



June 10, 2010

Health Resources and Services Administration  
Department of Health and Human Services  
Attention: HRSA Regulations Officer  
Parklawn Building Rm. 14A-11  
5600 Fishers Lane  
Rockville, MD 20857

**RE: Solicitation of Comments on Notice of Intent to Form Negotiated Rulemaking Committee, 75 Fed. Reg. 26167, et.seq. (May 11, 2010)**

To Whom It May Concern:

The National Association of Community Health Centers (NACHC) is pleased to respond to the above-cited notice from the Health Resources and Services Administration (HRSA) within the Department of Health and Human Services (DHHS) soliciting comments on HRSA's intent to establish a Negotiated Rulemaking (NRM) Committee under the Federal Advisory Committee Act (FACA) in order to establish a comprehensive methodology and criteria for the designation of Medically Underserved Populations and Primary Care Health Professional Shortage Areas under sections 330(b)(3) and 332 of the Public Health Service Act, respectively (hereinafter, the Notice). NACHC is the national membership organization for federally-supported and federally recognized health centers (hereinafter interchangeably referred to as "health centers" or FQHCs) throughout the country, and is an Internal Revenue Code Section 501(c)(3) organization. NACHC also serves as a source of information, analysis, research, education, training, and advocacy regarding medically underserved people and communities.

**Background**

There are, at present, approximately 1,250 health center entities nationwide, which serve as the health care homes to twenty (20) million persons<sup>1</sup> at more than 8,000 sites located in all fifty (50) states, Puerto Rico, the District of Columbia, and every U.S. territory. Most of these health centers receive federal grants under Section 330 of the Public Health Service Act (42 U.S.C. §254b) from the Bureau of Primary Health Care (BPHC) within HRSA. Under this authority, health centers fall into four general categories: (1) centers serving medically underserved areas and/or populations (invariably poor communities); (2) centers serving homeless populations within a particular community or geographic area; (3) centers serving migrant or seasonal farm worker populations within a particular community or geographic area; and (4) centers serving residents of public housing projects. Although there are some slight differences in the grant

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<sup>1</sup> NACHC estimate based on the most recent UDS, estimated growth under ARRA to date, and patients of non-federally funded health centers.

requirements for each of these four program types, for all intents and purposes, the ways in which these health centers operate are identical.<sup>2</sup>

The Section 330 grant funds are intended to support the costs of providing a comprehensive array of preventive and primary care and enabling services to uninsured and underinsured low-income patients, as well as to maintain the health center's infrastructure. Nearly 70% of health center patients live in poverty. Patients from eligible communities<sup>3</sup> who are not low-income or who have insurance (whether public or private) are expected to pay for the services rendered. In 2008, on average, 37% of the patients served by health centers were Medicaid/SCHIP recipients, 8% were Medicare beneficiaries, 39% were uninsured and the balance were covered through other public insurance programs as well as private insurance.

To qualify as an FQHC, a health center must (among other requirements) be located in or serve a federally-designated Medically Underserved Area (MUA) or Medically Underserved Population (MUP) - high-need areas identified by the federal government as having elevated poverty and higher than average infant mortality, and where few physicians practice.

Additionally, a vast majority of health centers are located in or serve an area, population or facility that has been designated as a Health Professional Shortage Area (HPSA). While not a requirement to receive Section 330 funds, HPSA designation is a critical element in determining eligibility for funding and other resources and for allocating resources through a wide variety of federal programs beneficial to preserving and enhancing the health care safety net, including National Health Service Corps (NHSC) clinicians, International Medical Graduate (J-1 Visa) physicians whose return-home requirement is waived, and Medicare Provider Incentive Payments. Given the growing number of medically underserved communities and populations combined with the decreasing availability of state financial resources to support services to the underserved, securing and maintaining HPSA designation (and thus being able to access related benefits) is crucial to the continued operation of health centers.

## **Overall Comment**

NACHC appreciates HRSA's efforts in developing a more coordinated MUP and HPSA designation methodology and procedure that would, at a minimum<sup>4</sup>:

- Define consistently the indicators used for both designation types;
- Clarify the distinctions between MUPs and HPSAs; and
- Update both types of designation on a regular, simultaneous basis.

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<sup>2</sup> In addition to those health centers receiving grant funds pursuant to one or more of the Section 330 funding programs, there are certain entities that are designated by the Centers for Medicare and Medicaid Services (CMS) as FQHCs, by virtue of the fact that they meet all of the requirements to receive a Section 330 grant, but do not receive funding from HRSA (FQHC look-alike entities). For purposes of this comment, unless otherwise noted, we do not distinguish between grantees and FQHC look-alike entities, collectively referring to both types of organizations as "FQHCs" or "health centers."

<sup>3</sup> The term "community" in this context refers to either a geographic area or the specific population toward which the program is aimed.

<sup>4</sup> 75 *Fed Reg.* 26167 at p. 26169.

Further, NACHC strongly supports utilizing the NRM process to develop the designation methodology and procedure. We believe that engaging in an NRM, under which HRSA, technical experts and relevant stakeholders participate in a collaborative effort to discuss and resolve major issues involved in the rule prior to its publication, ultimately will result in an Interim Final Rule that more effectively and appropriately represents the interests of affected parties and the areas and populations at risk of underservice.

Notwithstanding our support for the NRM, NACHC has a couple of concerns regarding the procedure outlined in the Notice. NACHC recognizes that the process and procedure is, by and large, consistent with the process stipulated in both the Negotiated Rulemaking Act (NRM Act) and FACA. However, we believe that there is room for modification and improvement in the following areas:

**Section IV - Schedule for Negotiation<sup>5</sup>:** The Notice states that, in the event that consensus is not reached, the NRM committee can submit “a report specifying any areas of consensus and including other information, recommendations or materials that the Committee considers appropriate,” which HRSA will consider in drafting an Interim Final Rule. The NRM Act is more expansive in terms of additional information provided, allowing any Committee Member to include as an addendum to the report additional information, recommendations or materials (as opposed to information that the Committee deems appropriate).<sup>6</sup> Accordingly, NACHC recommends that HRSA adopt the more expansive language of the NRM Act in defining actions in the event that consensus is not reached.

**Section V.A. - Procedure for Establishing an Advisory Committee<sup>7</sup>:** The Notice states that, pursuant to FACA, NRM Committee will be “established only after approval of an agreed-upon charter. [HRSA has] prepared a draft charter and initiated the requisite consultation process. Following review of public comments on this Notice and upon successful completion of the approved charter, [HRSA] will form the Committee and begin negotiations.” Given that the charter impacts the duties of the Committee, NACHC suggests that HRSA solicit input from interested parties or, at a minimum, allow interested parties to review a “draft” charter prior to finalizing and filing the final charter.

### **Topics Addressed in the Notice**

In the Notice, HRSA solicited comments on the following three (3) topics<sup>8</sup>:

1. Whether HRSA has adequately identified the key issues in this designation rulemaking effort;
2. Whether HRSA has adequately identified key sources of subject matter technical expertise relevant to defining underservice and shortage and designating underserved areas and populations; and

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<sup>5</sup> 75 Fed Reg. 26167 at p. 26170.

<sup>6</sup> 5 U.S.C 566(f).

<sup>7</sup> 75 Fed Reg. 26167 at p. 26170.

<sup>8</sup> 75 Fed Reg. 26167 at p. 26168.

3. Whether HRSA has identified appropriate representatives of the various stakeholders/interests that will be affected by the final designation rules.

NACHC does have a few concerns regarding the topics on which HRSA requested comment, which we address below. Before commenting on these specific topics, however, we note that while the Notice is limited to Primary Care HPSAs, Congress did not specify such a limitation in the PPACA. Rather, Congress simply required a NRM to design a comprehensive methodology and criteria for designation of MUPs and HPSAs without any specification as to which HPSAs would be impacted. Thus, NACHC believes that the scope of the NRM should be expanded to include both Dental HPSAs and Mental Health HPSAs as well as Primary Care HPSAs.

In our comments below, NACHC responds specifically to questions #1 and #3.

***(1) Whether HRSA has properly identified the key issues in this designation rulemaking effort;***

NACHC believes that the scope of the list of questions identified in the Notice generally cover the most pressing issues that must be addressed by the NRM Committee and we commend HRSA for taking into consideration the full breadth of concerns, in particular those voiced during the two previous comment periods. While the scope appears comprehensive however, NACHC believes that a few of the identified issues require additional clarification. The success and effectiveness of the NRM process depends, in large part, on the clarity of the issues raised. Further, we believe that it is imperative to ensure that all identified issues are consistent with the considerations Congress specified in the Patient Protection and Affordable Care Act (PPACA). Accordingly, NACHC's comments on the key issues focus on two aspects: clarification of the issues presented and their consistency with the PPACA.

As a preliminary matter, taken as a whole, NACHC believes that while the issue of availability of health services and providers is adequately addressed, the **access** issue is not. This distinction is central to the function of shortage designations. While availability denotes a lack of sufficient primary health care resources within a geographic area, access is generally used to describe barriers to care experienced by certain populations, including cost, language, cultural differences, transportation, insurance status, and provider practice decisions that ultimately impede an individual or group's ability to receive care regardless of the number of providers "available" in the area. For example, lack of public transportation and a physician's decision to not participate in the Medicaid program create barriers to care for a population beyond geographic distance. Thus a population's distance to health care is simply one measure of access.

Finally, while we are not sure whether this additional concern should be treated as a key issue in its own right or viewed as relevant to one or several of the 12 specific questions listed in the Notice, we believe it important that HRSA consider that under the PPACA, Medicaid eligibility in 2014 will be expanded substantially, and consequently the number of Medicaid recipients (but not necessarily the number of Medicaid providers) will increase substantially by 2015. Thus, we believe it important that information and data be available relating to Medicaid participation by providers and Medicaid utilization. In this regard (and given the breadth of programs impacted by the MUP and HPSA designations), we also urge HRSA to strongly encourage the Centers for Medicare and Medicaid Services (CMS) to have appropriate CMS staff attend the NRM sessions.

Our specific comments on issues presented in the Notice and our recommended changes are outlined below.

***Question 2: “What specific underservice/shortage indicators should be included, for either or both designation types, and how should they be defined/measured?...What existing data sources are accurate and reliable enough to use, at the appropriate level?”***

Comment: NACHC believes that, as drafted, this question improperly presumes that the designation process will be based solely on presently available data sources. To ensure that the issue of appropriate data sources is considered fairly and without bias, we recommend striking the word “existing” from this question. Furthermore, the phrases “accurate and reliable” as well as “at the appropriate level” are vague and undefined and, as such, should also be struck from the question. As an alternative, NACHC recommends replacing this question with the following: “What are the acceptable, available and/or appropriate data collection methodologies?” Not only will these changes help clarify the way in which data will be considered, they also will more closely reflect Congressional intent specified in the PPACA that the designation process consider “the timely availability and appropriateness of data used to determine a designation to potential applicants for such designations,” and “the degree of ease or difficulty that will face potential applicants for such designations in securing the necessary data.”

With respect to specific underservice indicators, some years ago, HRSA revised the MUA designation criteria to allow the use of alternative health status data (such as low birthweight indices) in lieu of infant mortality data; however, no additional flexibility was allowed for the remaining medical underservice indicators. Yet in the 34 years since the initial publication of the rule on Designation of Medically Underserved Populations, so much has changed with respect to the demographics and health indices of the overall American population – not to mention those of populations that are most likely to be underserved by almost any measure – that we would all be wise to learn from this experience, and to focus on developing a methodology that allows for the flexible use of new data, indices, and information as it becomes widely available, and which clearly impacts the ability of population groups – and indeed, whole communities – to access needed health care services. Therefore, NACHC would strongly recommend that any new methodology allow for incorporation of new or emerging data that reflect a lack of access to care, either because they pose a barrier to access or because they clearly indicate a lack of access among the population experiencing them (for example, elevated HIV or Hepatitis A/B/C rates today, perhaps other indices in the future).

***Question 2a: “What provider availability measures should be used?”***

Comment: NACHC believes that the wording of this question fails to recognize the need to distinguish between apparent and actual availability, and between access and availability. As discussed above, these distinctions (in particular, accessibility) must be taken into consideration in order to ascertain a true measure of professional shortage. Further, in the PPACA, the distinction between access and availability was not lost on Congress when, it explicitly stated that the designation process consider “access” by considering “the extent to which the methodology accurately measures various barriers that confront individuals and population groups in seeking health care services.” Accordingly, NACHC recommends striking the word “availability” in this question and replacing it with “accessibility.”

***Question 2d: "What measures of utilization should be included?"***

Comment: NACHC believes that this question implies that the new designation methodology must include measures of utilization. Utilization is not necessarily a proxy for need. It also varies for some communities with certain demographic profiles (e.g., those with especially large immigrant, uninsured, or young populations). For this reason, NACHC recommends that HRSA change the wording of this question to read as follows: "Should measures of utilization be included, and if so, which ones?"

***Question 3: "What methodology or methodologies should be used to incorporate/combine the impact of these various underservice indicators on access? Should indicators be combined in the same way or in different ways for use in MUP and HPSA designations?"***

Comment: Given Congress' desire that "the methodology accurately measures various barriers that confront individuals and population groups in seeking health care services," NACHC recommends that this question be followed by "How should indicators be weighed or factored in when data are not available?"

***Question 4: "Within provider availability measures (such as population-to-clinician ratios), which clinicians/providers should be included? How do we define full-time-equivalents (FTEs), as opposed to 'head counts'?"***

Comment: As discussed above, NACHC believes it is vital to ensure that the designation process captures actual (versus apparent) availability and the distinction between access and availability. Accordingly, NACHC urges HRSA to strike the word "availability" and replace it with "accessibility" as well as strike the phrase "as opposed to 'head counts'" in its entirety.

***Question 5: "In counting the clinicians available within an area (or to a population group) for designation update purposes, should those clinicians placed in the designated area under a Federal program be included?"***

Comment: NACHC believes that this question is redundant as it addresses the same issue as Question 4 (namely, *who* is included in the physician count). Accordingly, NACHC recommends deleting the question in its entirety.

***Question 8: "What is the role of Facility designations, which are included under the HPSA authority (in Sec. 332 of the PHS Act)?"***

Comment: As drafted, this question appears to suggest or imply that there is a role for Facility designations. NACHC believes that whether there is a Facility designation role is an issue for the NRM Committee to resolve. Accordingly, NACHC recommends that HRSA re-word this question to read as follows: "Is there a role for Facility designations, and if so what is that role?"

***Question 9: "How should appropriate threshold levels of various underservice/shortage indicators incorporated in the method be identified to separate those areas, population groups and facilities found to qualify for designation from all others?"***

Comment: As drafted, the meaning of this question is unclear and, similar to Question #8, it appears to suggest or imply that there should be separate or distinct levels of underservice/need. NACHC believes that whether there are separate levels is an issue for the NRM Committee to resolve. Accordingly, NACHC recommends that HRSA re-word

this question to read as follows: "Should there be separate or different levels of need, and if so, what's the impact on designations?"

***Question 10: "How can the revised methodology and procedures be designed so as to reduce the burden of the designation application and update process on States and local entities?"***

Comment: As drafted, this question does not get to the fundamental issue of "who controls the process." Accordingly, NACHC recommends that HRSA add the following: "Who is in control of the designation process, states or localities?" and "How should localities be defined?"

***Question 12: "How can the new methodology be implemented in a manner that minimizes disruption and assures equity to the various areas affected?"***

Comment: The purpose of this NRM process is to reconsider the current designation methodologies and to determine whether they are appropriate, in whole or in part, and if not, which methodologies should be utilized. As drafted, however, this question implies that there will be a new methodology. NACHC believes that the consideration of the current versus potential new methodologies is within the purview of the NRM committee – given that no decision has been made on what the final methodology will be, HRSA should remain open to the possibility that the current methodology will not change. Further, NACHC believes that using the phrase "various affected areas" minimizes Congress' concerns for the health care safety net when it explicitly stated that the designation process consider "the impact of the methodology and criteria on communities of various types and on health centers and other safety net providers." Accordingly, NACHC recommends that HRSA re-word this question to read as follows: "If there is a new methodology, how can it be implemented in a manner that minimizes disruption to various types of communities, the health care safety net, and access for patients?"

Toward that end, NACHC continues to believe that the MUA/MUP designation process should exist to identify communities that either lack a health center or lack a sufficient number of health centers, but not to determine whether existing health centers should be able to continue receiving funding or other benefits. Instead, existing health centers should not be subject to MUA/MUP designations once they are operational, but rather should be expected to justify continued federal support by demonstrating that they continue to serve a population or populations in need within their service or catchment areas (by means of the reporting that they are required to file annually on the demographics and health needs/status of those they serve). If existing health centers wish to reach out and serve new communities or populations, then the MUA/MUP designation process could be used to determine whether those new areas/populations are indeed eligible for a health center expansion.

***(3) Whether HRSA has identified appropriate representatives of the various stakeholders/interests that will be affected by the final designation rules?***

NACHC commends HRSA for developing a comprehensive list of proposed Committee participants representing various stakeholders and interested parties. (See Section III of the Notice<sup>9</sup>). However, NACHC believes that by not including "health centers" explicitly, there is a

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<sup>9</sup> 75 Fed Reg. 26167 at p. 26169.

glaring omission which requires modification. The PPACA indicates that the Secretary should consult with relevant stakeholders, including, among others, "national, State and regional organizations representing affected entities, State health offices, community organizations, health centers ...." (emphasis added). This statutory language clearly demonstrates Congress' intent to include on the Committee both representative organizations as well as health centers themselves. Further, as front-line providers furnishing services in designated areas, NACHC believes it is imperative to include health centers representing different geographic/regional areas. Accordingly, NACHC requests that HRSA explicitly include "health centers" in the list of Committee participants, and suggests that at least two health center representatives be appointed to the Committee, one representing an urban health center and one a rural health center.

NACHC also suggests that HRSA increase the number of Primary Care Association (PCA) participants from three to four. We believe this increase is important to allow HRSA to assure that there is one PCA from each of the following population categories: urban, rural, mixed urban and rural, and frontier.

NACHC is concerned that the participant groups listed do not include representation from organizations that represent those populations that have particular difficulty accessing health care services. Consequently, NACHC suggests that HRSA add to the list of participants a stakeholder from an African-American organization (such as the NAACP or the Urban League), a Hispanic organization (such as the National Council of La Raza) and an Asian and Pacific Islander organization (such as the Association of Asian and Pacific Community Health Organizations). In addition, to the extent that the process resulting from the NRM would impact two key populations that currently have their own statutory population designation – the homeless and migrant/seasonal farmworkers – then we would also recommend the addition of representatives from organizations that represent those populations.

### **Designation of the NACHC Representative and Alternate**

We appreciate HRSA's proposal to include NACHC as a participant in the NRM Committee and look forward to such participation. To this end, we nominate as our representative Mr. Daniel Hawkins, Senior Vice President of NACHC's Public Policy and Research Division. Mr. Hawkins directs NACHC's overall policy agenda and strategies, policy-related research and data analysis, and oversees the association's information dissemination and technical assistance activities, as well as collaborative training programs between NACHC and PCAs.

We understand that each NRM Committee participant may also designate an alternate to assist the identified representative, or Lead Member (Mr. Hawkins). Given the breadth of the issues to be discussed at the various meetings, NACHC requests the ability to appoint more than one alternate, one of whom will attend each meeting with Mr. Hawkins, rotating their participation based upon their expertise and how it relates to the specific agenda discussed at that particular meeting.

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## **Conclusion**

Thank you for the opportunity to respond to the above-referenced notice soliciting comments on HRSA's intent to establish a NRM Committee in order to establish a methodology and criteria for designating MUPs and HPSAs. We look forward to the opportunity to serve as a negotiation participant during the upcoming year. 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).

Sincerely,

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  
Associate Vice President of Executive Branch Liaison