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**Analysis of the Proposed Rule on Designation of Medically Underserved
Populations and Health Professional Shortage Areas**

Peter Shin, PhD, MPH
Leighton Ku, PhD, MPH
Emily Jones PhD (cand.)
Sara Rosenbaum, J.D.^a

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Executive Summary

Numerous safety net programs and health care providers depend on Medically Underserved Area and Population (MUA/P) and Health Professional Shortage (HPSA) designations to qualify for federal funding, physician subsidies and placement, and health-related investments to improve access to care for communities and populations at high risk of poor health. These resources are particularly critical for federally-qualified health centers at a time when the number of uninsured is growing and the capacity of the safety net shrinking. On February 29, 2008, the Department of Health and Human Services (HHS) released a proposed regulation to alter the way these designations are made. This report provides the first up-to-date analysis of the effects of the new regulations; the impact analysis contained in the *Federal Register* notice was based on 1999 data, while this one uses data from 2005.

Several technical problems limit the usefulness of the new designation methodology:

- 1) The formula excludes key access variables, such as percent of the population uninsured, and does not adequately adjust for non-physicians.

^a Numerous people contributed to this report. Staff of the Robert Graham Center, including Robert Phillips, Andrew Bazemore, Stephen Petterson, and Imam Xierali provided the data impacts of the proposed regulations and made many useful suggestions. Professor Thomas Ricketts of the Cecil G. Sheps Center for Health Services Research at the University of North Carolina kindly shared some of his data and unpublished analyses. Dan Hawkins and Michelle Proser of the National Association of Community Health Centers provided substantial advice concerning the content of this report. All opinions expressed are those of the authors. This should not be viewed as expressing the positions of The George Washington University, the American Academy of Family Physicians, the National Association of Community Health Centers, or the RCHN Community Health Foundation.

- 2) The methodology jeopardizes the designation status of one in four urban and one in six rural and frontier areas.
- 3) The model used to estimate impacts uses outdated data and may not be flexible to account for new types of data.
- 4) The need for a safety net facility designation to preserve existing health centers appears to reflect the general awareness that the data and formula limitations may not adequately capture level of underservice.

It is impossible to say with certainty what designation level health centers will receive under the proposal – and thus what level of priority for funding – but our analysis with more current data indicates that the new rule will result in a much larger adverse impact than was illustrated in the *Federal Register*:

- 1) Only one-third of all health center sites – 34 percent of existing FQHC sites – may meet Tier 1 qualification, a status indicator of high need for additional resources.
- 2) Fewer areas and health centers will receive designation of underservice: 67 percent of health center sites (substantially less than the 92 percent in 1999) could meet Tier 2 criteria, which adjusts for low-income population and excludes some federally-supported primary care clinicians (such as National Health Service Corps clinicians, those receiving J-1 visas or other clinicians working at FQHCs). Finally, 33 percent of health center sites – 1,130 – do not appear to meet Tier 2 status and will have to rely on safety net facility designation, the *lowest priority* group for funding. HHS estimates that only 16 of the existing health centers will be unable to meet the qualifications to be designated as safety net facilities, however.
- 3) 29 million people (39 percent of the baseline population) live in MUA areas that might lose designation under the more lenient Tier 2 criteria.
- 4) Urban areas and northeastern and northwestern states are particularly hard hit.

Note

Since this report was initially released, HHS issued a *Federal Register* notice on April 21, 2008 that extended the comment period for the proposed rule through May 29, 2008. The notice included some clarifications in policy and requested comments on additional topics, although it did not modify the proposed regulatory language itself.

Although this analysis is focused on the needs of FQHCs, there are major implications for other parts of the health care system, especially the health care safety net. This is because if implemented, the proposed rule could essentially reduce or freeze health care resources for entities and geographic areas that either become newly designated with a relatively low funding priority, that are eligible as only as safety net facilities or that fail to meet even these more limited need criteria. Indeed, numerous federal health care agencies, such as HRSA and the Centers for Medicare and Medicaid Services (CMS) use MUA and HPSA designations to establish program funding and payment policies (including provider eligibility for special Medicare and Medicaid payment rates under the FQHC, RHC, and Medicare shortage area programs). Despite the enormous policy implications of the designations, the regulations are silent on their meaning for resource and payment policy, although the Preamble to the regulation

hints at several points about what the policy impact of a change in designation status might be. Thus, a major deficiency of the proposed regulations is that, although they establish rules for setting Tier 1, Tier 2 or safety net facility designations, they do *not* indicate how these designations or how the scores that underlie these designations would be used to develop program policy across the range of federal programs and activities that utilize these criteria in determining eligibility for resources or special payment rules or other designations that have major resource implications. For example, would non-health center providers that qualify as safety net facilities be eligible for special Medicare or Medicaid treatment under the Medicare provider incentive payment program or as Rural Health Clinics? Without further clarification, it is difficult to fairly anticipate the effects of the new rules.

Because this analysis focuses only on the impact of the rule for health centers, it significantly understates its potential effects. Because of the enormous implications of the rule for basic health care access and population health, a sensible course of action at this point would be withdrawal of the proposed rule, and the use of a more transparent and comprehensive policy developmental process that includes not only formulaic considerations of shortages and underservice but also extensive, formal consultation with key health system stakeholders such as Governors and state legislatures, affected health care entities, public health experts, and patients and consumers.

Introduction

In 2000, the Institute of Medicine defined the safety net as health care providers that by mission or by law provide a greater than average level of service to low-income and medically vulnerable populations in both urban and rural communities.¹ The Health Resources and Services Administration (HRSA), the federal agency within the United States Department of Health and Human Services that administers several programs that support the safety net, currently utilizes two types of shortage designations to target federal resources for improving access to health care services: the Health Professional Shortage Area (HPSA), and the Medically Underserved Area/Population (MUA/P). Both designation systems exist as formal federal policy; the HPSA designation is part of the National Health Service Corps authorization,² while the MUA designation is an element of the community health centers statute.³ As of 1995, half of all counties in the United States were designated MUAs or HPSAs and 88 percent of all counties contained a MUA or HPSA.⁴

Because being designated is foundational to qualifying for assistance under numerous programs, any changes to the designation process will have potentially tremendous implications for the health care safety net. The underservice designations have been used to help prioritize the distribution of federal and state funds to provider shortage areas with high health care needs. More than 34 federal programs depend on these shortage designations for eligibility and funding

¹ Institute of Medicine 2000. "America's Health Care Safety Net: Intact but Endangered." Washington, DC: National Academy Press

² <http://bhpr.hrsa.gov/shortage/hpsaguidepc.htm>

³ <http://bhpr.hrsa.gov/shortage/muaguide.htm>

⁴ General Accounting Office. September 1995. "Health Care Shortage Areas: Designations Not a Useful Tool for Directing Resources at the Underserved." GAO/HEHS-95-200. <http://www.gao.gov/archive/1995/he95200.pdf>

preference purposes (see Table 1 for a list of programs).⁵ Almost \$3 billion in federal funds were dispensed through programs that use the HPSA or MUA system to determine eligibility in FY 2005 and these designations are sometimes used by states as well.⁶

As Table 1 shows, the two designations are critical for receiving federal and state aid. The MUA/P designation is required for receipt of community and rural health center grants, as well

Table 1. Federal and State Programs that Use HPSA or MUA/P Designation⁷

Program	Designation Used
Medicare Provider Incentive Payments	Geographic HPSAs only
National Health Service Corps: Scholarship and Loan Repayment Programs	HPSAs
FQHC Operating Costs Grants	MUA or MUP
FQHC and Look-Alike Cost-Based Reimbursement	MUA or MUP
Rural Health Clinic Cost-Based Reimbursement	Geographic or population HPSA (not facility HPSAs) or MUA (not MUP)
Exemption for new physicians opening practices from Medicare limitations on “customary charges”	Non-metropolitan HPSAs
Training: Nurse practitioners/Nurse midwives	HPSA
Training: Physicians Assistants, General Internal Medicine, General Pediatrics, Family Medicine, General Practice Dentistry, Mental Health Professionals, among others	HPSAs (or other qualifying sites such as migrant health clinics)
Area Health Education Center Program	HPSAs
Physician Education Loan Repayment Program	HPSA
Limited Prescriptive Authority for Advanced Practice Nurses and Physician’s Assistants	HPSA or MUA/MUPs
Medically Underserved Community-State Matching Incentive Program	Rural HPSA or MUA
J-1 visa waiver program, allowing foreign-born physicians to remain in the U.S.	HPSA, MUA, or MUP
State Rural Provider Incentive Grant	HPSA

⁵ Health Resources and Services Administration. “Shortage Designation.” www.bhpr.hrsa.gov/shortage; accessed April 10, 2008; Government Accountability Office. October 2006. “Health Professional Shortage Areas: Problems Remain with Primary Care Shortage Area Designation System.” GAO-07-84. <http://www.gao.gov/new.items/d0784.pdf>

⁶ Ibid.

⁷ Health Professions Resource Center, Center for Health Statistics, Texas Department of State Health Statistics. October 26, 2007. “Benefit and Incentive Programs Related to HPSA, MUA & MUP Designated Sites.” <http://www.dshs.state.tx.us/CHS/hprc/benefits.pdf>; Alaska Department of Health & Social Services. “Federal Programs that Use HPSA and MUA/P Designations.” http://www.chems.alaska.gov/PCRH/documents/HPSAfedprograms_000_000.pdf; South Carolina Department of Health and Environmental Control, Primary Care Office. “Shortage Designations.” <http://www.scdhec.gov/health/opc/hpsa.htm>

for cost-based reimbursement for “look-alike” health centers that are not Federally Qualified Health Centers (FQHC) or rural health clinics (RHC).⁸ The HPSA designation has been used to help improve or maintain an adequate supply of primary care physicians, especially by the National Health Service Corps in their process of assigning physicians to various locations and granting scholarships and loan repayment programs.⁹ In addition, the Centers for Medicare and Medicaid Services’ (CMS) Medicare Incentive Payment Program spends about \$148 million annually to give extra payments to providers in HPSAs. “J-1 visa” programs for foreign physicians trained in the United States use HPSA designation to determine where in the U.S. these physicians may practice to gain a waiver of the requirement that they return to their home countries for at least two years following graduate medical education in the U.S. In addition, health professionals’ education and training grants are targeted at providers within HPSAs.¹⁰

Community health centers (CHC) stand out among the safety net providers that rely heavily on the current MUP/HPSA designations for establishing and expanding practices and for funding. Between 1985 and 2007 alone, the number of CHC sites increased from 1,015 to over 5,000, and the number of patients served increased from five million to 16 million.¹¹ Because they anchor the primary care safety net in many rural and frontier communities and inner cities, serving as a medical and health care home for patients with complex medical and social needs and often without health insurance, any changes in designation process and scores should be expected to preserve and enhance their effectiveness. However, recent government evaluations indicate the methodology for HPSA (as well as MUA/P) designation does not accurately identify areas of health care needs or effectively help prioritize the need for assistance.¹² The new rule proposes to address these concerns and indicates that a majority of health centers would continue to qualify. However, our assessment suggests that the impacts are understated and many existing sites and largely urban health centers will be placed at financial and operational risk.

Health Professional Shortage Areas: History and Current Rules. Though the earliest efforts to systematically identify medically underserved locations date back to the 1930s, the creation of the National Health Service Corps in 1970 necessitated the creation of a method for determining which areas should be considered underserved and thus benefit from the new program. The first designation, called a Health Manpower Shortage Area (HMSA), was simply defined as a population-to-primary care physician ratio higher than 4,000 to 1.¹³ This was amended by Section 332 of the Public Health Services Act in 1976, leading to new criteria issued in 1978 of 3,500:1 for geographic area designations and 3,000:1 for population group designations.¹⁴

⁸ Health Resources and Services Administration. “Guidelines for Medically Underserved Area and Population Designation.” <http://www.bhpr.hrsa.gov/shortage/muaguide.htm>; accessed April 10, 2008.

⁹ Health Resources and Services Administration. February 29, 2008. “HRSA Proposes Rule to Revise, Combine HPSAs, MUPs.” Press Release. <http://newsroom.hrsa.gov/releases/2008/hpsaproposedrule.htm>

¹⁰ GAO-07-84.

¹¹ National Association of Community Health Centers analysis of Uniform Data System data, 2007.

¹² GAO/HEHS-95-200.

¹³ Emergency Health Personnel Act of 1970, Public Law 91-623.

¹⁴ Public Health Services Act, 42 USC 263a, Sec. 332 (a)(1)(A); Ricketts, T., Goldsmith, L., Holmes, G., et al. 2007. “Designating Places and Populations as Medically Underserved: A Proposal for a New Approach.” *Journal of Health Care for the Poor and Underserved* 18: 567-589.

The Health Professional Shortage Area designation was created in 1978, and the criteria for determining HPSA status have not changed since 1993.¹⁵ HPSA designation can be given to a geographic area, population, or facility. For geographic HPSA designation, areas that exceed a population-to-primary care physician ratio of 3,500:1 (or 3,000:1 under special circumstances) qualify for geographically based HPSA designation, as long as the area can be defined as a rational service area and there are an insufficient number of providers in adjacent areas. Certain categories of physicians, such as National Health Service Corps members and those serving under the J-1 visa program, are excluded from the ratio calculations, as are many types of nonphysician practitioners.

If they do not qualify for geographic HPSA designation, safety net providers that serve underserved populations can be designated as HPSA facilities either through population or facility designation.¹⁶ A population designation requires a population-to-provider ratio of at least 3,000:1, and the facility must survey area physicians to demonstrate that the population in question is in fact underserved.¹⁷

Facility-level designations have no provider ratio requirements for FQHCs and look-alikes, but Rural Health Clinics must additionally certify that they provide care to anyone regardless of their ability to pay.¹⁸ In 2002, all FQHCs were given automatic HPSA status, although this was redundant for about half of the health centers, since they are located in geographic- or population-defined shortage areas.¹⁹ Of facility designations in 2002, 63 percent were community health centers, 23 percent were rural health clinics, and 14 percent were federal or state correctional institutions.²⁰

Under current methods, each geographic, population, or facility HPSA is given a score based on factors capturing the need for primary care providers: the ratio of population to primary care providers, the poverty rate, the infant mortality or low birth weight rate, and the travel time or distance to the nearest available site of primary care. Some programs use the score as well as the overall HPSA designation to determine eligibility and funding levels.²¹ HPSA designations are required to be updated every three years, unlike the MUA/P designation, which has no expiration date.²² However, despite legal requirements to review designations, HHS has not published a list of designated HPSAs in the Federal Register since 2002, allowing technically expired HPSAs to remain active.²³

Medically Underserved Areas/Populations: History and Current Rules. In order to qualify for Community Health Center grants, health centers must be located in a medically underserved area. The Medically Underserved Area (MUA) designation was created by the 1973 Health

¹⁵ 42 CFR Part 5; GAO-07-84.

¹⁶ 42 CFR Part 5.

¹⁷ GAO/HEHS-95-200.

¹⁸ GAO-07-84.

¹⁹ Health Care Safety Net Amendments of 2002; GAO-07-84.

²⁰ GAO-07-84.

²¹ GAO-07-84.

²² A Guide to Federal Health Professional Shortage (HPSA) and Medically Underserved Area/Population (MUA/P) Designations in Washington State. January 2, 2007. http://www.doh.wa.gov/hsqa/ocrh/HPSA/HPSA_Guide.pdf

²³ GAO-07-84.

Maintenance Organization Act, and from the outset included three factors in addition to the physician-population ratio used to calculate the HPSA. The MUA designation is based on an Index of Medical Underservice, which is a composite of the:

- 1) poverty rate,
- 2) proportion of residents over age 65,
- 3) infant mortality rate, and
- 4) population-to-primary care physician ratio (although, as with HPSAs, certain types of physicians are excluded)²⁴

High needs populations can also receive status as a Medically Underserved Population if they face significant economic, sociological, and/or cultural and linguistic barriers to primary care.²⁵ The index for a Medically Underserved Population (MUP) is calculated using the same variables and methods as an MUA calculation, but only the population in question (for instance, only low-income individuals) is counted, and only the physicians that serve this population are factored into the index.²⁶

In contrast to the HPSA process, MUAs and MUPs are not subject to review at any point. Because MUA/P designations are based on older data, the GAO calculated in 1994 that about half of the county-sized MUAs would no longer qualify for the designation if more data was used to perform the calculations.²⁷ The GAO even took the dramatic step of recommending that MUA and HPSA designations be eliminated as requirements for participation in all federal programs and replaced by criteria for inclusion that are more tailored to the goals of each program.

In response to the GAO evaluation, the Health Resources and Services Administration (HRSA) released a Notice of Proposed Rulemaking on September 1, 1998, which would have unified the designation process and resulted in a very large number and proportion of providers losing their MUA/P or HPSA designations.²⁸ Over 800 comments were received; most from stakeholders concerned about losing their designations. The main criticisms, other than the massive loss of designated areas, were that not enough current data was utilized and that the new method was not grounded in a theory of access and underservice. HRSA withdrew the proposed rule, but maintained a commitment to improve the designation process.²⁹

²⁴ Ricketts, T., Goldsmith, L., Holmes, G. et al. 2007.

²⁵ Health Resources and Services Administration. "Guidelines for Medically Underserved Area and Population Designation." op. cit.; GAO/HEHS-95-200.

²⁶ On average, the number of primary care FTEs is multiplied by 0.21 to yield the number that serve low-income populations. See Ricketts, T., Goldsmith, L., Holmes, G., et al. 2007.

²⁷ GAO/HEHS-95-200.

²⁸ Goldsmith, L., Holmes, M., Osterman, J. and Ricketts, T. 2007. "A Proposal for a Method to Designate Communities as Underserved: Technical Report on the Derivation of Weights." Department of Health and Human Services. <http://bhpr.hrsa.gov/shortage/weightderivation.htm>

²⁹ Ricketts T., Goldsmith L., Holmes J. et al., 2007.

Proposed Rule and Methods

On February 29, 2008, the Department of Health and Human Services released a notice of proposed rulemaking to modify the methods used to designate underserved areas and populations.³⁰ In the new proposal, HRSA recommended a revised methodology that created a single “Index of Primary Care Underservice” to determine the level of underservice in both HPSA and MUA/P areas.³¹ The primary goal of the proposed change is to consolidate the procedures for making designations, streamlining and simplifying the system for facilities seeking designation, but continuing to differentiate HPSAs and MUPs in light of the multiple uses for these designations.³² Other priorities stressed by HRSA were that the criteria be science-based and not dramatically alter the number of areas and facilities that are designated as underserved or serving the underserved, thus disrupting service.³³

The new scheme includes three levels of designation, which are considered in this order for each area or facility:

- 1) **Geographic HPSA** – designated solely based on service areas
 - **Tier 1**, with all non-federal primary care clinicians included in the ratio
 - **Tier 2**, excluding federally-supported primary care clinicians (such as National Health Service Corps clinicians, those receiving J-1 visas or other clinicians working at FQHCs)
- 2) **Population MUP** – also based on service to specific underserved populations
 - **Tier 1**, with all non-federal primary care clinicians included
 - **Tier 2**, excluding federally-supported primary care clinicians
- 3) **Safety-net facility HPSA** – a new designation
 - An FQHC, RHC or similar public or non-profit safety net provider that is not in a HPSA or MUP as described above, which serves at least a certain percentage of Medicaid and uninsured patients

As noted above, in each geographic and population category, there are two tiers of shortage. Tier 1 designations are given to areas, populations, and facilities that exceed the population-to-provider ratio threshold with all clinicians are counted. Tier 2 designations are given to areas and populations that exceed the threshold only when federally-sponsored clinicians are excluded from the calculation. Since Tier 2 includes fewer primary care clinicians, the population-to-provider ratio is higher and more areas qualify for HPSA or MUP status under Tier 2 than under Tier 1. In assigning federal resources, it is likely that areas with Tier 1 status will be considered a higher priority than those with Tier 2 status.³⁴

³⁰ Department of Health and Human Services. Feb. 29, 2008. “Designation of Medically Underserved Populations and Health Professional Shortage Areas.” *Federal Register* 73(41):11232-81.

³¹ 42 CFR Parts 5 and 51c. February 29, 2008. “Designation of Medically Underserved Populations and Health Professional Shortage Areas: Proposed Rule.”

³² Health Resources and Services Administration. February 29, 2008. op.cit.

³³ Ricketts T., Goldsmith L., Holmes J., et al. 2007.

³⁴ The preamble to the February 29 proposal discussed Tier 1 and 2 criteria and said: “Both types of designations could be eligible for federal programs authorized to place resources in MUPs or HPSAs. However, Tier 2 areas

The third designation category, which apparently gets the lowest funding priority, is the safety-net facility HPSA. It is granted to health centers as long as 40 percent of their patients are Medicaid-eligible and uninsured in metropolitan areas (30 percent in rural areas and 20 percent in frontier areas). The designation criteria also require that the uninsured account for at least 10 percent of patients. The proposed rule would then create a new MUP consisting of the low-income and Medicaid-eligible population served by a safety-net facility designated FQHC.

The idea behind the new measure of underservice described in the proposed rule is that demographic, economic and health characteristics of each area affect how the population-to-practitioner ratio actually translates, in the real world, to access or lack of access to primary care. While the general methodology for designation is still based on a population-to-practitioner ratio approach, it now reflects some “corrections” for underestimates that were previously not accounted for in the previous model. Over 20 variables from national datasets were tested for inclusion in the new model, and nine were found to be adequate for better estimating “need” for primary care services (see Table 2). Additionally, the new methodology involves use of “barrier-free populations” calculations, which reflect the number of people within a geographic area that primary care providers could service under the optimal conditions, to address relative capacity of primary care in a geographic area.

Despite concerns about the types and number of providers used in the previous model, the new methodology continues to use the same types of providers and weights to yield the provider ratio: doctors of medicine and osteopathy are given a full weight of 1 (and residents counted as 0.1), while Nurse Practitioners, Certified Nurse-Midwives, and Physician’s Assistants are given a weight of 0.5.³⁵ The complex algorithm used in the new methodology uses both the population-to-provider ratios and need indices to compute a final score. If that score is greater than 3,000, then an area or population may be considered to meet the criteria for designation as a HPSA or MUP.

Table 2. Variables Reflecting the Need for Primary Care

Demographic	Economic	Health Status
Percent nonwhite	Percent of population below	Death rate

would typically be eligible only to maintain the approximate levels of federal resources already deployed, while Tier 1 areas could apply for additional resources.” (p. 11247). The April 21 extension says: “In the preamble, a statement in section IV. B. Methodology ... inaccurately reflects our intent and the potential effect regarding eligibility for organizations designated Tier 2 designations will not be eligible for additional Federal resources. That is not the case. No provision in the proposed rule imposes any such limitation and it is not our intent to do so. Under the proposed rule, whether designated via Tier 1, Tier 2, or Safety Net Facility all entities will be equally eligible to compete for new or expanded health center funding. Similarly, all entities designated through Tier 1, Tier 2, or Safety Net Facility will be equally eligible to compete for National Health Service Corps (NHSC) placements. In contrast to the health center policy described above, NHSC placements are site specific pursuant to section 333(a) of the Public Health Service Act. For example, while a health center grantee may be eligible for health center funding for all of its sites, only some of its sites may be eligible under law for NHSC placements.” (p. 21301). The use of Tier 1, Tier 2, or safety net facility designations and their applications in programmatic decisions is entirely absent from the proposed regulatory language, however, and the interpretation remains unclear to us.

³⁵ Ricketts T., Goldsmith J., Holmes L., et al. 2007.

	200 percent of the poverty level	
Percent Hispanic	Unemployment rate	Low birth weight rate
Percent Elderly		Infant mortality rate
Population Density		

The new rule also continues to allow for state and local involvement under the new designation process in defining rational service areas, identifying special populations groups as medically underserved, or collecting new and more localized data for undesignated areas. Although the new rule aims to minimize state and local involvement with the use of national datasets, the impact analysis suggests most states may have to invest considerable effort to collect data, particularly for urban areas that may lose their designation or are under-scored.

Impact of the Proposed Change

This section examines the impacts in greater detail and is primarily based on the **1999** analyses published in the February 29 *Federal Register* and more recent analyses based primarily on **2005** data by Professor Thomas Ricketts of the University of North Carolina (who helped design and test the methodology)³⁶ and researchers at the Robert Graham Center.³⁷

Relatively little of the information provided in the *Federal Register* actually help to assess the effect of the rules on the number of FQHCs affected or on the size of the population in the areas served by FQHCs. Health centers, in particular, have relied heavily on federal resources to effectively improve access over the past 40 years for millions of Americans who face substantial barriers to health care due to such factors as geographic isolation, cultural and language differences, poverty, uninsurance, and lack of available providers.³⁸ Despite the effectiveness and fragility of the safety net, the new formulas for designation are more likely to disrupt, rather than improve, access to care for millions of Americans by increasing the uncertainty that health centers face. While the *Federal Register* found few health centers would be adversely impacted, the impact analysis was compromised by the use of outdated data collected in 1999. New analyses presented here suggest that the impact is strikingly different and that a much larger number of health centers could be in jeopardy because of the proposed regulations.

Table 3 summarizes some key findings using both the published 1999 analyses and the new 2005 analyses. Of particular importance, the table shows that the 1999 analysis indicated that 89 percent of existing FQHCs (including clinic sites that provide the full range of primary care services) met Tier 1 criteria, the highest priority status, and 92 percent met Tier 2 criteria.

³⁶ Ricketts, T. Aug. 10, 2007. "Impact Testing of the Proposed Revised Methodology for Designating Underserved Areas," Draft final report submitted to HRSA.

³⁷ These analyses are currently unpublished, but should be released in the near future.

³⁸ Hadley, J.,Cunningham, P., and Hargraves, J.L. 2006. "Would Safety-Net Expansions Offset Reduced Access Resulting from Lost Insurance Coverage? Race/Ethnicity Differences." *Health Affairs* 25(6):1679-1687; Shi, L., Stevens G.D., Wulu J.T., et al. 2004. "America's Health Centers: Reducing Racial and Ethnic Disparities in Perinatal Care and Birth Outcomes." *Health Services Research*, 39(6, Part I), 1881-1901; Shin, P., Jones, K. and Rosenbaum, S. 2003 "Reducing Racial and Ethnic Health Disparities: Estimating the Impact of High Health Center Penetration in Low-Income Communities." George Washington University Medical Center, Center for Health Services Research and Policy.

However, the same analysis using more current data indicates that *only 34 percent of existing FQHC sites may meet Tier 1 criteria and only 67 percent could meet Tier 2 criteria*. That is, two-thirds (66 percent) of FQHC sites – 2,256 – might fail to meet Tier 1 criteria. While analysis of Tier 1 designation shows the difficulty in achieving high priority status, analysis of the Tier 2 designation may be more noteworthy because those areas or health centers that fail to meet the criteria are most likely to receive no new or additional resources. In 1999, only eight percent of FQHC sites that provide comprehensive primary care would be excluded from Tier 2 status under the new rule. However, in 2005, about 33 percent of FQHC sites – or 1,130 – do not appear to meet Tier 2 status. In effect, application of more recent data indicates fewer areas and health centers will receive the designation of serving an underserved area or population (or a facility-level designation).

Table 3. Changes in the Number of Areas and FQHC Sites Under the Proposed Methodology, Using 1999 and 2005 Data

	1999			2005		
	Baseline	Number (%) Retained or Gained, using Tier 1	Number (%) Retained or Gained, using Tier 2	Baseline	Number (%) Retained or Gained, using Tier 1	Number (%) Retained or Gained, using Tier 2
Designated HPSA areas	2,282	1,660 73%	2,103 92%	2,412	1,125 47%	1,807 75%
New HPSA counties		325	777		165	381
Designated MUA/P areas	3,458	2,319 67%	3,018 87%	3,754	1,910 51%	2,837 76%
New MUA/P counties		168	387		64	170
Number of FQHC sites in designated areas	1,481	964 62%	1,364 92%	3,433	1,177 34%	2,303 67%

Note: Tier 2 method also includes the low-income population group adjustment. FQHC sites include only clinics that provide the full range of primary care services.

Source: 1999 data from the *Federal Register*, 2005 data from Prof. Ricketts and analysis by the Graham Center.

Table 3 also shows changes in the number of areas (primarily counties, but some sub-county areas) that currently qualify as HPSA or MUA/P areas. Not surprisingly, most areas that have CHCs contain both HPSA and MUA/P designations. While the majority of areas would retain some level of designation under the new rules, the 2005 data indicate that a smaller share of areas would retain their status than the analysis that accompanied the February 2008 proposed regulation, which relied on 1999 data.³⁹ Additionally, even though the 2005 data indicate that 16

³⁹ As much as possible, the 2005 analyses used data and definitions that paralleled the 1999 analyses. A small portion of the difference might be due to minor computational differences or situations where data could not be updated or replicated. For example, it was not possible to exclude primary care clinicians employed at FQHCs, other than those who were National Health Service Corps, State Loan Repayment Program or J-1 visa clinicians in the 2005 analyses. However, the 1999 analyses indicate that making these adjustments has a small impact. For example, Table VI-11 in the February 29 preamble indicates that deducting other FQHC clinicians would increase the number of FQHCs that qualify for Tier 2 status by only 2.4 percent.

percent of areas would be newly designated as HPSAs and five percent of MUA/P areas would be newly qualified as MUA/P, these percentages are substantially less than those supplied along with the proposal.

Although both urban and rural areas are adversely affected, the proposed methodology is relatively harsher in its treatment of urban areas. Tables 4 and 5 demonstrate the results of the 2005 analyses for these areas currently qualified as MUAs, which is particularly important for the allocation of funding for FQHCs. As seen in Table 4, more than one-quarter (28 percent) of urban MUA areas and about one-sixth of rural and frontier areas (17 percent and 18 percent, respectively) could lose their designations under Tier 2 criteria. However,

Table 4. Effect of the Proposed Methodology on the Number of MUAs, Using Tier 2 Low-income Criteria and 2005 Data

Geographic type	Number of baseline MUAs	Number of MUAs losing designation under new method	Percent change of MUAs losing designation
Urban (metropolitan)	2,376	672	-28%
Rural	961	168	-17%
Frontier*	417	7	-18%

* Frontier areas have a population density below 7 people per square mile.
Source: 2005 data from Prof. Ricketts and analysis by the Graham Center.

Table 5 shows that the results are even less balanced when one considers the number of people living in those areas. Almost 29 million people (39 percent of the baseline population) live in urban MUA areas that might lose status using Tier 2 criteria. Both the number and percent of people living in rural or frontier MUA areas that could lose status is much smaller than those of

Table 5. Effect of the Proposed Methodology on the Number of People Living in Areas with MUA Status, Using Tier 2 Low-income Criteria and 2005 Data

Geographic type	Number of people living in baseline MUAs (millions)	People in MUAs losing status under new method (millions)	Percent change of people living in MUAs losing status
Urban (metropolitan)	73.66	28.75	-39%
Rural	12.08	1.81	-15%
Frontier*	1.86	0.32	-17%

* Frontier areas have a population density below 7 people per square mile.
Source: 2005 data from Prof. Ricketts and analysis by the Graham Center.

Table 6. Changes in Number of Designated Areas and FQHC Sites Losing MUA Status by State, Under Tier 2 Low-income Criteria, Using 2005 Data

State	Percent of designated areas retaining MUA status	Percent of FQHC Sites retaining MUA status	State	Percent of designated areas retaining MUA status	Percent of FQHC Sites retaining MUA status
Alabama	85%	71%	Missouri	83%	70%
Alaska	71%	83%	Montana	80%	42%
Arizona	90%	80%	Nebraska	71%	100%
Arkansas	91%	84%	Nevada	90%	86%
California	74%	73%	New Hampshire	22%	11%
Colorado	60%	52%	New Jersey	66%	75%
Connecticut	58%	67%	New Mexico	90%	86%
Delaware	50%	33%	New York	68%	67%
District of Columbia	56%	26%	North Carolina	71%	83%
Florida	59%	39%	North Dakota	74%	53%
Georgia	81%	73%	Ohio	77%	58%
Hawaii	75%	47%	Oklahoma	92%	92%
Idaho	97%	85%	Oregon	70%	21%
Illinois	79%	76%	Pennsylvania	72%	60%
Indiana	75%	48%	Rhode Island	29%	13%
Iowa	73%	30%	South Carolina	87%	71%
Kansas	54%	50%	South Dakota	74%	79%
Kentucky	89%	89%	Tennessee	73%	84%
Louisiana	93%	85%	Texas	91%	93%
Maine	56%	27%	Utah	90%	86%
Maryland	63%	50%	Vermont	56%	36%
Massachusetts	52%	47%	Virginia	62%	59%
Michigan	73%	72%	Washington	56%	26%
Minnesota	60%	68%	West Virginia	83%	82%
Mississippi	87%	78%	Wisconsin	67%	54%
			Wyoming	92%	25%

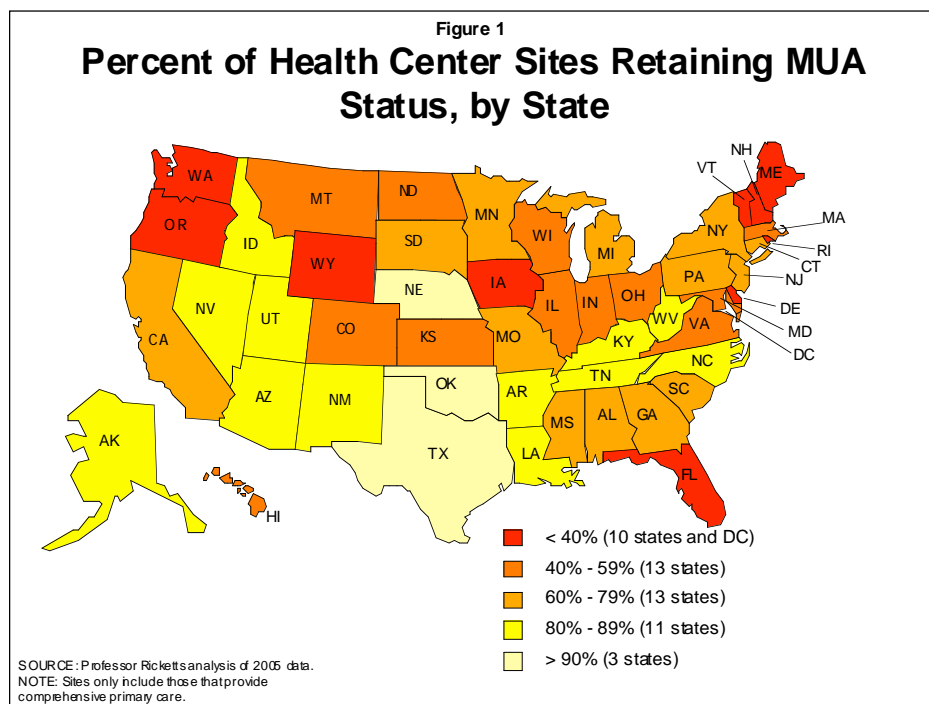
Note: FQHC sites include only clinics that provide the full range of primary care services. Therefore, some satellite clinics are excluded.

Source: 2005 data from Professor Ricketts and analysis by the Graham Center.

urban areas However, in contrast to estimates based on 1999 data, the loss in designation for rural and frontier areas (as well as urban) appear to be substantially greater when using more current data.

Table 6 presents state-by-state data on the percentage of designated areas and FQHC sites that could retain their MUA status under the Tier 2 criteria, using 2005 data. In 15 states, more than half of health center sites could be in jeopardy of losing MUA designation: Delaware, District of Columbia, Florida, Hawaii, Iowa, Indiana, Maine, Massachusetts, Montana, New Hampshire, Oregon, Rhode Island, Vermont, Washington, and Wyoming. Additionally, Table 6 shows that no state will be able to retain all its MUA designations.

Figure 1 shows that some health centers in all states, except Nebraska, are expected to lose their MUA area designation, with some of the largest losses occurring among states in the northeast and the northwest. In 11 states (Delaware, District of Columbia, Florida, Iowa, Maine, New Hampshire, Oregon, Rhode Island, Vermont, Washington, Wyoming), more than three out of five FQHC sites that provide comprehensive primary care would lose their MUA designation.



Analyses of the caseloads of current FQHCs indicate that almost all have caseloads of Medicaid and uninsured patients that are large enough to qualify for safety-net facility HPSA designations under the new proposed regulations. Less than 20 health centers appear to fail to meet those criteria. However, as noted previously, it is not yet clear whether health centers with a safety-net facility designation (rather than a HPSA or MUP designation) will be eligible for additional federal resources in the future or not.⁴⁰

⁴⁰ However, the April 21 notice indicated that all entities that qualify as Tier 1, Tier 2 or safety net facilities will be “equally eligible to compete for new or expanded health center funding.” As discussed earlier, however, this proviso is not included in the regulatory language, nor does it say whether Tier 1, Tier 2 or safety net status or the scores underlying these designations will be used in specific funding decisions for FQHCs or the other uses of these designations.

Technical and Conceptual Challenges

It is worth noting that the analyses presented are based on the service areas or populations for FQHCs or their sites as they were defined in 1999 or 2005. It is possible that some of the facilities could reconfigure their service area or population definitions so that they would continue to qualify under the proposed rules. While it is beyond the scope of this analysis to consider alternative service or population definitions that might be used to qualify these areas. There are a number of technical and conceptual challenges that HHS ought to consider in improving or redesigning the proposed methodology.

Rural Preference. As noted above, the proposed methodology provides a strong advantage to rural over urban areas, particularly because of reliance on the population-to-provider ratio and population density. But access to primary health care is more complex than these measures indicate. According to Healthy People 2010, the two most important indicators of access to health care are having a usual source of health care, such as a primary care physician, and health insurance status.⁴¹ Research by the Agency for Healthcare Research and Quality indicates that among the uninsured, rural residents are more likely to have a usual source of care than those living in metropolitan (urban) areas: only 52 percent of uninsured residents in metropolitan areas have a usual source of care, compared with 71 percent of uninsured rural residents.⁴² Similarly, rural Medicaid beneficiaries are more likely than urban beneficiaries to have a usual source of care, even after controlling for health status, age, race, and other factors.⁴³

The proposed methodology obscures the serious challenges that face many urban residents in accessing health care services. Even when primary care providers are located close to urban residents, many urban residents have little or no access to affordable primary care unless safety net clinics or community health centers are present.

The Population-to-Provider Ratio. Under the proposed methodology, after the complex computations are done, the designation of HPSA, MUA or MUP status relies on whether the ratio of population to primary care providers is greater than 3,000:1. This is intended to correspond to the historical ratio of population to primary care providers used to designate HPSAs: there must be a 3,500:1 ratio of population to providers or 3,000:1 in special circumstances.⁴⁴ The preamble to the regulation offers the justification that a number of studies, mostly from the mid-1990s, suggested a typical patient caseload for primary care physicians of about 1,500 patients per provider. HRSA states that the 3,000:1 ratio is thus a very conservative test for areas with substantial shortfalls.⁴⁵ One might reasonably wonder whether a lower

⁴¹ United States Department of Health and Human Services. "Healthy People 2010, Leading Health Indicators." http://www.healthypeople.gov/Document/HTML/uih/uih_4.htm

⁴² Larson, S., et al. July 2004, "Health Care in Urban and Rural Areas, Combined Years 1998-2000" Chartbook 13, Agency for Healthcare Research and Quality.

⁴³ Long S., King J. and Coughlin T. 2006. "The Health Care Experiences of Rural Medicaid Beneficiaries," *Journal of Health Care for the Poor and Underserved* (17):575-59.

⁴⁴ United States Health Resources and Services Administration. "Health Professional Shortage Area Primary Medical Care Shortage Designation Criteria." <http://www.bhpr.hrsa.gov/shortage/hpsacritpcm.htm>

⁴⁵ *Federal Register* 73(41): 11246, Feb. 29, 2008.

standard, such as 1,500:1 is more reasonable, given the evidence. In 1996, HRSA defined an adequate ratio to be 2000:1.⁴⁶

Even if one believes that a 3,000:1 ratio might have been reasonable ten years ago, is it still reasonable, given changes in medical practice? Data from the National Ambulatory Medical Care Survey indicate that primary care visit rates (visits per 100 persons per year) increased by 21 percent from 1995 to 2005, signaling a trend of rising utilization.⁴⁷ If primary care utilization is rising, the “target” population-to-provider ratio may need to be adjusted downward, to reflect current physician/clinician workloads. If these ratios were adjusted to reflect changes in medical practice and utilization, then a more reasonable target might be about 2,500 rather than 3,000.

Additionally, non-physician measures have a significant impact on the ratio. However, the formula does not adequately address the decision to include (or exclude) certain types of non-physicians and discount rates applied to them. Nor does it include any adjustment for states where licensure laws limit the scope of practice. While the lack of non-physician data and the exclusion of non-physicians will likely lead to inaccurate estimates, an arbitrary decision without additional research to use the same measure is just as likely to lead to significant inaccuracies.

The Role of the Uninsured. An important gap in the proposed methodology is the lack of information about insurance status, a key predictor of access to health care (along with having a usual source of care). The percent of people who are uninsured is not included in the nine “need” factors used in HRSA’s formula. The reason given is that these data are not available at a local area level. While this was true in the late 1990s, when HRSA began work on this issue, this is no longer the case. The Census Bureau has already developed experimental estimates of the number and percent of people uninsured at the county level in the year 2000.⁴⁸ More important, the Census Bureau has just begun to collect health insurance data as part of the annual American Community Survey and will release these findings in late 2009. This will provide sample-based estimates of insurance coverage in all counties and jurisdictions with population greater than 65,000 in 2009; more detailed estimates for smaller areas, eventually including census tracts, will be available in later years by pooling data over multiple years. (See point #5 below for more discussion about census tract level information and the American Community Survey.)

Information about the uninsured could also have been included in the first step of the formula, which estimates benchmark “barrier free” utilization rates for a white, non-poor population by age and gender. Almost all elderly have insurance through Medicare, but large percentages of non-elderly adults and even children are uninsured. That is, the “barrier free” utilization of many non-elderly adults and children is reduced because many are uninsured. Leaving out insurance status creates a bias in favor of elderly residents of an area. If the “barrier free” calculations only included those who have insurance for all 12 months of a year, this would better correspond to

⁴⁶ HRSA, Federal Office of Rural Health Policy. “Facts About...Rural Physicians.”

http://www.shepscenter.unc.edu/research_programs/rural_program/phy.html; Center for Rural Health, North Dakota. “Health Professional Shortage Areas (HPSAs) and Medically Underserved Areas (MUAs)”

<http://ruralhealth.und.edu/pdf/hpsa.pdf>

⁴⁷ Burt, C., et al. June 29, 2007. “Ambulatory Medical Care Utilization Estimates for 2005,” *Advance Data from Vital and Health Statistics*, No. 388, Centers for Disease Control and Prevention.

⁴⁸ United States Census Bureau. “Model-Based Estimates Small Area Health Insurance Estimates for States and Counties.” <http://www.census.gov/hhes/www/sahie/index.html>

“barrier free” utilization and would modestly increase the weights given to the non-elderly population of an area.

The Accuracy and Timeliness of Provider Data Sources. One of HRSA’s objectives was to use national data as much as possible to simplify the calculations. An important question is whether the existing national data are adequate. The most important element in the proposed methodology is the number of practicing primary care providers in an area, used to estimate the population-to-provider ratio. The chief data source is the American Medical Association’s (AMA’s) physician masterfile. But the AMA masterfile is often out-of-date. Much of the key information, such as a physician’s address and whether he or she is still practicing, is based on surveys sent out every three or four years. One study found that the masterfile was inaccurate in capturing when physicians stopped practicing.⁴⁹ Equally of concern, even if information is up-to-date, the address(es) given for a physician might not correspond to where he or she practices. The AMA asks for a preferred address, and in some cases, also gets an office address. But many physicians work in multiple settings and the masterfile address information may not capture the actual practice sites or the percentage of time spent at each location. For example, a family practice resident may be based at a teaching hospital located in the inner city and use that as the preferred address, but actually spend the majority of time practicing in a suburban clinic. This affects not only those affiliated with teaching hospitals, but a large number of practicing physicians and other clinicians. There are additional gaps in provider data. For example, the data on nurse practitioners appears to be based on a survey collected in 2001.

Changes in Data Sources and Availability. Because health service areas do not necessarily correspond with county lines, it is desirable to have relevant data available at relatively small geographic levels, such as at the census tract level.⁵⁰ Some of the data used to measure need, including key indicators of poverty, are collected at census tract levels as part of the “long form” of the decennial Census, which is administered to one in every six households once every ten years. But the Census Bureau does not plan to collect long form data in 2010, the next decennial census. It is replacing the long form with the American Community Survey (ACS), mentioned above. The Census Bureau plans to continue to produce census tract level data using multiyear compilations of ACS data, beginning some time after 2010, but may suppress estimates in some areas in which the sample size is too small. Thus, census tract level data might not be available for some areas, particularly when creating appropriate Rational Service Areas. At the very least, the change in data sources means that estimates of income or employment might change substantially in the near future.

⁴⁹ Rittenhouse, D., et al. 2004. “No Exit: An Evaluation of Measures of Physician Attrition.” *Health Services Research* 29(5): 1571-88. See also Kletke, P. 2004. “Physician Workforce Data: When the Best is Not Good Enough,” *Health Services Research* 29(5): 1251-6.

⁵⁰ Census tracts are small areas defined by the Census Bureau, normally corresponding with a population between 1,500 and 8,000 persons.

Implications

Our analysis suggests that the effects of HRSA’s proposed regulation are strikingly different than those presented on February 29, although there is some uncertainty due to ambiguity in the regulatory policies, as well as the uncertainties associated with any complex data analysis conducted in a very short time period.

One of the most serious concerns is that, although the proposed regulation offers great detail about how MUAs and HPSAs will be scored and designated, including safety net facilities, there is almost no discussion or regulatory language about how these designations or scores will be used (or not used) in making programmatic decisions about: the funding of FQHCs, the allocation of NHSC clinicians, the designation of rural health clinic (RHC) status, the provision of Medicare provider incentive payments or the approval of J-1 visa waivers. Without clearer explanation of these policy options or decisions, it is almost impossible to understand the impact of these proposed regulations.

Analysis of the expected effects of HRSA’s proposed regulations using more recent data demonstrates that federally qualified health centers, which anchor the safety net in thousands of communities, face significantly greater funding uncertainties than anticipated. The analysis shows substantially greater numbers of existing health centers are in jeopardy of losing additional funding and federal health resources than presented in the impact analysis that accompanied the proposed rule. The use of old and inaccurate provider files, lack of uninsured data, and rural bias are likely to lead to such inaccurate estimates – for example, the new methodology underestimates the need for a large number of health centers or sites, despite evidence that the number of uninsured is growing.⁵¹ The new methodology also shows that health centers in mostly urban, northeast and northwestern areas would be most at risk of losing their designation.

The creation of the designation of last resort, “safety net facility,” appears to reflect a general awareness that the data and formula limitations may not adequately capture levels of underservice in different communities across the country. However, the application and implications for safety net facility designation are not entirely clear. There is some indication that the facility designation can be applied organization-wide. For example, at present, if 40 percent of urban health center patients have Medicaid and 10 percent are low-income, the patient population can be designated as an MUP. Does this mean that their MUP status under these conditions is set as at the same lower priority level for funding allocation? The proposed rule also suggests Tier 1 and 2 designations may be applied organization wide if some or a majority of sites qualify for the same tier designation. If true, what number or percentage of sites would qualify as a majority? Although almost all existing FQHCs would be eligible for safety net facility HPSA designation, the new rule presents significant challenges for investing in existing centers or services in non-MUA/HPSA areas. However, to date, no official policy clarification has been provided regarding how HRSA intends to balance funding for new and existing programs.

⁵¹ Hadley, J. and Cunningham, P. 2004. “Availability of Safety Net Providers and Access to Care of Uninsured Persons.” *Health Services Research* 39(5): 1527-1546.

Although this analysis focused on the needs of FQHCs, there are major implications for other parts of the health care system, such as Medicare payment levels for physicians practicing in underserved areas and for the allocation of National Health Service Corps staff and resources. In general, the new rule jeopardizes the broader safety net by essentially reducing or freezing health care resources for entities and areas that either receive a relatively low priority funding designation or else lose their designation altogether. While the designation process allows for urgent requests for redesignation, this type of request can be triggered only upon a “sudden” (undefined) decrease in primary care capacity or at a point in which a health care safety net system has been so damaged that it must essentially rebuild itself. Essentially, the new rule violates at least one of the Department’s stated goals-- to avoid disruption of the existing health care safety net.

This analysis underscores the powerful implications that flow from a broad reformulation of the concept of medical underservice. There have been no developments in any federal statute whose operations turn on this designation process that would suggest a need for such a wholesale revamping of the concepts of medical underservice or health professions shortages. Indeed, the proposed rule appears to run directly counter to the large increase in the number of uninsured persons, growing evidence of primary care shortages across the country, and the Administration’s eight-year effort to expand and strengthen the health centers program.

Because this analysis is limited to consideration of the impact of the rule on health centers, it actually understates the profound implications of the proposed rule for access to basic health services at a particularly critical time in U.S. health policy. In view of the proposed rule’s significant deficiencies, particularly in relation to the importance of the designation process to the broader formulation of U.S. health policy and ultimately, to population health, it is evident that the challenges in reshaping the rule go beyond simply completing the comment period, evaluating the comments, and issuing a revised rule.

In our view, the rule’s shortcomings are significant enough that under the circumstances, a reasonable course of action would be to withdraw the proposed policy. This is a step that this Administration has taken in the past (for example, in the case of the HHS’s limited English Proficiency guidelines or its Medicaid managed care regulation) when it has determined that a policy is fundamentally inconsistent with a sensible policy direction. Withdrawal in this case could be accompanied by a far more open and transparent policy development process that considers not only the formulaic aspects of medical underservice and health professions shortage area designation, but also the real world impact of such a major policy change. Policy development considerations, as well as the law (in this case, the federal Administrative Procedures Act) permit an approach to policy development that includes formal and extensive policy consultations with affected stakeholders, including Governors and state legislatures, affected health care entities such as hospitals, state and local medical societies and health centers, and entities representing health care consumers. Through such a formal consultation, it may be possible to arrive at a more sound and modified approach to the designation of areas, populations, and communities with high health care need.

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