walk-in VFC-eligible underinsured children, and report utilization by one of the methods described under #6 under Guidance Details and submitting with the justification for deputization.
 - Justifying to CDC the use of VFC deputization arrangements, identifying FQHCs/RHCs that are willing to deputize other VFC providers, and identifying VFC providers they recommend for deputization.
 - Justifying the need for deputization of LHDs in their jurisdictions, receiving notification from CDC authorizing deputization by FQHC/RHCs, and signing each deputization MOU to validate that such approval was received from CDC and that all other conditions and responsibilities for implementation have been met.
 - Ensuring that the deputizing FQHC(s)/RHC(s) and the deputized VFC provider(s) have signed the MOU, submitted it to the awardee, and retained a copy of the signed MOU.
 - Collecting the number of underinsured children, doses, or visits (measurement to be determined by awardee), by age from deputized sites and annually reporting these data to CDC in the VFC Management Survey.
 - Ordering or approving vaccine orders from the deputized VFC sites.
 - Maintaining ongoing oversight of all VFC-enrolled providers.
 - Assessing compliance with the deputization arrangement during routine VFC compliance site visits to the deputized sites.
- **FQHCs or RHCs that are extending their VFC authority through the deputization of other VFC providers are responsible for:**
 - Signing and fulfilling the terms of the MOU.
- **LHD and designated non-LHD VFC providers that are deputized with extended VFC authority are responsible for:**

- Signing the MOU deputizing the VFC provider to immunize underinsured children, retaining a copy of the MOU during the time that the MOU is in effect, and fulfilling the terms of the MOU.
 - Annually signing the VFC provider enrollment form that describes the provider's responsibilities under the deputization arrangement.
 - Tracking and reporting at least quarterly to the VFC awardee the utilization data chosen by the awardee.
- **CDC is responsible for:**
 - Developing and communicating to VFC awardees and other federal agencies the DHHS-approved guidance on extending VFC authority pertaining to immunization of underinsured children.
 - Developing a template for the MOU with input from HRSA and CMS.
 - Developing language describing responsibilities of the deputized VFC provider for inclusion in the annual VFC enrollment form.
 - Approving awardee justifications and requests for authorizing FQHC/RHC deputization of other VFC providers in their jurisdictions, with input from HRSA and CMS.
 - Receiving from VFC awardees the number of deputized clinics and the aggregate measure of utilization of deputization.
 - Evaluating annually the programmatic use of VFC deputization arrangements to determine if additional guidance is required.
 - **HRSA is responsible for:**
 - Communicating the DHHS-approved guidance on VFC deputization arrangements to FQHCs that are Section 330-funded health centers or are FQHC Look-Alikes.
 - **CMS is responsible for:**
 - Communicating the DHHS-approved guidance on VFC deputization arrangements to RHCs; communicating to State Medicaid Agencies the DHHS-approved guidance on VFC deputization arrangements.
 - **DHHS is responsible for:**
 - Approving the guidance on VFC deputization arrangements.

Attachment B

Definition of terms

- **Annual VFC enrollment form:** The legally required form signed each year by participating VFC providers indicating the terms of participation in the VFC program.
- **Deputization:** The formal extension of VFC authority to provide VFC vaccines to eligible underinsured children from a participating FQHC or RHC to another VFC-enrolled provider. Under this arrangement, the deputizing FQHC or RHC retains its full scope of authority as a VFC provider while extending the authority to deputized VFC providers to immunize underinsured children with VFC vaccine.
- **Deputized VFC provider:** A VFC provider to which authority to vaccinate underinsured children with VFC vaccine is extended by an FQHC or RHC through the MOU.
- **Deputizing FQHC/RHC:** An FQHC or RHC that is extending authority to another VFC provider via the Memorandum of Understanding (MOU).
- **FQHC:** A Federally Qualified Health Center as defined under section 1905(i)(2) of the Social Security Act.
- **MOU:** A jurisdictional Memorandum of Understanding coordinated by the VFC awardee and signed by all parties: the VFC awardee, deputizing FQHCs and RHCs, and the deputized VFC providers. The MOU indicates that all parties agree the deputized VFC providers are being recognized as agents of the FQHCs/RHCs for the sole purpose of vaccinating underinsured children with VFC vaccine.
- **RHC:** A Rural Health Clinic as defined under section 1905(i)(1) of the Social Security Act.
- **Underinsured:** A child who has commercial (private) health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only); or a child whose insurance caps vaccine coverage at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.
- **VFC awardee:** 61 VFC program awardees that include the 50 states, the District of Columbia, the cities of Chicago, New York, Philadelphia, Houston, and San Antonio, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands.
- **VFC provider site:** An immunization provider site that has been approved by the VFC awardee to provide VFC vaccines to eligible children. A pre-enrollment site visit by the VFC awardee is required prior to approval, and a VFC provider agreement is signed that indicates the terms of participation in the VFC program. VFC providers must meet the minimum requirements of participation prior to enrollment. See <http://www.cdc.gov/vaccines/programs/vfc/recruit-enroll.htm>.