



**Geiger Gibson Program/  
RCHN Community Health Foundation Research Collaborative**

**Issue Brief #5**

**Designation of Medically Underserved and Health Professional Shortage Areas:  
Analysis of the Public Comments on the Withdrawn Proposed Regulation**

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*Emily Jones, PhD (cand.)  
Leighton Ku, PhD, MPH  
Joseph Lippi, BA  
Ramona Whittington, MPH  
Sara Rosenbaum, JD*

## Executive Summary

In February 2008, the Health Resources and Services Administration (HRSA) proposed new regulations that would have modified and combined the Health Professional Shortage Area (HPSA) and Medically Underserved Area/Population (MUA/P) designation processes.<sup>1</sup> The comment period was extended twice in response to the large volume of comments, through June 30th. On July 23rd, HRSA effectively withdrew the proposed rule, announcing that in light of its preliminary review of comments, the agency had elected to develop a new proposal.<sup>2</sup> This Research Brief highlights some of the salient issues surrounding the proposed rule, based on an analysis of the public comments by researchers at the George Washington University School of Public Health and Health Services and the RCHN Community Health Foundation.<sup>3</sup>

Of the total 725 comments filed, 205 comments were received prior to the end of the first comment period (April 29, 2008), while the majority - 520 - were received subsequent to the extension of the initial comment period. Analysis of the comments underscores that opposition was broad, particularly once the comment period was extended and commenters had the opportunity to offer specific analysis beyond a simple extension request. Seventy-eight percent of post-extension commenters specifically recommended that the regulation be withdrawn and/or recommended increased stakeholder involvement in the rulemaking.

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<sup>1</sup> 73 FR 11232 (February 29, 2008).

<sup>2</sup> 73 FR 42743 (July 23, 2008).

<sup>3</sup> For more detail about the proposed rule, see: Shin, P., Ku, L., Jones, E., and Rosenbaum, S. [Analysis of the Proposed Rule on Designation of Medically Underserved Populations and Health Professional Shortage Areas](#). Geiger Gibson/RCHN Community Health Foundation Research Collaborative. Research Brief #2. April 2008, revised May 2008.

The comments that addressed the merits of the proposed rule, rather than merely seeking its withdrawal, expressed a series of concerns:

- The absence of a collaborative stakeholder process related to a fundamental health planning tool;
- Concern about the complexity of the regulation and the lack of access to critical data needed to complete the designation process;
- Extensive uncertainty about the policy implications of the proposed changes for health center grant eligibility, rural health clinic designation status, the assignment of National Health Service Corps professionals, and other resources;
- Uncertainty over the meaning of the “safety net facility” designation; and
- Concern regarding the use of a 3000:1 provider-to-population designation standard as too restrictive in relation to applicable standards of care. The use of a provider supply designation as a minimum criterion, even when adjusted as the proposal attempted for need and access barriers, effectively eliminates the statutory concept of medical underservice.

Ultimately, these designations are important in addressing ways to bolster the health care safety net. It is important to note, though, that while a shortage of primary care providers is one manifestation of problems in the safety net, there are also other important issues such as health care access, insurance coverage, and the incidence of disease. It is to HRSA’s credit that the agency made the difficult decision to withdraw the proposal in light of the substantial amount of concern found in the public comments. The agency should consider the process of developing a new proposal as an opportunity to engage with stakeholders to find the optimal way of designating medically underserved or provider shortage areas.

Our review of the comments suggests that while redesigning the regulation, the agency should:

- Consider engaging stakeholders through a more formal engagement process;
- Provide a complete explanation of the policy effects of any proposed changes;
- Develop specific approaches to designating communities experiencing medical underservice separately from communities that experience an actual shortage of primary health care professionals; and
- Devise a provider shortage measure that reflects an appropriate standard of care.

## **Introduction**

This analysis is the fifth in a series of research briefs published by the Geiger Gibson/RCHN Foundation Research Collaborative at the George Washington University School of Public Health and Health Services. In this brief we examine the public comments filed with the United States Department of Health and Human Services regarding proposed regulations to revise the method that the agency uses to designate health professional shortage areas and medically underserved areas and populations. These designations are utilized for resource allocation under various federal programs including the community health centers program and the National Health Service Corps; the designations are also critical for purposes of Medicare and Medicaid payment, since both laws provide special payment rules for certain classes of providers located in or serving such areas.

## **Background**

The Health Resources and Services Administration (HRSA) currently utilizes two types of designations to target federal resources for improving access to health care services: the Health Professional Shortage Area (HPSA) and the Medically Underserved Area/Population (MUA/P). The proposal used a single “Index of Primary Care Underservice” (IPCU) to calculate both the HPSA and MUA/P designations. The original notice of proposed rulemaking (NPRM) was issued on February 29, 2008 and comments were requested within 60 days, or before April 29. On April 21, in response to preliminary concerns, HHS extended the comment period another 30 days to May 29, 2008. On June 2, HHS once again extended the comment period another 30 days to June 30, 2008.<sup>4</sup>

On July 23, the proposed rule was withdrawn<sup>5</sup> and HRSA stated that the agency

received many substantive comments on the proposed rule...Based on a preliminary review of the comments, it appears that HRSA will need to make a number of changes in the proposed rule.<sup>6</sup>

This NPRM was the second consecutive time that a proposed change to the designation process was withdrawn. A 1994 GAO report criticized the current designation process and recommended that MUA and HPSA designations be eliminated as requirements for participation in federal programs and replaced by criteria for inclusion that are more tailored to the goals of each program.<sup>7</sup> In response to mounting momentum for change, HRSA released an NPRM on September 1, 1998 which would have unified the designation process. However, analyses indicated that it would result in a very large number and proportion of providers, especially rural providers, losing their MUA/P and HPSA designations.<sup>8</sup> Over 800 public comments were received, expressing concerns about the loss of up to half of then-current designations, the failure

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<sup>4</sup> Health Resources and Services Administration. “Proposed Rule: Designation of Medically Underserved Populations and Health Professional Shortage Areas.” <http://www.bhpr.hrsa.gov/shortage/proposedrule/>

<sup>5</sup> 73 FR 42743 (July 23, 2008).

<sup>6</sup> Ibid.

<sup>7</sup> Government Accountability Office. “Health Care Shortage Areas: Designations Not a Useful Tool for Directing Resources at the Underserved.” GAO/HEHS-95-200, September 1995.

<sup>8</sup> Goldsmith, L., Holmes, M., Osterman, J., and Ricketts, T. “A Proposal for a Method to Designate Communities as Underserved: Technical Report on the Derivation of Weights.” Department of Health and Human Services. Included as an appendix in the Feb. 29, 2008 notice of proposed rulemaking.

of the methodology to reflect a coherent theory of underservice and access, and the use of old data. HRSA withdrew the proposed rule, but maintained a commitment to improve the designation process.<sup>9</sup>

Changes to the designation process are likely to have tremendous implications for the health care safety net. More than 34 federal programs depend on these shortage designations for the determination of program eligibility and funding.<sup>10</sup> For example, HPSA designations are used to identify areas with an inadequate supply of primary care providers. Among other uses, the designation is used to assign National Health Service Corps clinicians, determine which rural clinics and physician practices count as federally-qualified rural health clinics eligible for enhanced Medicare and Medicaid payments, and identify areas in which foreign trained doctors may practice with J-1 visas. In FY 2005, almost \$3 billion in federal funds was dispensed through programs that use the HPSA or MUA system to determine eligibility, and these designations are used by states as well.<sup>11</sup>

Under federal law, community health centers (CHCs) must be located in areas designated as medically underserved, which include areas identified as HPSAs. The medical underservice designation standard is broader than just a measure of health professional shortage, instead encompassing communities and populations whose combined health status and limited access to care create a risk of medical underservice on a community- or population-wide basis. Thus, many health centers are located in geographic areas that technically have an adequate supply of physicians but where access to care is barred by high poverty, cultural isolation, and reliance on Medicaid, a payer which is increasingly not accepted in private practice.<sup>12</sup>

Clearly, designation as a shortage area or medically underserved community is vital to the allocation of resources. The dual designation process has worked well: between 1985 and 2007, the number of federally funded health center sites increased from 1,015 to over 6,672, and the number of patients served increased from five million to 16 million.<sup>13</sup> These patients depend on the already-strained safety net for care, and a reduction in funding due to the proposed designation methodology changes has significant implications for the communities and populations that receive services.

The proposed HRSA regulation would have effectively eliminated the medical underservice designation, relegating the health care providers in medically underserved communities without extensive provider shortages (the agency proposed using a high 3000:1 provider to population ratio) to no formal status other than the ill-defined “safety net” facility designation. The proposed regulations also failed to extend protection of Rural Health Clinic (RHC) designation or Medicare fee enhancement qualifications to physician practices and RHCs that serve areas without a formal, steep supply shortage.

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<sup>9</sup> Ricketts, T., Goldsmith, L., Holmes, G., Randolph, R., Lee, R., Taylor, D., and Osterman, J. 2007. “Designating Places and Populations as Medically Underserved: A Proposal for a New Approach.” *Journal of Health Care for the Poor and Underserved* 18: 567-589.

<sup>10</sup> Government Accountability Office. October 2006. “Health Professional Shortage Areas: Problems Remain with Primary Care Shortage Area Designation System.” GAO-07-84.

<sup>11</sup> Ibid.

<sup>12</sup> GAO/HEHS-95-200.

<sup>13</sup> Uniform Data System data, HRSA.

## **Methods and Limitations**

Our analysis is based on a review of public comments to the NPRM which were posted on the federal website, [www.regulations.gov](http://www.regulations.gov), as of August 4, 2008, when HHS staff stated that there were few, if any, outstanding comments.<sup>14</sup> As of August 4, a total of 803 comments were posted on the website; those that were mailed or faxed were then scanned and posted.<sup>15</sup> All of the comments were reviewed and coded in a master database by trained staff of the George Washington University Department of Health Policy or the RCHN Community Health Foundation.

We excluded 78 comments because they were duplicates (the same letter submitted by the same person and posted on the website more than once) or could not be read because the attachment was missing or unreadable. Each non-duplicate comment was counted separately, and after these exclusions, 725 comments remained for analysis. Some letters had multiple signatories, so the total number of individuals or organizations expressing views is larger than 725. There were also a limited number of comments based on form letters, where the same (or very similar) comments were submitted by multiple people within an organization, most often by community health centers or other providers. We counted each of these as a separate comment since they were signed by different people.<sup>16</sup>

The coding was spot-checked for consistency and recoded as necessary, and about two-thirds of the comments were read by a single reviewer to improve consistency of coding. Nonetheless, there is likely some inconsistency in coding across reviewers or across comments. For example, it is relatively easy to determine when a commenter has specifically requested withdrawal of the regulation, but it may be harder to decide how to classify a commenter as expressing general opposition to the NPRM versus taking a neutral stance or even supporting it, with major modifications. Coders took a conservative approach in classifying comments as either opposing or supporting the proposed rule; when no overall opinion was expressed, even if there were several pages of suggestions, the letter was coded as neutral overall.

## **Results**

### **1. Overview**

Overall, more than half of the 725 comments (52 percent) oppose the proposed regulation; only 6 percent express explicit support for the proposal, including supporters who condition their support on the adoption of suggested modifications (see Table 1). The remaining comments did

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<sup>14</sup> At least five additional comments were posted on or after August 15, 2008; at least one of these is a duplicate. These comments are not included in this analysis.

<sup>15</sup> Despite HRSA's policy of posting all comment letters, some comments may not have been counted or included. For example, we received copies (through separate channels) of a May 23 letter signed by 26 U.S. Senators and a May 29 letter signed by the governor of Washington state that were not posted on the federal website. In order to be consistent in our methodology, we did not use these comment letters in our analysis.

<sup>16</sup> There were many form letters, which is not uncommon in public comments for this type of rulemaking.

not express clear support or opposition for the overall proposal, although they offered comments on specific aspects of the rules.

<b>Table 1: Summary of Comments Generally Supporting or Opposing Proposal by Date</b>			
	<b>Percent of Comments</b>		
	<b>Before April 29 (520)</b>	<b>After April 29 (205)</b>	<b>All Comments (725)</b>
<b>Oppose or Support Proposal</b>			
Oppose proposal	21%	63%	<b>52%</b>
Support proposal (as is or with modest changes)	1	8	<b>6</b>
<b>Request for Additional Time or Modifications</b>			
HRSA should withdraw the proposed regulation	1	44	<b>32</b>
Extend comment period	84	5	<b>27</b>
Increase stakeholder involvement in developing a new proposal	1	34	<b>25</b>

Within the 6 percent of comments that expressed support, only 12 comments explicitly supported the proposed rule with no changes; 10 of these comments were based on a form letter described below. Other supporters of the proposed rule consistently made suggestions on how to improve the proposed rule.

One in three comments (32 percent) suggested withdrawing the rule. One in four comments (25 percent) requested that stakeholders become part of the rulemaking process.

## 2. The Significance of Pre - and Post - Extension Time Periods in Relation to the Comments

Because the NPRM revised its due date for comments two additional times beyond the original date (April 29), the substance of the comments varies by when they were submitted. For most of this analysis, we group the comments by date, since most letters submitted before the original due date of April 29 are simply neutral extension requests that included relatively little other commentary.<sup>17</sup> Comments submitted after April 29 offer more substantive opinions about the proposed rules. Most of the comments (84 percent) sent before April 29 ask for an extension, versus only five percent of post-April comments, and 76 percent of the comments submitted before the original deadline are neutral, with no palpable support or opposition to the proposed rule. In addition, many of those who commented by that date also sent additional comments later, so this analysis focuses primarily on comments received after April 29.

### a. Comments Submitted by April 29

The overwhelming majority (84 percent) of the 205 comments submitted by April 29 request an extension of the comment period. In this initial set of letters, 21 percent express opposition to the NPRM; the majority of the comments are short and neutral, simply requesting more time to analyze the regulations. Of those requesting an extension, most (76 percent) request a 90-day extension (only one comment requested a shorter extension period of 60 days). Ten percent

<sup>17</sup> In some cases, we could not ascertain the date the letter was written and assigned the letters based on when they were posted on [www.regulations.gov](http://www.regulations.gov). If an undated comment was posted after April, as the vast majority of comments were, it was coded as being submitted after April.

request an extension of 120 days, and the remainder either request more than 120 days or do not specify the length of the requested extension.

These early comments do make some substantive comments that foreshadow the large body of substantive comments that follow, particularly:

- difficulty in assessing the impact of the new regulations (41 percent);
- complexity of the proposed regulations (25 percent);
- adverse effects on certain populations (18 percent); and
- problems obtaining the necessary data (17 percent).

Because of these broad concerns, HHS did extend the comment period twice, each time for another 30 days, due to continuing opposition and unresolved issues.

#### *b. Comments submitted after April 29*

Various types of organizations submitted comments after April 29; letters from community health centers and other providers were the most numerous (see Appendix A for analysis by commenter type). The majority of the 520 comments (63 percent) submitted oppose the NPRM, and all but a few include specific suggestions for improvement. The overall position could not be determined for 28 percent of the comments; these comments also offer suggestions, but the author's overall position could not be characterized as either in support of or opposed to the proposed regulation. Only 8 percent of the comments express support for the rule, with a quarter of these supporting the rule in its published form and three quarters offering support contingent on modifications to the NPRM. Ten of the 11 letters that express support without modification (2 percent of all post-April comments) are based on a very short form letter generated by business owners of various types in Arizona; this form letter mentions the advantages of utilizing updated local data as the sole reason to support the proposed rule.

In addition to offering an overall opinion, and specific suggestions regarding the substance of the rule, many commenters offer criticism and express opinions about how the NPRM process should proceed:

- Nearly half (44 percent) of the post-April letters specifically request that the proposed rule be withdrawn (a significant number of additional comments do not specifically request withdrawal, but ask for greater stakeholder input into a new proposal, which implicitly involves withdrawal).<sup>18</sup>
- Over one-third (34 percent) ask that stakeholders be included in the rulemaking process and approximately one in six (14 percent) specifically request that a Negotiated Rulemaking process be pursued.
- About 8 percent also emphasize that the designations should not be recalculated using the old methodology while a new methodology is developed, requesting maintenance of the status quo while a satisfactory replacement methodology is devised. Presumably this recommendation reflects the fact that HRSA has estimated that 50 percent of existing

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<sup>18</sup> Under the Administrative Procedure Act, an agency may not engage in substantive discussions with outside parties about the content of the regulations after the proposal has been issued, so entering into new discussions about the regulations would necessitate withdrawing the existing proposal and beginning the process anew, so that discussion or negotiation precedes a new NPRM.

HPSAs would lose their designation if the older methodology is applied using newer data.<sup>19</sup>

- Despite the first and second extension periods, a number of post-April 29 commenters (5 percent) request an additional extension of the comment period, ranging from 90 to 180 days.

A number of specific themes that emerge from the post-April comments are shown in Table 2. The most salient issue is the difficulty with understanding the impact of the proposed regulation. About a third of respondents commented that the proposal was complex, confusing, or unclear (32 percent) and that it was not possible to assess the expected impact (30 percent). A common theme (33 percent) was that the NPRM failed to explain the policy implications of the change in the methodology and that it was not possible, as a result, to know the policy implications of the changes.

<i>Specific Issue</i>	<b>Percent of Comments</b>
<b>Proposal Difficult to Understand</b>	
Proposal is complex, confusing or unclear	32%
It is not possible to assess the expected impact	30
Need policies on how designations will be used programmatically (e.g., for National Health Service Corps, Medicare payments, etc.)	33
<b>Consequences of the Proposal</b>	
Certain types of communities (e.g., urban, rural, elderly, etc.) could be adversely affected	26
Comment provided state or local impact data	22
<b>General Problem Areas</b>	
Concern about safety net facility designations	35
3000 to 1 population-to-provider ratio is too restrictive	39
Need to exclude additional physicians from provider counts	43
Problems with some of the high need indicators	29
<b>Data Issues</b>	
Unable to get certain types of data (e.g., subcounty data, provider counts) to assess impact	25
Data presented by HRSA are too old	16

Furthermore, 26 percent of all comments are able to identify certain types of communities or vulnerable populations such as the elderly or uninsured that would be adversely affected by the proposed changes. Twenty-two percent of the comments include data on state or local impact.<sup>20</sup>

Over one-third (35 percent) of the comments express concern with the safety net designation category or scoring method. Some of the confusion stems from the preamble in the NPRM stating that facilities designated under the safety net facility designation would not receive any new funding. In addition, the NPRM asks stakeholders to propose a scoring method, rather than providing a methodology. The April 21 extension notice tries to clarify the contradiction by

<sup>19</sup> Responses from HRSA to questions from the Senate Health, Education, Labor and Pensions Committee, May 9, 2008.

<sup>20</sup> HRSA’s analysis of the comments and informal discussions with states indicates that 23 states conducted analyses using state and local data; see footnote 21 on page 10 for more information. Health Resources and Services Administration. “Proposed Rule: Designation of Medically Underserved Populations and Health Professional Shortage Areas.” <http://www.bhpr.hrsa.gov/shortage/proposedrule/>

acknowledging the lack of a proposed scoring method for the safety net facility designation and assuring readers that all designations were equally eligible to apply for funding. The fact that HRSA did not propose a method made it impossible for the public to comment meaningfully on the NPRM, and none of the comments propose a scoring method, even a rudimentary one. Commenters often note the absence of a scoring system and that despite the potential adverse consequences of being relegated to safety net status, HRSA offered no explanation of what such a relegation would mean in terms of funding levels.

Other specific issues identified by commenters included opposition to use of a 3000:1 population-to-primary care provider ratio, which would have become the driving and critical threshold for designation. That is, the NPRM proposed to rely exclusively on actual physician supply rather than a measure that would be sensitive - as is required in the medical underservice statute - to questions of access and health status. Among the commenters, 39 percent identify the approach as too restrictive; several commenters remark that designation should not rest on any fixed supply measure. Many commenters suggest a lower provider-to-patient ratio of 1500:1 or 2000:1, which more closely approximates existing standards of primary health care.

Another commonly cited issue (43 percent of comments) is the manner in which the NPRM would have counted or excluded certain providers in calculating the ratio. The NPRM failed to exclude all physicians who are already engaged in practice where there is a risk of medical underservice in calculating shortages, thereby essentially penalizing communities that, but for the presence of such physicians, would actually experience physician shortages. Specifically, many comments state that physicians at rural health clinics should also be excluded from Tier 2 calculations. Other commenters raised similar concerns with how the NPRM treated nurse practitioners and physician assistants practicing in underserved communities. Still other commenters noted that the NPRM failed to adjust for the existence of primary care health providers that do not treat Medicaid or uninsured patients.

Almost 30 percent (29 percent) of the comments highlighted issues with the manner in which the NPRM proposed to use high need indicators. Some commenters indicated their inability to understand the proposed methodology, while others noted the absence of certain seemingly obvious high need indicators, such as the presence of a high actual or estimated uninsured population. Others suggested the need for a measurement method that would capture information on the presence of historically underserved racial and ethnic minority populations.

In general, problems accessing or generating the necessary data, cited by 24 percent of comments, are often mentioned in connection with both of the above issues: provider counting and the high need indicators. The primary issue is that many states do not have accurate provider counts available. Collecting, analyzing, and reporting data is viewed as a burden; 16 percent of comments state that the rules were too costly or complex to administer. In addition, 16 percent point out that the data presented by HRSA in the NPRM is too old.

Additional issues include a perceived bias against urban or metropolitan regions, cited by 8 percent of comments, particularly because the methodology relied virtually wholly on supply and failed to adjust for the classic indicia of medical underservice as required by law, including the

lack of actual provider access as well as health measures indicating a high level of population health need.

Many comments ask for the establishment of an appeals process, or a way for currently designated health centers to be grandfathered in as safety net facilities to retain their eligibility for funding. Finally, many commenters noted that rational service areas are difficult and burdensome to define.

## **Discussion**

This review suggests several major areas of concern, as well as generally strong opposition to the NPRM, which seems to be consistent with the preliminary analysis conducted by HRSA and noted in its July 23<sup>rd</sup> statement.<sup>21</sup> The main findings are:

- a substantial level of opposition and, at best, confusion surrounding the proposed rule;
- the rule's lack of transparency regarding the policy implications of its proposed formula changes;
- the rule's reliance on a measure of shortage so high as to create a national health planning tool that falls well below the appropriate standard of primary health care; and
- failure of the rule to reflect the statutory measure of medical underservice, to the detriment of historically underserved populations, especially those in urban areas.

Many of the comments are extensive, and the resources that stakeholders expended on responding to this NPRM are a testament to the level of concern. Sixty-three percent of the post-April comments can be easily characterized as opposing the proposal, while only eight percent support the proposal. Almost half of the post-April comments (44 percent) specifically call for withdrawal, and many others implicitly request withdrawal by suggesting that HRSA delay implementation or produce more analysis of the effects before finalizing the rule. The vast majority of the comments offer numerous reasons for opposing the proposed rule; the most important and recurring reasons include insufficient stakeholder involvement, the complexity and opacity of the proposal, the absence of policy explanations, including an explanation of the safety net designation, a 3000:1 population-to-provider ratio that does not satisfy professional standards of care, and problems with how providers would be counted or community need would be measured.

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<sup>21</sup> However, statements on the HRSA website are less consistent with this analysis. The site, touting the virtues of the possible inclusion of state and local data in the proposed methodology, says that of 23 states that conducted their own analysis using state and local data sources, the “consensus is that a large majority of their areas would be retained.” First of all, it is not clear whether the agency is referring to publicly submitted comments or private discussions with states to define the group of states that conducted analysis using their own data and to arrive at this conclusion, and according to our analysis, it is not correct that states do not feel the threat of de-designations. Our analysis is also inconsistent with the next statement on the website, which highlights feedback from states that “the proposed method captured new areas of need better.” This depends on whether the commenter believes that the new methodology captures actual need better than the current HPSA/MUA system, which is not an opinion that was expressed by the majority of states. Health Resources and Services Administration. “Proposed Rule: Designation of Medically Underserved Populations and Health Professional Shortage Areas.” <http://www.bhpr.hrsa.gov/shortage/proposedrule/>

In our view, there are several specific areas of concern that should guide the agency in future efforts to develop a proper designation system.

*1. Involve stakeholders and provide more transparency*

Over a third (34 percent) of post-April comments suggest that stakeholders should be a part of the rulemaking process, and 75 comments (14 percent) specifically suggest a Negotiated Rulemaking process. Input from stakeholders is clearly needed to address technical, and even conceptual, problems.

Stakeholders appear to believe that there was inadequate consultation with them before the proposal was issued. While HRSA (and the University of North Carolina, which served as its technical contractor) met with a number of stakeholders about their approach several years ago, the agency did not maintain lines of communication with a broad set of parties after that time and the proposal puzzled and frustrated many entities that would be directly affected by the outcome. One option is Negotiated Rulemaking, a regulatory approach that involves a formal process for convening a panel of stakeholders to negotiate key elements of a proposal before it is formally proposed. Such a process helps ensure consultation while the proposal is being developed, which increases transparency and buy-in and ultimately enables a more successful rulemaking process. Of course, the public comments submitted after the proposed regulation is issued will always be an important additional source of information for regulators on how stakeholders are affected.

*2. Clarify policy implications, particularly for safety net providers and programs*

Many comments express frustration at the complexity of the proposed regulations and the aspects of implementation that are confusing or unclear. The proposed regulations are quite technical and computationally intensive; although HRSA included some national analyses of the expected impacts, the data used were out-of-date and of marginal help. HRSA tried to be helpful by disseminating a spreadsheet “calculator” that allowed state or local organizations enter local data and determine whether they would meet criteria as a Tier 1 or Tier 2 area. However, there were technical problems and multiple versions of the calculator, so it was difficult for entities to know whether the calculations were correct. There are also concerns about the availability of accurate and current state or local data to use as inputs.

A major concern is that although MUA/P and HPSA designations are used in diverse ways in a number of federal programs, the rules fail to explain how the revised designations would be applied in actual program operations for community health centers, rural health clinics, National Health Service Corps assignments and so forth.

One example of the problem of opacity concerning policy implications involves the so-called “safety net facility” designation, a new designation for health care providers located in areas that did not meet a sufficiently high-need measure related to the shortage of physicians. Analyses by George Washington University indicated that approximately one-third of communities with

health centers would not meet these designations.<sup>22</sup> Furthermore, the regulation's February 29<sup>th</sup> preamble added to this confusion by failing to delineate the extent to which safety net facilities would continue to qualify for resources, and if so, under what circumstances. Further efforts by HRSA to clarify the matter in its April 21<sup>st</sup> notice only added to commenter confusion, particularly because the agency offered no means of scoring relative need among the facilities that fell out of the standard high-need tiers and into the catch-all safety net designation.

### *3. Concerns about the 3000:1 population to provider ratio*

In the proposed regulation, the most important component of the calculations used to designate status is an adjusted population-to-provider ratio. Areas with a final score greater than 3000 would attain Tier 1 or Tier 2 status and areas with lower scores would not receive a high designation. In addition to being at odds with the statutory concept of medical underservice, the 3000:1 ratio raised a series of concerns related to the accessibility and quality of care and to the ability of health centers, the National Health Service Corps, and other programs to realize their statutory mission of reducing disparities in health and health care.

Some are concerned that a simple supply measure of population-to-provider ratio would, alone, become the dominant criterion for designation. For example, many urban areas have a relatively high concentration of physicians, but large numbers of people are unable to receive care from them because community physicians do not serve uninsured or Medicaid patients. Data analysis indicates that urban areas were far less likely to attain Tier 1 or Tier 2 status because of problems like these.<sup>23</sup> These geographic areas may not have a documented physician shortage, but still experience serious problems of medical underservice and limited health care access. The current approach to designating medically underserved areas permits a more flexible approach to incorporating information about medical access and outcomes, as well as the population to provider ratio. Under the new approach, an area with ostensibly adequate physician supply but very low access would not attain high priority status, even if it had high levels of infant mortality, uninsurance or other health problems.

If the HPSA designation methodology is being updated, it is essential to also develop a new index of medical underservice that, either alone or in combination with a measure of provider shortage, would identify communities at high risk for poor health, low access, and health disparities despite an apparently adequate supply of physicians. The purpose of the medical underservice designation is quite different from the purpose of a formula that measures simple physician supply. Thus, in order to remain adherent to the health center statute, the medical underservice phenomenon must be given formal recognition and its own distinct measurement tool.

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<sup>22</sup> Shin, Ku, Jones, and Rosenbaum, 2008a; Shin, P., Ku, L., Jones, E., and Rosenbaum, S. [Grantee-Level Estimates Show that 31 Percent of All Health Centers would Fail to Meet Tier Two Status under HRSA's Proposed MUA/MUP/HPSA Designation Regulations](#). Geiger Gibson/RCHN Community Health Foundation Research Collaborative. Research Brief #3. May 2008.

<sup>23</sup> Shin, Ku, Jones, and Rosenbaum, 2008b.

In addition to the general issue with using a ratio, many comments further expressed that a 3000:1 population-to-provider ratio is simply too high. Given the extensive health needs of health center patients (and in recognition of HRSA's 1996 suggestion that 2000:1 might be more appropriate for rural areas),<sup>24</sup> it is evident that the ratio must be reconsidered to more appropriately reflect current medical practice patterns.<sup>25</sup>

#### *4. Gaining accurate measures of provider availability*

If a population-to-provider ratio is the centerpiece of the proposed methodology, then accurate provider counts are essential. Commenters convey the reality that available data often are outdated and inaccurate, and many providers do not serve uninsured and Medicaid patients but are counted anyway. The burden of collecting and accessing provider data is noted by many commenters. The chief data source is the American Medical Association's (AMA's) physician masterfile, which is often out-of-date and inaccurate in terms of practice address.<sup>26</sup> The data on nurse practitioners appears to be based on point-in-time information collected in 2000. Another issue is the discounting of midlevel providers to 0.5 FTE of a physician. Finally, a common suggestion from rural health clinics is that, like physicians at an FQHC, physicians at rural health centers should be excluded from the provider count to determine Tier 2 designation.

#### *5. Developing high need indicators*

The issue of how to define and measure high need also must receive much closer scrutiny. The comments reflect extensive confusion around this issue, particularly because the NPRM failed to take into account either extensive uninsurance, high health needs, or the lack of access to area providers evidenced by low rates of care for Medicaid and uninsured patients. Although sub-state measures of uninsurance are not currently available, they will be available soon because the Census Bureau's American Community Survey is beginning to ask about insurance status and that survey has a generous sample size that will enable measurement in local areas. In addition, the proposed high need indicators include non-white and Hispanic population measures, but some suggested that other categories, such as Asians, may be appropriate, particularly because of problems of language-related barriers to health access.

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<sup>24</sup> Perlin, J. and Miller, L. et al. "Report of the Primary Care Subcommittee; VHA Physician Productivity and Staffing Advisory Group. Veterans Administration; June 30, 2003; Goodman, D., Fisher, E., Bubolz, T., Mohr, J., Poage, J. and J. Wennberg. 1996. "Benchmarking the U.S. Physician Workforce." *Journal of the American Medical Association* 276(22): 1811-1817 [erratum published in JAMA 1997 277 (12): 966.]; HRSA, Federal Office of Rural Health Policy. "Facts About...Rural Physicians."

[http://www.shepscenter.unc.edu/research\\_programs/rural\\_program/phy.html](http://www.shepscenter.unc.edu/research_programs/rural_program/phy.html); Center for Rural Health, North Dakota. "Health Professional Shortage Areas (HPSAs) and Medically Underserved Areas (MUAs)" <http://ruralhealth.und.edu/pdf/hpsa.pdf>

<sup>25</sup> Burt, C., et al. June 29, 2007. "Ambulatory Medical Care Utilization Estimates for 2005," *Advance Data from Vital and Health Statistics*, No. 388, Centers for Disease Control and Prevention.

<sup>26</sup> Rittenhouse, D., et al. 2004. "No Exit: An Evaluation of Measures of Physician Attrition," *Health Services Research*, 29(5): 1571-88; see also Kletke, P. 2004. "Physician Workforce Data: When the Best is Not Good Enough," *Health Services Research* 29(5): 1251-6.

## *6. Remediating data and methodological problems*

Under the proposed methodology, state or local agencies can use local data for designations, in lieu of national data. But the burden of collecting, analyzing, and reporting this data could be significant for some state agencies or other organizations. One commenter describes this as an “unfunded mandate.” The lack of accurate and timely provider data is the most salient problem, but other types of data issues are also mentioned.

Because health service areas do not necessarily correspond with county lines, it is desirable to have relevant data available at relatively small geographic levels, such as census tract. But the Census Bureau does not plan to collect long form data in 2010, the next decennial census, which is the basis for data for specific, localized geographic areas. The Census Bureau plans to continue to produce census tract level data using multiyear compilations of American Community Survey data, but may suppress estimates in some areas in which the sample size is too small. Thus, census tract level data might not be available for some areas.

## *7. Remediating other problems*

The comments suggest the importance of addressing several other issues, including the lack of an appeals process, the absence of a grandfathering clause so that communities do not lose their health care resources, and the need to more rationally define service areas.

## **Conclusion**

The large volume of public comments demonstrates that there is substantial interest in this issue. While the negative nature of the majority of comments led HRSA to withdraw the regulation, it also represents an important opportunity. In our view, the agency should take this as a signal to reach out to the diverse body of stakeholders and engage them in discussions about how to improve the process of rulemaking and how to improve the designations to better meet the nation’s health needs, rather than just being an obscure exercise in number-crunching. A Negotiated Rulemaking process is one way to develop this broader discussion, but other processes may also be relevant or appropriate.

Those engaged in the next conversation have many specific recommendations to remain aware of as they proceed. More generally, though, the idea of uniting the MUA/P and HPSA designations should be carefully scrutinized. Considering the disparate purposes for which the MUA/P and HPSA designations are used, the two designation types should continue to be calculated in separate ways that better correspond to their programmatic purposes and needs. These designations are an important foundation underlying varied policies that bolster the health care safety net, and it is important to note that a shortage of primary care providers is just one manifestation of community health need. The concept of medical underservice is too valuable to be diluted or overtaken by the concept of provider shortage.

## **Appendix A: Post-April Comments by Commenter Type**

Diverse stakeholders submitted comments after April 29, as shown in Table 3; the mix of commenter types was similar before April 29 but this analysis focuses on post-April comments since they are more substantive. The overall reactions to the proposed rule, as well as the recommendations for moving forward, vary by commenter type.

<b>Organization Type</b>	<b>Number of Comments</b>	<b>Percent Recommending Withdrawal</b>	<b>Percent Recommending Stakeholder Involvement</b>	<b>Percent Opposed</b>	<b>Percent Supporting As-Is or With Modifications</b>
<b>Total – All Types</b>	<b>520</b>	<b>44%</b>	<b>34%</b>	<b>63%</b>	<b>8%</b>
Community health centers	166	52	44	<b>81</b>	<b>1</b>
Primary Care Associations	33	58	45	<b>61</b>	<b>0</b>
Other local health providers	124	31	24	<b>56</b>	<b>7</b>
State or local agencies	65	22	17	<b>37</b>	<b>31</b>
Other state associations	61	74	34	<b>77</b>	<b>2</b>
National health or consumer organizations	39	49	62	<b>56</b>	<b>3</b>
Others	32	28	13	<b>44</b>	<b>25</b>

The largest group of commenters is comprised of community health centers; 166 submitted comments. About half support withdrawal of the regulation and greater involvement of stakeholders in a new proposal (52 and 44 percent, respectively). Four out of five (81 percent) oppose the proposal and only 1 percent support it. Thirty-three comments come from state Primary Care Associations (PCAs), the organizations which represent community health centers in their respective states. A solid majority (58 percent), recommend withdrawal, and almost half also recommend stakeholder involvement (45 percent). More than three out of five PCAs oppose the proposed regulation and none supports it.

A large number (124) of other health providers (e.g., local physicians, hospitals or nurses) also submitted comments. A third (31 percent) support withdrawal and one-fifth want greater stakeholder involvement. A majority (56 percent) oppose the regulation and only 7 percent support it.

Sixty-five state and local public health agencies commented, including state or local health departments, state primary care offices, and governors or county executives. While more than one-third (37 percent) oppose the proposal, almost as many (31 percent) support it, either as-is or with modest modifications. About one-fifth explicitly recommend withdrawal or greater stakeholder involvement (22 and 17 percent, respectively).

State associations, such as state medical, hospital, family physician or nurses associations, submitted 61 comments, or 12 percent of the total, and these are dramatically more negative than average. About three in four (74 percent) recommend withdrawal and 77 percent oppose the proposal; just 2 percent voice support for the proposal.

Thirty-nine national health or consumer organizations submitted comments, including the National Association of Community Health Centers, National Rural Health Association, American Hospital Association, the American Medical Association, American Osteopathic Association, American Nurses Association, American Academy of Physicians Assistants, National Association of Public Hospitals and Health Systems, Association of State and Territorial Health Officers, National Health Care Council for the Homeless, AARP and the National Council for La Raza. Half (49 percent) recommend withdrawal and 62 percent recommend greater stakeholder involvement in another proposal. A modest majority (56 percent) opposes the proposal and three percent support the NPRM.

The balance of comments (32) is from academic health centers, businesses, Congressmen and concerned citizens. Almost half (44 percent) oppose the proposal, while one-quarter (25 percent) support it. One-quarter (28 percent) suggest withdrawal and 13 percent recommend more stakeholder involvement.

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