



July 5, 2011

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
**Attention: CMS-3213-P**  
P.O. Box 8010  
Baltimore, MD 21244-1850

The National Association of Community Health Centers, Inc. (NACHC) is pleased to respond to CMS' proposed rule relating to influenza vaccination standards for certain Medicaid and Medicare providers (76 Fed. Reg 25460 et seq., 5/4/11). NACHC is the national membership organization for federally qualified health centers (hereinafter interchangeably referred to as "health centers" or "FQHCs") throughout the country, and is a non-profit, Section 501(c)(3) tax exempt organization. We are, of course, particularly interested in responding to this proposed rule as it includes requirements specifically applicable to FQHCs.

#### **Background**

There are, at present, more than 1200 health centers with more than 8000 sites serving more than 20 million patients nationwide. Most of these health centers receive federal grants under Section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b) from the Bureau of Primary Health Care (BPHC), within the Health Resources and Services Administration (HRSA) of HHS. Under this authority, health centers fall into four general categories (1) those centers serving medically underserved areas, (2) those serving homeless populations within a particular community or geographic area, (3) those serving migrant or seasonal farmworker populations within similar community or geographic areas, and (4) those serving residents of public housing. Approximately 100 FQHCs do not receive a Section 330 Public Health Service Act grant but have been determined by CMS, per recommendation of HRSA, to meet all the requirements that must be met by Section 330 grantees (Sections 1861(aa)(4)(B) and 1905(l)(2)(B)(iii) of the Social Security Act). These FQHCs are often referred to as "FQHC look-alikes."

To qualify as a Section 330 grantee, a health center must be located in a designated medically underserved area or serve a medically underserved population. In addition, a health center's board of directors must be made up of at least fifty-one percent (51%) users of the health center and the health center must offer services to all persons in its area, regardless of one's ability to pay. BPHC's grants are intended to provide funds to assist health centers in covering the otherwise uncompensated costs of providing comprehensive preventive and primary care and enabling services (such as translation, transportation services, smoking cessation classes, etc) to uninsured and underinsured indigent patients,

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as well as to maintain the health center's infrastructure. Patients from eligible communities, who are not indigent and are able to pay or who have insurance, whether public or private, are expected to pay for the services rendered. Approximately 35 percent of health center patients are Medicaid recipients, approximately 40 percent are uninsured, and approximately 7.5 percent are Medicare beneficiaries. This 7.5 percent Medicare patient load translates into 1.5 million Medicare beneficiaries receiving services from FQHCs.

### **Influenza Vaccinations at FQHCs**

NACHC supports CMS's proposed rule to establish influenza vaccination standards for groups of providers including FQHCs. As grantees, health centers are required in Section 330 of the PHS Act to provide certain preventive health services, one of which is "immunizations against vaccine-preventable diseases" 330(b)(1)(A)(i)(III)(dd)). FQHCs that do not receive a 330 grant ("FQHC look-alikes") --must also meet this service requirement. Moreover, BPHC expects health centers to follow the recommendations of the Advisory Committee on Immunization Practices (ACIP) which, as CMS points out, currently calls for the provision of influenza vaccination to all persons 6 months of age or older.<sup>1</sup>

While NACHC is supportive of the general thrust of CMS's proposed rules, we have several concerns and suggestions relating to the specifics of the proposal as well as in response to CMS's request for comment as to how the proposed rule could be strengthened to better address disparities in the vaccination rates.

### **The cost to FQHCs of implementing this rule**

NACHC believes that CMS has underestimated the administrative costs to health centers of complying with the proposed rule. In 2009, health centers provided over 3.2 million seasonal and H1N1 influenza vaccines to 2.9 million patients. We calculate that 15 percent of health center patients are vaccinated over the course of the influenza season. This estimate is well below the assumption CMS has provided that 40 percent of Americans are vaccinated during the same time period. With nearly 98 percent of health center patients citing that their usual source of care is at a health center, we can assume that the majority of patients would have been vaccinated at the health center. CMS assumes that the 60 percent of the total patient population would now be vaccinated. Following this assumption, then 12 million health center patients (60 percent of the 20 million patients served by health centers) would be vaccinated or 9 million health center patients would be newly vaccinated. The cost to health centers would be \$40.5 million dollars.

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<sup>1</sup> 76 Fed. Reg., at 25461

## **Medicaid payment to FQHCs**

Many state Medicaid agencies do not cover all of the costs incurred by health centers in providing influenza vaccinations to their adult Medicaid patients. In July 2003, George Washington University's School of Public Health and Health Services/Center for Health Services Research and Policy published a study of Medicaid coverage of immunization for non-institutionalized adults. The study found that 44 state Medicaid agencies offered coverage for flu vaccines. But it also found that 33 states deny full reimbursement coverage for vaccines, a substantial number of states do not reimburse providers for vaccine administration, and in many states the patient must pay a co-payment for the service. In this latter instance, the health center, per the conditions of its 330 grant, would be carrying some or most of these co-payment costs for the vast majority of their Medicaid patients as their income would likely be below 200 percent of the federal poverty line. Moreover, there is an understandable concern that, with regard to adults, some states will cut back on their current vaccination coverage or increase patient cost for this preventive service, given the difficult economic straits that many states are in today.

As CMS notes in the preamble to this rule, FQHCs are reimbursed by state Medicaid agencies on the basis of an all-inclusive per visit rate. This per visit rate may or may not cover the full cost of the purchase of influenza vaccines and the provider's time for administering the vaccine since states vary substantially on how they calculate a health center's PPS per visit rate, what constitutes a visit and/or an allowable cost, the number of allowable visits per day, the definition and process of a change in scope, etc. Nonetheless, CMS notes that inclusion of FQHCs in this rule will "greatly assist" in reaching the goal of addressing the needs of vulnerable populations and diminish health care disparities. NACHC requests, therefore, that in finalizing this rule, CMS instruct state Medicaid agencies that they must offer an FQHC an opportunity to request a change in scope of services to reflect the increased cost that the center will incur to comply with this new rule and to provide such an increase in the center's per visit payment if the center is able to demonstrate such a cost increase.

## **Addressing disparities in influenza vaccination**

In the preamble to its proposed rule, CMS solicits comments on how the proposed rule could be strengthened to address disparities among the populations that receive influenza vaccinations. In response to this request, we note that research has suggested that policy aimed at increasing or at least maintaining supply of influenza vaccine has been shown to limit the disparities between ethnic minorities and white populations in terms of influenza vaccination rates. A study<sup>2</sup> that examined the impact of vaccine shortages on disparities in vaccination rates among Hispanic and African American minorities concluded that disparities could be reduced by implementing policies aimed at the supply of vaccine. It recommended a program similar to Vaccines for Children (VFC) for adults that receive care in safety net facilities such as FQHCs in order to sustain supply for these facilities. A program of this sort would strengthen the supply of vaccine available to health centers, as the vaccine would be supplied at little to no cost, reducing barriers to an FQHC obtaining enough vaccine to support their population.

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<sup>2</sup> Yoo et al, Am J Prev Med 2011;40(1), pg. 9

Another study noted that explanations of racial disparities include barriers to preventive care including costs, transportation, language and lack of insurance, as well as false impressions of influenza severity, and minority patient mistrust.<sup>3</sup>

Health centers play a key role in surmounting the causes of these disparities, since they serve everybody in their catchment area regardless of ability to pay, serve substantial numbers of minorities, provide transportation services and focus on the provision of services in a manner that underlines cultural competency (provision of translation services, etc.). These barriers can best be surmounted, however, when the efforts of the health center are part of an active partnership with CDC and state and local health departments working together to craft target awareness strategies, assuring that educational materials are in the appropriate language and using relevant messages, etc.

In fact, between 1995-2001, NACHC, BPHC, and the Center for Disease Control/ National Immunization Program engaged in just such a partnership resulting in a very successful 10-state project called “Together for Tots,” which included a partnership with state primary care associations, clinical networks, health departments and health centers in community-based initiatives to build infrastructure to increase and sustain immunizations rates for infants and children under age 2 who receive care at health centers. This effort resulted in consistent, often, statistically significant improvement in the average immunization coverage rates in health centers in those ten states. In short, health centers need a partner(s) and support in their community and beyond to assure the success of these efforts to reduce disparities in the receipt of vaccinations and we ask that CMS, play an active role in supporting these efforts.

Finally, we note that the Affordable Care Act (ACA) includes a number of provisions that offer opportunities for CMS to facilitate the increase of influenza vaccinations to Medicaid recipients. For example, the ACA allows states to obtain vaccine from the CDC at reduced rates and provides an incentive of a 1 percent increase in FMAP beginning in 2013 to all states that cover ACIP recommended vaccines in their Medicaid program with no cost-sharing. 42 USC 1396d(b)(5). As ACIP recommends all persons over the age of 6 months receive an annual flu vaccine, this provision in the ACA could lead to an increase in the number of Medicaid programs that cover influenza vaccination, thereby easing the cost burden on health centers and other safety net providers. Moreover, the ACA will require all new private health plans to cover ACIP recommended vaccinations. We highlight these provisions in the ACA so as to encourage CMS to publicize these payment opportunities to State Medicaid agencies and to stress the importance of CMS assuring that these ACA plan requirements are enforced—as implementation of these provisions can assist in addressing influenza vaccination disparities.

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<sup>3</sup> Linn et al, JAGS, Vol. 58, No. 7, (July 2010), p. 1338

### **Clarification regarding patient education materials**

The proposed rule includes requirements that patients receive vaccine education at the time of immunization as well as use of interpreters for patients to ensure all are educated on the vaccine. We believe this is an important step towards confronting one of the barriers to vaccine coverage, patient perception of the efficacy of flu vaccine. According to CDC, however, federal law requires the distribution of a Vaccine Information Statements (VIS) to all patients receiving immunizations. We are seeking clarification therefore as to whether the proposed rule would require further or additional patient-education materials beyond this distribution.

Thank you for the opportunity to submit these comments. If you have any questions about the comments presented herein, please call or email me at 202-296-0158 or [rschwartz@nachc.com](mailto:rschwartz@nachc.com).

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Roger Schwartz". The signature is fluid and cursive, with the first name "Roger" and last name "Schwartz" clearly distinguishable.

Roger Schwartz, Esq.  
Associate Vice President and Legal Counsel  
National Association of Community Health Centers