May 8, 2008

Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: *Designation of Medically Underserved Populations and Health Professional Shortage Areas; Proposed Rule Change*

Dear Secretary Leavitt:

On behalf of organizations listed below, we would like to provide the following comments on the proposed rule, *Designation of Medically Underserved Populations and Health Professional Shortage Areas,* which was released on February 29, 2008. We appreciate the extension of the comment period until May 29.

In the proposed rule, the Health Resources and Services Administration (HRSA) would change how the agency designated Medically Underserved Areas and Populations (MUA/Ps) and Health Professional Shortage Areas (HPSA). Specifically, the rule is a major attempt to revise and consolidate the process for making these designations. It follows a failed proposal in 1998, attempts to correct problems in the current designation process and address perceived shortcomings of the earlier approach. As you know, in 1998, HRSA received 800 public comments on the proposal, principally citing concern over the negative impact on existing safety net programs. As a result, the agency withdrew the rule to perform further testing and revision. <u>In our view, the proposed rule is both unnecessarily complicated and is ambiguous regarding its effects on medically underserved areas. Consequently, our recommendation is that you withdraw the rule.</u>

<u>Background</u>

Currently, a geographic area can be designated as a primary care HPSA if it 1) is a rational service area (RSA) for the delivery of primary care, 2) has less than one primary care physician (PCP) per 3,500 people, or less than PCP per 3000 people with unusually high needs for primary care services or insufficient capacity of nearby providers, and 3) its contiguous areas are overutilized or too distant to meet local needs. Roughly 24 percent of US counties are RSAs that currently qualify for whole-county HPSA status, but smaller qualifying RSAs (homogenous neighborhoods, communities or population clusters) are found in an additional 40 percent of US counties.

Medically Underserved Areas are geographic areas (contiguous county areas or smaller) that reach a certain score or lower on the Index of Medical Underservice (IMU), which is a summary of weighted values for four characteristics of these areas: 1) the ratio of primary medical care physicians per 1,000 population, 2) infant mortality rate, 3) percentage of the population with incomes below the poverty level, and 4) percentage of the population age 65 or over. The same criteria can be applied to underserved population groups within an area of residence to declare a Medically Underserved Population (MUP). There are approximately 1,435 whole county MUAs and 1,090 counties with subcounty MUA or MUP designations.

According to information in the Federal Register, the goals of the proposed rule are the following:

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

Concerns with the Proposed Rule

Despite the stated goals of the proposed rule, we are concerned that as formulated, it will have a significant impact on access to health care and primary care providers in this country. More importantly, however, it is entirely unclear which medically underserved areas will be affected, positively or negatively, and yet the effect on primary care physicians and on state and federal programs would be enormous.

More than 34 federal programs depend on these shortage designations for eligibility and funding preference purposes. For example, the Medicare Provider Incentive Payments are made to physician practices in HPSAs and physician loan repayment programs are dependent on service in HPSAs. The rule does not specify how these programs administered by the department or agency will be affected.

According to a preliminary analysis by the Robert Graham Center for Policy Studies in Family Medicine and Primary Care (attached to this letter), approximately 600 HPSAs, containing nearly 32,000 primary care physicians and 32 million people, could lose designation under the rule, jeopardizing access to care for underserved people. It also could de-designate more than 900 MUAs, which contain 38,000 primary care physicians and 31 million people. We believe that it may have negative consequences for more than 10,000 family physicians who practice in HPSAs and MUAs, which may be de-designated in the proposed rule. We would expect a similar situation affecting general internists as well. In addition, however, under some scenarios, a handful of states may benefit in some ways from the rule change. Nonetheless, the lack of transparency about the process and data to be used make it uncertain what the rule would do.

In addition, other organizations have tried to analyze the proposed rule and have found it highly confusing and indeterminate. Specifically, a report from the School of Public Health and Health Services at George Washington University estimates preliminarily that urban areas and northeastern and northwestern states would be particularly hard hit. Specifically, the School has found that under the proposed rule, fewer areas and health centers would receive designation of underservice. As the School points out in its analysis, the loss of MUA/P and HPSA designation may have broad implications for the nation's health care safety net. Additionally, it may be that HRSA s using the HPSA redefinition to shift certain types of poverty to benefit different regions.

Recommendations

At a time when the health care safety net is severely frayed and the shortage of primary care physicians has been growing concern, as documented most recently by the Government Accountability Office, we believe it is unreasonable for HRSA to hurriedly push this revision without more extensive consideration of its effects and the impact on patient care in this country.

We recommend strongly that HRSA withdraw the proposed rule, and suspend updating current HPSAs and MUAs. The Agency should use this time to more extensively examine the implications of this change on patient access to primary care services in consultation with family physicians, general internists, community health centers and others and determine a method of designation that is not detrimental to patients, physicians, and other health care services.

Sincerely,

Rick Kellerman, MD, FAAFP
Board Chair
American Academy of Family Physicians

Scott Fields, MD
President
Society of Teachers of Family Medicine

Mark Robinson, MD
President
Association of Family Medicine Residency Directors

Allen Dietrich, MD
President
North American Primary Care Research Group

Michael K. Magill, MD
President
Association of Departments of Family Medicine

David C. Dale, MD, FACP
President
American College of Physicians

Lil Anderson
Board Chair
National Association of Community Health Centers

CC: Health Resources and Service Administration
Department of Health and Human Services
Attention: Capt. Andy Jordan
8C-26 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Impact of Proposed Rule on Designation of Medically Underserved Populations and Health Professional Shortage Areas: 73 Fed. Reg. 11232, et seq (February 29, 2008)

Stephen Petterson, PhD, Andrew Bazemore, MD, MPH, Imam Xierali, PhD, Robert L. Phillps, Jr., MD, MSPH

The Department of Health and Human Services recently proposed to restructure the primary care shortage area designation process. Preliminary analyses using the proposed new methods point to dramatic impact on the landscape of shortage areas, with loss of designation for areas containing 31.8 million persons and 31,000 primary care physicians, and gains for 11.5 million persons and 5,100 primary care physicians.

Introduction: This notice of proposed rule making (NPRM) is a major attempt to revise and consolidate the process for designating Medically Underserved Areas and Populations (MUA/Ps) and Primary Care Health Professional Shortage Areas (HPSAs).[1] It follows an earlier failed proposal in 1998-99 (NPRM1) and attempts to correct problem of both the current designation process and address perceived shortcomings of the NPRM1 approach. This notice was presented to the public February 29, 2008 with a 60 day period for comments prior to implementation. Changes to the designation process have far-reaching consequences for providers and populations in underserved areas, as 34 federal programs depend on these shortage designations for eligibility and funding preference purposes.[2,3] This brief summarizes a preliminary analysis of the impact of the updates and changes on the potential designation of current HPSAs, MUAs and undesignated areas and the population, providers, and health care delivery sites within each.

Current Methods for Designation: Currently, a geographic area can be designated as a primary care HPSA if it 1) is a rational service area (RSA) for the delivery of primary care, 2) has less than one primary care physician per 3,500 people, or less than one PCP per 3000 people with unusually high needs for primary care services or insufficient capacity of nearby providers and 3) its contiguous areas are overutilized or too distant to

---

[1] Department of Health and Human Services, "Designation of Medically Underserved Populations and Health Professional Shortage Areas," *Federal Register* 73(41):11232-81, Feb. 29, 2008.

[2] Health Resources and Services Administration. "Shortage Designation." www.bhpr.hrsa.gov/shortage.

[3] Government Accountability Office. October 2006. "Health Professional Shortage Areas: Problems Remain with Primary Care Shortage Area Designation System." GAO-07-84

meet local needs.(http://bhpr.hrsa.gov/shortage/hpsacritpcm.htm). Roughly 24% of U.S. counties are RSAs that currently qualify for whole-county HPSA status, but smaller qualifying RSAs (homogenous neighborhoods, communities or population clusters) are found in an additional 40% of U.S. counties. Medically Underserved Areas are geographies (contiguous county areas or smaller) that reach a certain score or lower on the Index of Medical Underservice (IMU), which is a summary of weighted values for four characteristics of these areas: 1) the ratio of primary medical care physicians per 1,000 population, 2) infant mortality rate, 3) percentage of the population with incomes below the poverty level, and 4) percentage of the population age 65 or over. The same criteria can be applied to underserved population groups within an area of residence to declare a Medically Underserved Population (MUP). There are approximately 1,435 whole county MUAs and 1,090 counties with subcounty MUA or MUP designations. The stated goals of the NPRM process are:

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

The new process by which a 'rational service area' – counties plus state and locally-designated aggregations of smaller areas - would achieve shortage designation involves six steps

1) Calculate the "effective barrier free population" – the utilization rate of the population if it did not have any barriers to care, adjusted for age and gender. This calculation relies on 1996 estimates of the number of visits per physician from the Medical Expenditure Panel Survey.
2) Obtain a count of the number of full-time equivalent(FTE) PCPs (primary care providers), which includes not just physicians as in the current system but includes a discounted FTE count for hospital residents, nurse practitioners, physician assistants and certified nurse midwives.
3) Calculate the base population-to-provider ratio (the proxy for need for services) by dividing the effective barrier-free population by the number of FTE PCPs.

4) Adjust the base population-to-provider ratio for community characteristics that impact available resources – develop "weighted scores" using nine variables, which indicate a greater need for services but a lower utilization rate than the average "barrier-free" population. The variables are 1) percent non-white, 2) percent Hispanic, 3) percent of population greater than 65 years, 4) percent of population earning less than 200% of FPL 5) unemployment rate, 6) standardized mortality rate 7) low birth weight rate, 8) infant mortality rate, and 9) population density.
5) Add the resulting scores are added to the base ratio to derive the adjusted population-to-provider ratio (the proxy for the relative need for services in the area). Determine if the adjusted ratio is greater than the threshold for under-service – compare the adjusted population-to-provider ratio to the predetermined threshold ratio of under-service (proposed at 3000:1).
6) Determine tiers of shortages – remove the number of federally-sponsored PCPs (NHSC personnel, providers obligated under State Loan Repayment Program, physicians working under J-1 visa waivers, all other PCPs providing services at Section 330-supported health centers) from the total number of FTE PCPs.
    i. Tier 1 designation – areas that continue to exceed the threshold even when all federally-sponsored PCPs are included.
    ii. Tier 2 designation – areas that exceed the threshold only when the federally-sponsored PCPs are excluded.

Updated Data Analysis: Our analysis borrows and benefits from an updated impact testing of the proposed new methodology for designation of underserved areas contracted by DHHS and executed by the Sheps Center in 2007. This impact testing was an update to that done in 2000-01, using data from 1998-1999. This update included some revisions to the originally proposed methodology, including updated weights and adjustment more reflective of recent access surveys and population data. Using Ricketts Area-level files, we were able to produce estimates of the impact of the proposed regulations on all current HPSAs and MUAs, including estimates of the number of people, physicians, and health centers that might be impacted

Results: Impact on People, Populations, and Safety Net Facilities: Using data made available by the Sheps Center, we estimate loss of designation for 605 current HPSAs, containing 32 million persons 31,565 primary care physicians (about half of them family physicians) (Table 1). We estimate loss of designation for 917 current MUAs, containing 31 million persons, and nearly 39,000 primary care physicians (Table 2). We also estimate new designations for 381 counties, which include 12 million persons, 5,105 primary care physicians federally qualified health centers. Tables 3 -5 break these down by existing HPSAs and MUAs, as well as by persons, physicians and FQHCs.

Table 1
Summary Table
Impact of "Automated" Redesignation of Current HPSAs Based on National Data.

		Proposed Regulations	
		Yes	No
Current Regulations	Yes	Areas=1,807 Affecting 46 Million people and 20,001 PC Physicians	Areas=605 Affecting 32 Million people and 31,565 PC Physicians
	No	Areas=381 Affecting 12 Million people and 5,105 PC Physicians	Areas=1,730 Affecting 210 Million people and 217,619 PC Physicians

Note: The 1730 areas not covered by either current regulations or proposed regulations include 739 whole counties and the part of 991 counties not currently included in HPSAs. Calculations are based on data made available to Robert Graham Center by Dr. Thomas Ricketts.

Table 2
Summary Table
Impact of "Automated" Redesignation of Current MUAs Based on National Data.

		Proposed Regulations	
		Yes	No
Current Regulations	Yes	Areas=2,837 Affecting 57 Million people and 26,074 PC Physicians	Areas=917 Affecting 31 Million people and 38,828 PC Physicians
	No	Areas=170 Affecting 4 Million people and 1,538 PC Physicians	Areas=1,195 Affecting 208 Million people and 207,850 PC Physicians

Note: The 1730 areas not covered by either current regulations or proposed regulations include 446 whole counties and the area within 749 counties not currently included in MUAs. Calculations are based on data made available to Robert Graham Center by Dr. Thomas Ricketts.

Significance: Given the array of entitlements and federal, state, and local assignments of resources that depend on these designations, the potential effects of a revised system are vast and their political and economic importance considerable. In 1998, the last proposed designation revision generated 800 public comments, principally citing concern over the negative impact on existing safety net programs, which resulted in its withdrawal for further testing and revision.

Concerns: The proposed regulations document is concerning for several reasons (See Table 5 (Appendix) for details):

- The use of a dated information assessment doesn't permit transparency in the assessment of impact of these proposed changes. HRSA should make an updated impact analysis, using contemporary data, available to all constituents prior to closure of a comment period.
- Inner city urban areas and populations risk a negative impact, due to the strong weighting of low population density in the designation process.
- The impact analysis relies on multiple data sources,
    - Of mixed quality, particularly regarding non-physician providers
    - And frequently intersecting old and contemporary data
- The proposed implementation process is not clearly defined
- The three levels of determination appear to open the door for radical increases in the number of shortage areas, potentially obscuring areas of greatest need. Specifically,
    - There exists a strong potential for manipulations of rational service area (RSA) geographies to meet new designation criteria
    - The second step of the designation process as described many allow jurisdictions with more resources to achieve designation.
    - There are a large number of partial HPSAs apparently eligible to become full county HPSAs.

Potential benefits: There are several potentially positive outcomes from these rules, including:

- The automatic designation of some underserved counties, especially in rural areas and jurisdictions without resources
- The designations of new safety net clinics based on their patient data and measures of underserved populations served
- That physicians may be better-reimbursed for care of underserved people in some areas
- That underserved populations surrounded by otherwise well-off people receive resources that they would not have previously

APPENDIX:

Table 3. Additional Information Regarding HPSA Impact Based on Tier 2 with Low Income Approach

			Not Designated by New Method			Designated by New Methods		
		Total	Number of Areas	Population	PC Physicians in Area	Number of Areas	Population	PC Physicians in Area
Current Designation	Single County	755	83	1,862,003	1,457	672	10,991,236	3,814
	Geographic Part County	686	104	3,279,969	3,184	582	15,231,261	6,433
	Low Income Population	971	418	26,749,479	26,924	553	19,366,156	9,754
	Subtotal	2,412	605	31,891,451	31,565	1,807	45,588,653	20,001
Undesignated Counties	No Designation	1,120	739	79,514,888	74,755	381	11,514,428	5,105

Table 4. Additional Information Regarding MUA Impact Based on Tier 2 with Low Income Approach

			Not Designated by New Method			Designated by New Methods		
		Total	Number of Areas	Population	PC Physicians in Area	Number of Areas	Population	PC Physicians in Area
Current Designation	Single County	1,434	262	11,424,365	8,596	1,172	25,297,055	10,505
	Geographic Part County	2,008	506	9,906,605	21,054	1,502	25,229,277	12,611
	Low Income Population	312	149	9,552,651	9,178	163	6,197,354	2,958
	Subtotal	3,754	917	30,883,621	38,828	2,837	56,723,686	26,074
Undesignated Counties	No Designation	616	446	36,353,475	32,697	170	3,834,314	1,538

Analysis based on data supplied by Thomas Ricketts used in his "Final Report" analysis. Tables 1' and 2' correspond to the first two Tables in the executive summary of Rickett's paper.

Table 5. CHCs Potentially Losing Geographic Designation

			Not Designated by New Method			Designated by New Methods		
			Number of Areas	CHC	RHCS	Number of Areas	CHC	RHCS
Current Designation	Single County	1,434	262	283	345	1,172	954	1,448
	Geographic Part County	2,008	506	630	233	1,502	1,215	305
	Low Income Population	312	149	216	129	163	217	129
	Subtotal	3,754	917	1,129	707	2,837	2,386	1,882
Undesignated Counties	No Designation	616	446	245	297	170	59	175