

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS (NACHC)

Summary of Proposed Rule on Designation of Medically Underserved Populations and Health Professional Shortage Areas:

73 Fed. Reg. 11232, et seq (February 29, 2008)

Overview

The current notice of proposed rule-making (NPRM) is the second proposal to revise and consolidate the methodology and process for designating medically underserved areas and populations (MUAs and MUPs) and area, population group and facility health professional shortage areas (HPSAs). While it combines the designation process, the proposed rule does not combine the designations themselves – they will remain separate.

In general, the proposed rule is a vast improvement over the first NPRM (NPRM1) as well as the current designation methodology. HRSA estimates that, under both the current formula and NPRM1, approximately ½ to two-thirds of the current unduplicated HPSAs/MUAs would have lost their designations. Under the proposed rule, those numbers improve dramatically – close to 90% of geographic areas and low-income population groups will retain their unduplicated HPSA/MUA designations. Further, for those designations lost under the proposed methodology, the proposed rule includes a new “safety-net” facility designation, which qualifies for facility designations those organizations that meet the “safety-net facility” requirements because the patient populations they serve meet a minimum percentage of Medicaid-eligible and/or low-income uninsured.

The methodology in NPRM1 appeared to have a disproportionate negative impact on rural and frontier areas, a situation which has been rectified by the proposed rule. Further, the proposed rule encompasses 3 methods (in descending order) to obtain designation: (1) geographic area designation based on national data; (2) population group designation (MUPs) within those areas that do not meet the area designation criteria; and (3) the new safety-net facility HPSA designation discussed above. During each stage, national data can be supplemented by data that is more up-to-date and/or accurate, both from the state and local levels.

Despite these improvements, it appears that health centers did not fare as well under the proposed methodology as other organizations, in particular rural health centers, which retain 94% of their designations. Estimates show that nearly 180 health centers will lose their geographic area and/or population group designations – still an unreasonably high number. While more than likely those centers could qualify for “safety-net” facility designations, there are outstanding questions regarding the scope of the safety-net facility designation as well as the criteria used to qualify.

Further, in resolving NPRM1’s disproportionate negative impact on rural and frontier areas, the proposed rule appears to have replaced it with a disproportionate negative impact on metropolitan areas. Finally, a key component of the designation process is the defining of

rational service areas (RSA) by each state. While the proposed rule permits service areas to be re-configured, consistent with rational service area (RSA) parameters, the state role has not yet been clarified with respect to the level of involvement of relevant stakeholders and local individual communities.

The summary below outlines the key provisions of the proposed rule and provides a more in-depth analysis of the concerns noted above, as well as other preliminary considerations.

Comment Submission Date – April 29, 2008¹

The Designation Process

- **Goals**
 - To establish a uniform HPSA and MUA designation process and criteria.
 - To enable greater universal application by using national data, thus reducing the need for independent data collection (state/local data and population group data can be submitted if national data does not result in designation).
 - To automate the scoring process, thus minimizing state and local efforts in gathering data and updating designations.
 - To expand the state role in defining rational service areas and identifying underserved populations and unusual local conditions.
 - To reduce the need for population group designations, which typically are more resource-intensive, by adjusting an area's base ratio, which should increase the designation of areas with concentrations of underserved populations.

- **Additional key elements**
 - Proposed procedures for processing designation/withdrawal requests – the proposed procedure to request designation (and withdrawal of designation) is similar to the current HPSA designation procedure, adding in consultation and comment requirements from the current MUP process. According to the preamble to the proposed rule, the proposed procedures involve an interactive process between DHHS, the state and individual applicants, and provide various stakeholders (including state, city and county health agencies and officials, and State Primary Care Associations) with opportunities to comment on designation requests (see page 11248). The proposed procedure applies to the designation of primary care HPSAs, as well as dental and mental health HPSAs, although new criteria for these last two have not been proposed. (The proposed rule abolishes podiatry, vision care, pharmacy and veterinary care HPSAs in their entirety).

¹ Given the complexity of the proposed rule (as evidenced by the length of time between the first NPRM in 1998-99 and the publication of this proposed rule), NACHC believes that the current comment period of sixty (60) days is insufficient and inadequate to conduct a thorough review and analysis of the rule's methodology and its impact on specific communities. Accordingly, NACHC has requested an extension of the comment period from 60 days to between 120 – 150 days.

- Proposed procedures to transition current designations – the new criteria will be phased in over 3 years from the date that the final rule is published.
 - The oldest MUA/HPSA designations will be reviewed first, but the state will have input into the review schedule.
 - An existing designation will remain in effect until it is reviewed.
 - States will be afforded opportunities to comment on the adjusted population-to-provider ratios, including the effects on communities (as well as comments by the affected entities), and to provide recommendations to resolve overlapping boundaries between existing MUAs/HPSAs and correct inaccurate data that was used in the calculation.

- Continuation of the automatic facility HPSA designations – the proposed rule recognizes the automatic facility HPSA designation for FQHC sites and provides for continued automatic designation of those facilities that, after publication of the new criteria, are not covered by another HPSA /MUA designation. It also reiterates the current statutory language that requires sites designated through the automatic process to demonstrate that they meet the new designation criteria 6 years after the automatic designation. (Note: NACHC proposed legislation would extend auto HPSAs permanently and eliminate the 6 year limit).

- Clinician counts – as described above, the proposed rule excludes certain PCPs from the FTE count in determining whether an area will receive a Tier 1 or a Tier 2 designation. Further, the proposed rule allows midlevel practitioners to be included in the count as .5 FTE or a different weight based on his/her scope of practice in the state.

- Designation of a geographic area as a HPSA/MUA – to be designated as a geographic area HPSA/MUA, an area must: (1) meet the requirements to be a rational service area; and (2) have an adjusted population-to-provider ratio equal to or greater than 3000:1 (a detailed explanation of the calculation for this ratio is described below). Unlike the current designation process, the proposed process does not require all designation requests to include a demonstration that the resources in all contiguous areas are excessively distant, over-utilized, or otherwise inaccessible for the population. Rather, an analysis and consideration of contiguous area resources will be required only if: (1) the state does not have a system of RSAs or has a partially developed system which does not include all areas contiguous to the requested area; and (2) the population center for the requested area is less than 30 minutes from the nearest providers.

- Additional designations – for those areas that do not qualify as geographic area HPSAs/MUAs, the proposed rule provides for 2 additional options for designation:
 - Population group designations (MUPs) within those areas that did not meet the area designation criteria; and

- New safety-net facility HPSA designation for organizations that meet the requirements for “safety-net facilities” because the patient populations they serve meet a minimum percentage of Medicaid-eligible and/or low-income uninsured patients. The proposed rule notes that the population group of uninsured and Medicaid-eligible patients served by an FQHC with a safety-net facility designation will be considered a MUP.

- *Preliminary concerns with the designation process*

State Role in Establishing Rational Service Areas:

- The proposed rule encourages states to develop state-wide systems which divide the territory into “rational services areas.” This approach raises a fundamental question as to whether and to what extent existing service areas will be modified or otherwise impacted.
- The proposed rule addresses parameters for defining a RSA, but does not address: (1) the manner by which states would manage this process (deferring to the state plan); or (2) the extent to which individual communities will have input into the process and/or flexibility to request modifications to state determinations from the federal government.
- The preamble to the proposed rule indicates that the proposed approach to developing RSAs “seeks to foster an increased partnership between the various levels of government involved in designation, including a significantly larger [S]tate and local role in defining services areas,” and encourages states to develop these state-wide systems of RSAs with community input (see pages 11236, 11249). However, the proposed rule itself does not explicitly require consultation with and input from stakeholders, including PCAs, PCOs, and the communities themselves. While consultation with communities and other stakeholders may be implied (based on the preamble language), the proposed rule requires that the state-wide system of RSAs be developed “in consultation with [DHHS] and be approved by the State health department (or other designee of the Governor).”

Further, the proposed rule explicitly requires input from “affected community officials/stakeholders” only if the state intends to define RSA parameters using criteria that differs from the general RSA criteria specified in the proposed rule.

- “Travel time” is used as a measure to determine whether the RSA is appropriate to ensure accessibility of services to the population; however, using travel time as a measure may be problematic for rural areas which lack public transportation and whose residents may not have private transportation.

Automatic Facility Designations – presently, the automatic facility HPSA designation for FQHC sites requires that 6 years from the date of automatic designation, the FQHC must demonstrate that it meets the then current designation rules to maintain the designation. However, it is anticipated that the upcoming reauthorization bill

removes this language. Similarly, this language should be struck from the applicable section of the proposed rule that addresses the designation procedure (§ 5.6).

Safety-Net Facility Designations

- The proposed rule provides for facility HPSA designations for facilities that qualify as “safety-net facilities” (§ 5.301). The rule specifically mentions FQHCs as entities eligible for this designation if they serve a minimum percentage of low-income uninsured and Medicaid eligible patients. Specifically:
 - For metropolitan areas, at least 40% of the patients served must be either Medicaid-eligible or uninsured.
 - For rural, no-frontier areas, at least 30% of the patients served must be either Medicaid-eligible or uninsured.
 - For frontier areas, at least 20% of the patients served must be either Medicaid-eligible or uninsured.

Given the scarcity of health care resources in frontier and rural areas, it is more likely for health centers located in those areas to serve the entire community, representing a wide cross-section of payor source and insurance status. However, the 20% difference between frontier area and urban areas appears to be excessive, even taking into consideration the availability of other health care resources (or lack thereof). While there are often more provider resources in urban/metropolitan areas where medical colleges and major hospitals may be located and to which private physicians are attracted, many of these resources are in fact not available to low-income individuals and families without insurance, or their insurance requires high deductibles and high co-pays to be paid at time of service, and many providers refuse to serve Medicaid patients.

- The proposed rule indicates that the population group of uninsured and Medicaid-eligible patients served by an FQHC with a ‘safety-net facility HPSA’ will be considered a MUP. Modification is required to clarify and specifically state that the entire population served by the health center, consistent with the health center’s approved scope of federal project, will be designated as a MUP, not just the uninsured and Medicaid population as the language of the proposed rule seems to state. Further, clarification is required as to whether the Safety Net Facility HPSA/MUP is considered a Tier 1 or Tier 2 designation and, if it is a Tier 2 designation, would the health center be excluded from participating in any expansion funding (Additional explanation of and concerns regarding the Two-Tier designation system can be found below).

Review of Existing Designations

- According to HRSA’s estimates, the expected impact of the proposed methodology is a significant improvement from the expected impact of NPRM1 (see pages 11253-56). When adding together the estimated number of geographic areas and low-income population groups that will retain designation under the proposed methodology:

- Approximately 92% of the total current HPSAs will retain their designations (as opposed to 29% under NPRM1).
- Approximately 87% of the total current MUAs will retain their designations (as opposed to 70% under NPRM1).
- Approximately 87% of the “total” unduplicated HPSAs/MUAs will retain their designations (as opposed to 67% under NPRM1).
- Approximately 88% of the “health center only” unduplicated HPSAs/MUAs will retain their designations (as opposed to 76% under NPRM1).

As noted above, on their face, these percentages are a vast improvement over the expected impact of NPRM1. However, when you look more closely at the percentages of unduplicated HPSAs/MUAs, the improvement for “health center only” is not as great as the improvement for “total.” In particular, while the percentage of “total” unduplicated HPSAs/MUAs that will retain their designations increases from 67% to 87%, the percentage of “health center only” unduplicated HPSAs/MUAs increases from 76% to 88%. Further, 94% of the “rural health center only” unduplicated HPSAs/MUAs will retain their designations under the proposed methodology.

Apparently, while experiencing some improvement, health centers did not fair as well under the proposed methodology as other organizations. Further, based on the numbers above, the 12% of the “health center only” unduplicated HPSAs/MUAs that will lose their geographic area and/or population group designations represents 176 health centers – still an unreasonably high number.

Those health centers which are unable to retain their geographic area and/or population group designations under the proposed methodology can still qualify for automatic facility designation for HPSA purposes and may qualify for safety-net facility designation. However, as noted above, there are outstanding questions regarding the scope of the safety-net facility designation as well as the criteria used to qualify. Further, given that Section 330 funding is awarded to entities with approved scopes of project, it is unclear whether a safety-net facility designation would encompass the health center’s entire scope of project (and, if not, whether the health center would be required to qualify separately each of its facilities, on a facility-by-facility basis).

The actual impact of the proposed rule on health centers can only be gauged by reviewing current HPSAs/MUAs with health centers located in or serving them. Given that local communities, PCAs, NACHC, and public officials would want to know specific impact on communities for their constituencies, obtaining a list from HRSA of the impacted communities and health centers would be time-saving and cost-effective (as opposed to each of these groups attempting to calculate the data itself). To date, HRSA has not supplied such list.

Negative Impact on Urban Areas

- There were many questions regarding whether the methodology set forth in NPRM1 had a disproportionate negative impact on rural and frontier areas and populations. The proposed methodology apparently rectifies that situation.

However, the proposed methodology appears to have a greater negative impact on metropolitan/urban areas and populations than on rural and frontier areas/populations. When calculating the number of areas that will retain their designations through both the geographic area and the population group methodologies, the negative impact on rural and frontier areas and populations is negligible (almost 100% of those areas retain their designations). However, only 82% of metropolitan areas and 81% of metropolitan populations will retain their HPSA/MUA designations (see page 11258). While it is important to correct any disproportionate impact on rural/frontier areas presented by NPRM1, maintaining similar outcomes for metropolitan areas/populations should be equally important.

Definition of “Medical Facility” – the definition in § 5.2(i) refers to the old FQHC definition in Section 1861(aa)(4) of the Social Security Act, which excludes HCH programs. The proposed rules should be modified to reflect the current definition, which no longer includes the exclusion of HCH programs.

Methodology to determine the population-to-provider ratio

- **Goals**
 - To simplify the process so that it is understandable and usable.
 - To make the process intuitive, with face validity.
 - To incorporate better measures of health status and access.
 - To utilize scientifically recognized methods which can be replicated – “weighting” of variables based on verifiable statistical relationships.
 - To minimize disruption of existing designations while focusing designations to more needy areas and populations.
 - To perform better than the current system by fairly and consistently identifying places and persons in need of services that face barriers to meeting those needs.
- **Conceptual framework**
 - Determine the level of “effective need” in an area by adjusting the “barrier-free” utilization rate using community characteristics that, due to barriers to care, result in (1) an initial reduction (delay) in utilization (and thus an understatement of demand for health care services); and (2) a subsequent increase in utilization when the patient can no longer delay care.
 - Compare the effective need to the available supply of primary care providers in that area to determine the adjusted population-to-provider ratio.
- **Six steps**
 - Calculate the “effective barrier free population” – the utilization rate of the population if it did not have any barriers to care, adjusted for age and gender.

- Calculate the actual number of FTE primary care providers – include all PCPs (physicians, NPs, PAs, CNMs).
- Calculate the base population-to-provider ratio (the proxy for need for services) – divide the effective barrier-free population by the number of FTE PCPs.
- Adjust the base population-to-provider ratio for community characteristics that impact available resources – develop “weighted scores” based on 9 variables which, due to barriers to care, indicate a greater need for services but a lower utilization rate than the average “barrier-free” population; add the resulting scores to the base ratio to derive the adjusted population-to-provider ratio (the proxy for the relative need for services in the area). Eight of the variables are grouped into 3 categories, as follows:
 - Demographic variables
 - Percent of non-white (NONWHITE)
 - Percent of Hispanic (HISPANIC)
 - Percent of population greater than 65 years (ELDERLY)
 - Economic variables
 - Percent of population earning less than 200% of FPL (POVERTY)
 - Unemployment rate (UNEMPLOYMENT)
 - Health status variables
 - Actual/expected death rate (SMR)
 - Low birth weight rate (LBW)
 - Infant mortality rate (IMR)

The ninth variable is “Population Density (DENSITY),” which is a measure of the market potential for an area as well as an indicator of the rural or urban character of a place.

- Determine if the adjusted ratio is greater than the threshold for under-service – compare the adjusted population-to-provider ratio to the predetermined threshold ratio of under-service (proposed at 3000:1).
- Determine tiers of shortages – remove the number of federally-sponsored PCPs (NHSC personnel, providers obligated under State Loan Repayment Program, physicians working under J-1 visa waivers, all other PCPs providing services at Section 330-supported health centers) from the total number of FTE PCPs.
 - Tier 1 designation – areas that continue to exceed the threshold even when all federally-sponsored PCPs are included.
 - Tier 2 designation – areas that exceed the threshold only when the federally-sponsored PCPs are excluded.
- ***Preliminary concerns with the proposed methodology***

Under-Service Threshold Score

- The threshold population-to-provider ratio has not changed from the ratio set forth in NPRM1 – 3000:1 – despite concerns that the threshold was too high, which were expressed by the planning committee nine years ago, by current reviewers, and acknowledged in the rule itself.
- HRSA stated that it considers 3000:1 an appropriate benchmark because it is twice the ratio of 1500:1, which has been determined through various means to represent a reasonable level of appropriate care. However:
 - If 1500:1 is a “reasonable” level of care, why is it appropriate to require a benchmark twice that number to determine that under-service is present?
 - To ensure that unmet need is properly addressed, wouldn’t it be more appropriate to use a benchmark closer to the “reasonable” level of 1500:1 (*e.g.*, 2000:1)?

More than likely, using such a conservative threshold will understate the amount of unmet need, in some communities significantly.

Two-Tier Designation System

- The proposed rule indicates that both Tier 1 designations (areas that exceed the 3000:1 threshold when all federally-sponsored PCPs are counted) and Tier 2 designations (areas that exceed the threshold only when the federally-sponsored PCPs are excluded) would be eligible for resources under federal programs that utilize HPSA/MUA designations. However, it also indicates that while Tier 1 areas would be eligible for additional resources, Tier 2 areas would typically be eligible only to maintain the existing level of resources.
- Given that all PCPs providing services at Section 330-supported health centers are considered federally-sponsored and, thus, excluded from the total PCP calculation to determine whether an area is Tier 1 or Tier 2, several questions arise:
 - Would this result in the designation of a significant number of areas with one or more health centers as Tier 2, thus negatively impacting those health centers’ ability to access new resources?
 - Would this result in Tier 2 designation for all FQHC facility HPSA designations, thus impacting the ability of health centers that do not qualify for another HPSA designation to access new resources?
 - If the answers to these questions are “yes,” such limitations on a health center’s ability to access additional resources appears to be wholly inconsistent with the goal of growing and expanding health centers.

NOTE: The preamble states that DHHS will include in total FTE calculations the number of NHSC and Section 330 health center practitioners already allocated or funded when making decisions regarding the allocation of additional NHSC and health center funds; however, that is not mentioned in the rule itself.

Community Variables

- In theory, the “weighting” of scores based on community variables that impact the availability of resources should accurately adjust the need for services. However, by limiting the health status variables to the 3 that are noted above and not permitting individual communities to use health status variables which could have a greater impact based on their specific populations, the proposed methodology does not sufficiently consider the differences among health centers and their populations.
- HRSA indicated that certain variables were not used because the data was not available in small areas (or in all states). However, given the time that has elapsed since the initial determination of variables and advances that may have occurred in data collection during that time period, a question arises as to whether such justifications still hold true.