

NACHC ALERT

June 8, 2012

CDC Issues New Guidance on Deputization Arrangements under the Vaccine for Children Program

Summary: NACHC urges all health centers, before executing VCF deputization arrangements (1) to review any memorandum of understanding to assure that it includes adequate protections from liability, and (2) to seek legal counsel as necessary.

On April 30, 2012, the Centers for Disease Control and Prevention (CDC), with input from the Health Resources and Services Administration (HRSA) and the Centers for Medicare and Medicaid Services (CMS), issued a new guidance authorizing Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to “deputize” local health departments and, as necessary, other providers to administer Vaccine for Children (VFC) immunizations to underinsured children (*Guidance for Use of Vaccines for Children (VFC) Deputization to Extend Access to Underinsured Children with VFC Vaccine*). The VFC program establishes a pediatric vaccine distribution program under which “vaccine-eligible” children can receive certain vaccines from program-registered providers at no cost to the patient or to the provider.¹ All program-registered providers are authorized to administer vaccines to certain “vaccine-eligible” children:

- Children who are uninsured (*i.e.*, children who are not enrolled in or not entitled to benefits under a health insurance policy or plan).
- Children who are enrolled in the Medicaid program.
- Children who are Native Americans or Alaskan Natives.

Under current law, only FQHCs and RHCs are authorized to administer VFC vaccines to underinsured children – children who are enrolled in and entitled to benefits under a health insurance policy or plan but who do not receive benefits to support the costs of the vaccines.²

For several years, FQHCs and Primary Care Associations (PCAs) nationwide have been approached about “deputizing” local / state health departments (or other registered providers) to allow them to administer VFC vaccines to underinsured children, thus facilitating the immunization of a greater number of such children by alleviating barriers based on availability of vaccines or capacity to furnish the vaccines. While NACHC has consistently recognized the goal

¹ Section 1928(a) of the Social Security Act (42 U.S.C. § 1396s(a))

² Section 1928(b) of the Social Security Act; 42 U.S.C. § 1396s(b)

of deputization as laudable, in the past, we have voiced concerns regarding the legality of such arrangements given the statutory parameters and the lack of written official guidance and/or assurances from the federal government that centers would not be held liable for: (1) allegations of inappropriate diversion of VFC vaccines; (2) insufficient oversight and monitoring of the deputized providers; and/or (3) the acts or omissions of the deputized providers, whether in connection with the actual provision of the vaccines or in complying with all VFC provider responsibilities and requirements.

The new guidance seeks to alleviate these concerns and to fulfill prior requests for written guidance authorizing the extension of VFC vaccines to underinsured children served by non-FQHC providers. It includes: (1) an overview of the issue; (2) steps to establish and secure approval of a deputization arrangement; (3) a sample Memorandum of Understanding (MOU) to authorize the deputization and an overview of necessary elements; and (4) summaries of the responsibilities of the VFC awardee agency, the FQHC (or RHC), the deputized provider, and each of the involved federal agencies. Among other things, the guidance addresses the following:

- CDC approval of the deputization arrangement must be granted prior to execution of the MOU. To secure approval, the respective VFC awardee agency must justify the need to use deputization to reach underinsured children, generally based on a lack of sufficient access to FQHCs (or RHCs). The CDC will evaluate the justification and if approved will notify the awardee agency that the FQHC (or RHC) may deputize approved VFC providers through the MOU.
- Under the arrangement, the CDC and the VFC awardee agency retain oversight responsibility over the deputized providers “in the same manner they do over all other VFC providers,” while the FQHC retains authority to participate as a VFC provider for purposes of its own patients (the agreement does not terminate the FQHC’s ability to participate in the VFC program).
- The deputized provider must comply with all VFC provider responsibilities and requirements, and must report utilization information to the VFC awardee agency and to the FQHC.
- The MOU must comply with the elements addressed in the guidance.

While NACHC believes that the guidance and the MOU provide valuable information and represent a good “first step,” we also believe that the MOU in particular raises several concerns by failing to adequately protect FQHCs from allegations of diversion or other liabilities. For example:

- It is unclear which entity – the deputized provider, the FQHC, the VFC awardee agency, the CDC – would be responsible for the deputized provider’s misuse of the vaccines for ineligible children or its failure to comply with other VFC provider responsibilities regarding, among other things, screening and documentation.
- Given that there is no meaningful oversight by the FQHC, it is also unclear whether and the extent to which the FQHC would be liable for a deputized provider’s professional malpractice based on the FQHC’s negligence for failure to supervise.

Of particular concern, the MOU is silent with respect to a clear and explicit statement that the FQHC will be held harmless from any liabilities arising from: (1) the deputized provider's non-compliance with VFC program requirements, misuse of VFC vaccines, and/or professional liability; and (2) the CDC's and VFC awardee agency's authorization and/or oversight of the deputization arrangement.

NACHC provided comments to HRSA regarding our specific concerns and requesting certain modifications to alleviate these concerns. In the meantime, we strongly urge all health centers approached to execute these arrangements to carefully review the MOU to ensure that it addresses the aforementioned concerns and includes adequate protections from liability, and to seek legal counsel as necessary. In particular, the MOU:

- Should not include language indicating that the FQHC confers authority to the deputized provider to serve as the “agent” of (or to act on behalf of) the FQHC. Typically, principals are responsible for the actions and omissions of their agents; thus, inclusion of this language could result in unforeseen liabilities for the FQHC.
- Should specify that the CDC and the VFC awardee agency retain their respective responsibilities for oversight of the deputized provider's VFC operation, including monitoring the use of the VFC vaccines for eligible underinsured children.
- Should specify that the FQHC retains all of its rights, privileges and authorities to participate in the VFC program as a VFC provider, including the ability to access VFC vaccines needed to immunize the FQHC's VFC-eligible children and to provide such vaccines.
- Should include a provision requiring the deputized provider to report the utilization of VFC vaccines under the deputization arrangement to the FQHC (and not just to the VFC awardee agency).
- Should include a specific provision either holding the FQHC harmless or at a minimum, recognizing that the FQHC is not responsible for the actions or omissions of the deputized provider, the CDC, or the VFC awardee agency. Sample language includes the following:
 - It is expressly understood and agreed that neither the deputizing FQHC nor its respective directors, officers, agents, and employees shall be liable for any acts or omissions of the deputized provider related to the provision of vaccines to underinsured children pursuant to this MOU (including the deputized provider's compliance with all VFC program requirements and all VFC provider responsibilities and the appropriate use of VFC vaccines solely for eligible children), or for any acts or omissions of the VFC awardee agency and/or CDC related to the authorization provided hereunder or the required oversight of the deputized provider's VFC operations.
 - The VFC awardee, CDC and the deputized providers agree to defend and hold harmless the deputizing FQHC and its directors, officers, agents, and employees from any and all claims, losses, liabilities or damages, including attorneys' fees, costs and expenses, arising out of a deputized

provider's (i) performance, failure to perform or negligent performance of any of its obligations under this MOU; and/or (ii) violation of any term or condition of this MOU (including, but not limited to, the deputized provider's obligation to comply with all VFC program requirements and all VFC provider responsibilities).

NACHC will continue to monitor developments regarding the VFC deputization guidance and MOU and will provide updates as we receive them.