

Negotiated Rulemaking Committee on the
Designation of Medically Underserved Populations
and Health Professional Shortage Areas

(10/31/11)

Appendices and Addenda

Addenda to the Report

Additional Views of NRM Committee Members

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Additional Views of NRM Committee Members

This addendum, which represents the views of certain members of the Negotiated Rulemaking (NRM) Committee, presents important information in support of several key Committee decisions related to the designation process presented in the full Committee report.

Purpose of the Committee

Before presenting this information, however, it is important to keep in mind the original purpose of the NRM Committee, as established by Congress. In enacting the Patient Protection and Affordable Care Act (PPACA), Congress directed HHS to establish a comprehensive methodology and criteria for designation of Medically Underserved Populations (MUPs) and Health Professional Shortage Areas (HPSAs) utilizing a Negotiated Rulemaking (NRM) process. In doing so, Congress directed that the methodology and criteria should take into account the following factors:

- The timely availability and appropriateness of data used to determine a designation to potential applicants for such designations;
- The impact of the methodology and criteria on communities of various types and on health centers and other safety net providers;
- The degree of ease or difficulty that will face potential applicants for such designations in securing the necessary data; and
- The extent to which the methodology accurately measures various barriers that confront individuals and population groups in seeking health care services.

We believe that the expectation of Congress, as evidenced by the language of the statute, was that the NRM Committee should define methodologies and criteria to identify all areas and populations experiencing either underservice or a shortage of primary care providers and services, and that the issue of resource allocation would be the responsibility of program managers at HRSA, consistent with the manner in which such decisions have been made for the past 35 years. Congress did not direct the Committee to consider the amount or level of available resources which could be allocated to the communities or populations designated in developing the new methodologies and criteria. In fact, the current methodologies do not include an analysis of existing resources. Rather, resource allocation is a separate process determined by the Health Resources and Services Administration (HRSA) in the context of federal resources provided by the Congress, based on various factors including, but not limited to, the extent of shortage and/or underservice in the respective community/population. In this respect, securing a shortage or underservice designation is merely the eligibility threshold which must be met for a community or population to be considered for the placement of federal resources – the designation itself neither directs such placement nor functions as the determinative factor in making resource allocations.

While we respect the few NRM Committee members who voiced a dissenting opinion to the Committee's recommendations, because they believed that the Committee should include a consideration of currently available resources in their decisions, we also believe that their position, while well-meaning, is not only at variance with both the language of the authorizing statute and with prior practice but also with the clear charge to the Committee to establish a methodology which when promulgated as regulation would transcend any particular point in time or level of available resources, and be in place for years to come. In other words, the rule

established by the NRM Committee should stand the test of time; basing it on present circumstances that more than likely will change before the rule is even published stagnates what should otherwise be a dynamic methodology, and makes for less than ideal policy.

Rationale for Specific Provisions

The Committee agreed to use four criteria to guide its development of MUA/P and HPSA designations: the criteria and methodologies should be evidence-based, easy to explain, reasonable, and not harmful to existing safety net providers. We feel the Committee's recommendations met these criteria.

Setting the MUA Designation Threshold at a Meaningful Level

Given the lack of a uniformly agreed-to national definition of "medical underservice," the Committee was tasked with determining a method to identify medically underserved communities. This necessitated recommending an upper limit or threshold by which communities can be designated as underserved, thus becoming eligible for, but not entitled to, federal resources. After much deliberation regarding the point at which the nation's neediest communities would be adequately captured by the designation process, the vast majority of Committee members agreed to a one-third cut off (that is, a threshold under which areas containing one-third of the US. civilian population would qualify). Those communities below the cut off would be deemed designated. It is noteworthy that this newly proposed threshold is more restrictive than the original, and still current, designation threshold (50%).

It is important to note that the awarding of federal resources to address the needs of people living in designated MUA/Ps is based on a *competitive* process that requires applicants to submit extensive documentation of need, as well as other information regarding the applicant's ability to properly utilize the resources in question and its compliance with numerous programmatic requirements. Thus, securing an MUA/P designation is merely the initial step necessary to apply for federal resources, but it does not, in itself, determine whether resources will be awarded nor the extent of such resources. HRSA has effectively managed dozens, if not hundreds, of such application solicitations, reviews, and award cycles over the past several decades, and has managed that process admirably. Most recently, it received more than 800 applications for health center New Access Points – almost 3 times the number of awards it expected to make; every one of the applications was reviewed and scored, and only the highest-scoring applications were funded. This process is clearly the most appropriate way of prioritizing and managing the distribution of resources which can vary significantly from year to year.

Recent studies and reports underscore the appropriateness of the Committee's recommended threshold. For example:

- The Medical Expenditure Panel Survey (MEPS) found that 35% of poor adults and 30% of near poor/low income adults did not have an ambulatory care visit in 2008. That same year, 44% of Hispanics, 35% of African Americans, and 36% of Asian Americans also went without an ambulatory care visit. More than half of the uninsured (57%) did not have a visit.¹
- Latest Census figures document that more than a third of the US population is low income (below twice the federal poverty line), with racial/ethnic disparities widening. More than 1 in 5

¹ Soni A and Roemer M. Characteristics of Those Without Any Ambulatory Care Visits in 2008: Estimates for the U.S. civilian Noninstitutionalized Adult Population. MEPS Statistical Brief 334. July 29, 2011. http://www.meps.ahrq.gov/mepsweb/data_files/publications/st334/stat334.pdf

children – and more than 1 in 3 minority children – lives in poverty (at or below the federal poverty line).²

- People without a usual source of health care are more likely to have unmet needs for care, more hospitalizations, and higher costs of care while receiving fewer preventive care services.³ More than half of the uninsured have no usual source of care.⁴ Nearly 30 percent of young adults (18-24 years) had no usual source of care as well as 33 percent of Hispanics. For individuals who were low-income 32 percent of those living in poverty and 31 percent between 100-199% FPL did not have a usual source of care.
- A Commonwealth Fund survey found that 28% of working age adults (52 million) were uninsured at some point during 2010, up from 26% (45 million) in 2003. At the same time, 16% (29 million) were underinsured – double the rate in 2003 (16 million). Together, these two groups make up 44% of working age adults.⁵
- A UCLA-RAND study revealed that high community-wide uninsurance rates have adverse “spillover” effects that may harm even insured individuals living there. Privately insured, working age adults residing in communities with high uninsurance are less likely to have a usual source of care in communities with lower uninsurance rates. They are also more likely to report difficulty getting needed care and less likely to report being satisfied with their care.⁶
- A recent study published in the *New England Journal of Medicine* found that community characteristics can have a detrimental effect on the health of individuals living there. Communities that have high poverty rates also show much greater prevalence of poor overall health than communities with more elevated income levels.⁷
- Using 2006 MEPS data, researchers found that the odds of African Americans having at least one office-based physician visit were almost 30 percent lower than Whites. However odds improved for African Americans in predominantly White neighborhoods. Therefore, efforts to improve access to health care services and to eliminate health care disparities for African Americans and Hispanics should not only focus on individual-level factors but also include community-level factors.⁸

Given the above information, it is clear that the one-third threshold for MUA designation, supported by an overwhelming majority of the Committee, is appropriate – it is evidence-based, easy to explain, and

² DeNavas C, Proctor BD, Smith JC. Income, Poverty, and Health Insurance Coverage in the United States: 2010. US Census Bureau, September 2011. <http://www.census.gov/prod/2011pubs/p60-239.pdf>.

³ Starfield, B., & Shi, L. (2004). The Medical Home, Access to Care, and Insurance: A Review of Evidence. *Pediatrics*, 113(5 Suppl), 1493-1498

⁴ National Center for Health Statistics. Health, United States, 2010: With Special Feature on Death and Dying. Hyattsville, MD. 2011

⁵ Collins SR, Doty MM, Robertson R, Garber T. Help on the Horizon: How the Recession Has Left Millions of Workers Without Health Insurance, and How Health Reform Will Bring Relief—Findings from The Commonwealth Fund Biennial Health Insurance Survey of 2010. The Commonwealth Fund. March 16, 2011. <http://www.commonwealthfund.org/Publications/Fund-Reports/2011/Mar/Help-on-the-Horizon.aspx?page=all>.

⁶ Gresenz CR and Escarce JJ. Spillover Effects of Community Uninsurance on Working-age Adults and Seniors: An Instrumental Variables Analysis. 2011 *Medical Care* 49(9):e14-e21. <http://www.rwjf.org/coverage/product.jsp?id=72828>

⁷ Ludwig J, et al. Neighborhoods, Obesity, and Diabetes – A Randomized Social Experiment. 2011 *NEJM* 365(16):1509-1519.

⁸ Gaskin, D J et al. Residential Segregation and Disparities in Health Care Services Utilization *Med Care Res Rev* published online 4 October 2011

reasonable given the purpose of designation and the data available. Moreover, using a one-third cut off for designation of communities and areas does not mean that resources will be targeted to the entire population of such areas. Subsequent federal intervention resources will be targeted to those populations within the designated rational service area that clearly have unmet health care needs. As such, we urge the Secretary to adopt the threshold identified in the NRM Committee report and supported by a substantial majority of the Committee.

Provider “Back-Out”: Avoiding a “Yo-Yo” Designation Cycle

The vast majority of Committee members also support a recommendation to exclude federally-supported MDs, NPs, and PAs from the provider to population (P2P) count. In particular, the P2P should exclude or “back out” those providers who are serving there as a direct result of a federal intervention in these underserved and under-resourced communities: National Health Service Corps Scholars and Loan Repayment recipients, State Loan Repayment Program (SLRP) recipients and providers who work at Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) that accept patients regardless of ability to pay. A substantial majority of the Committee was concerned that including these providers could trigger a “yo-yo” effect, under which a designated area is assigned resources to address the identified need, and those resources are then included in the subsequent provider count, which results in the area losing its designation and consequently losing the resources assigned there, once again making it eligible for designation. The Committee believed that by backing out these federally-supported providers, this “yo-yo” effect could be avoided.

National P2P estimates run by John Snow International (JSI) for HRSA and the Committee demonstrate that these clinicians, when counted, effectively increase provider-to-population ratios. In other words, as was noted by several Committee members, the community’s capacity to provide adequate primary care to its residents is heavily dependent on these federally-supported clinicians, especially in rural and frontier areas. Including these individuals in the provider counts may result in areas losing their designations, thus creating real harm to underserved communities and the populations residing within such communities. This is particularly critical for those communities on the “margin” of designation, that are in danger of cycling on and off designation, placing communities already at risk for poor health and poor access at even greater risk.

In early MUA and HPSA model tests, JSI compared the impact of the full provider back out with a model that backs out only 50% of the same providers. These impact tests show notable impacts on the designation status of areas with FQHCs and RHCs, resulting in anywhere from 5 percent to 25 percent of FQHCs and RHCs losing their designations, compared with a full provider back-out. It follows, then, that a model run without any back outs would lead to even fewer designations.

It is important to bear in mind that the primary reason we have not seen a “natural experiment” exploring the consequences of the “yo-yo” effect is because such an experiment has been deemed harmful policy. To attempt to fully demonstrate the existence and extent of the “yo-yo” effect would necessitate creating the very situation that the placement of federally-supported providers hopes to avoid – real harm to underserved communities resulting in poorer health status and less access. Thus, not including a back out of federally-supported providers is contrary to one of the NRM Committee’s guiding criteria: to cause minimal disruption to existing safety net providers.

Based on the above, we believe that excluding federally-supported providers in the provider count to determine P2P ratio is necessary to ensure appropriate placement of federal resources while not

creating any undue harm to underserved communities which could result from the “yo-yo” effect discussed above. As such, we urge the Secretary to adopt the full provider “back-out” included in the Committee’s report and supported by a substantial majority of the Committee.

Additionally, at least one Committee member believes that providers working at corrections facilities (federal, state, and local), should each be counted *for the population of the facility they work at ONLY*, for purposes of determining facility designations.

Addendum to the Report to the Secretary

submitted by:
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October 28, 2011

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Dear Ms. Sitko:

As a member of the Negotiated Rulemaking Committee (the Committee) on the Designation of Medically Underserved Populations (MUPs) and Health Professional Shortage Areas (HPSAs) it was a privilege to serve as one of 28 members and as the representative of the American Hospital Association. While the Committee was unable to reach a consensus on its recommendations on a process for designation of MUPs, HPSAs, and Medically Underserved Areas (MUAs), the Committee did identify many thoughtful options for use in a designation process.

When the Committee last met it was primarily for the purpose of discussing recommendations to the designation process for MUPs and MUAs and come to some closure regarding the final recommendations for MUPs, MUAs, and HPSAs. Numerous votes were taken on approval or rejection of components that would contribute to the designation process for MUPs, MUAs, and HPSAs. Although represented by an alternate, I was not present at the final meeting and thus have several unanswered questions regarding the origins of some of the factors that form the infrastructure for designation that were justifiable anecdotally, but not adequately supported by scientific research at least to my satisfaction.

Furthermore, we did not review a final report at the last meeting and our review of that report was done through electronic communication on drafts circulated by staff from the Health Resources and Services Administration (HRSA). This final review process was necessary in order to meet the October 31, 2011 deadline established by HRSA. Consequently the review of the final report was hasty and cumbersome. As a result there have been issues that were confused in translation and merit clarification. For these reasons and again, given the lack of consensus, I am taking the opportunity as allowed by § 566(f) of the Negotiated Rulemaking Act (Pub. L. 101-648, 5 U.S.C. 561-570) to submit as an addendum to the report some additional comments.



Conceptual Framework

As stated in the final report, the Committee identified several key concepts to guide us during our analysis and evaluation of methodological alternatives. From this conceptual framework the Committee made dozens of decisions regarding rational service areas (RSAs), population-to-provider (P2P) ratios, medically underserved areas (MUAs), medically underserved populations (MUPs), and geographic health professional shortage areas (HPSAs). The decisions were made using a balance of scientific and expert knowledge that thoughtfully and judiciously weighed the impact of multiple variables.

The following concepts were selected to reflect the Committee's desire to have a relatively simple, data-driven designation process for increasing access and placing providers in areas of greatest need:

- The proposed new methodologies should be based on scientifically-recognized methods, and the contribution of each variable to the overall measure should be informed by evidence or some scientifically verifiable relationship.
- The proposed methodological approaches are intended to be understandable and usable by those seeking or affected by the designation.
- New criteria should be reasonable and have face validity.
- The development of new designation criteria and processes should involve a consideration of their potential impact on existing safety-net providers and the communities they serve.

This conceptual framework has served its purpose well in leading the Committee towards its recommendations and serves as the framework used by me in the comments which follow.

Rational Service Area

The Committee proposes to define a rational service area (RSA) as an area that meets four criteria:

1. Made up of discrete geographic basis areas,
2. Area is continuous,
3. Different parts of area are interrelated, and
4. Area is distinct from adjacent contiguous areas.

Regarding this fourth criterion, RSAs will be considered distinct if, among other criteria, clinician capacity of the adjacent service areas is unable to accommodate the primary care needs of the service area. The threshold of insufficient capacity should be defined as P2P of 2000:1.

The scientific basis for setting this P2P ratio as the threshold for insufficient capacity is not apparent. A reference to the evidence or scientifically verifiable relationship between P2P of 2000:1 and insufficient capacity is warranted as the conceptual framework requires if it is to be accepted.

The Committee provides States the option of petitioning HRSA to create a State-wide RSA that divides a State into RSAs that are each discrete, continuous, interrelated and distinct. I am supportive of this petitioning process and believe it permits a more reasoned and meaningful RSA particularly for States with large frontier areas.

Population-to Provider Ratio

The Committee recommends some significant revisions to the process of counting primary care clinical providers. First, members support broadening the definition to include not only primary care physicians but also midlevel primary care providers. Second, members support excluding or backing-out from the

count certain primary care providers who may be practicing in an area or site under a federal service obligation or as part of a federally-funded or supported health center or clinic.

Including midlevels such as nurse practitioners (NPs), physician assistants (PAs), and certified nurse midwives (CNMs) as primary care providers expands the number of providers significantly so it is essential that one has an understanding of their productivity. Presently the Committee proposes a 0.75 relative weighting to NPs, PAs, and CNMs as an estimate of contribution to primary care. However, scope of practice for midlevel clinical professionals varies considerably from State to State, and the Committee wants to avoid creating a scenario that makes it more difficult for RSAs within States with a narrower scope of practice to become eligible for designation as HPSAs, MUPs, or MUAs than is warranted given the limitations on productivity of these professional in their states. Furthermore we need to correct a maldistribution of primary care physicians by allocating available resources to those designated as HPSAs, MUPs, or MUAs.

The scientific basis for determining the relative weight for productivity of NPs, PAs, and CNMs is not apparent as the conceptual framework requires. A reference to the evidence or scientifically verifiable relationship on weighting of midlevels is warranted if it is to be accepted. In addition, PAs or NPs specializing in obstetrics and gynecology would be included as .25 FTE, in a manner consistent with the weighting of OB/GYN physicians. I believe it would be more consistent if PAs or NPs specializing in obstetrics and gynecology are weighted as 75% of .25 (or .1875) of an FTE (consistent with the .75 weighting of midlevels) or whatever relative productivity weight is assigned to other midlevel providers.

The Committee recommends continuing to exclude certain foreign medical graduates from the primary care provider count. The Committee also recommends excluding National Health Service Corps scholars and loan-repayment recipients, State Loan Repayment Program recipients, and providers who work at HRSA grant-funded health centers, FQHC look-alikes, and hospital-based or independent RHCs that accept patients regardless of ability to pay. I agree these adjustments are necessary to avoid the “yo-yo” effect in which an area is designated as underserved; an intervention occurs as a result of the designation; the newly placed practitioners are counted and result in a loss of designation; the intervention is removed; and the area again becomes underserved.

Medically Underserved Areas

Medically Underserved Areas (MUAs) are determined based on four statutory components: health status, the availability of health professionals, accessibility of care and ability to pay. However, there is no statutory requirement to limit the U.S. population eligible for designation to a specific threshold under this revised methodology.

According to the final report, the Committee established a threshold on the resulting index for designating MUAs such that the impact testing models would designate the worst scoring 33% of the U.S. population.

For MUAs, the current index of medical underservice (IMU) is set at 62 which represented the score of the median of all U.S. counties at the time the Regulation was drafted. The level at which the IMU is set for designation of future MUAs is not the purview of the Committee, but rather it is contingent upon the

demand for and allocation of program resources being administered by an Agency within HHS such as CMS or HRSA.

Therefore, any reference to a threshold for designation should be clear that it serves only for modeling and comparative analysis and not as a benchmark for eligibility or designation of MUAs. In addition, it should be made clear that the Committee did not discuss scoring for MUAs, MUPs, or HPSAs, which, given its key role in determining designations is a deficiency in the overall Negotiated Rulemaking process.

Geographic Health Professional Shortage Areas

To qualify for a geographic primary care health professional shortage area (HPSA) designation, applicants need to demonstrate they are in a RSA for primary care and meet P2P thresholds adjusted as appropriate by health status and poverty. Additionally, the Committee recommends revising the geographic HPSA designation method to allow for a scoring adjustment that addresses the unique needs of frontier areas. By adjusting the requirement to measure standardized mortality rates and percent low income, all frontier areas with P2P ratios above 1500:1 will be designated as geographic HPSAs. Whatever the appropriate ratio may be, I enthusiastically support this adjustment so that the well known needs of frontier areas are adequately captured in a manner that is reasonable and offers face validity as implied by the conceptual framework.

Population Group HPSAs

Not all populations within geographic areas have equal access to primary care clinicians. Therefore the Committee recommends maintaining population group-specific HPSA designations. In fact the Committee recommends two distinct paths to population group HPSA designation. I support this recommendation.

Facility HPSA

The Committee recommends revising the criteria for facility HPSA designation. FQHCs and RHCs meeting the requirements of the NHSC statute for service without regard to ability to pay would remain automatically eligible for designation as facility HPSAs as statutorily required. The Committee recommends continuing the current process of allowing facilities not located in designated geographic HPSAs to apply for facility designations provided that they can demonstrate service to existing designated areas or population groups. I support continuing the current process.

In addition, the Committee revised the criteria for facility HPSA designation by creating new pathways to designation for magnet facilities, safety net providers, and essential primary care providers in a community. I am generally supportive of the new pathways for facility HPSAs. However, it is not apparent as to the scientific basis for determining that essential primary care providers in a community are facilities providing primary care services to at least 70% of the population in a RSA as required by the conceptual framework. A reference to the evidence or scientifically verifiable relationship between the primary care services provided by providers and the percent population in an RSA is warranted if it is to be accepted.

Furthermore, under the proposed revised facility designation process, a medical facility could demonstrate insufficient provider capacity by satisfying at least two of four additional criteria such as a P2P of 1500:1, counting all patients seen (by the provider) in a facility in the last year; the wait for appointments is more than 14 days for new and 7 days for established patients or the practice is closed to new patients; patient encounters per clinician exceed 4400 per year; or the average patient care hours per clinician exceed 40 hours per week.

It is not apparent that the criteria for insufficient provider capacity are scientifically verifiable, have face validity, or are reasonable for designation of a facility as a HPSA as required by the conceptual framework. Therefore, references supporting the criteria for insufficient provider capacity are warranted if they are to be accepted for this purpose.

Facility HPSA- Dependent Medically Underserved Population Designation

According to the report, the Committee recommends creating a facility HPSA-specific medically underserved population (MUP) designation to address concerns that some safety-net facilities, despite serving populations that are clearly underserved, might be located in areas that no longer meet geographic or population group criteria.

If a facility cannot meet the criteria for either a geographic HPSA, population HPSA, or MUP, that is if a facility or a provider otherwise cannot demonstrate that it addresses the components of health status, barriers to access, ability to pay, or P2P then it cannot be meeting a shortage or addressing underservice and without further evidence, it seems unlikely that such a facility serves an underserved population. This category of facility HPSA seems to fail the guidelines of the conceptual framework requiring understandable methodological approaches that are reasonable and have face validity.

It seems a contradiction to allow facilities to qualify for designation under this process if they no longer qualify for HPSA, MUA, or MUP designation. For these reasons I oppose this specific designation category and hope it will be rescinded in the final rule.

Impact Analysis

JSI was diligent in modeling dozens of scenarios for consideration by the Committee, and we owe them a debt of gratitude for the time and expertise that was put into the effort. JSI delivered detailed models of the national impact of all the scenarios requested by the Committee in a very timely manner. However, as stated in the final report, some gaps in data exist. Furthermore, it was not possible to run full impact testing of the population designation methodologies or facility designation methodologies because the data requirements make testing difficult if not impossible at a national level. The Committee recommendations reflect the knowledge gleaned from the available data, which however, cannot be considered an absolute determinant of the overall impact of the models.

In addition, there was not sufficient time for JSI to model the final options on a State level for final consideration. State level modeling was requested so there would be a greater understanding of the advantages and disadvantages of the recommendations as proposed by the Committee at a State level. In addition, according to JSI the impact analysis was inaccurate for some areas such as frontier areas that should clearly have been identified, but were not. This information is necessary to make recommendations that consider the impact at a State level and not just the average impact across the nation. Voting on final recommendations with incomplete information compromised my confidence in some of the scenarios and further research is warranted.

Transition Plan

As the transition is made from the current designation process to the new designation process the Committee recommends re-evaluation of existing HPSA and MUA/P designations over a four year period which seems a reasonable period of time. In addition, for those who upon re-evaluation lose their designation, it is only reasonable to establish a grace period to phase out their participation in any agency program in which they are participating.

Frequency of Publication and Withdrawal

In the case of a proposed withdrawal of a designation and subsequent appeal, the Secretary may request, and the State primary care organization must submit within 30 days such data and information as necessary to evaluate particular proposals or request for designation or withdrawal of designation. Given the appeal process requires submission of data by a State agency or organization and the information they submit may come from and would otherwise affect a provider it seems reasonable that this timeline should be extended to 90 days.

Urgent Review and Automatic Designations

In the event a sudden and dramatic change in primary medical care services that leaves an area or population underserved or with a shortage, the Committee recommends the Secretary review urgent requests on behalf of the affected community within 30 days of receipt. I support this process and timeframe for urgent review and automatic designations.

I appreciate the opportunity and it was a privilege to serve on the Committee. I think our task was ambitious, but in the end, the negotiated rulemaking process was unsatisfactory and could not produce a consensus. There is clearly a need for more analysis on the part of HRSA before a final rule can be promulgated. I strongly urge you to keep in mind the dissenting opinions in the areas where consensus was not reached or even in the cases where there were abstentions as these have merit.

I would like to extend my thanks to the Committee's members, HRSA staff, and JSI who worked diligently and honorably and with the best interests of patients and providers in mind. In conclusion, the recommendations represent the best effort of the group and however imperfect the outcome may appear it is a step forward from where we were 14 months ago.

Sincerely,

/s/

John T. Supplitt

Senior Director

American Hospital Association

Constituency Sections for Metropolitan and Small or Rural Hospitals

Addendum Minority Report

submitted by:

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Introduction

This minority report is submitted to the Final Report of the Negotiated Rulemaking Committee on the Designation of Medically Underserved Populations and Health Professional Shortage Areas, since the Committee did not reach full consensus on the report to the Secretary. It is the understanding of the signatories to this Minority Report that the Secretary will now consider the work of the committee and make her determination as to the contents of a proposed rule.

The committee accomplished a great deal in the 14 months of its deliberations. But due to a number of factors, including a fixed deadline on the completion of the report, we feel that the Committee did not complete its work of drafting a proposed rule that has been fully vetted and tested. We further believe that much positive and useful analysis has been completed by the committee, the statistical consultants hired to support the committee, and the analysts staffing the committee from the Health Services Resources Administration (HRSA). This analysis provides the record of the committee's work, and was presented to the committee, most especially in the last few meetings the committee held. However, we believe it is important for the Secretary to conduct the additional analyses that can validate the final decisions made by a majority of the committee, or identify modifications to those decisions, to assure that the rule will be most effective in promoting the objectives of the affected programs. Our objective in writing this minority report is to achieve the best possible public policy in this area for the American people, and if we had felt that the final report had achieved this goal, we would in good conscience supported the final report.

In this Minority Report we describe our principal reasons for not supporting the Final Report. The two authors of this document, Timothy McBride and William Scanlon, support and endorse this document. In addition, the authors of this Minority Report have sought input on this Minority Report from members of the Committee to make sure we are presenting the best possible course for adjusting the final policy recommendations by the Secretary. However, the opinions expressed here are our own, and not those of any other members of the committee, who voted to support the final report.

Principles guiding Committee Decisions

As noted in the Final Report, the committee adopted a framework that specified its decisions should meet four criteria. The decisions were to be:

- Evidence-based;
- Simple enough to explain and implement;
- Reasonable, and
- Protective of the safety net.

In general, it is with regard to the first of these criteria that we believe the committee's decisions fall short. The committee assembled a large amount of data during its deliberations and had extensive discussions regarding analyses based on these data, largely produced by an external consultant. However, with a deadline to complete its work, the committee made numerous decisions based on its collective expert judgment and without direct support from any external data or published evidence that would justify a particular choice. In some instances, conflicting evidence had been presented over the course of the committee's deliberations without reconciliation as to which was valid. In addition, due to the variety of backgrounds and perspectives of persons on the committee, what constituted

evidence was often unclear, or viewed differently by different members. The varieties in these perspectives were not reconciled adequately in the end.

In addition, we believe that in some cases the decisions made by the committee violated the criteria of being “simple enough to explain”. Instances of this will be identified below, but an example is a formula used in the HPSA rule, which is quite complex, and based on a mathematical formula that was not revealed to the full committee until the final day of deliberations. Whether justifiable or not, policy in the U.S. needs to be simple enough so that its impacts can be transparent to the individuals affected by the policy, otherwise the constituents affected will not be likely to support the policy change.

Finally, a full understanding of the impacts of the decisions made by the committee was not possible due to the pressing deadline facing the committee. Selected impact analyses were provided, but these should be regarded more as starting points that suggest areas that need fuller attention, rather than a complete analysis that would validate the underlying decisions. In an important instance, the definition of medically underserved populations, a partial impact analysis was conducted between the penultimate and the last meeting which revealed a substantial problem with the decisions made at the penultimate meeting (93% of the nation could be designated underserved). While the designation decisions were adjusted at the last meeting, no impact analysis of the revised criteria was conducted. Further analyses can likely shed light on many important issues, both improving policy and increasing confidence in same.

Concerns about Designation of Too Many Areas and Persons

There is no precise demarcation between shortage or underservice and adequate supply. The shortage or underservice designation process can then be viewed as an instrument to direct the

resources of programs like the National Health Service Corps or Section 330 funding to areas or persons most in need. Historically there have been concerns that the shortage and underservice designations have resulted in too many areas and persons designated and that program resources -- rather

Table 1. Descriptive information on shortage areas in the U.S.		
	Top Quartile- Worst “Shortage”	Bottom Quartile- Lesser “Shortage”
Average HPSA Score	16.9	7.6
Percent with 0 FTEs	23.6 %	9.9%
Number of FTEs	2.42	7.26
Number of FTEs Short of Dedesignation	2.94	1.07
Percent in Poverty	22.38 %	13.58 %
Average Population	17,315	28,034
Source: Tabulation of HRSA Supplied Data.		

than going to the neediest areas -- are disproportionately received by less needy areas.⁹ The result is not surprising as individual providers supported by these programs are more likely to choose better off communities with better amenities, fewer problems and challenges, and more professional colleagues.

⁹ US GAO, *Health Professional Shortage Areas: Problems Remain with Primary Care Shortage Area Designation System*. GAO-07-84. Washington, D.C.: October 24, 2006. _____, *Health Workforce: Ensuring Adequate Supply and Distribution Remains Challenging*. [GAO-01-1042T](#). Washington, D.C.: August 1, 2001; _____, *Health Care Access: Programs for Underserved Populations Could Be Improved*. [GAO/T-HEHS-00-81](#). Washington, D.C.: March 23, 2000.

The disparity that exists among current HPSAs as shown in Table 1, which compares the HPSAs in the top quartile and the bottom quartile in terms of HPSA score.

Even with the ARRA and ACA funds available in the last two years, the competition for the limited available resources remained high as shown by the number of vacancies in the National Health Service Corps (Table 2). In fact, with the additional funding, restrictions on the number of vacancies a site could post were relaxed—adding more competition for these finite resources. With the likelihood of more limited future funding in the future (which seems very likely in the current fiscal environment), this situation will undoubtedly be worse.

The newly proposed HPSA criteria will not lessen the competition for resources, and in fact is likely to increase competition by expanding the areas that are designated. The thresholds defining HPSA disparities were selected so that the aggregate amount of Medicare bonus payments would remain roughly the same. However, the impact analysis indicates the committee’s decisions would result in a 25

Fiscal Year	Field Strength	New Vacancies	Total Vacancies
2007	3,820	2,774	5,022
2008	3,601	2,529	6,356
2009	4,760	2,772	7,697
2010	7,530	2,643	9,039

Source: HRSA

percent increase in the designated population and a similar increase in the number of elderly designated. It was acknowledged, however, that the impact analysis does

not account for the number of RSAs that will be defined when local data are taken into account that are more accurate than the data available to the committee (such as hours worked, influencing FTE provider counts, the key variable defining HPSA). The committee did not seek to estimate the increase in Medicare bonus payments and HPSA designations that could result. There is only a 3 percent gap between the estimated Medicare spending under the new designation and current spending.

These considerations raise particularly important issues. An argument was made that designating a large segment of the population as underserved does no harm. The premise is that HRSA determines the allocation of program funds and that the agency can determine those most in need. This premise is problematic on two grounds. First, the designation of too many areas means that the volume of applications HRSA receives may strain its resources and preclude more comprehensive reviews. Second, areas that are better off will likely have more resources to assemble data and other materials to support their applications. This is particularly worrisome given the option for locally generated survey data to be used to define areas. One can imagine a larger higher income area with pockets of poverty having the resources to conduct an extensive survey to have some of those pockets designated. In contrast, areas where poverty is the norm may have significant difficulty in assembling an application using existing data sources. As a result, if more areas are competing for at least the same level of funding (and predictably, a lower level of funding), and less needy places may be competitive for these funds because they have more resources, then the outcome of committee’s decisions could be less targeting of needed resources than is optimal or desired. It is even possible that the targeting of future resources could be less desirable than the current distribution. In addition to the targeting of HRSA resources expanding the designated areas and people may undermine the intended incentive created by the Medicare bonus. An incentive acts an inducement only if earning it requires a certain response. In this case, the incentive to practice in needier areas could be weakened by the ability to earn the same bonus by practicing in less needy areas, another paradoxical response to the totality of the committee’s decisions.

The proposed threshold for Medically Underserved Areas (MUAs) raises similar concerns. The committee selected a threshold so that one-third of the US population was designated as underserved. The rationale offered was that this threshold is less than the one-half of the population designated in the original rule 35 years ago. This argument has no face validity. The notion that the committee is acting conservatively by designating 33 percent of the country instead of the 50 percent designated in the 1970s is specious. In particular, medical care delivered in the U.S. today bears little resemblance to that delivered in the 1970s. In 1975, health care spending was 8 percent of GDP as compared to almost 18 percent today. The per capita supply of providers has increased significantly as well. The number of generalist physicians per capita increased 19 percent in non-metro areas and 11 percent in metro areas from 1991-2001.¹⁰ In addition, there has been a 24 percent growth in the number of primary care practitioners per capita (defined as primary care physicians, nurse practitioners and physician assistants) between 1995 and 2005.¹¹ Finally, the committee reviewed evidence (from the Medical Expenditure Panel Survey) early in its deliberations that demonstrated a relatively low percentage of individuals report not receiving or delays in receiving needed care.

We believe it is important for the Secretary to try to identify a valid empirical basis for defining the underservice threshold and consider substituting it for the committee's 1/3 threshold. We believe that a far more detailed analysis of the impact of the HPSA designation approach on the Medicare incentive payment is needed to inform the final decision. We further believe it is important for HRSA to examine the potential for locally defined RSAs to increase the amount of the Medicare bonus payments and at a minimum, consider adjusting the HPSA thresholds to maintain the Medicare bonus payments at current levels, in particular to meet the committee's goal of targeting resources to the most needy in the safety net. We also ask the Secretary to consider whether the current method of fixing the thresholds in the rule which does not allow adjustments over time for the level of available program resources should be modified to help assure better targeting of program resources to the neediest areas.

Concern about Designating the Right Areas or Populations

We have concerns about a number of committee decisions that affect which areas or groups of people will be designated. They include:

- Conceptual model used to define underservice
- Backout of federal physicians
- Weights assigned to poverty
- Designating HPSAs with intermediate population to provider ratios
- Structure of the index of underservice

Conceptual model used to define underservice. The Committee spent a great deal of time determining a conceptual framework for capturing medically underserved areas. A spirited discussion of methods and models consumed considerable time and effort by the committee, with sincere and useful contributions made by many members of the committee. Nevertheless, the inevitable disagreements between well-

¹⁰ US GAO, PHYSICIAN WORKFORCE:Physician Supply Increased in Metropolitan and Nonmetropolitan Areas but Geographic Disparities Persisted. Washington, DC. GAO-04-124, October 2003.

¹¹ GAO 2008 is US GAO, PRIMARY CARE PROFESSIONALS: Recent Supply Trends, Projections, and Valuation of Services, Washington, DC GAO-08-472T, February 2008.

intentioned individuals with differences of opinions led to some difficulty in determining a final conceptual framework or model upon which to base the final measure, especially one that can be supported with a rigorous external evidence base outside of the committee's work, which notably, is an important criteria the committee itself set for the policy decisions to be made.

What was eventually recommended by the Committee was to use an index of underservice, analogous to current practice. Underservice by definition implies a deficiency or difference. In this context, underservice might be considered as the difference in service need for an area or population and the supply of services available to that area or population. The underservice index recommended by the committee majority is a weighted sum of measures of need and the services available. Again while this index is similar to current practice, that does not mean it is a conceptually valid framework for measuring underservice. While it may be desirable to give higher weight to need proxies in defining underservice, it is important to assess whether the recommended index so heavily discounts the available service levels to the point of their being ignored. This type of impact analysis was not conducted during the committee's deliberations.

Given the difficulty encountered in finding an underlying framework or theory to use for setting the index, the committee also resorted in the end to using "expert opinion" for setting the weights used in the formula for the MUA index. Some committee members, including those who have signed this Minority Report voiced many concerns for months about using expert opinion rather than an empirical basis for setting weights, but the concerns went unheeded. So in the end, the final index was determined not by empirical evidence nor from evidence obtained from the literature, but instead was determined by a vote of the committee. This leads to a decision that can be difficult to explain or justify when implemented. In particular, an outside party affected by the decisions of the committee might ask the basis for the decisions made, and suggest that if they are based on the unique set of participants on this committee, why wouldn't a different committee, otherwise configured come up with a different index and weights?

We recommend that the Secretary seek rigorous, defensible evidence-based analysis to support the development of a conceptual model underpinning the MUA index, and that the weights in the index be also supported by empirical analysis, peer-reviewed literature or other published analysis. We further recommend that when these decisions are made that they be made while closely following the spirit of the recommendations made by the full committee, and using the variables the committee decided were important to consider in the development of the index, to the extent possible, defensible, and desirable.

Backout of federal physicians. In the current rule, certain physicians supported by federal funding are not counted in determining population to provider ratios. The rationale is that these physicians may only reside in a community on a temporary basis and counting them will lead to a yo-yo effect in terms of designation and de-designation. While recognizing the disruption caused by such a yo-yo effect, steps to prevent one must be weighed against the distortions created in the measured provider capacities of different communities. Communities with uncounted federal providers will be treated the same as communities with fewer providers. The committee decided to expand the types of physicians receiving federal support that are to be excluded. The same rationale, a potential yo-yo effect, was offered. However, there was no evidence presented of the extent of any potential yo-yo effect and how the extent may vary by type of federal support. In fact, in very early discussions of this topic, some members of the committee disputed the presence of a yo-yo effect citing the long tenure in single locations of some physicians that would be excluded.

We believe it is important for HRSA to assemble data to affirm the presence and extent of a yo-yo for the different types of physicians or other providers that might be excluded and potentially adjust the committee's backout decision so that communities are treated equitably over time.

Weights assigned to poverty. There is no dissent on the conclusion that persons in poverty are more likely to be in ill health and to have more difficulty accessing health care services. From the outset, the committee recognized the importance of taking the extent of poverty in communities or populations into account as a proxy for health status or access. However, it became clear that there were two important issues with using poverty as a proxy for lack of access to health services. The first is that it is widely recognized that the current measurement of poverty in the US, the Federal Poverty Level, is substantially flawed. The second is that the circumstances of persons in poverty, particularly access to health care, may vary considerably across the U.S. due to range of reasons that include cost-of-living, government policies, and other local considerations.

The problem of measuring economic well-being was recognized by the committee early on. Current poverty measurement does not take into account the significant geographic variation in the cost of living or purchasing power. Persons in higher cost areas with incomes nominally above the federal poverty level may be significantly worse off than persons with income below the federal poverty level in low cost areas. The committee spent considerable time trying to determine if there were better measures of economic well-being that would adjust of geographic differences in costs of living. It was concluded that while the problem of measuring poverty is recognized, no alternative measure of poverty that would remedy this problem exists at this time. However, the Final Report supported by the committee does not adequately express the long-term concerns about the poverty measure, nor recommend the Secretary monitor the development of alternative poverty measures by the Census Bureau and others for potential use in future revisions of this rule.

Despite the concerns raised about the poverty measure, the committee subsequently decided to limit the variables used to define need in order to simplify the designation process, a decision which led to assigning very significant weights for poverty status in the determination of HPSAs, MUAs, and MUPs. The importance of poverty as a proxy for health and access may be sufficient reason to use federal poverty status, despite flaws in the measure. At a minimum, however, it is important to understand the impacts of the inaccuracies in the measure. For example, it was observed that unless the threshold for MUAs was set at a level of one-third of the population, certain areas of the country would have no MUAs. While this suggested a need to examine whether this result occurs because of flaws in the poverty measure, as opposed to low scores on other measures of underservice, this analysis was not explored by the committee

A final concern in this area is the very significant relationship between poverty status and eligibility for government programs, in particular Medicaid. Although this relationship is not uniform of course, the fact that states set eligibility rates as varying percentages of poverty for different eligibility categories only serves to exacerbate the problems of measurement of true access problems among persons with incomes below the federal poverty level. For example, if in one area of the country the Medicaid eligibility level for most populations is close to 100 percent of the poverty line (e.g., New York), then in fact the access problems faced by low-income persons in that state will be lower than they would be in a state that sets its eligibility levels very low as a percent of poverty (e.g., Missouri). None of these issues were explored to any depth by the committee even after they were raised by some committee members.

We recommend that additional analysis is needed to explore and disentangle the relationship between poverty status, government insurance eligibility levels and the relationship of these to need/access to safety net services. We further recommend to the Secretary that HHS work with other agencies to improve on the poverty measures, and local poverty data that can be used for the purposes of shortage designations. Finally, when such improved poverty measures are available that they be considered for incorporation into future revisions of the shortage designations rule,

Designating HPSAs with intermediate population to provider ratios The committee recommended that an area be designated a HPSA if its population-to-provider ratio exceeded 3000:1 or in the case of rural frontier areas, exceeded 1500:1. For non-rural frontier areas, it also recommended that some areas with a population-to-provider ratio between 1500:1 and 3000:1 be designated. The designation decision for these areas with intermediate population to provider ratios is to be based on an area's population-to-provider ratio and an index based on area mortality and poverty. The recommended designation decision involved creating a two dimensional graph of these two variables and drawing an exponential curve between the two thresholds 3000:1 and 1500:1. Areas falling to the left of the curve would be designated and those to the right not.

The initial drafts of the Final Report raised several concerns about the selection of the particular exponential curve which is simply one of an infinite number of possibilities. Some of these concerns were partially resolved in the last two days the committee met, but a full resolution was not achieved. In particular, this important decision must meet three tests, and be explained thoroughly in the report: what method was chosen by the committee for this decision; what specific line was chosen (that is, mathematically, what is the formula for the line); and finally, specifically why did the committee make these decisions, using what evidence-based criteria?

To the committee's credit, revisions to the Final Report now include an explanation of the specific line chosen, and the method used for computing this line (as noted, a complicated exponential curve). But two major concerns remain. First, the committee was presented with no evidence from any peer-reviewed literature or other evidence base to justify the decision of the specific curve chosen (over all other possibilities). Discussion suggested while the shape of the curve was determined by variables in the equation, the positioning of the curve was set by a budget constraint based on Medicare spending available (as noted in the Final Report). Second, the final curve chosen fails the simplicity test set by the committee for all policy decisions, which was clearly recognized by the committee in its deliberations. These two points lead to a major concern for implementation of the policy. If the policy is not simple enough to be understood by those affected by it, and if the decision to choose one curve over the many other alternatives is not justified or explained then those communities who do not qualify for federal funds as a result of the setting of the curve based on one function can rightly argue that the decisions made were arbitrary and not justified, and thus a remedy is needed.

We recommend that additional analysis be undertaken to explore the impacts of decisions about HPSA designation of areas between the two thresholds has on communities. For example, an analysis could be conducted that compared areas "just designated or close to the curve" to those that were "close but not designated" to determine if there are meaningful differences between these areas in terms of the concepts being measured. In this way, a final shape of this curve could be arrived at with more confidence that it is drawn in such a way to maximize its ability to distinguish areas more in need from those that are less so. We feel that the committee, and the statistical consultant was proceeding with due diligence on analyses before the Final Report was completed, and that the intent of the committee is clear, but that adequate analysis was not completed before final decisions were made. We finally feel

that evidence (particularly published evidence if possible) should be found to justify any policy decisions made about the selected thresholds and the curve defining designations between the thresholds. Finally, we believe that the final decision about the criteria defining designations between the thresholds should be a simple enough formula that will meet a standard of reasonableness in the eyes of the broader community affected by these decisions. A suggestion is that the excellent work completed by the committee to date be used as a starting point for setting the final criteria, even if these are a more simple function, or step functions that approximate the more elegant and complex function discussed by the committee and approved in its Final Report.

Final Comments

This Minority Report lays out the major concerns of the two undersigned members of the committee, Timothy McBride and William Scanlon, who decided that they could not support the Final Report, in large part because they did not support any of the major decisions of the committee on thresholds for HPSAs, MUAs, MUPs, and HPSA-special populations. It should be reiterated though that we believe that the committee created a major body of excellent work that can be built upon before the Secretary determines a final rule. The decisions made by the committee have not been adequately tested to the point where they can be defended when presented to the populations affected. But with further work, and additional analysis, the committee's excellent work to date can be respected and enhanced to the point where it can lead to implementation of an improved rule. We believe that the very high percentage of the committee who supported the final report demonstrates to the Secretary a significant and widespread and rather remarkable level of support of the principles reflected in the Report. We sign and present this Minority Report, however, in the spirit that the excellent work of the Committee can best be respected and fulfilled with further work by HRSA reflecting the concerns we express here. We understand that HRSA may appoint an Advisory Committee to complete the work of the NRPM, keeping true to the spirit of what the committee proposed. Most significantly we firmly believe that the well-being of the wide array of people and providers affected by the decisions made by this committee, as well as taxpayers, can best be preserved and enhanced with due diligence to the concerns raised in this Minority Report, and that this will in the end lead to stronger support of the Final Rule proposed by the Secretary.

Minority Report respectfully presented and supported by:

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