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Bureau of Health Professions
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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 critieria:

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,

John T. Supplitt
Senior Director
American Hospital Association
Constituency Sections for Metropolitan and Small or Rural Hospitals