

Summary of Comments

Following the February 29, 2008 publication of the Notice of Proposed Rulemaking (73 FR 11232), the comment period remained open through June 30, 2008 (including two 30-day extensions). In this time, over 700 comments were received, categorized, and analyzed. A wide range of comments were submitted, including positive feedback, requests for clarification, specific criticisms, and suggested changes. Often, there was little consensus among the commenters on a given matter. The comments are summarized briefly below:

A. Development Process for the Proposed Rule

Many commenters made requests or comments about the process used to develop the proposed rule. The most frequent request was to extend the comment period to allow stakeholders more time to analyze the proposed rule and its potential impact. Alternately, other commenters urged withdrawal of the proposed rule. Some commenters requested clarifications on the meaning and intent of some parts of the proposed rule, especially the sections on designation types. Additionally, some commenters requested an increase in stakeholder participation in rule making.

B. Population Methodology: Calculation of Effective Barrier-Free Population

A few commenters questioned the basic premise behind using the effective barrier-free population calculation, i.e., that the level of care needed by underserved populations can be adequately estimated by the age-gender adjusted utilization rates of populations with minimal access barriers. Some commenters questioned the validity of the Medical Expenditure Panel Survey utilization data used in the calculation. Several requested clarifying language and explanation of rationale. Other commenters offered various suggestions on how to make the calculation a more accurate predictor of need. Some proposed that the effective barrier-free population methodology be amended to include health status indicators to account for potential higher care needs in underserved populations (in addition to weighting the population-to-provider ratio by health status indicators).

Conversely, others expressed concern that the methodology might over-adjust for age due to inclusion of age as an element in the barrier-free population calculation and as a weighted high-need indicator. Several commenters expressed concern that age-gender adjustment of the population appeared, in some cases, to show increases “across-the-board” or decreases below actual numbers. A few commenters recommended that the adjustment be made optional or that actual population numbers be allowed in the calculation.

C. Provider Methodology: Types, Counts, Weights

Many commenters addressed aspects of the provider methodology, including provider types and weighting.

Primary Care Provider Sub-Specialties

A number of commenters urged that pediatricians, obstetricians, and gynecologists be weighted at lower than one full-time equivalent (FTE) because these providers do not exclusively provide primary care; they reasoned that counting these providers as a whole FTE could over-estimate the effective number of primary care providers, and thereby mask need. Conversely, other commenters recommended additions to the definition of primary care providers in the methodology, such as physicians in “urgent care” units.

Health Professions Provider Types

Some commenters applauded the addition of mid-level providers (nurse practitioners, physician assistants, certified nurse mid-wives), while others questioned/opposed it. Some stated that mid-level practitioners should be included because they are an essential part of the healthcare team, and are helping fill critical provider shortages. Others recommended that they be omitted from the practitioner count, or that their weight be substantially lowered because of inconsistent scope of practice across States, and lack of comprehensive data sources.

A few commenters said that interns and residents should not be counted, even as 0.1 practitioner weight, because they are unable to provide the same level or amount of care as a physician. In addition, some commenters noted that some physicians, while located in an underserved community, are not available to the majority of underserved people who live there, and should therefore not be included in the provider counts; for example, physicians working in closed systems (managed care, prison, colleges) or physicians who do not accept Medicare/Medicaid.

Several commenters requested clarification on the guidelines to determine the number of hours that constitute part-time versus full-time FTE.

D. Adjusted Ratio Methodology and Other Methodological Considerations

Many commenters remarked about the weighted high-need indicators used to adjust the population-to-practitioner ratio for community characteristics (health status, economic, demographic, and population-density factors). Overall, commenters expressed a desire for adjustments that are predictive of relative need for health care resources; representative of all populations/areas; and equitable to all populations/ areas. Several requested clarifying language and explanation of rationale.

High-Need Indicators to be Included in New Rule

A number of commenters gave positive feedback on the expanded set of high-need indicators included in the February 2008 proposed rule. For example, some commenters praised the inclusion of population density as a way to make the methodology more accurate for determining shortage in rural and frontier areas. In contrast, other commenters expressed concern about the appropriateness and applicability of the indicators, and made suggestions for new or amended ones. For example, some commenters criticized the proposed methodology as being biased against urban areas due to inclusion of the population density factor.

Other commenters strongly recommended that new health status indicators be added to better capture primary care need, access, and utilization. Also, many commenters urged that the methodology be changed to take into account particular cultural, regional, and other population-specific needs. For example, some urged inclusion of high-need indicators that address culturally and linguistically appropriate care. Others thought that the proposed indicators were not equitable to all populations/areas because the methodology only explicitly recognized the Hispanic subpopulation. In addition, some commenters expressed concern about possible redundancy of the “Percent Hispanic” and “Percent Non-White” high-need indicators.

Some commenters urged that States be allowed to select locally relevant indicators; these comments centered around a desire to include factors that adequately demonstrate regional need, exclude factors that are inapplicable to local demographics, and exclude factors for which reliable data are not available.

Relative Weighting of High-Need Indicators

A number of commenters made suggestions about how strongly each of the high-need indicators should be weighted relative to one another. Some urged stronger weighting of health status factors, while others urged stronger weighting of demographic and population-density factors.

Unit of Analysis for High-Need Indicators

Some commenters questioned whether the factor weights adequately represented all relevant geographic regions given that they were developed based on a sample of counties designed to approximate rational service areas (RSAs). The commenters were concerned that this process excluded many urban counties and some highly urbanized States, and that the resulting weights might not be applicable in these areas. A few commenters noted that weighting of population density appeared to disadvantage urban areas by deducting points for very dense areas.

Other Methodological Considerations: High-Need Indicators, Medical Underservice, and Health Professional Shortage

Several commenters stated that the high-need indicators should collectively be given a stronger “weighting” relative to the population-to-provider ratio so that these community factors would be as prominent as the concept of health professional shortage in the proposed Index of Primary Care Underservice.

Some commenters more broadly questioned the consolidation of the HPSA and MUA designation processes under the proposed rule; they favored leaving distinct the concept of health professional shortage and the more general concept of medical underservice. Other commenters supported the idea of a combined index that integrates a more comprehensive set of indicators of underservice, and helps better identify underserved areas and populations.

E. Designation Types: Tiers, Facility, Population Group, and Provider “Back-Out” Issues

Many commenters requested clarification on the proposed designation types, including the purpose of having multiple types, the intended “order of operations” for which one to use, the criteria and process for each, and the anticipated effect on resource allocation. Commenters also offered some specific suggestions.

Tier 1, Tier 2, and Provider “Back-Out” Issues

A number of commenters expressed support for the proposed two-tier system that offered “back-out” of FQHC, NHSC/State Loan Repayment Program, and J-1 Visa clinicians for Tier 2 calculations. Conversely, many others felt the two-tiered system was too ambiguous and complex, and urged adoption of a single method in which all federally obligated/sponsored clinicians would be backed out. They argued that including any federally obligated/sponsored providers in Tier 1 counts would create a “false sense” of primary care adequacy and still leave the area vulnerable to a “yo-yo” effect in which designation status is achieved and then lost.

Many commenters expressed a desire for primary care providers at Rural Health Clinics (RHCs) to be included in the “federally sponsored” provider definition and to be excluded from at least the Tier 2 calculations. Among other suggested exclusions were primary care providers at FQHC Look-Alikes, Critical Access Hospitals (CAHs), and facilities funded by the Indian Health Service. In addition, some commenters suggested that interns and residents be excluded from Tier 1 and 2 provider counts until their commitments are fulfilled.

Safety Net Facility Designation

Many commenters requested clarification or expressed concern about the safety-net facility primary care HPSA designation, particularly the scoring methodology and effect on resource allocation. Commenters offered various opinions on eligible facility types and designation threshold. Some were concerned that the safety-net facility definition was too restrictive, and urged that other facility types be eligible for the designation (e.g., RHCs, CAHs, FQHC Look-Alikes, correctional facilities). Others recommended that the safety-net facility designation be omitted outright.

Population Designation

Several commenters urged that the explicitly recognized list of subgroups be broadened to include others such as pediatrics populations; all patients whose services are paid for by other programs of DHHS; tourists; and Native Hawaiians, Pacific Islanders, and Southeast Asians. A couple said that the Native American Population should receive an automatic designation. Others requested clarification on designation by Governors, urging that existing designations be “grandfathered.”

Other Designation Comments

Multiple commenters proposed special designation methods for frontier and small areas, such as adoption of a Frontier or Small Community designation, or allowing indefinite designation for areas with populations below a given threshold. Others suggested that HPSA designations be maintained for pharmacy, veterinary, vision specialty, and podiatry, citing the dependence of rural areas on these specialties for primary care. A few requested that Poison Control Centers and their specialists be automatically designated because they provide care to underserved populations. In addition, some commenters sought clarification on how Automatic HPSAs would be handled under the proposed methodology.

F. Designation Threshold

A significant number of commenters expressed concerns, uncertainty, and suggestions about threshold in the proposed rule. Some questioned the rationale for the 3000:1 threshold; many suggested that 2000 to 2500 would be more reasonable. Others argued that any figure above an average primary caseload of 1500:1 should be deemed shortage. A number of commenters also urged that the threshold be lowered in certain special circumstances. For example, some suggested that, whatever threshold for designation is selected (3000:1 or some other), any community should be considered eligible that needs at least one additional primary care clinician to achieve that threshold. Others recommended that due to the unique challenges and needs of special populations (e.g., medically indigent, uninsured), the qualifying threshold should be lower for these populations.

G. Implementation Process Issues: Data Limitations, Unit of Analysis, Designation Burden

Many commenters had concerns and suggestions about various aspects of the implementation process.

Availability and Adequacy of Data Needed to Make Designations

A number of commenters expressed concern about the availability and adequacy of data needed for designation, especially at the sub-county level and in low population regions. Commenters cited data availability/reliability issues both for community status indicators and for provider counts, especially mid-level providers. Some commenters requested guidance on how to impute sub-county data from State-level data. Several cautioned that using county-wide averages in place of actual sub-county data could “mask” pockets of need and health disparities. A few

commenters were concerned about the accuracy of Medicaid data, and suggested that protocols are needed between HRSA and State Primary Care Offices to allow Medicaid data to be gathered and utilized.

Use of Rational Service Area (RSA) as the Unit of Analysis

A number of commenters addressed the use of RSAs as the unit of analysis, with some questioning the applicability of RSAs for States that do not use counties as RSAs. A significant number of commenters thought that large counties should not be considered as rational service areas, in part because this could “mask” pockets of need, especially in urban underserved areas. In addition, some commenters stated that RSA boundaries would not be a reliable indicator of population served because some patients travel across RSA boundaries to seek care due to a variety of factors.

Partners to be Included in Designation Process

Several commenters suggested that HRSA partner with other Federal Agencies, such as CMS, to address issues that affect both agencies (e.g., RHC certification, MIP). Some also suggested that HRSA include relevant stakeholders in the RSA determination process, including Primary Care Associations, local health departments, FQHCs, RHCs, NHSC sites and the impacted community itself. In addition, some commenters encouraged HRSA to allow states more flexibility to designate areas and populations based on State-based benchmarks instead of national benchmarks that might not capture regional variation and disparities.

Cost, Burden, and Complexity of Designation Process

Commenters had several concerns about the potential cost, burden, and complexity of designation under the proposed rule. While many commenters requested increased stakeholder involvement in the designation process, many others were concerned that the proposed methodology would increase the burden of States in terms of costs, time, expertise, and other resources, particularly for the collection and analysis of data needed for designations. Also, a number of commenters felt the proposed rule was unnecessarily complicated and ambiguous, and that this complexity was in opposition to the stated goals of creating a simpler and less effort-intensive process for identifying and designating underserved areas and populations.

A number of commenters requested clarification and made recommendations on other aspects of the designation process including: the review cycle for designations; whether data will be used from the site level or the organization level; measures to ensure continuity of care; urgent review process; and inclusion of an appeal process.

H. Impact on Designation Status and Program Eligibility/Competitiveness

The majority of commenters expressed concern or uncertainty about various aspects of the impact of the proposed rule.

Adequacy of Impact Analysis

Many commenters thought the impact analysis provided in the proposed rule was not sufficient to accurately gauge the rule’s impact. These doubts largely centered around data and methodological issues such as the use of 1999 data and the development of factor weights using a sample that some did not view as broadly representative. In the absence of certainty about the rule’s impact, commenters generally assumed a worst-case scenario, predicting loss of designation and associated resources. Many commenters requested that HRSA update its impact analysis so that the proposed rule’s impact could be better estimated and understood.

In a number of cases, commenters performed their own analyses using local data. Many reported considerably more negative outcomes than indicated in the proposed rule's impact analysis. In contrast, in most of the analyses conducted during the comment period by State Primary Care Offices (PCOs), there was little or no negative impact reported on FQHCs, particularly if the safety net facility designation was included in the analysis. Several PCOs also noted that the proposed method retains a much greater percentage of designations than would remain if current methods were re-applied today to update designations.

Concerns and Considerations about Potential Impact

Most concerns about impact centered around the unknown effect of the rule on designation status, resource allocation, and access to/quality of care. Many commenters questioned whether they would lose their designation status. Others wondered how the proposed rule would impact the overall number and distribution of designations. A great many were deeply concerned about the effect of designation type (Tier 1, Tier 2, Safety Net Facility, Population Group, and Automatic) on eligibility and competitiveness for programs and associated resources that rely upon the designation. Commenters requested clarification on any differences among these designation types for program eligibility and competitiveness.

Also, many commenters anticipated that the proposed rule would undermine the safety-net infrastructure, and thereby diminish access to care, quality of care, and well-being of communities. Commenters expressed special concern about the impact on recruitment and retention of clinicians that could result from loss of designation status and program eligibility/competitiveness. Such loss was predicted to negatively impact access and quality. Others felt that the rule might negatively impact geographic regions (rural/frontier and urban) because each of these types of areas is affected by unique challenges that they felt the methodology did not fully address. In addition, many commenters expressed special concern about how the proposed rule would affect various vulnerable populations.