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Part III

Department of Health and Human Services

**42 CFR Parts 5 and 51c
Designation of Medically Underserved
Populations and Health Professional
Shortage Areas; Proposed Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 5 and 51c

RIN 0906-AA44

Designation of Medically Underserved Populations and Health Professional Shortage Areas

AGENCY: Department of Health and Human Services (DHHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would revise and consolidate the criteria and processes for designating medically underserved populations (MUPs) and health professional shortage areas (HPSAs), designations that are used in a wide variety of Federal government programs. These revisions are intended to improve the way underserved areas and populations are designated, by incorporating up-to-date measures of health status and access barriers, eliminating inconsistencies and duplication of effort between the two existing processes. These revisions are intended to reduce the effort and data burden on States and communities by simplifying and automating the designation process as much as possible while maximizing the use of technology. No changes are proposed at this time with respect to the criteria for designating dental and mental health HPSAs. Podiatric, vision care, pharmacy, and veterinary care HPSAs, which are no longer in use, would be abolished under the rules proposed below.

Additional background information will be available for review on the web site of the Health Resources and Services Administration: <http://bhpr.hrsa.gov/shortage>. The methodology is also described in a journal article recently published in the *Journal of Health Care for the Poor and Underserved* entitled "Designating Places and Populations as Medically Underserved: A Proposal for a New Approach" (Ricketts et al. 2007).

DATES: Comments on this proposed rule are invited. In particular, comments are invited regarding the indicators of need and the weighted values of the health care practitioners used in the methodology. To be considered, comments must be submitted on or before April 29, 2008.

ADDRESSES: You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://>

www.regulations.gov. Click on the link "Submit electronic comments on HRSA regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address only: Health Resources and Service Administration, Department of Health and Human Services, Attention: Ms. Andy Jordan, 8C-26 Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Health Resources and Service Administration, Department of Health and Human Services, Attention: Ms. Andy Jordan, 8C-26 Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Rockville address, please call telephone number (301) 594-0816 in advance to schedule your arrival with one of our staff members: Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 8C-26 Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. (Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the HRSA drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

FOR FURTHER INFORMATION CONTACT: Andy Jordan, 301-594-0197.

SUPPLEMENTARY INFORMATION: The Secretary of Health and Human Services

proposes below a consolidated, revised process for designation of Medically Underserved Populations (MUPs) pursuant to section 330(b)(3) of the Public Health Service Act (as amended by the Health Centers Consolidation Act of 1996, Public Law 104-299), 42 U.S.C. 254b, and for designation of Health Professional Shortage Areas (HPSAs) pursuant to section 332 of the Act (as amended by the Health Care Safety Net Amendments of 2002, Pub. L. 107-251), 42 U.S.C. 254e. Currently, regulations at 42 CFR Part 5 govern the procedures and criteria for designation of HPSAs, while designation of MUPs has been carried out under the Grants for Community Health Services regulations at 42 CFR Part 51c.102(e), and implementing **Federal Register** notices.

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I. Background

An earlier version of proposed rules for a consolidated, revised MUP/HPSA designation methodology and implementation process was published on September 1, 1998 [63 FR 46538–55]. Those proposed rules generated nearly 800 public comments, principally concerning the perceived high impact in terms of the safety-net programs which would have lost their existing designations if the rule were finalized. Comments were also received on several other important issues related to the methodology, types of primary care clinicians included, and data collection burden. On June 3, 1999, a **Federal Register** document was published [64 FR 29831] which extended the comment period based on the large volume of comments received and the level of concern expressed. In light of the volume of comments, it was determined that the impact of the proposal as published would be more carefully tested, possible revisions and alternative approaches developed as necessary, and a new notice of proposed rulemaking (NPRM) would be published.

A. Explanation of Provisions

This proposed rule describes a revised methodology which combines indicators of diminished access to health care services, shortages of health professionals, and reduced health status. Developed by a research team at the University of North Carolina's Cecil G. Sheps Center in consultation with staff from the Health Resources and Services Administration (HRSA) and a group of State partners in the designation process, this approach was also tested with a comprehensive impact analysis (see section VI).

This proposed rule will replace the existing Part 5 with regulations governing both MUP and HPSA

designations, and will make conforming changes to Part 51c. Together, these changes meet the legislative requirements for both MUP designation and HPSA designation, while consolidating the two processes to the greatest extent possible given the differences in the two authorities. This combined metric, which we propose to call "the Index of Primary Care Underservice," will replace the existing MUP and HPSA criteria and procedures, while maintaining the two separate designations in order to meet the legislative requirements of the relevant statutes. Note that the abbreviation MUP used here includes not only population group designations but also the populations of designated geographic areas, also known as medically underserved areas or MUAs. Similarly, the abbreviation HPSA includes not only geographic area designations, but also population group and facility designations.

Pursuant to Section 302(b) of the Health Care Safety Net Amendments of 2002, a copy of this NPRM will be submitted to the Committee on Energy and Commerce of the House of Representatives and to the Committee on Health, Education, Labor and Pensions of the Senate upon or before the date of its publication, in fulfillment of the statutory requirement for a report to those committees describing any regulation that revises the definition of a health professional shortage area. HRSA has also asked a panel of outside experts to review the proposed methodology and provide an assessment of its appropriateness, validity, and general approach.

These regulations will not be finalized until the public comment period referenced above is over, and any comments received during that time from the public, the panel of outside experts, and from the referenced House and Senate Committees have been taken into consideration. Moreover, this rule will not be finalized until 180 days after delivery of the report to the Congressional committees identified above, in accordance with statute.

B. Current Uses of Designations

The MUP and HPSA designations are currently used in a number of Departmental programs. The major use of MUP designations is as a basis for eligibility for grant funding of health centers under sections 330(c) and (e) of the Act, which require that these health centers serve medically underserved populations. The major use of HPSA designations is by the National Health Service Corps (NHSC); health professionals placed through the NHSC

can be assigned only to designated HPSAs.

Other health centers not funded by section 330 grants but otherwise meeting the definition of a health center in section 330(a)—including those which provide services to a MUP—may be certified by the Centers for Medicare and Medicaid Services (CMS) upon recommendation by HRSA as federally qualified health center (FQHC) look-alikes. FQHC look-alikes, like all health centers funded under Section 330, are eligible for special Medicare and Medicaid reimbursement methods.

Clinics in rural areas designated either as an MUA or as a geographic or population group HPSA, and whose staff include nurse practitioners and/or physician assistants, may be certified by CMS as Rural Health Clinics (RHCs). These RHCs are also eligible for special methods for determining Medicaid and Medicare reimbursement.

Physicians delivering services in an area designated as a geographic HPSA are eligible for the Medicare Incentive Payments (MIP) of an additional 10 percent above the Medicare reimbursement they would otherwise receive. The Medicare Modernization Act of 2003 included beneficial changes to this incentive program. Payments to providers are now automated based on the zip codes of the providers, and the information on eligibility is now available on the CMS Web site. The MIP, also known as the HPSA Bonus Payment, is distinct from the Physician Scarcity Area Program, which does not use HRSA designations in determining eligibility.

Interested Federal Government Agencies and State Health Departments can also recommend waiver of the return-home requirements for an International Medical Graduate physician who came to the United States on a J-1 visa, in return for three years of service by that physician in a particular HPSA or MUA.

In addition, a number of health professions programs funded under Title VII of the Public Health Service Act give preference to applicants with a high rate of training health professionals in medically underserved communities and/or for placing graduates in medically underserved communities, defined (in Section 799B of the Act) to include both HPSAs and MUPs.

For most of the programs that use these designations, designation of the area or population to be served is a necessary but not sufficient condition for allocation of program resources, in that other eligibility requirements must also be met and/or there is competition

among eligible applicants for available resources.

II. Revising the Methodology and Designation Mechanisms

A. Relevant Statutes

Authorizing Statutes

The current HPSA criteria date back to 1978, when they were issued under Section 332 of the Public Health Service (PHS) Act, as amended in 1976; their predecessor, the "Critical Health Manpower Shortage Area" or CHMSA criteria, dates back to the 1971 legislation creating the NHSC. Section 332(b) of the Public Health Service Act states that the Secretary shall take into consideration the following when establishing criteria for the designation of areas, groups, or facilities as HPSAs: (1) The ratio of available health manpower to the number of individuals in an area or population group, and (2) Indicators of a need for health services, notwithstanding the supply of health manpower.

The current MUA/P criteria date back to 1975, when they were issued to implement legislation enacted in 1973 and 1974 creating grants for Health Maintenance Organizations (HMOs) and Community Health Centers (CHCs), respectively. Section 330(b)(3) of the Public Health Service Act defines "medically underserved population" as the population of an urban or rural area designated by the Secretary of Health and Human Services as an area with a shortage of personal health services, or a population group designated by the Secretary as having a shortage of such services. No specific criteria were included in the statute.

Health Care Safety Net Amendments of 2002

The Health Care Safety Net Amendments of 2002, Public Law 107–251, as amended by Public Law 108–163, included modification of Section 332 to require the "automatic" designation as HPSAs of all FQHCs and RHCs meeting the requirements of Section 334 (concerning the provision of services without regard to ability-to-pay) for at least six years. After six years, such entities must demonstrate that they meet the designation criteria for HPSAs, as then in force.

This legislative provision appears to have had two major goals:

1. To avoid requiring FQHCs or RHCs from going through two separate designation processes. Given that most FQHCs must demonstrate service to an MUP in order to be funded (or to be certified as an FQHC look-alike), it was deemed unnecessary to also require

these entities to obtain a HPSA designation in order to apply for placement of NHSC clinicians. Similarly, every RHC must obtain one of several types of designation in order to achieve RHC status (either a HPSA, MUA, or Governor Designated and Secretary Certified Shortage Area designation); arguably, those for whom this was not a HPSA designation should not be required to obtain a second type of designation to apply for NHSC. (It is worth noting that this goal will be met once the regulations herein are in force, since areas and population groups designated or updated under the criteria herein would be both HPSAs and MUPs, eligible for the FQHC, RHC and NHSC programs).

2. To allow a long transition period for phasing in the new designation criteria as they might affect existing projects. Existing FQHCs and RHCs will have plenty of time to show that the areas where they are located, the populations they serve, or the facilities involved in fact meet the new criteria, so that their services will not be disrupted due to the criteria change.

Although an extensive impact analysis of the proposed new criteria has been conducted to demonstrate that such disruption is unlikely in all but a few cases, this legislatively required smooth transition should ease concerns about the changes and allow plenty of time to adapt to the new designation criteria.

B. Purpose of Revising the Methodology and Designation Process

As previously stated, the current HPSA and MUA/P criteria date back to the 1970s. The original CHMSA criteria required that a simple population-to-primary care physician ratio threshold be exceeded to demonstrate shortage. The HPSA criteria went further and allowed a lower threshold ratio for areas with high needs as indicated by high poverty, infant mortality or fertility rates, and for population groups with access barriers. The original MUA/P criteria, still in effect, employ a four-variable Index of Medical Underservice, including percent of the population with incomes below poverty, population-to-primary care physician ratio, infant mortality rate and percent elderly.

Since the time these designation criteria were first developed, there has been an evolution both in the types of requests for designation received and the application of the HPSA criteria. Instead of relatively simple geographic area requests, such as whole counties and rural subcounty areas, more requests have been made for urban

neighborhood and population group designations. The availability of census data on poverty, race, and ethnicity at the census tract level has enabled the delineation of urban service areas based on their economic and race/ethnicity characteristics. Areas with concentrations of poor, minority and/or linguistically isolated populations have achieved area or population group HPSA designations based on their limited access to physicians serving other parts of their metropolitan areas. As a result, the differences between HPSA and MUA/P designations have become less distinct.

The methodology for identifying underserved areas, as well as the process by which interested State and community parties can obtain designation as underserved areas, are being revised to accomplish several goals and alleviate problems associated with the existing methods of designation.

In revising the underlying methodology for identifying underserved areas, our goals were to create a new system that:

- (a) Is simple to understand for those who seek designation;
- (b) is intuitive and has face validity;
- (c) incorporates better measures or correlates of health status and access;
- (d) is based on scientifically recognized methods and is replicable;
- (e) minimize unnecessary disruption;

and

- (f) constitutes an improvement over current methods in fairly and consistently identifying places and people who are in need of primary health care and who encounter barriers to meeting those needs.

In revising the designation process, our goals were to:

- (a) Consolidate the two existing procedures, sets of criteria, and lists of designations;
- (b) make the system more proactive and better able to identify new, currently undesignated areas of need and areas no longer in need;
- (c) automate the scoring process as much as possible, making maximum use of national data and reducing the effort at State and community levels associated with information gathering for designation and updating;
- (d) expand the State role in the designation process, with special attention to the State role in definition of rational service areas;
- (e) reduce the need for time-consuming population group designations, by specifically including indicators representing access barriers experienced by these groups in the criteria applied to area data.

These goals are explained more fully below. We believe the proposed methodology and designation process address all of these goals and therefore offers a significant improvement in the identification of communities experiencing limited access to primary care services. In turn, we believe these revisions will assist the Department in targeting key resources more effectively to areas of greater relative need for assistance.

1. Methodological Goals

Simplicity

The new underservice measure must be understandable and usable by those who seek designation. In this vein, we decided the new methodology should continue to use the population-to-provider ratio as the fundamental metric of underservice because such ratios are well-recognized and understood by the program participants and would provide some continuity between a new proposal and the older methods that included the ratios very prominently in the calculations. Discussions with the federal agencies and stakeholder groups during the development of the revised approach also revealed a preference for using that metric as the basis for a revised method.

Face Validity

The new underservice measure must be intuitive and have face validity. For example, factors that reflect progressively worse access should result in proportionately increasing scores.

Incorporate Better Measures or Correlates of Health Status and Access

While both designation statutes speak of the inclusion of health status indicators, the only specific measure of health status historically mentioned in either statute or included in the existing designation criteria is infant mortality rate.

Low birthweight rate is a more robust indicator of health status because there are more events per unit population. Because both infant mortality and low birthweight rate are nationally available for all counties and for a limited number of sub-county areas (generally, for places of population 10,000 or more), these measures were incorporated in the proposed methodology. In addition, a new measure of actual/expected death rate (standardized mortality ratio) is incorporated.

As described in more detail in section IV, this methodology further incorporates other correlates of health status and access, such as ethnic minority status and unemployment, based on ready national availability of

data and the health inequalities literature.

Science-Based

The new underservice measure must be based on scientifically recognized methods and be replicable. For example, the current Index of Medical Underservice comprises four variables, each of which contributes approximately a quarter to the maximum score. In other words, each of the four variables are weighted equally. However, there is no empirical justification for why the income variable should have a weight equal to the infant mortality rate variable. Rather, in designing the new methodology, we believed the contribution of each variable to an overall measure should be based on some verifiable statistical relationship. As discussed further in section IV, the new methodology used an overall conceptual framework to describe access and used analytical techniques such as regression and factor analysis to arrive at the weighting/scoring system proposed herein.

Minimize Unnecessary Disruption

Partly due to the Health Care Safety net Amendments of 2002, as described earlier, we have attempted to achieve a reasonable transition to this new methodology for underserved areas. Though the revised designation method will not (and should not) generate the exact same designations as the previous method, we have attempted to minimize unnecessary disruption where applicable. The new measure will allow us to better focus the designations to more needy areas and populations.

Acceptable Performance

The new system must perform better than the current designation criteria using updated data, and it should be seen as an improvement by the multiple key stakeholder groups who rely on these designations. We used many different evaluating criteria for this guiding principle, but the fundamental criterion we used is whether the method fairly and consistently identifies places and people who were in need of primary health care and who had barriers to meeting those needs.

2. Designation Process Goals

Consolidation and Simplification

The separate statutes authorizing MUP and HPSA designations address the same fundamental policy concern: That is, the identification of those areas and populations with unmet health care needs for the purpose of determining eligibility for certain Federal health care resources. The existence of two similar

but quite distinct procedures and sets of criteria has been confusing to many and has often led to contradictory or inconsistent results.

The legislative requirements for the two designations are similar in many respects, but the designation processes have, until now, been largely separate. A major reason for the disparity in the designation process is that regular updating of HPSAs is required by statute, though such updating is not statutorily required for the MUA/Ps and has not regularly been done.

The rules proposed below attempt to establish uniform procedures and criteria, not only to simplify the designation process for the agencies, communities, entities, and individuals involved, but also to increase the efficient and effective use of Departmental resources. To do so, all the legislatively mandated elements of both statutes are included in the proposed procedures. The revised criteria for geographic HPSAs and MUAs are identical, as are those for most types of MUPs and corresponding population group HPSAs, wherever permitted by statutory requirements. Since facility designations are only authorized for HPSAs, this is one domain for which the two could not be the same.

Proactivity

The proposed methodology can be applied using national data obtained by HRSA and made available to State partners in the designation process, thereby enabling more universal application of the designation criteria. Applicant familiarity with the designation process should also become less of a factor in obtaining designation, and the need for independent data collection by applicants will be less of a barrier and burden.

The national databases include updated versions of the data used in the development of this methodology: Provider data from appropriate professional associations, such as the American Medical Association (AMA) physician data; socio-demographic data from the U.S. Census Bureau or a vendor which produces intercensal estimates; unemployment data from the Department of Labor; and health status data from the National Center for Health Statistics. At the same time, States and communities will continue to have the opportunity to substitute State and local data for the national data if the State and local data are more reliable and/or more current. Data from recognized sources such as State Data Centers, economic forecasting agencies such as J.D. Powers, and similar entities, and

that are used for other state purposes may be submitted. Provider data may be secured from a variety of sources: State licensing boards, state or local professional societies, professional directories, etc. Data sources, methodologies, and dates must be specified.

Automation

The proposed methodology will enable a more automated process for designation, through the use of a tabular method for scoring areas and updating these scores. The new method makes considerable use of census variables for which data are available not only at the county level but also at subcounty levels (e.g., for census tracts and census divisions), so that a wide variety of State- and community-defined service areas can be evaluated for possible designation. Also, an interactive system for processing designation requests and updates will permit State partners in the designation process to work together with the federal designation staff using the same databases. The intent is to minimize the effort required by States, communities, and other entities to designate an area or update its designation.

Increased State Role

The proposed approach seeks to foster an increased partnership between the various levels of government involved in designation, including a significantly larger State and local role in defining service areas, underserved population groups and unusual local conditions. The new criteria are less prescriptive in terms of travel time and mileage standards for defining service areas.

Each State will be encouraged to define, with community input and in collaboration with the Secretary, a complete set of rational service areas (RSA) covering its territory. Once developed, these service areas will be used in underservice/shortage area designations unless and until new census data or health system changes require further area boundary changes. Currently the agency allows States to provide their own provider data through a new interactive system. States with more reliable data can substitute them for national data, which will reduce the time required for case-by-case review.

Reduce the Need for Population Group Designations

Designation of population groups is typically more resource-intensive than designation of geographic areas, both from the standpoint of data collection (since obtaining data for a particular population is often more difficult than

for the area as a whole) and in terms of review. As discussed below, specific indicators included in the proposed approach represent the access barriers of poverty/low income, unemployment, racial minority or Hispanic ethnicity, population density and population over 65 years. This approach specifically adjusts an area's base population-to-primary care clinician ratio for the effects of these variables. Therefore, it is hoped that this method will reduce the need for specific population group designations by increasing the probability of designation of geographic areas with concentrations of these groups.

III. Development of Methodology To Achieve Goals

A. 1998 NPRM and Summary of Comments Received

Following consultation with two panels of experts and in-house impact testing, an NPRM to revise the designation methodology was published on September 1, 1998. Those proposed rules (referred to hereinafter as "NPRM1") would have created one process for simultaneous designation of MUPs and HPSAs; set forth revised criteria for designation of MUPs using a new Index of Primary Care Services (IPCS); and defined HPSAs as a subset of the MUPs, consisting of those MUPs with a population-to-practitioner ratio exceeding a certain level. The use of RSAs would have been required for application of both the MUP and HPSA criteria.

The IPCS score would have been calculated based on a weighted combination of seven variables: Population-to-primary care clinician ratio, percent population below 200% poverty, percent population racial minorities, percent population Hispanic, percent population linguistically isolated, infant mortality rate or percent low birthweight births, and low population density. The maximum possible IPCS score would have been 100, and RSAs whose IPCS score equaled or exceeded 35 would qualify for MUP designation.

In counts of primary care clinicians, nurse practitioners (NP), physician assistants (PA), and certified nurse midwives (CNM) would have been included with a weight of 0.5 full time equivalents (FTE) relative to primary care physicians. There would have been two tiers of designations, with the first tier consisting of those areas which meet the criteria when all primary care clinicians practicing in the area are counted, and the second tier consisting of those additional areas which meet the

criteria when certain categories of practitioners (NHSC assignees and those practicing in CHCs) are excluded from clinician counts.

HPSA designation would have required a minimum population-to-primary care physician ratio of 3,000:1, but this threshold could only be applied to those RSAs found to have an IPCS score which exceeded the MUP designation threshold of 35.

The period for public comment on the 1998 proposed rule was extended to January 4, 1999. Over 800 comments were received, analyzed, and categorized. Major issues raised are summarized briefly below:

1. **Impact in Terms of Designations Lost**—Many commenters estimated that unacceptably high numbers of HPSA designations would be lost in their State if the proposed methodology were adopted, particularly in rural and frontier areas, as well as significant numbers of MUPs. They believed that the impact stated in NPRM1's preamble, in terms of percentages of designations lost, was substantially underestimated.

2. **Inclusion of nonphysician primary care providers**—A number of commenters objected to the inclusion of NPs/PAs/CNMs in primary care clinician counts, based on the additional burden on applicants of counting them, and cited the lack of adequate State or national databases for these clinicians. Others questioned the reasonableness of weighting them at 0.5 FTE relative to a primary care physician. Typically, responding NPs, PAs, CNMs, professional organizations representing them, and certain other health care advocates felt the 0.5 should be adjusted upward; others felt it should be adjusted downward, particularly in States where the scope of practice of these clinicians is limited. There were also concerns that NPs, PAs and CNMs who were not in clinical, primary care practice would be inadvertently counted if available data were used, and that truly underserved areas would lose designation as a result.

3. **Threshold for HPSA Designation**—The proposed 3,000:1 population-to-primary care clinician threshold ratio for HPSA designation was considered too high by many commenters, especially if NPs/PAs/CNMs were to be counted as well as primary care physicians.

4. **Urban/Rural Balance**—Many of the indicators selected for inclusion in the new IPCS (such as race, Hispanic ethnicity, linguistic isolation, and low birthweight births), were viewed as tending to bias the new index toward designation of urban areas (as compared with indicators like percent elderly,

which had been included in the previously-used Index of Medical Underservice and was seen as favoring rural areas).

5. HPSAs required to be a subset of MUPs—the proposed requirement that an area could receive HPSA designation only if it first qualified as an MUP (by having an IPCS score which exceeded the 35 threshold) was seen as threatening many legitimate currently-designated HPSAs (i.e., HPSAs with population-to-practitioner ratios higher than 3000:1 but whose poverty rates and scores on other IPCS variables were not high enough to achieve the IPCS threshold).

6. Two-tiered Designations—The idea of two-tiered designations was generally supported, but an issue arose as to which federally-supported primary care clinicians should be excluded from counts in tier 2. Most agreed that NHSC assignees and physicians in CHCs should be excluded (as the proposed rule did). Many felt that those physicians on J–1 waivers should also be excluded from tier 2 counts, and some suggested that primary clinicians in other safety-net settings (such as RHCs or State-funded health centers) should also be excluded.

On June 3, 1999, notice was given in the **Federal Register** that further analysis would be conducted, to include a thorough, updated analysis of the impact of the proposed approach as published, as well as the testing of alternatives based on analysis of the comments received. The Notice indicated that these impact analyses would be applied to the most current obtainable national data for all counties and currently-defined subcounty MUPs and HPSAs, and that one or more outside organizations would verify the impact testing. A new NPRM would then be published for public comment.

B. Development of Method Proposed in This NPRM

During the remainder of 1999, HRSA acquired components of the national databases necessary for impact testing, such as practice addresses for primary care physicians, PAs, NPs, and CNMs. An extensive data cleaning and provider site geocoding process ensued. Simultaneously, HRSA began working with researchers at HRSA-funded Rural Health Research Centers and Health Professions Workforce Centers to develop specifics of the plan for further analysis and testing. Ultimately, the Cecil G. Sheps Center of the University of North Carolina (UNC) was funded to undertake national testing of the previously-proposed methodology in NPRM1 and alternative methodologies,

and to coordinate efforts by other research groups who would do State or regional testing.

In January 2000, a group of sixteen State Primary Care Office (PCO) representatives volunteered to assist by providing recommendations for a revised approach to designation from their standpoint, as the ones primarily responsible for providing data to HRSA in support of designation requests and updates for their States. This led to a series of conference calls, a two-day meeting, and eventual preparation of draft recommendations for consideration by the appropriate federal officials. Meanwhile, researchers at the Sheps Center were considering alternative methodologies for simultaneous consideration of various indicators of shortage and underservice. The two groups met on several occasions to coordinate efforts; the methodology finally developed by Sheps researchers and used as the basis for these proposed rules was consistent with the recommendations of the group of PCOs.

Over time, the following specific steps took place:

(a) A comprehensive database for impact testing was established. This entailed: “cleaning” and geocoding the various physician databases acquired (from professional associations and from federal and State agencies approving J–1 visa waivers), and matching them with each other and with HRSA’s NHSC database; similar activity for data acquired on non-physician primary care clinicians (NP/PA/CNM); adding geocoded location data for HHS-sponsored safety-net provider sites, including CHCs, NHSC sites and RHCs; and the inclusion of appropriate Census data (or vendor-supplied intercensal estimates for Census variables) as well as data on other health status and access-related variables.

(b) The group of sixteen PCOs developed their recommended approach to a new designation methodology and provided their recommendations to HRSA staff. Their original recommendation was essentially to expand the number of high need indicators which could be used to adjust the population-to-practitioner ratio threshold for designation, to allow several different threshold levels depending on the number of high need indicators present, and then to compare the area’s actual ratio with the adjusted threshold appropriate for that area.

(c) HRSA staff worked with the UNC–Sheps Center team to develop a conceptual framework and a methodology responsive to concerns raised in public comments and in the

PCO recommendations. In response to the criticism of the earlier 1998 proposal as using appropriate indicators but an arbitrary weighting scheme, this methodology was developed based on a general conceptual framework of access and underservice and statistical methods. The overall goal was to identify areas and communities in need of services to increase access, relative to other communities across the country.

The conceptual framework and methodology will be described further in sections IV.A and IV.B. A more technical description is also provided in Appendix B. The way the method is applied to determine designation status is described in Sections IV.C and V. below. Finally, further details are available on HRSA’s Web site (<http://bhpr.hrsa.gov/shortage>) and in a journal article recently published in the *Journal of Health Care for the Poor and Underserved* entitled “Designating Places and Populations as Medically Underserved: A Proposal for a New Approach” (Ricketts et al., 2007).

(d) The impact of the proposed method on the number and population of geographic and low income designations at national and state levels was explored and compared with alternatives using updated national data allied to: (a) The criteria currently in place; (b) the criteria proposed in the September 1, 1998 rule, and (c) the new methodology proposed in this rule. In addition, impact analyses with State data were performed by Regional Centers for Health Workforce Studies and/or PCOs in four States. This analysis, discussed in detail in Section VI below, indicated that this proposed method would not have severe adverse effects on most safety net providers, and would—at the transition from the old method to the new—maintain a similar total underserved population.

(e) However, there remained concerns that some safety net facilities—despite serving populations clearly underserved, such as the uninsured—might be located in areas that did not meet geographic or population group criteria. Consequently, with the help of the group of 16 PCOs, a separate method was developed (hereafter referred to as the “facility designation method”) for facility designation of those safety-net facilities which could demonstrate high levels of service to the uninsured and/or Medicaid-eligibles. This was tested using the Uniform Data System for community health centers and found to support designation of most Section 330-funded health centers.

(f) The new methodology’s concepts and impact analysis approaches have been discussed in a preliminary fashion

at various meetings of national and State organizations whose members are affected by shortage/underservice designations.

IV. Description of Conceptual Framework and Methodology and Alternatives Considered

A. Conceptual Framework

In our model, as in health services research more widely, we consider utilization of services an outcome of the demand and supply forces within the healthcare system. The conceptual framework for the model is based on the idea that barriers to care reduce appropriate use, which is reflected in delayed and therefore higher subsequent use rates. We call this concept “thwarted demand.” For example, individuals with diabetes living in remote, rural areas may put off seeing their doctors regularly—not because they do not recognize the need for regular treatment—but because of the distances involved or other potential barriers. These barriers initially reduce utilization. When these individuals eventually do seek treatment, it is often because their condition worsened to the point where they could no longer defer treatment. As the severity of their condition worsens and their need for care increases, so too does their utilization of services, in terms of

treatment volume and/or intensity. They may require hospitalization, for instance, or present at an emergency room.

To estimate the dimensions of both the (a) delayed—and thus initially reduced utilization rate—as well as the (b) subsequent higher use rates, we created a methodology that centers around the level of care experienced by a “well-served population” in order to establish an initial standard against which an “under-served population” can be defined. In a “well-served population,” where there are no barriers to care, healthcare utilization will be an expression of healthcare demand (i.e., demand is not thwarted). The assumption was made that, for groups without significant barriers to care, primary care utilization rates would cluster around the most appropriate level of care and, in turn, that their demand for care will also reflect their need for care. In an “under-served population,” by contrast, demand will be initially thwarted and healthcare utilization will therefore understate true demand.

Moreover, healthcare needs tend to be greater in areas with disadvantaged populations. The health inequalities literature has shown, for example, that conditions like diabetes and cancer are more prevalent among minorities. In turn, we can expect that areas with a

high proportion of minorities will—on average—have greater healthcare needs than areas with a lower proportion of minorities. To the extent that healthcare needs tend to be greater in underserved populations, the level of healthcare utilization observed in underserved populations would understate true demand even further. Thus, the model adjusts for this increased need and thwarted demand.

As stated earlier, however, thwarted demand potentially creates a paradox since low access often results in subsequent illness that may require a higher level of health care use, in terms of either treatment volume or intensity. The entry of the patient into a structured care system may also induce subsequently higher rates of use of primary care services incident to hospitalizations or due to raised familiarity with the system. This paradox is likely to affect overall use rates in low-access areas in such a way as to increase use rates.

We accepted that these positive and negative factors would be simultaneously operating and sought ways to estimate their individual effects in terms of both initially reduced and subsequently increased visits. The net, overall need for services can be reflected in a combination of *visits precluded* with *visits induced*.

$$+ \frac{\text{Absolute number of reduced visits caused by access barriers} + \text{Absolute number of increased visits caused by delayed care or greater morbidity}}{\text{Total visits that would be demanded if population were barrier free}}$$

By adjusting for these bi-directional effects of thwarted demand, this methodology effectively allows us to ask, “What level of care would these individuals utilize if they were well-served and barrier free?” This adjusted utilization rate becomes the proxy in our revised model for the “effective need” in an underserved population. For example, an underserved area that contains 100 people may nevertheless “effectively need” the same level of services an area of 1,000 people needs. In this underserved area, the “actual” population may be 100 but the “effective” population can be thought of as 1,000.

We then compare this “effective need” in an underserved population to the available supply of primary care providers in that area to create a population-to-provider ratio. The underlying logic is that meeting community needs could be expressed in ratios of appropriate use to optimal

service productivity. The use rate would be expressed in population counts and the service productivity in practitioner counts. The goal was to reflect the level of a population’s need for office-based primary care visits in terms of an adjusted population count that took into consideration characteristics that would affect use of services.

We considered various other proxies for need besides the population-to-provider ratio. We ultimately decided to use an adjusted population-to-provider ratio for several reasons. First, the prominence of population-to-practitioner ratios in the two existing measurements of underservice was recognized. Discussions with the federal agencies and stakeholder groups during the development of the revised approach also revealed a preference for using that metric as the basis for a revised method. Furthermore, practical reasons for the use of this ratio as a starting point for the construction of an

index included the fact that such ratios are well-recognized and understood by the program participants and would provide some continuity between a new proposal and the older methods that included the ratios in the calculations.

Such a metric is also sensitive to the two different sources of unmet need—provider shortages and barriers to care—that programs which rely on the HPSA and MUA/P designations attempt to address. In HPSAs, by definition, access is restricted because there are few or no primary care health professionals who will take care of certain patients. The remedy for this is to supplement the professional supply with practitioners who will see all patients, in order to bring the numbers of professionals more into line with a level of supply generally considered adequate. For MUA/Ps, the primary reasons for designation relate to barriers to accessing existing primary care services (e.g., financial) or the combination of higher needs and lower

availability. The central task in combining these two systems was to find a common metric that was sensitive to both of these characteristics of underservice, which the adjusted population-to-provider ratio is.

B. Methodology

The model can be thought of as compromising six basic steps.

Step 1: Calculate the numerator for the population-to-provider ratio: The "effective barrier free population."

The first step is to estimate the effects that differences in the structure of the population would have on service utilization based on age and gender by assigning weights according to the national use rates for people without barriers to care. Accordingly, we call this the "effective barrier free population" because it allows us to estimate what the utilization rate would be, after adjusting for age and gender, if

the population of a community were able to use primary care services at the same rate as a population with no constraints due to factors like poverty, race, or ethnicity. This step is necessary because research shows that age and gender affect utilization rates independent of barriers to care. The elderly, for example, use services at higher rates than the non-elderly even when barriers to care are controlled for.

To calculate the "effective barrier free population," we adjust the area's base population to reflect differential requirements by age and gender for primary care services, using utilization rates for populations who are effectively "barrier-free." This adjustment uses the latest available Medical Expenditure Panel Survey (MEPS) utilization data to determine what the expected number of primary care office visits for the area's population would be (based on its age/gender make-up) if usage were at the

national average for persons who are non-minority, not poor, and employed. This total expected number of primary care visits is then divided by the corresponding current national mean number of primary care visits per person to obtain the "effective barrier free population." The effect of this adjustment is that a community with more older people or more women of child-bearing age than the average national age-gender distribution will appear to be a larger population than if the age-gender mix were like the nation's as a whole.

The utilization rates used in developing and testing the methodology proposed herein are shown in Table IV-1. These will be updated when this regulation is finalized and periodically thereafter by notice in the **Federal Register** that updated data will be posted on the HRSA Web site.

TABLE IV-1.—BARRIER FREE POPULATION USE RATE, ADJUSTED FOR AGE AND GENDER, EXPRESSED AS PRIMARY CARE VISITS PER PERSON PER YEAR

Age	Average primary care visits (per year) by age group category					
	0-4	5-17	18-44	45-64	65-74	75+
Male	5.164	2.499	2.867	4.410	6.052	8.056
Standard Error488	.401	.372	.386	.469	.533
Female	4.046	2.256	5.007	5.480	6.710	8.160
Standard Error491	.403	.373	.389	.456	.533*

The above table is from MEPS, 1996. These data are applied to the actual area age-gender total to derive the barrier free total utilization for a population with these age and gender characteristics. The corresponding national mean utilization rate is 3.471. *Imputed.

The calculations for Wichita County, Kansas are shown as an illustration of how this step of the model works. The chart below provides the population breakout by age and gender, the visit rates for each category, and the adjusted population that results from dividing by

the average visit rate. The steps are detailed below the chart.

The basic formula is:

$$\text{Barrier-free use rate} = 4.046 * (\# \text{ of females aged } 0-4) + 2.256 * (\# \text{ of females aged } 5-17) + 5.007 * (\# \text{ of females aged } 18-44) + 5.480 * (\# \text{ of females aged } 45-64) + 6.710 * (\# \text{ of}$$

$$\text{females aged } 65-74) + 8.160 * (\# \text{ of females aged } 75+) + 5.164 * (\# \text{ of males aged } 0-4) + 2.499 * (\# \text{ of males aged } 5-17) + 2.867 * (\# \text{ of males aged } 18-44) + 4.410 * (\# \text{ of males aged } 45-64) + 6.052 * (\# \text{ of males aged } 65-74) + 8.056 * (\# \text{ of males aged } 75+)$$

TABLE IV-1A.—APPLYING TABLE IV-1 USING WICHITA, KANSAS AS AN EXAMPLE

	Ages 0-4	5-17	18-44	45-64	65-74	75 and over
Females:						
Population	65	207	363	281	106	113
Multiplier (from Table IV-1)	4.046	2.256	5.007	5.48	6.71	8.16
Visits	262.99	466.992	1817.541	1539.88	711.26	922.08
Males:						
Population	93	234	386	108	321	94
Multiplier (from Table IV-1)	5.164	2.499	2.867	4.41	6.052	8.056
Visits	480.252	584.766	1106.662	476.28	1942.692	757.264
Female visits	5720.743					
Male visits	5347.916					
Total visits	11068.659					

For Wichita, the calculations are:

$$\text{Barrier-free use rate} = 4.046 * (65) + 2.256 * (207) + 5.007 * (363) + 5.480 * (281) + 6.710 * (106) + 8.160 * (113)$$

$$+ 5.164 * (93) + 2.499 * (234) + 2.867 * (386) + 4.410 * (108) + 6.052 * (321) + 8.056 * (94) = 262.99 + 466.992 + 1817.541 + 1539.88 + 711.26 + 922.08 + 480.252 + 584.766 + 1106.662 + 476.28 + 1942.692 + 757.264$$

= 11068.659 visits.
Using 1996 MEPS data, individuals who were barrier free had, on average, 3.741 visits to their primary care providers. If we then divide the barrier-free use rate by this average number of visits, we can obtain the “effective

barrier-free population” estimate. In Wichita, the calculation would be: Effective barrier-free population = 11068.659 ÷ 3.741 = 2958.74338.

This “effective barrier-free population” becomes the numerator—the “population” value—in the

population-to-provider ratio. For example, the actual population of Wichita, Kansas was 2,436. By going through these calculations, however, we see in Table IV–2 that the effective barrier-free population is 2,959.

TABLE IV–2

	A	B
County name	Total pop 1999	Effective barrier-free population
Wichita, KS	2,436	2959

Step 2: Calculate the denominator in the population-to-provider ratio: The supply of primary care providers.

The second step is to calculate the actual number of FTE primary care clinicians in the target area, including primary care physicians (allopathic and osteopathic), NPs, PAs, and CNMs in primary care settings.

Each active physician in the primary care specialties (i.e., General Practice, Family Practice, General Internal Medicine, General Pediatrics, Ob/Gyn) is included as 1.0 FTE unless there is evidence of less than full-time practice, in which case their actual FTE in the area is used based on guidance set by the Secretary on the calculation of FTEs.

As before, physicians in residency training in these specialties are counted as 0.1 FTE.

In this proposed rule, NP/PA/CNMs are also included, but they are counted either as 0.5 FTE or, at the applicant’s option, 0.8 times a State-specific practice scope factor running from 0.5 to 1.0 (in recognition that not all NP/PA/CNM practices operate at the same level due to state policies). We discuss this issue in further detail in section V.G below.

Data sources are: American Medical Association Masterfile-Dec. 1998, American Osteopathic Association-May 1999, American College of Nurse Midwives-1999, American Association

of Nurse Practitioners-1999, and American Association of Physician Assistants-July 1999.

For example, there are 2.5 FTE primary care providers in Wichita, Kansas, according to our national data.

Step 3: Calculate the base population-to-provider ratio.

The population-to-provider ratio is then calculated using the “effective barrier-free population” (from step 1) as the numerator and the number of FTE primary care clinicians (from step 2) as the denominator. Using Wichita, Kansas as an example, the base population-to-provider ratio is 1,183 (table IV–3, column E).

TABLE IV–3

County name	A	B	C	D	E
	Total pop	Effective barrier-free population	Tot FTE primary care	Actual population to FTE ratio (A÷C)	Effective barrier-free pop/FTE ratio (B÷C)
Wichita, KS	2436	2959	2.5	974	1183

Step 4: Adjust for increases in need for primary care services based on community characteristics.

Because the programs that rely on HPSA and MUA/P designations aim to improve access and thereby improve health, this consideration drove the design of the analysis to develop weights for *need for services* in areas and for populations. The fourth step of this methodology thus computes the effects of community factors that have been demonstrated to indicate an even greater need for services but also a lower utilization of services than the average well-insured and healthy population due to barriers to care.

The general approach was to take population-level variables that correlate with barriers to care and then determine the relationship of those variables to the

adjusted population-to-practitioner ratio described above, using regression analysis. From this analysis, the relative influence of those variables on the ratio would be derived and, from those parameters, scores could be estimated to adjust or “weight” the overall index.

Because step 4 can be quite technical, we present only an overview here. For a more detailed discussion of step 4 and its place in the overall methodology, please refer to Appendix B (please note that what we refer to in this rule as “step 4” is referred to as “steps 4–5” and “step 7” in Appendix B). The methodology is also described in a journal article recently published in the *Journal of Health Care for the Poor and Underserved* entitled “Designating Places and Populations as Medically

Underserved: A Proposal for a New Approach” (Ricketts *et al.*, 2007).

In developing step 4, we followed the conceptual framework of access proposed by Andersen and colleagues, who posit that there are predisposing and enabling characteristics that can represent need (Andersen *et al.*, 1973; Andersen 1995; Aday and Andersen 1975). There is no consensus set of community-level indicators that reflect need within their framework. Because the programs that rely on HPSA and MUA/P designations largely address unmet need by placing primary care practitioners in areas designated as underserved, we chose to use the effective barrier-free population-to-practitioner ratio (calculated in steps 1,

2, and 3) as a proxy indicator of relevant need for this step in the methodology.

We then ran regression analyses to examine how the ratio varied with socio-demographic indicators that research has shown to correlate with low access and/or poor health status (Mansfield *et al.*, 1999; CDC, 2000; Krieger *et al.*, 2003; Andersen and Newman 1973; Aday and Andersen

1975; Robert 1999; Robert and House, 2000; Kawachi and Berkman, 2003).

We also included factors in the regression model that closely parallel the statutory elements of the current HPSA and MUA designation processes (health status, ability to pay for services and their accessibility), and also directly relate to the programs they initially

were designed to support: the NHSC and the CHC Programs.

Three categories of high need indicators were ultimately used, for a total of nine indicators, as described in Table IV–4. These factors were used because they were shown by the regression to have independent effects on access to care as measured by the population-provider ratio.

TABLE IV–4.—VARIABLES USED IN CREATING PROPOSED METHOD

Demographic	Economic	Health status
Percent Non-white “NONWHITE”, (src: 1998 Claritas estimates).	Percent population <200% FPL “POVERTY”, (src: 1998 Claritas estimates).	Actual/expected death rate (adj) “SMR”, (src: National Center for Health Statistics, 1998: for previous 5 year period).
Percent Hispanic “HISPANIC”, (src: 1998 Claritas estimates).	Unemployment rate “UNEMPLOYMENT”, (src: Bureau of Labor Statistics, 1998).	Low birth weight rate “LBW”, (src: National Center for Health Statistics, 1998: for previous 5 year period).
Percent population >65 years “ELDERLY”, (src: 1998 Claritas estimates).	Infant mortality rate “IMR”, (src: National Center for Health Statistics, 1998: for previous 5 year period).
Population density “DENSITY” * (src: 1998 Claritas estimates)		

* Population density is a measure of the market potential for an area as well as an indicator of the rural or urban character of a place. As places become more densely populated, they tend to attract employment and services. Density is also associated with rural and urban settings and the behavioral characteristics of populations vary along that continuum (Amato and Zuo, 1992).

A number of other need indicators were considered in the development of the methodology. Table IV–5 provides a

brief listing and an explanation why they were not chosen. In many cases, these elements are highly correlated

with the ones listed above, so their impact on access is already captured by the variables that are included.

TABLE IV–5.—VARIABLES CONSIDERED FOR INCLUSION BUT NOT CHOSEN

Suggested variables	Reason for rejection
Percent low income elderly	Used elderly and low income.
Percent children <6	Used component in adjusted pop.
Percent children low income	Used overall low income.
Percent children <4	Used component in adjusted pop.
Dependency ratio (%>65+%/<18/total population)	Used combination of factors that capture this.
Racial disparity in low birth weight rates	Not available for small areas.
Disparity in IMR rates	Small numbers. ¹
Birth rate	Highly correlated with chosen measures.
Teen birth rate	Not available in sub-county areas.
Prenatal care (Kessner)	Unstable in small areas. ¹
Prenatal care index (Kotelchuck)	Unstable in small areas. ¹
Ambulatory care sensitive admissions (ACS rates)	Not available in all states.
Ambulatory care sensitive admissions for children	Not available in all states.
ACS rates restricted to common disease (diabetes, hypertension, cellulitis).	Not available in all states.
ACS rates for Medicare population	Not available in all states.
ACS Rates for common disease for Medicare population	Not available in all states.
Ratio of 100–200% poverty to 100% poverty	High correlation with chosen variables.
Uninsured population	Not available in small areas.
Uninsured <18 years	Not available in small areas.
Population density threshold (LT 6 p sq mile, 7 p sq mile)	Density used as a continuous variable instead.
Linguistic isolation	Not calculated on a regular basis. Imputed data. ²
Migrant impact	Not available.
Farmworker impact	Not available.
Seasonal worker impact	Not available.
Percent refugees, immigrant	Not calculated on a regular basis. Imputed data. ²
Medicaid eligible population	Not readily available in small areas.
Tuberculosis incidence	Not available in small areas.
HIV incidence	Not available in small areas.
STD incidence	Not available in small areas.
Cancer incidence	Not available in small areas.
Cervical cancer incidence	Not available in small areas.
Breast cancer incidence	Not available in small areas.
Hypertension rate	Not available in small areas.
COPD rates	Not available in small areas.

TABLE IV-5.—VARIABLES CONSIDERED FOR INCLUSION BUT NOT CHOSEN—Continued

Suggested variables	Reason for rejection
Diabetes rates	Not available in small areas.
Diabetes rates for children	Not available in small areas.
Asthma rates	Not available in small areas.
Asthma rates for children	Not available in small areas.
Smoking rates	Not available in small areas.
Smoking rates for children/adolescents	Not available in small areas.
Obesity	Not available in small areas.
Obesity among children	Not available in small areas.
Alcohol use rates	Not available in small areas.
Alcohol use rates for adolescents.	Not available in small areas.
Binge drinking rates	Not available in small areas.
Disparity measures (ratio of rates for whites and minorities for disease incidence various combinations).	Not available in small areas.
Raw mortality rate	Prefer adjusted mortality rate. ³
Disparity in mortality rate	Small numbers.
Cancer mortality	Small numbers.
Cardiovascular disease mortality	Small numbers.
Infectious disease mortality	Small numbers.
Suicide rate	Small numbers.
Teen suicide rate	Small numbers.
Percent rural population	Density captures.
Percent urban population	Density captures.
Perceptual measures (other designations)	Varied from state to state.

¹ Infant mortality remains a relatively rare phenomenon and published rates are often compiled from multi-year data. Comparing rates for small areas would compound the instability of those rates. The same problems are encountered with data that describe the character of prenatal care in small and rural areas, although these indices are based on assessments of all births, the degree to which prenatal care meets standards of adequacy in smaller and less populated areas may vary from year to year due to isolated events or poor care for a limited number of newborns due to factors that do not reflect the character of the health care in the area (e.g. weather, relocation).

² These data are reported by the Census Bureau and are "imputed" from other variables (reported ethnicity and the likelihood of being a refugee or immigrant). The data are not collected directly.

³ The mortality rate varies widely according to the age structure of a place. A much higher proportion of elderly is often associated with a much higher mortality rate. Adjusting for the age structure allows for a better comparison of the mortality burden of the community relative to its risk.

To calculate the adjustment factors or "weights," the actual value of each high need indicator was converted to a percentile relative to the national county distribution, using a conversion table (see Table IV-6). For all variables

except population density, the theoretically worst actual value corresponded to the 99th percentile (e.g., the higher the unemployment rate in an area, the higher the percentile.) In Wichita, Kansas for example, 3.59% of

the population were unemployed. Table IV-6 is used to translate this percentage into a percentile: In this case, Wichita falls in the 24th percentile.

TABLE IV-6.—HIGH NEED INDICATORS—BREAKPOINTS FOR CONVERSION FROM COMMUNITY VALUES TO NATIONAL PERCENTILES *

Percentile	Poverty	Unemp	Elderly	Density	Hispanic	Non white	Death rate	LBW	IMR
1	13.31	1.70	6.32	0.66	0.13	0.23	0.674	3.23	0.00
2	16.15	1.90	7.55	1.01	0.19	0.30	0.729	3.66	0.00
3	18.29	2.10	8.18	1.49	0.23	0.36	0.766	3.94	0.00
4	19.74	2.20	8.79	1.79	0.26	0.40	0.788	4.13	0.00
5	21.15	2.30	9.34	2.16	0.29	0.45	0.805	4.32	3.09
6	22.27	2.40	9.70	2.54	0.30	0.48	0.816	4.44	3.49
7	23.25	2.40	9.97	3.01	0.33	0.53	0.826	4.60	3.89
8	24.24	2.50	10.23	3.38	0.34	0.58	0.837	4.69	4.13
9	25.01	2.60	10.50	3.80	0.36	0.61	0.846	4.80	4.43
10	25.68	2.70	10.71	4.24	0.38	0.64	0.853	4.88	4.63
11	26.25	2.70	10.90	4.73	0.40	0.67	0.861	4.95	4.76
12	26.83	2.80	11.11	5.32	0.41	0.71	0.867	5.02	4.90
13	27.36	2.90	11.26	6.23	0.42	0.76	0.873	5.10	4.99
14	27.83	2.90	11.43	6.82	0.44	0.79	0.878	5.16	5.09
15	28.42	3.00	11.61	7.82	0.46	0.83	0.883	5.22	5.22
16	28.93	3.10	11.75	8.41	0.47	0.88	0.889	5.28	5.33
17	29.39	3.10	11.92	9.36	0.49	0.93	0.894	5.34	5.43
18	29.91	3.20	12.06	9.97	0.50	0.97	0.899	5.38	5.55
19	30.29	3.20	12.17	10.98	0.51	1.01	0.903	5.42	5.63
20	30.66	3.30	12.30	11.96	0.53	1.06	0.908	5.47	5.74
21	31.12	3.30	12.46	13.02	0.55	1.11	0.913	5.52	5.86
22	31.57	3.40	12.57	13.90	0.56	1.16	0.917	5.57	5.91
23	31.90	3.40	12.72	14.60	0.58	1.20	0.920	5.60	6.00
24	32.24	3.50	12.82	15.78	0.59	1.27	0.925	5.65	6.08
25	32.62	3.60	12.94	16.66	0.60	1.33	0.928	5.71	6.17

TABLE IV-6.—HIGH NEED INDICATORS—BREAKPOINTS FOR CONVERSION FROM COMMUNITY VALUES TO NATIONAL PERCENTILES *—Continued

Percentile	Poverty	Unemp	Elderly	Density	Hispanic	Non white	Death rate	LBW	IMR
26	32.98	3.60	13.04	17.63	0.62	1.40	0.932	5.76	6.27
27	33.43	3.70	13.14	18.40	0.64	1.49	0.937	5.80	6.32
28	33.71	3.70	13.24	19.03	0.65	1.54	0.938	5.84	6.39
29	34.07	3.80	13.33	19.94	0.67	1.63	0.941	5.88	6.45
30	34.45	3.80	13.41	20.92	0.68	1.73	0.945	5.92	6.53
31	34.83	3.90	13.51	22.15	0.70	1.79	0.948	5.96	6.62
32	35.15	3.90	13.63	22.85	0.72	1.89	0.952	6.00	6.68
33	35.57	4.00	13.73	23.76	0.74	1.99	0.956	6.03	6.74
34	35.85	4.00	13.83	24.61	0.76	2.06	0.958	6.08	6.82
35	36.22	4.10	13.90	25.83	0.78	2.12	0.961	6.12	6.88
36	36.53	4.10	14.02	26.76	0.81	2.20	0.965	6.15	6.95
37	36.82	4.20	14.12	27.67	0.83	2.29	0.968	6.20	7.05
38	37.07	4.30	14.18	28.48	0.85	2.44	0.971	6.24	7.11
39	37.34	4.30	14.26	29.56	0.87	2.57	0.974	6.28	7.18
40	37.62	4.40	14.31	30.35	0.90	2.69	0.978	6.33	7.26
41	37.83	4.40	14.39	31.51	0.93	2.82	0.981	6.36	7.35
42	38.16	4.50	14.49	32.46	0.95	3.04	0.985	6.41	7.42
43	38.35	4.50	14.57	33.33	0.98	3.18	0.989	6.45	7.48
44	38.63	4.60	14.67	34.49	1.01	3.35	0.992	6.49	7.55
45	38.85	4.60	14.76	35.63	1.04	3.49	0.996	6.54	7.61
46	39.14	4.70	14.84	36.72	1.07	3.67	0.999	6.60	7.67
47	39.44	4.80	14.94	37.69	1.11	3.87	1.002	6.63	7.74
48	39.74	4.80	15.00	38.72	1.15	4.04	1.005	6.67	7.81
49	40.06	4.90	15.12	39.88	1.20	4.22	1.009	6.70	7.86
50	40.31	4.90	15.20	41.38	1.24	4.44	1.013	6.76	7.91
51	40.61	5.00	15.31	42.64	1.27	4.65	1.018	6.78	7.98
52	40.93	5.00	15.43	44.24	1.30	4.90	1.021	6.82	8.08
53	41.21	5.10	15.52	45.78	1.35	5.17	1.024	6.86	8.14
54	41.49	5.20	15.63	47.24	1.39	5.50	1.027	6.91	8.19
55	41.72	5.20	15.71	48.65	1.44	5.81	1.030	6.96	8.27
56	42.04	5.30	15.78	49.94	1.49	6.12	1.034	7.00	8.32
57	42.35	5.30	15.91	51.61	1.54	6.37	1.039	7.06	8.43
58	42.62	5.40	15.99	53.18	1.60	6.72	1.042	7.10	8.50
59	42.98	5.50	16.09	54.53	1.65	7.03	1.045	7.14	8.58
60	43.38	5.50	16.21	56.26	1.72	7.31	1.049	7.20	8.66
61	43.67	5.60	16.30	58.03	1.80	7.74	1.052	7.25	8.76
62	44.01	5.70	16.39	61.20	1.88	8.23	1.055	7.29	8.81
63	44.25	5.80	16.52	63.54	1.98	8.69	1.060	7.33	8.87
64	44.65	5.90	16.67	66.32	2.08	9.24	1.064	7.38	8.92
65	44.90	5.90	16.76	68.59	2.16	9.60	1.067	7.44	9.02
66	45.15	6.00	16.86	70.91	2.26	9.97	1.071	7.50	9.11
67	45.38	6.10	16.96	73.19	2.37	10.40	1.074	7.55	9.18
68	45.77	6.30	17.11	74.78	2.48	10.96	1.079	7.61	9.24
69	46.13	6.40	17.24	79.13	2.60	11.54	1.083	7.65	9.35
70	46.52	6.50	17.38	82.37	2.74	12.36	1.087	7.73	9.41
71	46.90	6.60	17.49	85.72	2.89	13.18	1.093	7.78	9.54
72	47.19	6.70	17.64	88.76	3.05	14.08	1.097	7.83	9.64
73	47.48	6.80	17.76	92.97	3.17	14.81	1.102	7.90	9.76
74	47.85	6.90	17.90	97.05	3.35	15.80	1.108	7.95	9.89
75	48.14	7.00	17.99	101.55	3.58	16.60	1.112	8.01	10.00
76	48.49	7.10	18.17	107.04	3.78	17.38	1.117	8.07	10.16
77	48.83	7.30	18.33	113.07	4.03	18.18	1.122	8.14	10.27
78	49.15	7.30	18.48	120.40	4.35	19.40	1.127	8.23	10.34
79	49.66	7.50	18.64	129.38	4.61	20.67	1.132	8.30	10.50
80	50.03	7.70	18.88	137.50	5.04	22.01	1.137	8.42	10.63
81	50.39	7.80	19.10	147.51	5.62	23.26	1.143	8.48	10.75
82	50.88	7.90	19.29	157.66	5.99	24.48	1.146	8.56	10.94
83	51.22	8.00	19.53	168.72	6.64	25.73	1.153	8.69	11.11
84	51.70	8.10	19.79	184.45	7.43	26.83	1.160	8.81	11.28
85	52.21	8.20	20.09	198.45	8.05	28.24	1.167	8.93	11.53
86	52.63	8.40	20.31	215.14	8.88	30.57	1.173	9.04	11.76
87	53.05	8.60	20.62	236.02	9.74	31.78	1.181	9.16	11.98
88	53.51	8.80	20.89	264.75	10.66	33.74	1.190	9.24	12.25
89	54.01	9.00	21.25	291.58	12.34	35.30	1.200	9.36	12.50
90	54.75	9.30	21.54	321.29	13.82	37.43	1.210	9.58	12.81
91	55.46	9.50	21.92	357.86	15.88	39.16	1.218	9.77	13.15
92	56.23	9.80	22.33	413.68	17.90	41.17	1.230	9.92	13.58
93	57.26	10.10	22.67	488.71	21.81	43.77	1.238	10.17	13.87
94	58.23	10.50	23.16	595.16	25.73	46.18	1.252	10.35	14.21
95	59.13	10.80	23.53	755.53	28.66	48.01	1.268	10.55	14.79
96	61.07	11.50	24.53	995.22	34.72	52.62	1.289	10.87	15.63

TABLE IV-6.—HIGH NEED INDICATORS—BREAKPOINTS FOR CONVERSION FROM COMMUNITY VALUES TO NATIONAL PERCENTILES *—Continued

Percentile	Poverty	Unemp	Elderly	Density	Hispanic	Non white	Death rate	LBW	IMR
97	62.59	12.20	25.06	1356.41	42.03	57.51	1.310	11.31	16.56
98	65.07	13.20	26.22	1759.93	48.46	62.78	1.341	11.72	17.54
99	68.05	15.20	27.75	3090.35	65.75	69.42	1.407	12.47	19.70

Data Sources: Census Estimates from Claritas 1998; Bureau of Labor Statistics 1998, National Center for Health Statistics 1998.

The resulting percentile rankings for each of the high need indicators in the area are then converted to a score, using a second table (see Table IV-7), which expresses the results of the regression analysis in terms of partial scores or weights for each indicator. Using Table IV-7 and using Wichita as an example, we see that a percentile ranking of 24 for unemployment translates into a score of 32.21.

TABLE IV-7.—SCORES FOR HIGH NEED INDICATORS, GIVEN THEIR NATIONAL PERCENTILES

Percentile	Poverty	Unemp	Elderly	Density	Hispanic	Non white	Death rate	LBW/IMR
0	0.00	0.00	0.00	995.20	0.00	0.00	0.00	0.00
1	3.01	1.18	0.54	831.13	0.81	0.00	0.82	0.72
2	6.04	2.37	1.09	735.15	1.64	0.00	1.65	1.44
3	9.11	3.58	1.65	667.05	2.47	0.00	2.49	2.17
4	12.21	4.79	2.21	614.23	3.31	0.00	3.33	2.91
5	15.34	6.02	2.77	571.07	4.15	0.00	4.19	3.65
6	18.50	7.26	3.34	534.58	5.01	0.00	5.05	4.40
7	21.70	8.52	3.92	502.98	5.88	0.00	5.93	5.17
8	24.93	9.79	4.51	475.10	6.75	0.00	6.81	5.93
9	28.20	11.07	5.10	450.16	7.64	0.00	7.70	6.71
10	31.50	12.37	5.69	427.59	8.53	0.00	8.60	7.50
11	34.84	13.68	6.30	407.00	9.44	0.00	9.52	8.29
12	38.22	15.00	6.91	388.05	10.35	0.00	10.44	9.10
13	41.64	16.35	7.53	370.51	11.28	0.00	11.37	9.91
14	45.10	17.70	8.15	354.18	12.21	0.00	12.32	10.73
15	48.59	19.08	8.78	338.90	13.16	0.00	13.27	11.57
16	52.13	20.46	9.42	324.55	14.12	0.00	14.24	12.41
17	55.71	21.87	10.07	311.02	15.09	0.00	15.22	13.26
18	59.34	23.29	10.72	298.22	16.07	0.00	16.21	14.12
19	63.00	24.73	11.39	286.08	17.07	0.00	17.21	15.00
20	66.72	26.19	12.06	274.53	18.07	0.00	18.22	15.88
21	70.48	27.67	12.74	263.52	19.09	0.00	19.25	16.78
22	74.29	29.16	13.43	253.00	20.12	0.00	20.29	17.68
23	78.15	30.68	14.12	242.92	21.17	0.00	21.34	18.60
24	82.06	32.21	14.83	233.26	22.23	0.00	22.41	19.53
25	86.02	33.77	15.55	223.98	23.30	0.00	23.49	20.48
26	90.03	35.34	16.27	215.04	24.39	0.00	24.59	21.43
27	94.10	36.94	17.01	206.43	25.49	0.00	25.70	22.40
28	98.22	38.56	17.75	198.13	26.61	0.00	26.83	23.38
29	102.40	40.20	18.51	190.10	27.74	0.00	27.97	24.38
30	106.64	41.86	19.28	182.34	28.89	0.00	29.13	25.39
31	110.95	43.55	20.05	174.83	30.05	0.00	30.30	26.41
32	115.31	45.27	20.84	167.54	31.23	0.00	31.49	27.45
33	119.74	47.01	21.64	160.47	32.43	0.00	32.70	28.50
34	124.24	48.77	22.45	153.61	33.65	0.00	33.93	29.57
35	128.80	50.56	23.28	146.94	34.89	0.00	35.18	30.66
36	133.44	52.38	24.12	140.46	36.14	0.00	36.45	31.76
37	138.15	54.23	24.97	134.15	37.42	0.00	37.73	32.88
38	142.93	56.11	25.83	128.00	38.72	0.00	39.04	34.02
39	147.79	58.02	26.71	122.00	40.03	0.00	40.37	35.18
40	152.74	59.96	27.61	116.16	41.37	0.00	41.72	36.36
41	157.76	61.93	28.51	110.46	42.73	1.39	43.09	37.55
42	162.87	63.94	29.44	104.89	44.12	2.81	44.48	38.77
43	168.07	65.98	30.38	99.44	45.53	4.25	45.90	40.01
44	173.36	68.06	31.33	94.12	46.96	5.71	47.35	41.27
45	178.75	70.17	32.31	88.92	48.42	7.20	48.82	42.55
46	184.24	72.33	33.30	83.83	49.90	8.72	50.32	43.86
47	189.83	74.52	34.31	78.85	51.42	10.27	51.85	45.19
48	195.52	76.75	35.34	73.97	52.96	11.85	53.40	46.54
49	201.33	79.03	36.39	69.18	54.53	13.46	54.99	47.92
50	207.25	81.36	37.46	64.50	56.14	15.10	56.60	49.33
51	213.29	83.73	38.55	59.90	57.77	16.77	58.25	50.77
52	219.45	86.15	39.66	55.39	59.44	18.48	59.94	52.24
53	225.75	88.62	40.80	50.97	61.15	20.22	61.66	53.74
54	232.18	91.15	41.96	46.62	62.89	22.00	63.41	55.27

TABLE IV-7.—SCORES FOR HIGH NEED INDICATORS, GIVEN THEIR NATIONAL PERCENTILES—Continued

Percentile	Poverty	Unemp	Elderly	Density	Hispanic	Non white	Death rate	LBW/IMR
55	238.75	93.73	43.15	42.36	64.67	23.82	65.21	56.83
56	245.47	96.36	44.37	38.17	66.49	25.68	67.04	58.43
57	252.34	99.06	45.61	34.05	68.35	27.58	68.92	60.07
58	259.38	101.82	46.88	30.01	70.26	29.53	70.84	61.74
59	266.59	104.65	48.18	26.03	72.21	31.53	72.81	63.46
60	273.97	107.55	49.52	22.11	74.21	33.57	74.83	65.21
61	281.54	110.52	50.89	18.27	76.26	35.67	76.89	67.02
62	289.30	113.57	52.29	14.48	78.36	37.82	79.02	68.87
63	297.28	116.70	53.73	10.75	80.52	40.03	81.19	70.76
64	305.47	119.92	55.21	7.08	82.74	42.30	83.43	72.71
65	313.89	123.22	56.73	3.47	85.02	44.63	85.73	74.72
66	322.56	126.63	58.30	-0.09	87.37	47.03	88.10	76.78
67	331.49	130.13	59.91	-3.60	89.79	49.50	90.54	78.91
68	340.69	133.74	61.58	-7.06	92.28	52.05	93.05	81.10
69	350.18	137.47	63.29	-10.46	94.85	54.68	95.64	83.36
70	359.98	141.32	65.06	-13.82	97.51	57.39	98.32	85.69
71	370.12	145.30	66.90	-17.13	100.25	60.20	101.09	88.10
72	380.61	149.41	68.79	-20.40	103.10	63.11	103.95	90.60
73	391.49	153.68	70.76	-23.62	106.04	66.12	106.92	93.19
74	402.77	158.11	72.80	-26.79	109.10	69.24	110.01	95.87
75	414.50	162.72	74.92	-29.93	112.27	72.49	113.21	98.67
76	426.70	167.51	77.12	-33.02	115.58	75.87	116.54	101.57
77	439.43	172.50	79.42	-36.08	119.03	79.39	120.02	104.60
78	452.72	177.72	81.83	-39.09	122.63	83.07	123.65	107.76
79	466.63	183.18	84.34	-42.07	126.39	86.93	127.45	111.08
80	481.22	188.91	86.98	-45.01	130.35	90.97	131.43	114.55
81	496.55	194.93	89.75	-47.92	134.50	95.21	135.62	118.20
82	512.72	201.28	92.67	-50.78	138.88	99.69	140.04	122.05
83	529.81	207.98	95.76	-53.62	143.51	104.42	144.70	126.11
84	547.94	215.10	99.03	-56.42	148.42	109.44	149.65	130.43
85	567.23	222.68	102.52	-59.19	153.65	114.79	154.92	135.02
86	587.86	230.77	106.25	-61.93	159.23	120.50	160.56	139.93
87	610.02	239.47	110.26	-64.63	165.23	126.64	166.61	145.21
88	633.95	248.87	114.58	-67.31	171.72	133.26	173.15	150.90
89	659.97	259.08	119.28	-69.95	178.76	140.47	180.25	157.10
90	688.47	270.27	124.43	-72.57	186.48	148.36	188.04	163.88
91	719.97	282.63	130.13	-75.15	195.02	157.08	196.64	171.38
92	755.19	296.46	136.49	-77.71	204.56	166.84	206.26	179.76
93	795.11	312.13	143.71	-80.24	215.37	177.89	217.16	189.27
94	841.20	330.23	152.04	-82.75	227.85	190.66	229.75	200.24
95	895.72	351.63	161.89	-85.23	242.62	205.75	244.64	213.21
96	962.43	377.82	173.95	-87.68	260.69	224.23	262.86	229.10
97	1048.45	411.58	189.50	-90.11	283.99	248.05	286.36	249.57
98	1169.68	459.18	211.41	-92.51	316.83	281.62	319.47	278.43
99	1376.93	540.53	248.87	-94.89	372.97	339.02	376.07	327.76

This same conversion of percentages to percentiles to scores is then done for each of the nine high need indicators. An example is included in Table IV-8 to illustrate this step, again using Wichita as an example.

TABLE IV-8

High need indicators	Wichita County, KS
% < 200% Poverty	49.8%
Percentile Score	79
Unemployment Rate	3.59%
Percentile Score	24
% 65+	15.6%
Percentile Score	53
	41

TABLE IV-8—Continued

High need indicators	Wichita County, KS
Population/Sq Mile	3.7%
Percentile Score	8
% Hispanic	16.4%
Percentile Score	91
% Non-White	1.2%
Percentile Score	22
Death Rate	.67%
Percentile Score	0
LBW (Low Birth Weight)	7.78%
Percentile Score	71
IMR (Infant Mortality Rate)	88
	N/A *

TABLE IV-8—Continued

High need indicators	Wichita County, KS
Total Score To Be Added	1298

* The infant mortality rate was not used for Wichita County since it was unstable (too few events-births and death in low population county). The alternative low birth weight rate was used.

Because the same metric (i.e. population-to-provider ratio) was used to calculate both the effective barrier-free population and the scores, the scores can simply be added to the effective barrier-free population-to-

primary care provider ratio to derive the final adjusted population-to-primary care provider ratio. This adjusted ratio reflects the combination of the "effective barrier free population" (age-adjusted) and the effect of community needs and use factors.

These ratios can then be used to reflect the relative need of the areas, with the highest ratios indicating the areas of greatest need. An example is included in Table IV-9, again using Wichita as an example and Burlington, New Jersey for comparison. Column G

reflects the new measure of underservice proposed in these rules and is intended to resemble the current MUA/P method in that it creates a score or index of underservice.

TABLE IV-9

County name	Total pop 1999	Effective barrier-free population	Total FTE primary care	Actual population to FTE ratio (A÷C)	Effective barrier-free pop/ FTE ratio (B÷C)	Score from weights	Final adjusted effective barrier-free pop/ FTE ratio (E÷F)
	A	B	C	D	E	F	G
Wichita, KS	2,436	2,959	2.5	974	1184	1298	2482
Burlington, NJ ..	416,853	482,594	411.2	1014	1173.6	251.6	1425.3

Even though there are far fewer people in Wichita than in Burlington and the actual population-to-provider ratios are roughly equivalent (column D), this methodology shows that the true need in Wichita (i.e., the level of care the Wichita population would demand if they did not have any barriers to care) is actually much greater than in Burlington (column G).

Though this underlying methodology is conceptually and computationally complex, one advantage of this new method is that the actual calculations involved have been automated through the use of the conversion tables. The new method is, therefore, relatively simple to implement by State and local applicants. The system has also been developed in a way that allows an applicant to enter their area-specific or population-specific data into an Internet-based query system and have their score returned in real time. This would allow applicants to compare their level of underservice with those of other designated and undesignated areas and populations in an accessible system. Moreover, the use of a tabular method for scoring allows for future changes in the scaling of the scores when there are changes in the distribution of values. It also allows HRSA to update these values without having to change the overall approach to developing scores.

Step 5: Comparing the final adjusted effective barrier-free population-to-provider ratio against a threshold of underservice.

The fifth step in this method involves comparing the final adjusted ratios for various areas against a threshold of underservice. A county or other RSA will be designated as undeserved if its final adjusted ratio equals or exceeds this threshold. The threshold level proposed is 3,000 persons for every FTE primary care clinician. A population of

3,000, distributed according to the national average age-sex distribution, is about twice the normal load for a busy primary care physician, which is approximately 1500:1. Accordingly, when the threshold level of 3000:1 is reached, an area is already one primary care clinician short for each primary care clinician it has. The impact analysis in Section VI below deals with the effect of this choice on the number and population of designated areas.

While there is no one figure that is a universally accepted standard, the 3000:1 threshold is based on an adequacy ratio of 1500:1 as noted above and is similar to the target ratio used in a number of organizations and identified in a variety of studies:

- A study of the Canadian system and its process for measuring medical underservice, for example, identified 1500:1 or greater as a level of underservice appropriate for a recruitment incentive program (Goldsmith 2000).

- A Veterans Administration study recommended a target for a primary care panel between 1,000-1,400 patients (Perlin and Miller, 2003).

- According to the Bureau of Primary Health Care (unpublished data), Community Health Centers averaged 1,439 medical users per medical FTE in 1999, and this number is very consistent with the 1997 and 1998 figures. In addition, the NHSC reports an average of 1,527 patients per provider.

- A George Washington University (GWU) report on Standards for Managed Care related to the Balanced Budget Act of 1997 found that State Medicaid programs most frequently required that Medicaid HMOs have a panel size of 1500:1

- An article published in the *Journal of the American Medical Association* suggested benchmark ratios to compare

relative supply that were slightly above and below 1500:1 (Goodman et al, 1996).

- Using data from the National Ambulatory Medical Care Survey (NAMCS), which estimates visits per person per year to physicians, the national mean ratio of primary care physicians per population of 1498:1, very close to 1500:1.

The 3000:1 threshold is a very conservative estimate of the level of need and identifies the worst quartile of the areas analyzed, which is a similar standard to that used when the original thresholds were set in the existing designation methods. Moreover, this threshold is consistent with the level used for HPSA designation of high-need areas and population groups in the past.

Step 6: Determining tiers of shortage.

An important issue in the preparation of these regulations is whether federally-sponsored primary care providers who are present in currently-designated areas should be included in computations when updating the designations. On the one hand, including these providers in the provider count could result in "yo-yo" effects, in which an area is designated as underserved; a CHC or NHSC intervention occurs as a result of the designation; those practitioners are then counted, resulting in a loss of the designation; the intervention is removed; the area again becomes eligible for designation; and the cycle repeats itself. On the other hand, there are concerns about areas remaining on the list of designations whose needs have already been met through a federally supported program or provider. This has led to situations in which additional resources are allocated to an area where providers or clinics have previously been placed to help meet the needs of the area.

To deal with both sides of this issue, we propose to publish a two-tiered list of designations. Each designated area or population group will be identified as having either a first or second tier of shortage. Tier 1 designations will be those areas which continue to exceed the threshold even when all federal resources placed in the area are counted. Tier 2 designations will be those areas exceed the threshold only when certain federal resources placed in those areas are excluded.

Thus, one final set of calculations is undertaken to identify those "Tier 2" areas which fall below the threshold when certain federally-sponsored clinicians are counted but would exceed the threshold if they were withdrawn.

The federally-sponsored clinicians considered here are NHSC affiliated clinicians, clinicians obligated under the State Loan Repayment Program (SLRP) (a loan repayment program involving joint Federal and State funding), physicians with J-1 visa return-home waivers, and other clinicians providing services at health centers funded under Section 330.

When determining Tier 2 designations, these federally-sponsored clinicians are not counted in the denominator of the area's ratio. Finally, steps 3 and 4 are repeated to recalculate the final adjusted ratio using this lower clinician count and to compare it with the designation threshold. The areas exceeding the threshold when this

procedure is followed are identified as "Tier 2" designations.

Both types of designations would be eligible for federal programs authorized to place resources in MUPs or HPSAs. However, Tier 2 areas would typically be eligible only to maintain the approximate levels of federal resources already deployed, while Tier 1 areas could apply for additional resources.

C. Example Calculations

Table IV-10 shows calculations for actual population-to-provider ratios, the effective barrier-free population-to-provider ratios, the scores based on high need indicator percentiles for the area, and the resulting population to primary care clinician ratios.

TABLE IV-10.—EXAMPLE OF CALCULATION OF ADJUSTED POPULATION-TO-PRIMARY CARE CLINICIAN RATIO

County name	Total pop 1999	Effective barrier-free population	Total FTE primary care	Effective barrier-free pop/FTE ratio (B+C)	Score from weights	"Tier 1" Final adjusted effective barrier-free pop/FTE ratio (D+E)	Ratio w/o fed FTE (C-Federally sponsored clinicians)	"Tier 2" Final adjusted effective barrier-free pop/FTE ratio (G+E)
	A	B	C	D	E	F	G	H
Wichita, KS	2,436	2,959	2.5	1184	1298	2482	* 5918	7216
Burlington, NJ	416,853	482,594	411.2	1173.6	251.6	1425.3	1179.4	1431.0
Coconino AZ	116,977	127,492	91.7	1389.6	1161.4	2551	1444.7	2606.1
St. Lucie, FL	180,937	222,417	105.1	2116.5	918.3	3034.8	2314.7	3233.0
E. Baton Rouge, LA	395,635	447,680	379.5	1179.7	640.2	1819.8	1185.9	1826.1
Dunklin, MO	33,006	40,146	22.8	1764.6	1469.4	3234.1	1764.6	3234.1
Bronx, NY	1,185,970	1,366,382	1210.6	1128.7	1665.3	2793.9	1199.6	2864.8
Guernsey, OH	40,854	48,273	20.2	2389.8	751.7	3141.5	2389.8	3141.5
Rusk, WI	15,449	18,501	10.8	1713.0	1070.5	2783.6	8043.7	9114.2

* Non-federally sponsored FTE = 0.5; 2959/0.5 = 5917/1.

According to these calculations, Wichita would not qualify for designation as a Tier 1 underserved area. However, Wichita would qualify for designation as a Tier 2 underserved area when federally sponsored FTEs are deleted and high need weights are added.

D. Alternative Approaches Considered

A variety of other alternative measures and options were considered during the development of the method. The research team at the University of North Carolina conducted a comprehensive review of current and alternative measures of underservice, as noted in a 1995 report (Ricketts *et al.*, 1995). As part of this effort, two workshops were convened in 1999 and 2000 on modeling health professions supply and healthcare needs and on measurement of underservice. Several of the options considered and the reasons for not pursuing them are described below:

—There was consideration of using the *simple population to provider ratio as the index*, but there was no consensus on the "right" ratio, and there was strong interest in a more multi-factorial approach to take other high need factors into account. The PCO Work Group's initial recommendations were based primarily on the ratio, with adjustments to the ratio for high needs, similar to the current process for HPSAs. After continued discussion with HRSA staff and the contractors, the Work Group acknowledged that the proposed methodology accomplished much the same by incorporating the need variables into the analysis rather than adjusting the target ratio, although final agreement was held pending review of the impact data. The approach used in the 1998 proposal, which was an Index of Primary Care Services from 1-100 based on a variety of "need" factors, was not chosen partly due to the history and

partly due to the fact that such a scale had no intrinsic meaning as a measure of access, while a score related to a ratio of population to the providers is more easily understood across the board.

—We considered using *hospitalization rates for Ambulatory Care Sensitive Conditions (ACSC)* as proxies for underservice as they could reflect failures in the primary care system to meet the needs of the population. However, comprehensive data are not universally available, particularly at the sub-county level, where primary care analysis is based. In addition, the analysis indicates that these rates are more indicative of problems with access to care related to income, employment, and race, rather than to lack of providers or services.

—*Alternative methodologies used in Canada and the United Kingdom (UK)* were reviewed for possible use. In Canada, however, each province had a different methodology, which did not meet the comprehensive national

approach. In the UK, the focus was specifically on the location of General Practitioners (GPs), whose practice locations are partially controlled by the government. In addition, they were partially based on interviews with GPs to identify areas of underservice, which is not an approach that can be replicated on a national scale and has no scientific basis. Both countries did, however, have models that incorporated many of the same concepts used in this proposal, including distance to care (which has a functional similarity to population density in our model), census variables such as “class,” unemployment, age, and the availability of providers. This reinforces the validity of taking into account such variables when measuring access to care and underservice.

—Extensive research on the state of the art in health care access led to a paper by Dr. Donald Taylor (Taylor *et al.*, 2000) which examined the relationship between theoretical need for care and resources to provide the care. His conclusion was that there is no one simple construct of underservice and no unitary measure, but that there are several interlocking components that need to be considered. These conceptual components were not actually alternative measures of underservice but five components of a comprehensive model. His hypothetical model, at the county level, included the following components:

- Momentum: the economic and population dynamics of an area and changes over time
- Demand: based on the age and gender of the population
- Infrastructure: presence of hospitals and other providers, insurance coverage, etc.
- Need: based on proxies for health status
- FIT: describes the degree of “fit” of the various factors, which represents the level of service or underservice

The conceptual model, the *Taylor Indices of Underservice*, was tested using simultaneous multiple correlations and was found to be robust for the prediction of demand, infrastructure and needs but not for FIT and momentum. A latent variables testing method was applied and the concept of FIT was supported via this analysis. A second order confirmatory analysis (CFA) supported this result, which suggested that a combination of variables that reflect demand and infrastructure with appropriate proxies for need—especially the age structure of

the community—could generate a useful index, FIT, that summarized community underservice. The current proposal builds on this notion of FIT as a latent indicator of overall need, as reflected in the score that is calculated in the process.

For several reasons, Dr. Taylor’s approach could not have been used without modification for purposes of this rulemaking. For example, this approach did not appear to correlate well with indicators of utilization, which is considered a reliable indicator of access. Moreover, counties are not considered an appropriate level of analysis in many areas served by HRSA’s programs.

However, the principles and detailed analytical methods used in Dr. Taylor’s model were incorporated to a large extent in the current proposed methodology, which includes age/gender utilization projections for expressed need or demand, need (as captured by socio-demographic and health status indicators), and infrastructure (as reflected in unemployment, poverty, and availability of providers).

—*Years of Potential Life Lost (YPLL)* was also considered as a potential measure. However, similar to the ACSC analysis, there was a much stronger correlation between socio-economic factors (race, education, etc.) than with the presence or absence of primary care providers and services.

V. Description of the Proposed Regulations

A. Procedures (Subpart A)

The proposed approach to processing MUA, MUP and HPSA designation requests, set forth in Subpart A below, is an adaptation of the HPSA designation procedures currently in effect, as codified at 42 CFR Part 5. The previous procedures have been modified to include the particular comment and consultation requirements of the MUP legislation, but otherwise closely follow the present HPSA designation procedures, including those specifically required by statute.

As before, the proposed procedures involve an interactive process between the Secretary, the States, and individual applicants [see § 5.3(a)–(h)]. Any individual, community group, State or other agency may apply for designation of a geographic area or population group MUP and/or HPSA, or for a facility HPSA; the Secretary may also propose such designations. Such requests are reviewed both at State and federal levels, including a 30-day comment period for Governors, State health

agency contacts, State Offices of Rural Health, county or city health officials, State primary care associations (non-profit membership organizations representing federally qualified health centers and other community-based providers of primary care), appropriate medical, dental or other health professional societies, and heads of any facilities proposed for HPSA designation. Efforts are made to complete action on new designation requests within 60 days of receipt.

Annually, the Secretary will review all designations utilizing the proposed methodology, with emphasis on those for which updated data have not been submitted during the previous three years; this extends to MUA/Ps the review process previously used for HPSAs [see § 5.3(d)]. As part of such reviews, the latest relevant data from national sources described earlier (for those previously-designated areas which the Secretary requires be updated) will be made available by the Secretary to the appropriate State entities and others for review and comment. If no corrections are provided, the national data will be used as the Secretary’s basis for decisions. (The national data for census-collected variables are not typically corrected during the designation process with data from State and local sources. On the other hand, State and local data regarding provider locations and FTEs are often more up-to-date and accurate; use of such data in designation will continue to be encouraged where readily available.)

An expedited review process is also proposed for urgent cases [see § 5.3(i)], allowing designations to be obtained within 30 days of the date of request when a practitioner dies, retires, or leaves an area, thereby causing a sudden and dramatic increase in the area’s population-to-clinician ratio. The number of requests that will be processed per year on this expedited basis is limited.

Results of designation reviews will be provided in writing or electronically to applicants, State partners, and other interested parties [see § 5.4]. No less than annually, complete lists of designated HPSAs/MUPs will be published by notice in the **Federal Register** that an updated list will be posted on the HRSA Web site; more frequent updates will be posted online continuously, reflecting designation decisions as they occur. Two tiers will be identified in published or posted listings of designated shortage areas. As discussed previously, the first tier will include only those areas that meet the

designation criteria when all relevant (i.e., active primary care) clinicians in the area are counted, while the second tier will include those additional areas that meet the criteria when certain Federally-sponsored clinicians are subtracted.

The regulation also includes a section [§ 5.5] describing procedures for the transition from the current designation system to the new system. These include a process for resolution of any overlapping boundaries that may exist between currently-designated primary care HPSAs and currently-designated MUA/Ps at the time the new regulations go into effect. The new criteria for designation of MUA/Ps and/or primary care HPSAs will be phased in over a period of three years from the date of publication of the final rule in the **Federal Register**, with State input on the review schedule but with the oldest MUA/P and primary care HPSA designations being reviewed first. This will relieve States, communities and others from having to provide updated data on all designations that are more than three years old during the first year the new regulations go into effect.

In addition, the regulation includes a section [§ 5.6] describing how the “automatic designation” provisions of the Health Care Safety Net Amendments of 2002, as amended by Public Law 108–163, will be implemented. Briefly, all FQHC and RHC delivery sites that are automatically designated will be listed separately as “automatic” HPSAs until the area or population group they serve or the facility achieves designation under the proposed criteria or until 6 years from the date of their automatic designation, whichever comes first. Any FQHC or RHC sites still being carried on the list of “automatically” designated sites six years from their date of automatic designation will then be required to demonstrate that they meet the criteria in order to remain on the list, through the review process outlined in section § 5.6.

B. General Criteria for Designation of Geographic Areas as MUAs/Primary Care HPSAs

The criteria and methodology for designation of geographic areas as MUAs and primary care HPSAs are set out in Subpart B (§ 5.102). In brief, areas to be designated must first be RSAs for the delivery of primary care services. As described earlier, an adjusted population-to-primary care clinician ratio is then computed for each such area, by combining the area’s “effective barrier-free” population (based on age and gender utilization patterns) to its supply of primary care clinicians, with

adjustments for access barriers through additive scores for a defined group of demographic, economic, and health status variables. When this adjusted ratio exceeds the designation threshold of 3000:1, the area is eligible for designation. Under certain limited conditions, resources in contiguous areas must also be taken into consideration.

C. Rational Service Areas

The proposed rules would continue to require that each area proposed for geographic designation be a rational area for the delivery of primary care services. A general (or default) definition of the term “rational service area” is included [see § 5.103], in terms of geographic size and cohesiveness, which relates its size to the accessibility of primary medical services in the area within 30 minutes travel time, and its cohesiveness to topography, demographic distinctness from contiguous communities, and/or established market patterns. Contiguous RSAs would normally be defined so as to have a separation of at least 30 minutes travel time from the population center(s) of one RSA to the population center(s) of each contiguous RSA, with exceptions for RSAs within high-density portions of metropolitan areas that demonstrate cohesiveness in other ways.

RSAs may be defined in terms of U.S. Census Bureau geographic units, including counties, census tracts, census divisions, and Zip Code Tabulation Areas (ZCTAs), as long as data can be obtained at that level. However, States are allowed the flexibility to define their RSAs in terms of travel time parameters between 20 and 40 minutes, where the final RSA approach to be used is approved by the Secretary.

States are encouraged to develop a State-wide system that subdivides the territory of the State into RSAs, either incrementally or all at once, using the general RSA criteria specified in the proposed rule or State-specific criteria developed through the partnership process just mentioned. Where a State has developed such a statewide system of areas, the designation status of a particular RSA will be determined through application of the proposed geographic HPSA/MUA criteria to current data for the RSA, without regard to contiguous area resources. Elsewhere, the contiguous area considerations set forth in proposed § 5.105 are to be used.

The proposal allows for State and local input, but is expected to greatly reduce the level of effort required at the local and State level. At present, no

designation takes place without a specific request being submitted with the required information, including the defined service area, the data on population, physicians, and other appropriate information. Upon publication of a final regulation, HRSA will first score all existing MUAs and HPSAs using the national databases. Areas that qualify using those calculations will be designated as underserved with no need for input from the State or local level. The submission of additional information will only be required for those areas that do not qualify based on national data.

HRSA expects that a significant number of areas will qualify based on national data alone. For example, there were 877 whole county and 803 geographic service area HPSAs as of March 31, 2007. If the majority of these areas meet the criteria using the national calculations, 55 percent of the current designations (excluding the facility designations) would require no action on behalf of the State or local agency. In addition, many areas could be qualified with the submission of revised data on providers alone, which is a much simpler approach than currently required.

Areas where special population groups would need to be defined would continue to require State or local involvement, though we anticipate the number of these would decrease as a result of the inclusion of some of the need factors directly in the formula itself.

D. Applying the Designation Methodology

As mentioned above in section IV.B, the proposed rules provide that the Secretary of HHS will determine an adjusted effective barrier-free population-to-primary care clinician ratio for each RSA considered for a primary care underservice designation. The specific methodology for this calculation is set forth in proposed § 5.104. Tables IV–1 and IV–6 will be updated periodically by notice in the **Federal Register** that updated data will be posted on the HRSA web site as the national utilization data and national distributions of the variables used in the method change. (Updating these tables will not require proposed rulemaking, since the regulations themselves will not be changed.) The timeframe for updates will be determined by the availability of updated data for the nine high need indicators. Table IV–7, which appears in the regulation itself as Appendix A to Part 5, may also be recalibrated periodically, but not necessarily on the same timetable, since

revising it requires repeating the regression analysis.

E. Data Definitions

The proposed rules identify the data elements needed to determine the effective barrier free population, the high need indicator score, the final adjusted population-to-primary care clinician ratio, and the manner of calculation of these variables. See proposed § 5.104(a) to 5.104(c).

F. Population and Clinician Counts

Although the clinician count requirements are similar to those for physicians in the current Part 5, some important changes have been made. Foreign (International) medical graduates who are not citizens or permanent residents, but entered the U.S. on J-1 visas and have had their return-home requirements waived in return for obligated service, and/or are here on H visas, are to be counted in "first tier" designation calculations unless they have restricted licenses; they are to be excluded from "second tier" designation counts.

Similarly, clinicians providing medical services for the NHSC, as SLRP obligors, or at health facilities funded under section 330 of the Act are counted for the first tier and excluded from the second tier. It should be noted that, although the proposed rules would allow NHSC and section 330 health center practitioners to be excluded from the practitioner count for second tier designations, the numbers of these practitioners already allocated or funded are included by the Department in making decisions as to how to allocate additional NHSC and health center grant resources.

Also, the current HPSA provision allowing the discounting of physicians with restricted practices on a case-by-case basis is proposed to be eliminated because our experience has been that this provision is neither useful nor practical.

G. Non-Physician Primary Care Clinicians

The significant expansion over the past decade in the numbers of NPs, PAs, and CNMs practicing in primary care settings has made their inclusion in counts of primary care clinicians essential to the validity of any revised designation process, particularly in those States and areas where they practice, in effect, as independent providers of care and particularly given their role in the RHC program. However, there has been controversy as to whether available data permit them to be counted accurately and how they

should be weighted relative to primary care physicians.

There are several related issues involved. First, significant differences exist among the States as to the scope of practice allowed for these clinicians, including the extent to which they are allowed to work independently, and what medical tasks they are legally allowed to perform. Second, the national databases currently available for them have some limitations, particularly where practice addresses are concerned. While some States have accurate data on the number, location and practice characteristics of these clinicians, others do not. Finally, for those States in which non-physician clinicians can legally provide many of the same services as primary care physicians, exactly how they complement physicians and, therefore, how they should be weighted relative to physicians has not been well-defined.

This proposed rule includes these non-physician clinicians by requiring that all of them be counted with a weight of 0.5 relative to primary care physicians, unless the applicant opts for weighting based on the scope of practice in the State involved. (See State option for weighting described below.) Please note that the 0.5 relative weighting is proposed here only for purposes of estimating primary care clinician counts for shortage area designation purposes; it should not be construed as representing the relative cost or value of these providers' services compared to physician services.

For non-physician clinicians, there has been a long-standing acceptance of counting them as less than a full FTE, for a variety of reasons. In the Bureau of Primary Health Care, and its predecessors, which oversees the FQHC Program, productivity standards and calculations have used the .5 FTE figure. In part, this is a way to encourage these programs to hire non-physician providers in areas where recruitment is difficult but there may be some resistance otherwise to having a mixed practice model. Its use is also consistent with productivity standards currently used by CMS for RHCs and FQHCs, which are 2100 visits per year for NPs and PAs as compared with 4200 visits per year for physicians.

While there is no absolute standard for estimating the FTE contribution of a non-physician provider, there are also a number of studies in the literature that support an estimate of 0.5:

- An Integrated Requirements Model (Sekscenski *et al.*, 1999) in 1999 used a 0.5 FTE calculation.
- An article in Health Affairs in 1997 (Hart *et al.*, 1997) of staffing ratios

indicated patient volume levels for NPs from 875–1,000 per NP.

Given the lack of data regarding the impact of adding these providers to the designation process and the continued need to encourage the use of the range of providers who can help meet the needs of the underserved, we believe the 0.5 FTE approach is a reasonable choice for the proposed method.

Data on NPs, PAs and CNMs are available from national sources ("A Comparison of Changes in the Professional Practice of Nurse Practitioners, Physician Assistants, and Certified Nurse Midwives: 1992 and 2000" The Center for Health Workforce Studies at the University of Albany, available online at <http://bhpr.hrsa.gov/healthworkforce/reports/scope/scope1-2.htm>.) These data will be made available for use as a first approximation, but States will be encouraged to provide more accurate State data, where available.

Some have suggested that different equivalencies be used in different States, depending on the degree of independence allowed by the different State laws. This option is offered in the proposed rule. At the applicant's option, a maximum weighting factor of 0.8 can be used together with a State scope of practice factor between 0.5 and 1.0, using tables from "Scope of Practice of PAs, NPs, and CNMs in the Fifty States," (Wing *et al.*, 2003). This document is available at <http://bhpr.hrsa.gov/healthworkforce/reports/scope/scope1-2.htm>

Those Federally-sponsored NPs, PAs, and CNMs in the NHSC, SLRP, or at health facilities funded under Section 330 would be counted for Tier 1 designations but excluded for Tier 2 designations, just as done for physicians.

H. Contiguous Area Considerations

The previous HPSA criteria required that, when considering any area for designation, resources located in all contiguous areas must be shown to be excessively distant, overutilized, or otherwise inaccessible to the population of the area requested for designation. The approach proposed herein would eliminate this requirement wherever a set of RSAs has been developed, requiring consideration of contiguous area resources only in States where a system of RSAs does not exist, or in those portions of a State where RSAs have not yet been defined. See § 5.105.

I. Population Group Designations

The inclusion in the proposed methodology of a number of variables representing the access barriers and/or

negative health status experienced by certain at-risk populations is likely to decrease the need for specific population group designations, which tend to be more difficult procedurally for both applicants and reviewers. However, the proposed rules continue to provide for certain types of population group designations within geographic areas which, taken as a whole, do not meet the criteria for designation. (See Subpart C.) These generally build on the criteria for designating geographic areas, with several key differences. First, the proposed rules recognize two specific additional types of areas as rational areas for the delivery of primary care services for specific population groups (i.e. agricultural areas for migratory and seasonal agricultural workers; reservations for Native American population groups). Second, each variable is to be calculated based on data for the population group for which designation is sought, as nearly as possible, rather than on the population of the area as a whole.

The eligible population groups specifically identified for designation are: Low income populations (defined to include all those with incomes below 200% of the poverty level); Medicaid-eligible populations; linguistically isolated populations; migrant and seasonal farmworkers and their families; homeless populations; residents of public housing; and Native Americans.

A new category of MUP is recognized, consisting of those uninsured and Medicaid-eligible patients who are served by safety net facilities designated as primary care HPSAs under Subpart D. Finally, the category "other population groups recommended by state and local officials" is retained, consistent with the MUP statutory authority.

The proposed provisions also allow for HPSA designation of the "special medically underserved" populations as defined by section 330 of the PHS Act (as amended by Pub. L. 104-299), which are considered already designated as MUPs. These provisions include a "simplified" designation procedure for migrant, homeless and Native American population groups, for use in cases where the area in which the requested population group is located has been defined, data on the number of individuals in the population group is provided and the total is found to exceed 1000, but specific information on the number of FTE clinicians accessible to the population group is not available. In these cases, a population-to-clinician ratio of 3000:1 may be assumed. Requirements for the statutory "permissible" designation of "other population groups recommended by state and local officials" are included. "Local officials" for this purpose are defined. Such requests must document the "unusual local conditions" which are the basis for the request; these must

involve factors not already considered by the general criteria for designation of areas and population groups as set forth in Subparts A and B.

J. "Facility Designation Method": Designation of Facility Primary Care HPSAs

The criteria and procedures for designating facility primary care HPSAs are set out in proposed Subpart D. The current criteria for designation of "public or non-profit private medical facilities" as HPSAs are eliminated and replaced by new criteria for the designation of "safety-net facility" primary care HPSAs (see proposed § 5.301). These criteria would allow for HPSA designation of facilities not in geographic HPSAs designated under Subpart B, if and when these facilities qualify as "safety-net facilities" by virtue of their service to specified minimum percentages of patients that are Medicaid-eligible and/or low income uninsured, as measured by the number of patients treated under a sliding fee scale. Eligibility for this type of designation is limited to FQHCs, RHCs, or other public or non-profit private clinical sites providing primary medical care services on an ambulatory or outpatient basis. The minimum levels of service to indigent uninsured and/or Medicaid-eligibles are described in proposed § 5.301(b) and shown in Table V-1 below.

TABLE V-1.—MINIMUM LEVELS OF SERVICE TO INDIGENT UNINSURED AND/OR MEDICAID-ELIGIBLES

Metropolitan areas	Non-Metropolitan areas (except frontier areas)	Frontier areas
At least 10% of all patients are served under a posted, sliding fee schedule, or for no charge.	At least 10% of all patients are served under a posted, sliding fee schedule, or for no charge.	At least 10% of all patients are served under a posted, sliding fee schedule, or for no charge.
At least 40% of all patients are served either under Medicaid, under a posted sliding fee schedule, or for no charge.	At least 30% of all patients are served either under Medicaid, under a posted, sliding fee schedule, or for no charge.	At least 20% of all patients are served either under Medicaid, under a posted sliding fee schedule, or for no charge.

Payment source documentation to establish initial and ongoing designation as a facility primary care HPSA will be as required by the Secretary. This Safety Net Facility designation would not be recognized by CMS for RHC certification.

The criteria and methodology for designating federal and state correctional institutions and youth detention facilities as primary care HPSAs in § 5.302 are essentially unchanged from those in the current Part 5.

K. Dental and Mental Health HPSAs

The proposed procedures in Subpart A would apply to the designation of

dental and mental health HPSAs as well. The criteria currently in use for these types of HPSA designations are contained in Appendices B and C of the current part 5. No changes to these appendices are proposed at this time, but efforts are under way to revise the criteria for dental shortage areas (pursuant to Section 302(d)(1) of the Health Care Safety Net Amendments of 2002) and those for mental health professional shortage areas. When these efforts are complete, Appendices B and C will be revised.

L. Podiatry, Vision Care, Pharmacy And Veterinary Care HPSAs

The existing HPSA regulations at part 5 also contain, in appendices D, E, F, and G, criteria for the designation of vision care, podiatric, pharmacy, and veterinary care HPSAs. These criteria were originally developed for use in connection with student loan repayment programs for individuals in those health professions; however, these programs are no longer authorized or funded. Consequently, the proposed rule would abolish these types of designation by revoking these appendices.

M. Technical and Conforming Amendments

Minor technical and conforming amendments to the CHC regulations at 42 CFR Part 51c are proposed. These amendments refer to Part 5 for definition of designated medically underserved populations, and for factors to be considered in assessing the needs of populations to be served by grantee projects. In addition, they amend the definitions section of the CHC regulations to include a definition of "special medically underserved populations," which refers to language in the statute as amended by Public Law 104-299. This definition states that such populations are not required to be designated pursuant to part 5; this is consistent with their treatment under prior legislation. Finally, the amendments add a provision explicitly stating that a grantee which was serving a designated MUA/P at the beginning of a project period will be assumed to be serving an MUP for the duration of the project period, even if that particular designation is withdrawn during the project period.

VI. Impact Analysis

The agency has conducted an extensive analysis of the national impact of the proposed new designation methodology on the designation status of whole counties, previously-defined part-county geographic HPSAs and MUAs, and low-income population groups, as well as its impact on grant-funded CHCs, NHSC sites, and CMS-certified RHCs. This national analysis was conducted under a HRSA cooperative agreement with UNC's Cecil G. Sheps Center for Health Services Research, using data from national sources for all variables. In order to validate this national analysis, impact analyses using State data sources were performed by Regional Health Workforce Centers and/or PCOs in four states.

In the actual designation review process, evaluation of areas' potential designation status based on application of the criteria to national data would represent only the first step in an exchange with State and local partners. However, we believe that the aggregate results of this impact analysis (in terms of total numbers of areas designated or de-designated nationally) represent a reasonable approximation to the likely results of the real designation process. (If anything, these impact estimates may err on the side of overstating negative impacts, since local data in support of designation are more likely to be received from areas which the national

data would tend to de-designate than from areas which they would newly designate or continue in designation.)

The impact is shown below in a series of tables describing different types of impact, each of which enables comparison of several different scenarios. In general, the first column of each table shows baseline numbers corresponding to actual HPSA and MUA designations on September 30, 1999; the second column shows the revised numbers that would result if these designations were updated by applying the criteria now in force to the national database used in this analysis; the third column shows the revised numbers that would result if the methods proposed in the 1998 NPRM ("NPRM1") were applied; the fourth column shows the results of applying the criteria proposed herein ("NPRM2" criteria) to geographic areas only; the fifth column shows the estimated results of applying NPRM2 low-income population group criteria to areas not meeting the geographic criteria; and the final column shows the estimated combined results of applying the "NPRM2" criteria first to geographic areas and then to low-income population groups in areas not meeting the geographic criteria.

The first three rows of Tables VI:1-9 provides the breakout of the various types of HPSA and/or MUA/P designations, whole county geographic, partial county geographic, and low income populations. This breakout allows an analysis of the impact of the new method on the different types of designations if desired. Row 4 then is total of these three rows and includes the aggregate numbers that were used in the impact analysis. Row 5 calculates the percentage of the original HPSAs/MUA-Ps that was designated under the various methodologies using updated data. For example, in Table VI:1, 949 of the original 2282 HPSAs tested would still be designated using the current method and updated data, which is a retention rate of 41.6% (Column 3/Column 2). Row 6 is the number of new designations that resulted from the various designation methodologies, i.e. areas that had not previously been designated that would become designated. Row 7 is the total of Rows 5 and 6, capturing the total number of areas, old and new, that would be designated under the various options. Row 8 calculates the percentage of designated areas as a percentage of the original baseline number, in order to measure the impact of the various methods in terms of degree of change in the number of areas that would be designated. For example, under the updated current method with new data,

1055 areas would be designated, which is 46.2% of the baseline number of 2282 (Column 3/Column 2). The same general process is followed for each of the columns in the Tables VI:1-V:7. Table VI:8 and VI:9 follow the same process for the combined HPSA/MUA-P designations to assess the impact of metropolitan/non-metropolitan/frontier areas and populations, with the percentages and the actual numbers now in the same row rather than separate rows. For example, in Table VI:8, 49% of the total designations were retained using the updated current method; Row 2, Column 2 divided by Row 2 Column 1 (2188/4447).

A. Impact on Number of HPSA Designations

As column 1 of table VI-1 shows, in the baseline year of 1999 there were 832 whole counties, 858 part-county geographic areas, and 592 low-income population groups designated as HPSAs in the United States, for a total of 2282 designations.

Since approximately one quarter of the HPSAs are updated each year, the 2282 designations considered valid in 1999 represent the results of case-by-case review of requests received over the 1996-99 period from State and local sources, and were based on a combination of national, State and local data as of 1998 or earlier. Column 2 shows the impact of simultaneously updating all these designations using the current HPSA criteria applied to the Impact Test Data Base assembled by HRSA and the UNC Sheps Center. [This data base included 1998 data for population, income and other census variables (using Claritas intercensus estimates); 1998 national primary care clinician data; and county-level vital statistics data for the five-year period 1994-98.] The results indicate that only 949 or 42% of the 2282 baseline areas would retain their designations if updated under the current criteria. However, 106 additional counties would be newly designated, so that the new total number of HPSAs would be 46% of the original total.

Column 3 of Table VI-1 shows the impact of applying the HPSA criteria proposed in "NPRM1", as published in 1998, to the 2282 baseline areas, using the same Impact Test Data Base of 1998 national data. The results indicate that only 652 or 29% of the baseline areas would retain their HPSA designation; 71 counties would be added, for a new total of 723 HPSAs, 32% of the baseline total. It is therefore quite understandable that the public comments received on NPRM1 expressed concern about potential loss

of many HPSA designations. At the same time, it is useful to realize (from comparing column 3 with column 2) that 80% of the HPSA designations that would be lost if the NPRM1 criteria were adopted would also be lost by simply simultaneously updating all

areas using the HPSA criteria already in force.

By contrast, Column 4 of Table VI-1 shows that, when the NPRM2 Tier 1 geographic area criteria are applied, 1660 or 73% of the baseline HPSAs retain their HPSA designations. An additional 325 counties are newly designated, for a new total of 1985

HPSAs, 87% of the baseline total. While this result does not in itself demonstrate the superiority of the proposed NPRM2 method, it does indicate that application of the proposed method would not result in the loss of many existing HPSA designations, a major concern of commenters on the NPRM1 proposal.

TABLE VI-1.—IMPACT OF NPRM-1 AND NPRM-2 METHODS ON NUMBER OF HPSA DESIGNATIONS

Baseline HPSA status	Number of areas designated as of 1999 (baseline)	Number of areas designated by current criteria/updated data	Number of areas designated by NPRM1 (meets IPCS & HPSA) (*)	Number of areas designated by NPRM2-geographic method	Number of population groups additionally designated using NPRM2 low income pop group method	Total number of areas and pop groups designated using NPRM2-geographic and low income pop group method
Whole County Geographic HPSA	832	372	243	694	114	808
Part County Geographic HPSA	858	473	332	681	139	820
Low Income Population HPSA	592	104	77	285	190	475
<i>Subtotal: Number of Baseline HPSA Designations Retained</i>	<i>2,282</i>	<i>949</i>	<i>652</i>	<i>1,660</i>	<i>443</i>	<i>2,103</i>
<i>Percent of Baseline Designations Retained</i>		<i>41.6%</i>	<i>28.6%</i>	<i>72.7%</i>	<i>19.4%</i>	<i>92.2%</i>
New Designations (1,197 Counties had no Baseline HPSA Designation)		106	71	325	452	777
<i>Total Number of HPSA Designations</i>	<i>2,282</i>	<i>1,055</i>	<i>723</i>	<i>1,985</i>	<i>895</i>	<i>2,880</i>
<i>Total HPSAs as a Percent of Baseline</i>		<i>46.2%</i>	<i>31.7%</i>	<i>87.0%</i>	<i>39.2%</i>	<i>126.2%</i>

*For NPRM1, 4 areas are not included because of missing data.

We also estimated the results of applying the NPRM2 Tier 1 low-income population group designation criteria to those baseline HPSA areas and counties that do not meet the NPRM2 geographic criteria. Column 5 shows the number of low-income population group HPSAs that would result; they include 253 in areas previously designated as geographic HPSAs, 190 previous HPSA population groups retained, and 452 potential new low-income population group HPSAs in counties not previously HPSA-designated.

Column 6 shows the combined result of applying NPRM2 Tier 1 geographic and low-income population group criteria: 2103 or 92% of areas with baseline HPSA designations would keep either a geographic or a low-income population group designation if the NPRM2 criteria were applied, while 777 additional geographical areas or low-income population groups could potentially be designated. While this last number may seem large, this may be related to the fact that all areas designated with the NPRM2 approach are both HPSAs and MUAs. Under the previous criteria there were

considerably more MUAs than HPSAs. Therefore, in a new system with combined criteria, even if the total number of areas designated (as either MUAs or HPSAs) were to remain approximately the same as before, one could expect the number of HPSAs to increase.

B. Impact on Number of MUA/P Designations

As column 1 of table VI-2 shows, in the baseline year of 1999 there were 1411 whole counties, 1909 part-county geographic areas, and 138 low-income population groups designated as MUA/Ps in the United States, for a total of 3458 designations.

Unlike the case with HPSAs, regular reviews and updates to the list of MUA/Ps are not legislatively required, and no major review/update has occurred since 1982; rather, additions and deletions have been made upon request (requested deletions have been infrequent). Therefore, the 3458 MUA/P designations considered valid in 1999 include many not updated since 1982, plus the results of case-by-case review of requests received over the 1982-99

period from State and local sources. Column 2 shows the impact of simultaneously updating all these designations using the current MUA criteria applied to the Impact Test Data Base discussed above (assembled by HRSA and the UNC Sheps Center from 1998 data). The results are that only 1312 or 38% of these areas would retain their MUA designations. At the same time, 28 additional counties would be newly designated, so that the new total number of MUAs would be 39% of the baseline total. Thus, using the current methodology to update the MUA list would result in more change for MUAs than for HPSAs.

Column 3 of Table VI-2 shows the results of applying the MUA criteria proposed in "NPRM1", as published in 1998, to the same 3458 areas, using the same Impact Test Data Base of 1998 national data. Here 2405, or 70% of the baseline areas, would retain their MUA designation; 143 counties would be added, for a new total of 2548 MUAs, 74% of the baseline total. So the method proposed in NPRM1 would not have decreased existing MUA designations, in contrast to the effect it would have

had on HPSAs. And it would have performed significantly better than the option of updating using current criteria in terms of retention of MUA designations.

Column 4 of Table VI–2 shows that, when the NPRM2 Tier 1 geographic area criteria are applied, 2319 or 67% of the baseline MUAs retain their MUA designations. An additional 168

counties are newly designated, for a new total of 2487 MUAs, 72% of the original total.

TABLE VI–2.—IMPACT OF NPRM–1 AND NPRM–2 METHODS ON NUMBER OF MUA/P DESIGNATIONS

Baseline MUA/P status	Number of areas designated as of 1999 (baseline)	Number of areas designated by current criteria/updated data (*)	Number of areas designated by NPRM1 (meets IPCS) (**)	Number of areas designated by NPRM2–geographic method	Estimated number of pop groups designated using NPRM2–low income pop group method	Total number of areas and pop groups designated using NPRM2–geographic and low income pop group method
Whole County Geographic MUA	1,411	499	1,067	1,031	319	1,350
Part County Geographic MUA	1,909	795	1,286	1,233	347	1,580
Low Income Population MUP	138	18	52	55	33	88
<i>Subtotal: Number of Baseline MUA/P Designations Retained.</i>	<i>3,458</i>	<i>1,312</i>	<i>2,405</i>	<i>2,319</i>	<i>699</i>	<i>3,018</i>
<i>Percent of Baseline Designations Retained</i>	<i>.....</i>	<i>37.9%</i>	<i>69.5%</i>	<i>67.1%</i>	<i>20.2%</i>	<i>87.3%</i>
<i>New Designations (674 Counties had no Baseline MUA/P Designation).</i>	<i>.....</i>	<i>28</i>	<i>143</i>	<i>168</i>	<i>219</i>	<i>387</i>
<i>Total Number of MUA/P Designations</i>	<i>3,458</i>	<i>1,340</i>	<i>2,548</i>	<i>2,487</i>	<i>918</i>	<i>3,405</i>
<i>Total MUA/Ps as a Percent of Baseline</i>	<i>.....</i>	<i>38.8%</i>	<i>73.7%</i>	<i>71.9%</i>	<i>26.5%</i>	<i>98.5%</i>

*For Current Criteria, Updated Data, 327 areas are not included because of missing data.

We also estimated the results of applying the NPRM2 Tier 1 low-income population group designation criteria to those baseline MUAs and other counties that do not meet the NPRM2 geographic criteria. Column 5 of Table VI–2 shows the number of low-income MUPs that would result; they include 666 in areas previously designated as geographic MUAs, 33 previous low-income MUPs retained, and 219 potential new low-income MUPs in counties not previously MUA/P-designated.

Column 6 shows the combined result of applying NPRM2 Tier 1 geographic and low-income population group criteria: 3018 or 87% of areas with baseline MUA/P designations would keep either a geographic or a low-income population group designation if the NPRM2 criteria were applied, while 387 additional geographical areas or low-income population groups could potentially be designated, for a total of 3405 MUA/P designations, 98% of the baseline number.

C. Impact on Number of Unduplicated HPSA/MUP Designations

Areas and population groups designated under the criteria proposed herein would be considered both MUA/

Ps and HPSAs. Therefore, it is important to examine not only the impact on HPSA and MUA/P designations separately, but also the combined impact on unduplicated HPSA and MUA/P designations. This is shown in Table VI–3. As column 1 shows, 1610 whole counties were designated either as MUAs or HPSAs or both in 1999; 2350 additional part-county areas were geographically designated as MUAs and/or as HPSAs; and 487 low-income population groups in other areas were designated as MUPs and/or population group HPSAs, for a total of 4447 unduplicated baseline designations (as compared with the baseline HPSA total of 2282 and the baseline MUA/P total of 3458). We have characterized this combined group of basis areas as the “any designation” layer of areas.

Column 2 of Table VI–3 shows the impact on unduplicated number of designations of updating using the current HPSA/MUA/P criteria (against the 1998 database described above). 2170 or 48.8% of the baseline areas would retain designation; 18 additional counties would achieve designation, so that the new total of 2188 areas would be 49.2% of the baseline total.

Column 3 shows the impact of applying the previously-published NPRM1 criteria to the unduplicated baseline areas. Here 2994 or 67% of the baseline areas would retain their designation; with 42 new designations, a total of 3036 unduplicated designations would result, or 68% of the baseline number. This is compared to the 50% loss associated with updating under current criteria, but application of the NPRM1 criteria would still have decreased (nearly 1/3) of unduplicated designations.

Column 4 shows the impact of applying the proposed NPRM2 geographic criteria to the unduplicated baseline areas. Here a total of 2962 areas are geographically designated, or 67% of the baseline areas, roughly the same as the NPRM1 impact. However, when the estimated NPRM2 low-income population group adjustment is applied and added, we get the considerably more favorable combined result shown in Column 5: A total of 3882 designations (or 87% of the unduplicated baseline) are retained by the NPRM2 method, while 168 new designations are added, for a total of 4050 designations or 91% of the baseline.

TABLE VI-3.—IMPACT ON NUMBER OF COMBINED HPSA/MUA DESIGNATIONS

Baseline HPSA and MUA/P status	Number of areas designated				
	As of 1999 (baseline)	By current criteria/updated data	By NPRM1 (meets IPCS threshold)	By NPRM2 geographic method	Total using NPRM2 geographic and low income adjustment (2 step) method
Designated as Geog or Low Income Population HPSA or MUA/P as of 1999 (Old):					
Whole County Geog HPSA or MUA	1,610	734	1,177	1,163	1,536
Part County Geog HPSA or MUA	2,350	1,351	1,607	1,571	2,003
Low Income Population HPSA or MUP	487	85	210	177	343
Subtotal: Areas Designated (of 1999 Designated Areas)	4,447	2,170 48.8%	2,994 67.3%	2,911 65.5%	3,882 87.3%
New Designations (not Designated 1999)		18	42	51	168
Total: Areas Designated (of 1999 Designated and Undesignated Areas)	4,447	2,188 49.2%	3,036 68.3%	2,962 66.6%	4,050 91.1%

(Note: Tables VI-1 and VI-2 show that 777 new HPSA designations and 387 new MUA/P designations result when the proposed NPRM2 criteria are applied separately to baseline HPSAs plus other counties and to baseline MUAs plus other counties. By contrast, when the unduplicated set of baseline areas are used in Table VI-3, we find only 168 new designations that were not either HPSAs or MUAs previously. Also, while Tables 1 and 2 show the total numbers of Tier 1 HPSAs and MUA/Ps under NPRM2 to be 126% and 98% of their baselines, respectively, Table 3 shows that the total unduplicated designations under NPRM2 Tier 1 are only 91% of the unduplicated baseline. From here on, impact analysis results are displayed in terms of the unduplicated baseline areas.)

D. Impact on Population of all Designated HPSAs and/or MUPs

While the number and percent of designations retained and the new total number of designations under alternative methods are important measures of the impact of a change in criteria, these measures can also be misleading, since all areas are not equal; different areas have different populations, different levels of need, and different numbers of safety net providers. Using 1998 Claritas population estimates, the total population of all 1999-designated (baseline) HPSAs was 59.1 million, while the total population of baseline MUA/Ps was 72.1 million; the unduplicated total population of

baseline areas designated as HPSAs and/or MUA/Ps was 95.3 million.

Table VI-4 shows the impact of the various alternatives on this unduplicated total designated population. Updating using the current criteria against the 1998 Impact Test Database would lower the total designated population to 32.7 million, or 34% of the baseline. Use of the NPRM2 geographic criteria would result in a total designated population of 53.0 million, or 56% of the baseline. Finally, use of the NPRM2 method would result in a total designated population of 83.1 million, or 87% of the baseline. (This is actually quite close to the percentage expressed in number of designations, which was 91%.)

TABLE VI-4.—IMPACT ON UNDUPLICATED POPULATION OF HPSAS AND MUA/PS

Baseline HPSA and MUA/P Status	Population in areas				
	As of 1999 (Baseline)	By current criteria/updated data	By NPRM2 geographic method [A]	By NPRM2 low income adjustment (2 step) method [B](*)	Total using NPRM2 geographic and low income adjustment (2 step) method [A+B]
Designated as Geog or Low Income Population HPSA or MUA/P as of 1999 (Old):					
Whole County Geog HPSA or MUA	38,400,153	12,044,723	23,080,444	11,501,134	34,581,578
Part County Geog HPSA or MUA	37,747,979	17,986,210	24,044,227	8,308,592	32,352,819
Low Income Population HPSA or MUP (*)	19,132,742	2,199,545	4,692,078	6,352,471	11,044,549
Subtotal: Population in Areas Designated (of 1999 Designated Areas)	95,280,874	32,230,478	51,816,749	26,162,197	77,978,946
Subtotal: Share of Population in Areas Designated in 1999		33.8%	54.4%	27.5%	81.8%
Not Designated as Geog or Low Income Population HPSA or MUA/P as of 1999 (New):					

TABLE VI-4.—IMPACT ON UNDUPLICATED POPULATION OF HPSAS AND MUA/PS—Continued

Baseline HPSA and MUA/P Status	Population in areas				
	As of 1999 (Baseline)	By current criteria/updated data	By NPRM2 geographic method [A]	By NPRM2 low income adjustment (2 step) method [B](*)	Total using NPRM2 geographic and low income adjustment (2 step) method [A+B]
New Designations [28,490,624] Population in Areas without Baseline Designation)		481,198	1,111,149	4,057,976	5,169,125
Total: Population Areas Designated (of 1999 Designated and Undesignated Areas)	95,280,874	32,711,676	52,927,898	30,220,173	83,148,071
Total: Share of Population in Areas Designated in 1999	34.3%	55.5%	31.7%	87.3%

* Though these designations are associated with Low Income Population, the population counts provided here are for all residents of the area [Total Population].

The results in Table VI-4 suggest that use of the NPRM2 method will better target designations—both the number and population of all designated areas will decrease by about 10%. At the same time, the NPRM2 method should result in a much smoother transition from current designation levels than would either updating using current criteria (which would significantly decrease

MUAs) or updating using NPRM1 (which would significantly decrease HPSAs).

E. Impact on Number of CHCs Covered by Designations

Table VI-5 shows, for those CHC sites identified as located in areas which were designated in the baseline year, the percentage that retain their designations

under the various scenarios. Under the proposed method, 86% would be in areas that retain designation (either as a geographic area or as a low income population group—see fourth line of table, last column). By contrast, the NPRM1 method would have retained only 76%, while updating the designations under current criteria would have retained only 43%.

TABLE VI-5.—IMPACT ON NUMBER OF CHCs COVERED BY DESIGNATIONS

Baseline HPSA and MUA/P Status	Number of CHCs in areas				
	As of 1999 (Baseline)	By current criteria/updated data	By NPRM1 (meets IPCS threshold)	By NPRM2 geographic method	Total using NPRM2 geographic and low income adjustment (2 step) method
Designated as Geog or Low Income Population HPSA or MUA/P as of 1999 (Old):					
Whole County Geog HPSA or MUA	618	252	474	456	583
Part County Geog HPSA or MUA	741	354	583	453	629
Low Income Population HPSA or MUP (*)	122	31	61	51	93
Subtotal: CHCs in Designated Areas (% of 1999 CHCs) ...	1,481	637	1,118	960	1,305
.....	43%	75.5%	64.8%	88.1%
Not Designated as Geog or Low Income Population HPSA or MUA/P as of 1999 (New) New Designations (43 CHCs without Baseline Designation)		2	7	4	10
Total: CHCs in Designated Areas (% of 1999 CHCs)	1,481	639	1,125	964	1,315
.....	43.1	75.9%	62.1	88.8

* The number of CHCs is based on the number of FQHC, Community Health Center sites which offer a full range of primary care services and where the designation is based on area characteristics or low income. Most part-time, special population and satellite clinics are excluded.

F. Impact on Number of NHSC Sites Covered by Designations

Table VI-6 shows, for those NHSC sites identified as located in areas which were designated in the baseline year, the

percentage that retain their designations under the various scenarios. Under the proposed method, 86% would be in areas that retain designation (either as a geographic area or as a low income

population group—see fifth line of table, last column). By contrast, updating the designations using current criteria would have retained only 34%.

TABLE VI-6.—IMPACT ON NUMBER OF NHSC SITES COVERED BY DESIGNATIONS

Baseline HPSA and MUA/P status	Number of areas with NHSCs designation				Total using NPRM2 geographic and low income adjustment (2 step) method [A+B]
	As of 1999 (Baseline)	By current criteria/updated data	By NPRM2 geographic method [A]	By NPRM2 low income adjustment (2 step) method [B]	
Designated as Geog or Low Income: Whole County Geog HPSA or MUA	340	123	218	97	315
Population HPSA or MUA/P as of 1999 (Old): Part County Geog HPSA or MUA	414	172	245	119	364
Low Income Population HPSA or MUA/P	178	19	52	72	124
Subtotal: NHSC Areas Designated (of 1999 Designated Areas)	932	314	515	288	803
Subtotal: Share of NHSC Areas Designated in 1999		33.7%	55.3%	30.9%	86.2%
Designated as Geog or Low Income Population HPSA or MUA/P as of 1999 (New): New Designations (15 Areas with NHSCs without Baseline Designation)		0	0	4	4
Total: NHSC Areas Designated (of 1999 Designated and Undesignated Areas)	932	314	515	292	807
Total: Share of NHSC in Areas Designated in 1999		33.7%	55.3%	31.3%	86.6%

G. Impact on Number of RHCs Covered by Designations

Table VI-7 shows, for those RHC sites identified as located in areas which were designated in the baseline year, the percentage that retain their designations

under the various scenarios. Under the proposed method, 94% of RHCs in currently designated areas would be in areas that retain designation (either as a geographic area or as a low income population group—see fifth line of table, last column). An additional 94 RHCs

that were not in designated areas at the time of testing would be in areas designated under the new methodology, resulting in 97.5% of RHCs being located in designated areas. By contrast, updating under current criteria would have retained 46%.

TABLE VI-7.—IMPACT ON NUMBER OF RHCs COVERED BY DESIGNATIONS

Baseline HPSA and MUA/P status	Number of RHCs in areas designated				Total Using NPRM2 geographic and low income adjustment (2 step) method [A+B]
	As of 1999 (Baseline)	By current criteria/updated data	By NPRM2 geographic method [A]	By NPRM2 low income adjustment (2 step) method [B]	
Designated as Geog or Low Income Population HPSA or MUA/P as of 1999 (Old): Whole County Geog HPSA or MUA	2,173	946	1,503	569	2,072
Part County Geog HPSA or MUA	544	336	393	127	520
Low Income Population HPSA or MUA/P	125	24	43	42	85
Subtotal: RHCs Designated (of 1999 Designated Areas)	2,842	1,306	1,939	738	2,677
Subtotal: Share of RHCs Designated in 1999		46.0%	68.2%	26.0%	94.2%
Designated as Geog or Low Income Population HPSA or MUA/P as of 1999 (New): New Designations (120 RHCs in Areas without Baseline Designation)		11	28	66	94
Total: RHCs Designated (of 1999 Designated and Undesignated Areas)	2,842	1,317	1,967	804	2,771
Total: Share of RHCs Designated in 1999		46.3%	69.2%	28.3%	97.5%

H. Impact on Distribution of Designations by Metropolitan/Non-Metropolitan and Frontier Status

Table VI-8 enables comparison of the impact on number of designated areas in metropolitan, non-metropolitan, and frontier areas. (Here metropolitan areas are those so designated by the Office of Management and Budget; non-metropolitan areas are all other areas. Frontier areas are generally defined as

the subset of non-metropolitan areas with population densities less than 7 persons per square mile, but for the purpose of these impact tests a file of frontier areas was used that was provided by the Frontier Education Center and involved a more expansive definition of frontier areas that included a formula based on population density and isolation [time and distance from a market area as well as other factors]). Table VI-8 (last column) shows that,

while 91% of all baseline designations are retained under the proposed method, 82% of those in metropolitan areas, 98% of those in non-metropolitan areas, and 99% of those in frontier areas are retained. Therefore, non-metropolitan and frontier areas are not more negatively impacted than metropolitan areas (contrary to the impression many commentators seemed to have of the NPRM1 method).

TABLE VI-8.—IMPACT ON DISTRIBUTION OF DESIGNATIONS BY MET/NON-MET/FRONTIER

	Baseline	Current criteria updated	NPRM1	NPRM2 Geog	NPRM2 Geog + Low-income pop
Total No. of Designations	4,447	2,188 (49%)	3,036 (68%)	2,962 (67%)	4,050 (91%)
Metropolitan	1,880	861 (46%)	1,223 (65%)	1,112 (59%)	1,532 (82%)
Non-Metro	2,567	1,327 (52%)	1,813 (71%)	1,850 (72%)	2,518 (98%)
Frontier	1,026	544 (53%)	800 (78%)	751 (73%)	1,014 (99%)

I. Impact on Distribution of Population of Underserved Area and Underserved Populations by Metropolitan/Non-Metropolitan and Frontier Status

Table VI-9 enables comparison of the impact on the population of underserved areas and underserved populations in metropolitan, non-metropolitan, and frontier areas. Table VI-9 (last column) shows that, while the total designated population under the proposed method would be 87% of the baseline designated population, the metropolitan component of this NPRM2

designated population is 81% of the baseline metropolitan underserved, the non-metropolitan component is 99% of the baseline non-metropolitan underserved, and the frontier component is 102% of the baseline frontier underserved. Therefore, the designated population of non-metropolitan and frontier areas would not decrease. The metropolitan population identified as underserved would appear to decrease, however. We expect this represents better targeting of the metropolitan underserved under the proposed method: It may also represent

the fact that use of a national physician database together with gross estimates of the percent of urban practices devoted to low-income and uninsured populations leads to overestimates of the number of FTE clinicians and underestimates of the number of designations and the underserved population in metropolitan areas. This suggests that case-by-case activity will continue to be necessary in reviewing some urban designations, while many non-metropolitan designations will be able to be processed using national data together with the new method.

TABLE VI-9.—IMPACT ON POPULATION OF UNDERSERVED AREAS BY MET/NON-MET/FRONTIER

	Baseline	Current criteria updated	NPRM2 Geog	NPRM2 Geog + Low-income pop
Total Underserved	95,280,874	32,711,676 (34%)	52,927,898 (56%)	83,148,071 (87%)
Metropolitan Underserved	63,791,345	21,044,647 (33%)	31,951,255 (50%)	51,804,251 (81%)
Non-Metro Underserved	31,489,529	11,667,029 (37%)	20,976,643 (67%)	31,343,820 (99%)
Frontier Underserved	8,328,049	3,396,268 (41%)	5,784,509 (70%)	8,528,643 (102%)

J. Impact of Practitioner “Back-outs” on Number of Designations and Safety-Net Providers

The tables above represent the impacts when all clinicians are counted, i.e. the “Tier 1” designations. The tables below describe the impact of subtracting federally placed, obligated or funded

clinicians from the practitioner counts, i.e. the changes that occur when “Tier 2” designations are included. For example, Table VI-10 shows the effect on number of designations. Column 1 shows the number of baseline designations; column 2 shows the number of Tier 1 designations under the proposed method. Column 3 shows the

new total of designations if NHSC and SLRP clinicians are subtracted. Column 4 shows the revised total if physicians with J-1 visa return-home waivers who are performing obligated service are also subtracted. Finally, column 5 shows the total number of designations when any other CHC-Based clinicians are also subtracted.

TABLE VI-10.—IMPACT OF PRACTITIONER “BACK-OUTS” ON TOTAL NUMBER OF HPSA OR MUA/P AREAS DESIGNATED

Baseline HPSA and MUA/P status	Number of areas designated				
	As of 1999 (baseline)	By NPRM2 geographic and 2 step low income method Tier 1 (all primary care providers)	By NPRM2 geographic and 2 step low income method Tier 2-1 (Tier 1 less NHSC and SLRP providers)	By NPRM2 geographic and 2 step low income method Tier 2-2 (Tier 1 less NHSC, SLRP, and J-1 providers)	By NPRM2 geographic and 2 step low income method Tier 2-3 (Tier 1 less NHSC, SLRP, J-1, and any designation)
Designated as Geog or Low Income Population HPSA or MUA/P as of 1999 (Old):					
Whole County Geog HPSA or MUA	1,610	1,536	1,546	1,551	1,553
Part County Geog HPSA or MUA	2,350	2,003	2,010	2,015	2,038
Low Income Population HPSA or MUP	487	343	346	350	356
Subtotal: Areas Designated (of 1999 Designated Areas)	4,447	3,882	3,902	3,916	3,947
Subtotal: Share of Areas Designated in 1999		87.3%	87.7%	88.1%	88.8%
Designated as Geog or Low Income Population HPSA or MUA/P as of 1999 (New):					
New Designations (376 Areas Designated as HPSA or MUA without Baseline Designation)		168	168	168	172
Total: Areas Designated (of 1999 Designated and Undesignated Areas)	4,447	4,050	4,070	4,084	4,119
Total: Share of Areas Designated in 1999		91.1%	91.5%	91.8%	92.6%

As can be seen, the number of additional designations resulting from these practitioner back-outs is quite small. However, HRSA considered that there could be a significant impact on some particular safety-net projects, i.e. certain CHCs, NHSC sites, and RHCs.

Table VI-11 summarizes the impact on CHCs, NHSC sites, and RHCs. It indicates that 49 additional CHCs, 32 additional NHSC sites, and 43 additional RHCs are in areas which would receive Tier 2 designation (change from Column 2 to Column 5).

While this is not a large number, it clearly would be important for the affected sites. HRSA therefore concluded that the Tier 2 designations (with all three types of backouts) should be implemented.

TABLE VI-11.—IMPACT OF PRACTITIONER BACK-OUTS ON NUMBERS OF CHCs, NHSC SITES, AND RHCs COVERED BY DESIGNATIONS

Type of safety-net provider	Number in baseline designated areas	Number in NPRM2-designated tier 1 areas (All primary care clinicians counted)	Number in NPRM2-designated tier 1/tier 2-1 areas (NHSC and SLRP clinicians subtracted)	Number in NPRM2-designated tier 1/tier 2-2 areas (NHSC, SLRP and J-1 clinicians subtracted)	Number in NPRM2-designated tier 1/tier 2-3 areas (NHSC, SLRP, J-1, and other section 330 funded clinicians subtracted)
CHCs	1,481	1,315	1,322	1,328	1,364
(% of baseline CHCs)		(88.8%)	(89.3%)	(89.7%)	(92.1%)
NHSC sites	932	807	825	828	839
(% of baseline NHSC sites)		(86.6%)	(88.5%)	(88.8%)	(90.0%)
RHCs	2,842	2,771	2,790	2,794	2,814
(% of baseline RHCs)		(97.5%)	(98.2%)	(98.3%)	(99.0%)

In conclusion, it should be stated that it is impossible to predict the exact final impact on specific communities and States because of the iterative process built into the system. As described above, State and local officials will have the opportunity to examine the data used to develop these first

approximations during the actual designation process, and to correct inaccurate provider and other data. In addition, they will have the opportunity to reconfigure service areas so as to more closely identify the boundaries of areas where shortages now exist, which may have changed since some of these

service areas were constructed (particularly the MUAs). We believe this is a major strength of the proposal, since States and communities know best their service areas and practitioner supplies. At the same time, it makes it difficult to predict precisely the impact of the new method at the local level, since the data

used will be altered by State and local input.

VII. Economic Impact

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity, and available information. Regulations must meet certain standards, such as avoiding unnecessary burden. Regulations which are found to be "significant" because of their cost, adverse effects on the economy, inconsistency with other agency actions, budgetary impact, or raising of novel legal or policy issues require special analysis. The Department has determined that this rule will not have an annual effect on the economy of \$100 million or more. However, because this rule raises novel policy issues, it does meet the definition of a "significant" rule under Executive Order 12866.

The Regulatory Flexibility Act requires that agencies analyze regulatory proposals to determine whether they create a significant economic impact on a substantial number of small entities. "Small entity" is defined in the Regulatory Flexibility Act as "having the same meaning as the terms 'small business,' 'small organization,' and 'small governmental jurisdiction'"; "Small organizations" are defined in the Regulatory Flexibility Act as not-for-profit enterprises which are independently owned and operated and not dominant in their field.

The small organizations most relevant to this regulation would be Health Center grantees. The impact analyses discussed above suggest that very few health center service areas would lose MUA/P designation under the proposed criteria. In addition, because of the proposed new safety net facility type of designation, any negatively affected health center will be able to submit a request for this alternate type of designation. Moreover, the "automatic" designation of all FQHCs as HPSAs for six years under the Safety Net Amendments of 2002 will allow additional time for any transition to unfunded status that may prove to be necessary for some health centers.

With regard to small businesses, while the designation process may negatively affect some small profit-making health care-related businesses, it is unlikely that it could have a significant economic impact, defined as five percent or more of total revenues on three percent or more of all such small businesses. Physician practices can obtain a 10 percent Medicare Incentive Payment bonus for those services delivered in geographic HPSAs; however, this would be unlikely to

amount to five percent of the total revenues of a practice operated as a small business.

Private RHCs could be considered small businesses; non-profit RHCs could be considered small organizations. RHCs already certified based in part on an MUA or HPSA designation have not been adversely affected by loss of such designations in the past, since the legislative authority for them had a "grandfather" clause; once certified, the RHC certification could not be withdrawn based only on loss of designation. However, the Balanced Budget Act of 1997 provided that, effective January 1, 1999, an RHC in an area that has lost designation or was designated over 3 years ago is subject to loss of its RHC certification, unless the Secretary determines that the RHC is essential to the delivery of primary care services in its area. The impact analysis shows only 2% of the non-metro designations will be lost under the proposed new method, so the likely impact is minimal. Therefore, implementation of these regulations will not automatically decertify any RHCs.

"Small governmental jurisdictions" are defined by the Regulatory Flexibility Act to include governments of those cities, counties, towns, townships, villages, or districts with a population of less than 50,000. Typically, one can expect that such jurisdictions will be found in non-metropolitan areas. Our impact analysis indicated that only 2 percent of all designations in non-metropolitan areas are likely to lose a designation (see Table VI-8 above). This suggests that a substantial number of small government jurisdictions will not be affected. Furthermore, it is unlikely that the economic impact on any such affected jurisdictions would be significant, *i.e.* that they would lose more than 5 percent of their federal funding, as discussed in more detail below.

The impact on particular jurisdictions of loss of designation can take one or more of three forms: Loss of grant funding for primary care services, loss of a source of clinicians to provide primary care services, or loss of a more favorable level of Medicaid and/or Medicare reimbursement. The first of these types of impact would occur only in the case of a Health Center which has lost its area and/or population designation, and does not qualify for designation as a safety net site. Typically, grant funding forms approximately 25-30 percent of the income to a CHC; it is possible that such a health center would be able to continue in operation without this revenue. Moreover, dedesignation could

indicate that not only provider availability but also the income of the area's population had increased. As a result, the percentage impact on the economy of the area involved would likely be relatively low.

The second of these types of impact corresponds to an area which, due to loss of its HPSA designation, is no longer eligible for NHSC clinicians, once the tour of duty of any NHSC personnel already placed there is completed. If such an area has recently been dedesignated, logically there must have been an increase in the number of primary care providers in the area and/or a decreased population and/or improved demographics, so that loss of NHSC clinicians will be unlikely to have a major economic effect on the area. (Furthermore, the "automatic" HPSA designation of FQHCs and RHCs should mitigate any adverse effects here during the next several years.)

The third type of impact applies in the case of FQHCs and/or RHCs which lose eligibility for special reimbursement methods, and private physicians in former geographic HPSAs which lose the 10 percent Medicare bonus. None of these entities would actually cease receiving Medicare or Medicaid reimbursement; they simply would receive a lower level of reimbursement. In the latter case, it is a loss of 10 percent, but it is unlikely that it would amount to 5 percent of the physician's total revenue. In the FQHC/RHC case, there could be a 20-30 percent decrease in reimbursement to the provider in question, but again this would not necessarily be a major economic loss to the county or other jurisdiction as a whole.

It should also be noted that, to the extent that the proposed regulation ultimately results in some areas losing designation while others gain designation, and some areas therefore losing program benefits which go to designated areas while others gain such benefits, the total benefits available in a particular fiscal year will not decrease but will have been better targeted to the neediest areas, because the criteria will have been improved and will have been applied to more current data.

The Department nevertheless requests comments on whether there are any aspects of this proposed rule which can be improved to make the designation process proposed more effective, more equitable, or less costly.

VII. Information Collection Requirements Under Paperwork Reduction Act of 1995

Sections 5.3 and 5.5 of the proposed rule contain information collection

requirements as defined under the Paperwork Reduction Act of 1995 and implementing regulations. As required, the Department of Health and Human Services is submitting a request for approval of these information collection provisions to OMB for review. These collection provisions are summarized below, together with a brief description of the need for the information and its proposed use, and an estimate of the burden that will result.

Title: Information for use in designation of MUA/Ps and HPSAs.

Summary of Collection: These regulations revise existing criteria and processes used for designation of Medically Underserved Areas/Populations (MUA/P) and Health Professional Shortage Areas (HPSA). As discussed above, service to an area or population group with such a designation is one requirement for entities to obtain Federal assistance from one or more of a number of programs, including the National Health Service Corps and the Community and Migrant Health Center Program.

In order to initially obtain such a designation, a community, individual or State agency or organization must request the designation in writing. Requests must include data showing that the area, population group or facility meets the criteria for designation, although these data need not necessarily be collected by the applicant, but may be based on data obtained from a State entity or data available from the Secretary. If the request is made by a community or individual, the State entities identified in the regulation are given an opportunity to review it, which implies maintenance by these State entities of some record keeping on designation requests previously made or commented upon by the State. These requirements apply under both current rules and the proposed rule.

Once a designation based on the proposed criteria has been made, it must be updated periodically (at least once every three years) or it will be removed from the list of designations. Although in the past this requirement applied only to HPSA designations, the proposed rule would extend the regular periodic update requirement to MUA/P designations (in response to concerns raised by the GAO and Congressional committees, among others). The update process involves the Secretary each year informing State (and/or community) entities as to which of their designations require updates, and providing these entities with the most current data available to the Secretary for the areas, population groups and facilities

involved, with respect to the data elements used in designation. The State entities are then asked to verify whether the designations are still valid, using the data furnished by the Secretary from national sources together with any additional, more current or otherwise more accurate data available to the State entity (in consultation with the communities involved, as necessary). In the past, this has generally meant that the State (or community) entities have needed to verify primary care physician counts in most of the areas involved, especially subcounty areas, since only county-level physician data have typically been available from national sources. National population data have been largely limited to decennial census data and official Census Bureau intercensal county-level updates, so that State population estimates were sometimes necessary; other relevant data have generally been available from national sources.

Under the proposed new process, the data furnished by the Secretary will include provider data and population estimates for subcounty areas as well as counties, in an easily accessible database, and these data from national sources (including intercensal demographic and population projections) may be used without further collection and analysis, if acceptable to the State and community involved. This should minimize the burden on States and communities, except where the Secretary's data suggest withdrawal of a designation, in which cases the State or community will need to obtain local data to support continued designation. In such cases, the inclusion of non-physician providers under the proposed new rules will have a higher burden on those States or communities which wish to challenge provider data furnished by the Secretary.

Need for the information. The information involved is needed in order to determine whether the areas, populations and facilities involved satisfy the criteria for designation and, therefore, are eligible for programs for which these designations are a prerequisite. While furnishing such information is purely voluntary, failure to provide it can prevent some needy communities from becoming eligible for certain programs. The Secretary will make a proactive effort to identify such communities using national data, but feedback from State entities and others with appropriate data is vital to ensuring that the designation/need determination process is accurate and current.

Likely respondents. The entities that generally submit this designation-related information to DHHS are the State Primary Care Offices (normally within State Health Departments) or the State Primary Care Associations (non-profit associations of health centers and other organizations rendering primary care). The total burden placed on these entities will be determined by the number of applications they submit, review or update each year, and, therefore, will vary from State to State. Updates of all designated areas will not be required immediately when the new method is initiated; State entities will be given the opportunity to spread out updates of previously designated areas over a 3-year period following implementation of the proposed regulation.

Burden estimate. The overall public reporting and record keeping burden for this collection of information is estimated to be minimal under the new method. This is primarily because, while the new method will require some data collection from the same sources utilized in the previous MUA/P and HPSA designation procedures, there is no need to submit separate requests for the two types of designation and allows the use of national data where acceptable to the State and community. We also plan to allow electronic submission of data.

The burden for compiling a request for new designation (including supporting data) or for update of an existing designation, under the existing system, was estimated by consulting with State entities who prepare such requests/updates about the amount of time required for the various aspects of request preparation, varying these estimates for requests with several different levels of difficulty, and then factoring in the approximate frequency of that type of request. Similar estimates for the new system were then made, revising the contributing factors to account for those aspects that would require more or less effort under the new approach. These estimates also assume that some applications are State-prepared, while others involve both an applicant and a State consultation or review; the estimates include both parties' time where two parties are involved. Under the new method, States and communities may use data provided by the Secretary; as mentioned above; however, some may wish to provide their own data for primary care physicians, while others may wish to provide data for both primary care physicians and for the nonphysician primary medical care providers which are included in the new designation

criteria and system (Nurse Practitioners, Physician Assistants, and Certified Nurse Midwives). Use of State and/or

community data will be more likely in those cases where the national data suggest dedesignation. The estimates

below include consideration of the extent to which such local data collection will likely be necessary.

Designation type	Number of respondents	Number of expected responses	Hours per response	Total hours
MUA/P/HPSA Metro Area	54	391	27.4	10,713
MUP/HPSA Non-Metro Area	* 54	909	10.9	9,908
Facility Designations	25	70	2.6	182
Total	79	1,370	20,803
Mean	15.2

* The Non-Metro applications are completed by the same respondents who complete Metro Area designation requests. To prevent double-counting of respondents, these 54 are added only once; therefore, 79 is shown as the total.

Public comments on information collection requirements: Comments by the public on this proposed collection of information are solicited and will be considered in (1) evaluating whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have a practical use; (2) evaluating the accuracy of the Department's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhancing the quality, usefulness, and clarity of the information to be collected; and (4) minimizing the burden of collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses.

Address for comments on information collection requirements: Any public comments specifically regarding these information collection requirements should be submitted to: Fax Number—202-395-6974, or OIRA_submission@omb.eop.gov, Attn: Desk Officer for HRSA. Comments on the information collection requirements will be accepted by OMB throughout the 60-day public comment period allowed for the proposed rules, but will be most useful to OMB if received during the first 30 days, since OMB must either approve the collection requirement or file public comments on it by the end of the 60-day period.

Appendix A.—References

Works Cited

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Appendix B.—A Proposal for a Method To Designate Communities as Underserved

Technical Report on the Derivation of Weights

This Appendix is intended to provide more technical details about the proposed methodology and how it was developed. The principal authors of this document are, alphabetically: Laurie Goldsmith, Mark Holmes, Jan Ostermann, and Tom Ricketts.

The General Approach

The overall approach for deriving an empirical, data driven system to identify underserved areas and populations is to estimate the effect of demographic factors on the population-to-practitioner ratio, using a sample of counties as proxies for a health care market. These effects are then translated to a score which is added to an adjusted ratio for a total “need” measure. Thus, the implementation is similar to the current IPCS or MUA method in that it creates a “score” or “index” of underservice, however, the proposed system’s score is based on an adjusted ratio that is meant to represent an “effective” or “apparent” population and its primary health care needs.

There are eight steps to the project, which we divide for expository purposes into two distinct “Tasks”. Please note that the specific steps described earlier in the preamble to this rule may not match up to the steps described below (for example, “step 4” in the preamble matches up with “steps 4–5” and “step 7” in this appendix).

Task One: Calculate the Weights That Will Be Used To Adjust Ratios (“Analysis”)

This is the analytical portion of the project in which we explore the degree to which observable demographic characteristics tend to be associated with population to provider ratios. The specific steps in this task include:

1. Create an age-sex adjusted population.
2. Calculate the base population-provider ratio for regression to determine weights for need variables.
3. Select study sample primary care service area proxies.
4. Create factor scores to control for interactions of variables.
5. Run regression models to create weights for community variables.

Task Two: Calculate the Scores Based on These Factors (“Computation”)

This is the portion of the process in which scores are assigned to geographic areas based on the weights calculated in Task One.

6. Calculate the base population-practitioner ratio for designation determination.

7. Calculate the scores for each area based on the values for each variable for each area and add to the ratio.

8. Step 8: Compare the ratio to a designation threshold ratio.

We describe each of these steps in detail in the following sections.

Task 1: Analysis Steps

Step 1: Create an Age-Sex Adjusted Population

Using estimated visit rates from individual-level surveys, we weight the population to create a “base population.” In this manner, populations can be compared across areas. The use of these data for this adjustment are discussed in detail in reports and background papers for the proposal including the report that estimates the national impact of the NPRM–2 proposal, “National Impact Analysis of a Proposed Method to Designate Communities as Underserved” dated September 7, 2001; the background paper, “Designating Underserved Populations. A Proposal For An Integrated System Of Identifying Communities With Multiple Access Challenges,” which is in draft form; and the “Executive Summary” of the “Designating * * *” paper, which has been circulated in draft form to the Bureau of Primary Health Care.

The weights are summarized in Table 1.

TABLE 1.—VISIT WEIGHTS FOR AGE-SEX ADJUSTMENT

	0–4	5–17	18–44	45–64	65–74	75 and over
Female	4.046	2.256	5.007	5.480	6.710	8.160
Male	5.164	2.499	2.867	4.410	6.052	8.056

These are the original weights using 1996 data.

The weighted sum of these populations is calculated as 4.046 * (# Females 0–4) + 2.256 * (# Females 5–17) + . . . + 8.056 * (# Males 75 and over) and equals an age-sex adjusted number of visits for a particular population. Dividing this number of visits by the mean visit rate (3.741) creates a “base population”. Areas with equal base populations (and equal demographics) have an equal need for primary care visits per year. This adjustment allows us to compare, say, the population-based visit differentials between an area with a high concentration of elderly (with a higher need for visits) and an area with a high population of middle aged individuals (with a lower need for visits). The visit rates were obtained from the Medical Expenditure Panel Survey (1996) and were calculated for non-poor, white, non-Hispanic individuals. Employment status, which was included in the MEPS survey and was a significant correlate of use of service, was also intercorrelated with the other variables and

was not included in the final visit calculation.

Step 2: Calculate the Base Population-Provider Ratio for Regression To Determine Weights for Need Variables

With the base population in hand, we calculate the population-provider ratio to use in the regression to determine factor weights. When applying the formula for the initial estimation of weights, the number of practitioners is calculated as:

$$\text{Providers} = \text{physicians} - (\text{J1_physicians} + \text{MHSC_physicians} + \text{SLRP_physicians}) + .5 * [\text{midlevels} - (\text{NHSC_midlevels} + \text{SLRP_midlevels})] + .1 * [\text{residents} - (\text{NHSC_residents} + \text{SLRP_residents})]$$

where all practitioners are measured in FTE units and the practitioner total includes NPs, PAs and CNMs weighted according to agency guidelines. The number of practitioners used in the regression to determine weights for the

need variables represents only those practitioners that are considered to be the “private” supply. That is, the practitioners who would choose to practice in the community without federal support or incentives to practice in state- or federally-operated facilities. As such, government practitioners (whether federal or state) are not counted here. Community Health Center practitioners who are not federal employees, however, are counted since many of these are not “placed” into communities but are practitioners already located in the area that are “reclassified” as CHC practitioners for later subtraction from the practitioner supply at a later step. For the estimation of the formula, an area with no practitioners is dropped from use in the regression analysis to determine weights for the need variables as a ratio is undefined (not calculable).

Step 3: Select Study Sample

A sample of counties and county equivalents that serve as proxies for a health care market are then selected for analysis to derive formula weights. This step was done to identify places which functioned as primary care service areas and which reported stable, reliable, usable data. According to 2000 Census data, the median county land area is 616 square miles, corresponding to an approximate radius of 14 miles. The tenth and ninetieth percentiles are 288 and 1847 square miles, corresponding to approximate radii of 10 and 24 miles respectively. The approximate radius of a county that is between the tenth and ninetieth percentiles in land area reflects a consensus of the extent of distances traveled for primary care services. The report describing PCSAs developed by Dartmouth and VCU did not identify a median or mean size rather they indicated that "A land area of 1,256 square miles or a radius of 20 miles (assuming a circular shape) was used as a crude indicator of geographically large PCSAs." (Goodman, et al., 2003 p. 297). The population threshold we proposed of 125,000 was chosen based on a perception that cities and counties with populations greater than this level were likely to have many more specialists and tertiary care services structure that would substitute for primary care alone, thus skewing the relationship between primary care practitioners and population. No specific studies were done to further support this assumption. The PCSA project reported a median population of 17,276 with multiple PCSAs exceeding that threshold. Many U.S. counties meet these general qualifications and the process selected a range of counties that met three criteria, including:

- i. Populations below 125,000 (410 eliminated*)
 - ii. Area below 900 square miles (856 eliminated)
 - iii. Base population to provider ratio below 4250 (336 eliminated)
- *Some counties had combinations of both values.

The third criterion effectively eliminated very small counties and counties with unusual distributions of health practitioners. The goal was to determine the relationship of area characteristics to practitioner supply under "normal" conditions in order to create stable estimates of those relationships in order to apply them to all appropriate populations and areas.

These sample selection criteria were varied; we tested over 2000 combinations in the estimation process described in the next step to test for robustness and sensitivity. The variations included testing within the following ranges: Population 80,000–150,000; area 700–1200 sq. miles; ratio 3000–4250. Overall, the estimations derived from the models were not substantially different among the different samples. The study sample contained 1643 counties. Counties were chosen because they are well-defined and are not endogenous to the current system.

Using currently designated areas would lead to biased conclusions due to the fact the subcounty areas are carefully and deliberately constructed for purposes of designation. Furthermore, dividing a county into a subcounty-designated and subcounty-undesignated would generate an extremely large number of possible observations in the analysis since the county could be divided in many different ways and into many subsets of county parts. Finally, since some data are calculated and available primarily on a county level, measurement error is minimized by using counties. Using other units of analysis requires interpolating values for subcounty and multicounty areas based on the constituent geographic units.

Step 4: Create Factors

The proposed designation process, in keeping with the original MUA/MUP and HPSA approaches, identified commonly available statistics that correlated with a small number of primary care practitioners-to-population ratio. The selection of the measures was based on reviews of the scientific literature on access to care and preliminary work on the development of an alternative measures of underservice conducted by Donald H. Taylor, Jr. (Taylor & Ricketts, 1994). Candidate statistics were also suggested by a working group of State Primary Care Associations (PCAs) and Primary Care Offices (PCOs) convened by the Division of Shortage Designation (DSD) to gather state-level input into the process of revising the method. The staff and leadership of the DSD also provided extensive input into the design. More than 20 specific variables were suggested during this process. Some candidate variables could not be used, despite being highly correlated with low access and poor health outcomes, due to lack of availability of data for small areas (e.g. lack of health insurance). Ultimately, the high

intercorrelations among candidate variables restricted the calculation to 7–9 individual indicators (the actual number to be tested depended upon the specific combination of variables). The final choice of variables and the priority for inclusion in the analysis was based on the degree to which the variables best reflected underlying components of access as qualitatively assessed by the UNC-CH team, the PCA/PCO group, and staff of Bureau of Primary Health Care (BPHC). The final measures consist of demographic, economic and health status indicators (presented in Table 2).

Demographic: Population characteristics, especially racial and ethnic characteristics, have been consistently shown to affect access to primary care (Berk, Bernstein, & Taylor, 1983; Berk, Schur, & Cantor, 1995; Schur & Franco, 1999). Measures of the percent of population that is non-White and percent of population that is Hispanic were used to further adjust the ratio. The inclusion of the percentage of population older than 65 years was also included because communities with higher percentages of elderly have different community characteristics not captured in the initial population adjustment. This is likely due to the relative lack of younger people to provide supportive care and the fact that communities with declining economies, especially rural communities, have older age profiles that combine with other factors to create overall lower access.

Economic: Income and employment are very strong indicators of ability to access primary health care and to afford health insurance (Mansfield, Wilson, Kobrinski, & Mitchell, 1999; Prevention, 2000; Robert, 1999). The unemployment rate and the percent of population below 200 percent of the poverty level were used to further adjust the ratio.

Health Status: Certain populations and communities have higher than average need for health care services based primarily on their health status independent of other factors. Therefore, health status measures used to adjust the ratio include the standardized mortality ratio (General Accounting Office, 1996) and either the infant mortality rate or the low birthweight rate (Matteson, Burr, & Marshall, 1998; O'Campo, Xue, Wang, & Caughy, 1997). These special epidemiological conditions that increase need are not fully represented in the age-gender adjustment.

TABLE 2.—VARIABLES USED IN CREATING PROPOSED METHOD

Demographic	Economic	Health status
Percent Non-white "NONWHITE" Percent Hispanic "HISPANIC" Percent population >65 years "ELDERLY"	Percent population <200% FPL "POVERTY" Unemployment rate "UNEMPLOYMENT"	Actual/expected death rate (adj) "SMR" Low birth weight rate "LBW" Infant mortality rate "IMR"
Population density "DENSITY"		

These measures are highly intercorrelated. Table 3 below shows the Pearson-product

moment correlations. The first column shows that poverty and unemployment are

positively correlated (+0.64), meaning, in counties with high proportions of the

population living in poverty there is usually a higher unemployment rate. Poverty and density are negatively correlated (−0.55),

meaning that where there is higher density there are lower percentages of the population

living in poverty. The correlation matrix is population-weighted.

TABLE 3.—PERCENTILE CORRELATION MATRIX

	Poverty	Unemp	Density	Elderly	Hispanic	Non-white	SMR	IMR	LBW
Poverty	1.00
Unemp	0.64	1.00
Density	−0.55	−0.21	1.00
Elderly	0.36	0.28	−0.47	1.00
Hispanic	−0.32	−0.23	0.22	0.25	1.00
Non-White	0.10	0.12	0.22	−0.29	0.25	1.00
SMR	0.57	0.55	−0.04	0.04	−0.26	0.42	1.00
IMR	0.33	0.25	−0.10	0.08	−0.08	0.41	0.43	1.00
LBW	0.40	0.37	0.05	−0.05	−0.14	0.63	0.69	0.54	1.00

Variable Definitions

Variables were assigned a percentile based on the distribution of values of all U.S. counties to all U.S. counties. This allows for continuity in the use of the proposed scores if variables are defined differently in the future (e.g. the poverty measure is changed to 100 percent below poverty instead of 200 percent). It also allows policymakers a choice of how often (or whether) to update the percentile values without having to change the weights. If poverty conditions improve markedly across the nation, scores will tend to fall unless the percentile tables are updated. For all variables except DENSITY the theoretically worst value corresponded to the 99th percentile. At first glance, it might appear that places with very low population density would be worse off with regard to primary care access and health service needs. Places with extremely high density may also have problems caused by overcrowding and the population density may reflect problems that are commonly encountered in inner-cities. For this variable there is no apparent “right” direction for the weights. We arbitrarily specified the functional form such that lower population density corresponds to a worse off (higher percentile score) community. Accounting for the negative effects of very high density is described below.

We combined low birth weight and infant mortality into one measure (called *HEALTH*), defined as the maximum percentile of low birth weight and the infant mortality rate for a given area. This is due to a medium level of correlation between the two and the fact that not all areas report both measures. Finally, the use of the infant mortality rate in measures of underservice is required by existing law and there is precedent for using these measures as rough substitutes. The original Index of Primary Care Shortage described in NPRM-1 of September 1, 1998 used them interchangeably.

We defined nonwhite as the maximum of zero or the percentile minus 40, so that only the top (most nonwhite) 60 percent of areas get “points” for the nonwhite variable. In other words, all areas less than the 40th percentile are treated equally. There were two main reasons for this. The first is that many of the areas have low nonwhite percentages (the 40th percentile is about 2.6 percent nonwhite). By not making this

adjustment, we are differentiating areas that have little difference in the underlying measure. The second reason is that without this adjustment, the scores were not stable; small differences in the definition of this variable resulted in wide swings in the magnitude of the nonwhite variable when testing multiple randomly chosen samples. We experimented with a multitude of cutoff points (0–50 in 10 unit increments). In the final specification, small changes in the definition of NONWHITE had little substantive effect.

With the corresponding percentiles in hand, the associated scores were transformed to a logarithmic scale so that the highest derivative corresponded to the theoretically worst end of the scale. For example, the independent variable corresponding to poverty (*Inpcpov*) was defined as $In(100 - pcpov)$ so that the fastest acceleration in the poverty score occurs at high levels of poverty rather than at low levels. In other words, we specified the model to allow a greater score to accrue to areas “moving” from the 95th percentile to the 96th percentile than to areas “moving” from the 5th percentile to the 6th percentile. All variables were assumed to have this shape (so that the theoretically worst values have the largest derivative). A more detailed description of the regression approach is included at the end of this appendix (Notes to Appendix B).

Basing the Scores on the Population-Practitioner Ratio

Although this approach specifies the shape of the function as logarithmic and this constrains the rate of change in the scoring as variables differ from one percentile to another, it does not constrain the sign nor the absolute magnitude of the parameters that create the weights. That is, the regression models are indifferent to whether a parameter comes out positive or negative or how large or small it is when the statistical model is run to create the weights. The magnitude is the most important parameter of the three and will be used for estimating the scores but the potential effects of the size and sign of the weights must fit into our logic of additivity of factors. The magnitude of the weights are expressed as a synthetic unit which cannot be compared to any other unit—the weight for UNEMPLOYMENT, for example, when transformed to the log-normal

form and constrained to a positive value in the course of the estimation, is not a “percent of workforce not working but seeking work” but an abstract number that describes the relative contribution of that factor to a total access score at that percentile of unemployment given all the value of all the other variables and the population structure. The final model creates an estimate for the weight for each set of variables using this abstract number but that number has to be brought back into a logical relationship with the key unit of access we are using—the population portion of a practitioner-to-population ratio. The final combined sum of these abstract values has to be adjusted back to an interpretable relationship with the practitioner-population ratio. This requires that some form of restraint on the parameter (weight) values be imposed or the solution set may produce a “best result” that causes one or two variables to dominate the weighting and others to vary from positive indicators of barriers to access to negative in various combinations.

In the application of the process this means that the parameter is used along with the intercept of the regression models to generate the specific weight for each variable. This was done to normalize the scores so that the minimum score was zero. This is done by adding a fixed number to the log result.

In an unconstrained solution of the regression models this is, indeed, the case. There are possible solution sets that include mixes of positive and negative values; in statistical parlance the functions are “two-sided.” The logic of the scoring system anticipated this when we stipulated that factors which restrain use of services by creating barriers to access, also create subsequent higher levels of need likely to be met by higher levels of use, use of services that was preventable but now necessary. In the real community, both things are happening, an access program is promoting appropriate utilization by overcoming access barriers and all practitioners are involved in caring for people who are using the system because emergent conditions were not treated appropriately. The amount of the increase in use brought about by delayed care must be added into the reduction in use to produce a sum of the access “problem” in a community. To account for the “mirror” effects of these variables, the final value, the sum of the weights are doubled, to produce

a population estimate that is scaled to represent the overall effect on the population need.

Factor Analysis

Because many of these measures are highly correlated, we perform factor analysis in order to compute *factors* for the independent variables defined above. Essentially, factor analysis provides a method to translate

highly correlated variables into orthogonal measures to obtain more precise estimates and minimize the impact of multicollinearity in the variables of interest. Often used as an end product statistical tool, we use it here to improve the precision of the estimates.¹

Our procedure here was to decompose the independent variables into factors and then create scores based on these factors. The factor scores follow in Table 4. The largest

weight in the row is the one on which factor the variable weighs most heavily (except for SMR, which has two maximum weights of almost equal magnitude). Four factors might be interpreted as structuring the data:

- I. High health risk, nonwhite
- II. Geo-demographics
- III. Economic conditions
- IV. Hispanic

TABLE 4.—FACTOR SCORES

Variable	Factor			
	1	2	3	4
Poverty	-0.005	0.208	-0.423	0.044
Unemp	-0.044	-0.074	-0.338	0.009
Elderly	-0.039	0.355	0.021	-0.226
Density	0.042	0.440	0.051	0.189
Hispanic	0.018	-0.002	0.046	0.291
NonWhite	0.408	-0.012	0.136	0.099
SMR	0.206	-0.107	-0.226	-0.124
Health	0.353	0.066	0.100	-0.046

Step 5: Run Regressions

We regress the base population-to-private supply practitioner ratio on the scores obtained from the factor analysis (Ratio = Factor I + Factor II . . . + error). By combining the scores from the factor analysis with the estimated coefficients from the regression, we obtain the effect of our underlying variables on the ratio.

As an example, the factor analysis might yield a result such as:

Variable	Factor 1	Factor 2
Poverty2	.4
Unemployment ..	.3	-.1

Which we could translate into a matrix

$$\begin{bmatrix} .2 & .4 \\ .3 & -.1 \end{bmatrix}$$

Suppose regressing the ratio onto these two scores yields estimates of

Variable	Beta
Factor 1	1
Factor 2	-.4

which would translate to a vector

$$\begin{bmatrix} 1 \\ -.4 \end{bmatrix}$$

By multiplying these two matrices, we can obtain the total effect of one variable on the ratio:

$$(1) \begin{bmatrix} .2 & .4 \\ .3 & -.1 \end{bmatrix} \times \begin{bmatrix} 1 \\ -.4 \end{bmatrix} = \begin{bmatrix} .04 \\ .34 \end{bmatrix}$$

Thus, (in this simple example) the overall effect of Poverty on the ratio is calculated as .04 and the overall effect of Unemployment is .34. We use the rightmost matrix for computing the scores (see the next section) except for one correction (see below).

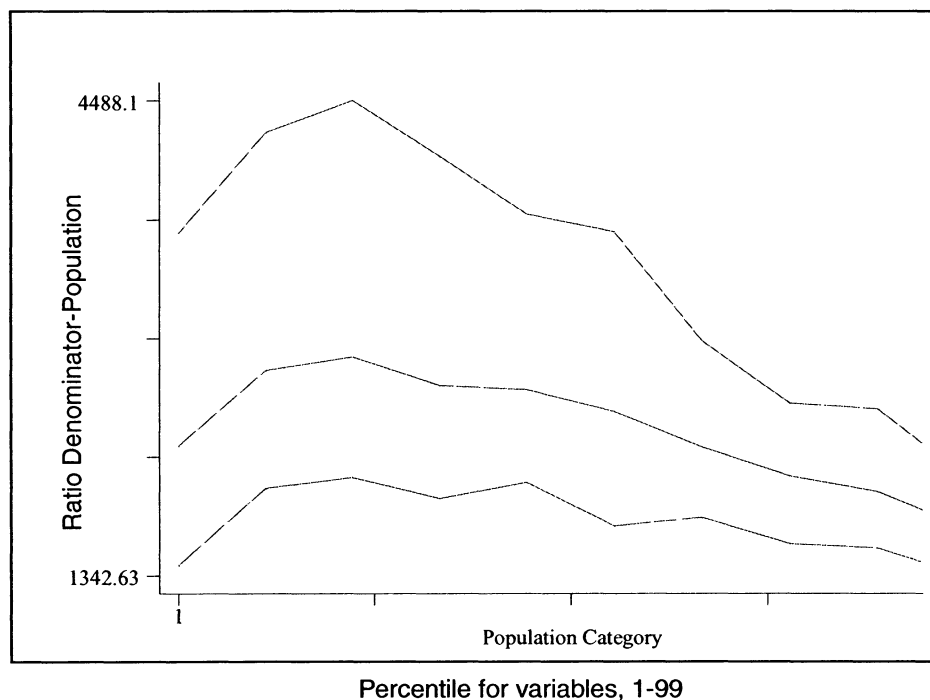
Weights/Heteroskedasticity

Because the dependent variable is a ratio with population in the denominator, we are concerned about possible heteroskedasticity in the dependent variable. This is the property that the sampling variability in the dependent variable is not constant across the sample. Specifically, we expect the ratio to be estimated more precisely as the population grows. See Figure 1 below for support of this hypothesis—the ratio tends to become less variable as the population increases (population category 1 is the lowest population category and population category 10 is the highest population category). (The upper and lower bands are the values for the 25th and 75th percentiles). The consequence of this violation is that the standard errors from the regression are biased and a more efficient estimator may exist. As such, we weight the regressions by the total population of the county.

¹ Greene (2003) (Greene W. *Econometric Analysis*, 5th Ed. Prentice Hall, New Jersey) acknowledges that the use of principal components regression is sometimes used in the presence of multicollinearity. One of his criticisms is the inability to interpret the underlying regression

parameters (p. 59), although this criticism is not very applicable here (the underlying parameters are never considered by the applicants.) More importantly, Greene lays out the tradeoffs: “If the data suggest that a variable is unimportant in the model, the theory notwithstanding, the researcher

ultimately has to decide how strong the commitment is to that theory.” One of the guiding principles was face validity, which essentially says conventionally accepted wisdom on important determinants of access should suggest included variables.

Figure 1: Heteroskedasticity in Ratio

There is a question of whether we are even dealing with a “sample” in the conventional statistical sense. If our analysis is composed of the population of interest, then classical statistical inference is a bit artificial; there is no uncertainty if we have data on all the units of interest. We argue that this is a sample in the conventional sense, for reasons including but not limited to the following:

a. Measurement error occurs more often than we expect. County population values are estimated in 1997 and the accuracy of provider supply is not 100 percent. As the nation observed in the presidential vote count in Florida, even simple computations are not immune from error. Thus, because the data used here are affected by measurement error, we have a sample drawn from the possible data for the population of counties.

b. The units used here are a sample of a much bigger population of interest. Not only are we interested in counties other than those included in the analysis due to sample criteria, ultimately we are using counties as approximations for “health care markets” or

rational primary care service areas, whether they follow the boundaries of a county or not. These methods are designed to be applied to data for future years and the construction of the areas may vary from one based on geography to ZIP code boundaries.

Other considerations, such as errors in model specification or the discrete “lumpiness” associated with using a dependent variable like this one provide support for the use of factor scores.

Sampling Error in the Regression

We wish to reduce the error in predicting the designation of communities. As such, we seek to incorporate the precision with which the regression parameters are estimated into the scoring procedure. As an example, it is entirely possible, given two factors, to have one coefficient be estimated as 100 with a standard error of 1 and the other coefficient to be estimated as 400 with a standard error of 1000. If asked which factor is more important, most people would probably admit that although the 400 is a larger point estimate, the 100 is probably more important

given its statistical significance. As such, the regression estimates are adjusted for the statistical significance by the algorithm defined below.²

1. Obtain the variance-covariance matrix V of the parameter estimates from the regression.

2. Compute the weighting matrix W defined as the inverse of the Cholesky transformation of a zero matrix except for the diagonal, which consists of the diagonal of V . (This is identical to a zero matrix with diagonal elements equal to the reciprocal of the standard errors of the parameter estimates).

3. Transform the vector of parameter estimates (omitting the constant) b by $b^* = b * W^*$ number of factors/trace(W). The trace() portion of the expression ensures the weights sum to the number of factors.

4. Compute $F = S b^*$ as above.

As an example, return to the hypothetical results for poverty and unemployment above. Suppose the (estimated) variance-covariance matrix from the regression was

² An alternative treatment would be to discard any statistically insignificant estimates. We have

strong conceptual biases against employing such stepwise procedures.

$$V = \begin{bmatrix} .04 & .01 \\ .01 & .49 \end{bmatrix}$$

$$\text{then } W = \begin{bmatrix} 1/\sqrt{.04} & 0 \\ 0 & 1/\sqrt{.49} \end{bmatrix} = \begin{bmatrix} 1/2 & 0 \\ 0 & 1/7 \end{bmatrix} = \begin{bmatrix} 5 & 0 \\ 0 & 1.42857 \end{bmatrix}$$

so

$$F = SWb * 2 / \text{trace}(W)$$

$$= \begin{bmatrix} .2 & .4 \\ .3 & -.1 \end{bmatrix} \times \begin{bmatrix} 5 & 0 \\ 0 & 1.42857 \end{bmatrix} \times \begin{bmatrix} 1 \\ -4 \end{bmatrix} * \frac{2}{5 + 1.42857}$$

$$= \begin{pmatrix} 2 \\ 6.42857 \end{pmatrix} \begin{bmatrix} .7714 \\ 1.557 \end{bmatrix}$$

$$(2) = \begin{bmatrix} .24 \\ .4844 \end{bmatrix}$$

The estimated scores in equation (2) differ from those obtained in equation (1) (page 17) due to the weight. Because the regression estimate for the first factor is estimated with roughly three times the precision as the estimate for the second factor ($5/1.42 \approx 3$), the estimate for the first factor (1) is weighted more heavily than the estimate for the second factor ($-.4$). In this case, this has the end result of increasing the scores from .04 to .24 for poverty and .34 to .4844 for unemployment. Vector F is the scoring vector used in the next step.

Although the process for obtaining matrix F is complex and multi-stage the process was completed for all possible values of the variables. Having done this, data describing a service area can be translated readily into percentile scores using a look-up table, a simple spreadsheet, or a web-based application. This parallels the existing MUA scoring process. Applicants do not need to perform Cholesky transformations or any other mathematical calculations. Fundamentally, the “weighting” step rescales the regression parameters, placing more weight on more precisely estimated parameters. We are not aware of other published research performing this reweighting, but there are at least two reasons this approach has intuitive appeal. The reweighted models performed better empirically in the sense of minimizing disruption to current designation status. We considered dropping statistically insignificant principal components from the regression and not weighting. Although this would be a more traditional use of principal components regression (with both its advantages and disadvantages), in addition to subpar performance, the omission of insignificant components drops factors that theory suggests should contribute to access barriers. At its core, this unconventional approach represented the best tradeoff we could devise between health care access theory, statistical theory, and empirical performance.

Task 2: Computation

Step 6: Calculate the Base Population-Provider Ratio for Designation Determination

Using the same age-sex adjusted population from Step 1, we calculate the population-practitioner ratio. All primary care practitioner FTEs in the area are counted to initially determine designation, this is termed the “Tier 1 designation ratio” and follows the FTE allocation of

*Providers = active non-federal, primary care physicians + 0.5 * primary care NPs, PAs, and CNMs + 0.1 * medical residents in training*

For applicants not meeting the threshold criterion, the FTEs for practitioners who are supported by safety net programs (e.g., NHSC providers, J-1 visa practitioners, CHC providers) are subtracted from the supply total and the applicant ratio is compared to the threshold. That step is termed “Tier 2 designations.” The formula for that calculation follows the same logic as in Step 2, above:

*Providers = physicians—(J1_physicians + NHSC_physicians + SLRP_physicians) + .5 * [midlevels—(NHSC_midlevels + SLRP_midlevels)] + .1 * [residents—(NHSC_residents + SLRP_residents)]*

Step 7: Calculate Scores

With row vector F in hand, we then turn to computing scores for geographical units. We compute the ratio of population to providers using the algorithm outlined above. We use the percentile scores as computed above for the counties. See the document “Completing the NPRM2 Application” for these percentiles.

We then calculate the score for the communities and add this score, upweighted by 2 to account for the 2-sided properties of the regression estimates so the total score for the community equals

*ADJUSTED RATIO (or “INDEX”) = RATIO + 2 * SCORE*

This is the total score for the community and determines its designation status. The applicants never see the regression multiplier; it is embedded in the tables.

Because the use of the multiplier for the score is applied at this stage of the process, it may be seen as an ad-hoc adjustment. The statistical logic for this has been described above, the policy logic for applying this adjustment is supported by these points:

1. The multiplier is used to account for the fact that the existing measures and processes including: the HPSA formula, the IPCS/MUA formulae, and the practical application of the CHC/RHC clinic placement process—all recognize the importance of the basic population-to-practitioner ratio in determining need. Indeed, some simple models run on the study sample provide evidence that the multiplier should be closer to 10 rather than 2 if the goal were to include every area containing a CHC under the proposed designation process (this assumes that the presence of a CHC is an indicator of need in and of itself as opposed to the result of the calculation of pre-existing unmet need). The IPCS mechanism provided for a maximum score from the population-practitioner ratio of 35 points. The maximum score available from other factors (poverty 35 points, IMR/LBW 5 points, minority 5 points, Hispanic 5 points, LI 5 points, density 10 points = 65 points) are, collectively, almost twice that in terms of potential contribution. Thus, the weighted contribution of the factors besides the ratio is roughly twice that of the ratio itself. Multiplying the ratio denominator by two intensifies the relative effect of the underlying, basic population to practitioner ratio in the designation process providing continuity with prior policy.

2. The multiplier functions as a scale/weighting factor. The score has a much smaller variance than the ratio. This is not just an annoyance—it is used to generate a prediction, and thus will have smaller variance than the dependent variable. The dependent variable and the score used here have some sort of meaning, a person per provider, although the various adjustments make this unit of measurement not as meaningful as we might think. One alternative we considered is rescaling the ratio and the score into z-scores and using these standardized measures rather than the unscaled measures. This rescaling would

involve multiplying the score by a larger factor than the ratio.

3. The multiplier helps control for the (observed) low ratios in, (e.g., metro) areas

with high scores. The following example illustrates this:

TABLE 2.—EXAMPLE SCORE AND RATIOS

County of HPSA	State	Ratio	Score	IPCS	IMR	LBW	Poverty
Bronx	NY ..	1357.2	1043.5	54	10.1	10.1	77.8
Coconino	AZ ..	1266.8	1005.6	56	8.1	7.2	65.1
Kings	NY ..	1634.7	897.8	52	10.3	9.2	59.2
East Baton Rouge	LA ...	1660.5	874	46	11.3	10.2	69
St. Lucie	FL ...	1138.5	873	44	10	7.3	67
Philadelphia	PA ..	1055.9	861.2	47	13.3	11.4	61.1
Mahoning	OH ..	1505.3	839.3	44	10.7	8.9	67.5

The (unmultiplied) maximum score is about 1300. The areas listed above are all in the worst 10 percent of scores. Note that these areas would not qualify without the “score × 2” multiplier rule (see below). Perhaps the ratio is a misleading measure in some circumstances.

4. The multiplier fills a statistical role. The score is (likely) more stable across years; e.g., if one physician moves out of a rural area, the ratio varies dramatically. The score is not going to change drastically across years. Thus, it should be given more weight.

5. The multiplier creates a standard which designates roughly the same number of people as the IPCS and the current HPSA designations.

6. It performs better than without the doubling. Although this particular argument has little theoretical basis, it is still compelling.

Why is a portion of the density score function negative?

The astute reader will note that the constant from the regression was dropped and never used. The reason for this is that the constant has no clear meaning in this context. We decided to norm the scores so that the minimum score—that is, the best area in the country—was zero. Thus, although in theory an area could receive a negative score if it had very favorable demographics and had a high population density, in practice no area had a negative score (by definition).

Step 8: Compare to Threshold

Areas are designated if and only if the “adjusted ratio” (or ratio+score) is greater than 3000. This threshold was adopted for its reflection of the clear need for a single full-time equivalent primary care physicians, its consistency with prior threshold values, and its familiarity to stakeholders.

Areas With No Practitioners

The problem of how to treat areas with zero providers emerged early in the process of ranking areas as medically underserved. There is an informative treatment of the phenomenon in Black and Chui (1981).^{*} For areas with zero providers, we have not made any firm recommendations and have treated them in one of three ways for various parts of the analysis.

^{*} Black, R. A., and Chui, K.-F. (1981). Comparing schemes to rank areas according to degree of health manpower shortage. *Inquiry*, 18(3), 274–280.

(a) Every area with zero providers automatically gets an adjusted ratio of 3000 (which guarantees them designation), to which a score for community need indicators are added. This results in all areas having a NPRM2 score, including areas with zero providers. This method was used in early tabulations and compilations.

(b) Automatically designate areas with zero providers without assigning an adjusted ratio or a score for community need indicators. Therefore, areas with zero providers will not have a NPRM2 total score. This has occurred when calculations and tabulations of the database using the NPRM2 scoring system was applied. The places with no score were dropped. This method was used in the final impact analysis.

(c) Assigning an arbitrarily small FTE to the area, such as 0.1 to create a score that is primarily dependent upon the denominator population. This was used only in selected tests of the scoring system as an alternative.

Notes to Appendix B: Regression approach for assignment of weights to correlates of “shortage”

The basic method for assigning weights to individual variables involved the estimation of a county-level linear regression model with the adjusted population-to-physician ratio as the left-hand side variable, and the variables described in step 4 as right-hand side variables. Coefficients on the right-hand side variables can be interpreted directly as average differences in the population-to-physician ratio for counties with specified characteristics relative to counties without those characteristics.

To reduce the effects of extreme outliers (e.g., population density in New York City, or per capita income in Silicon Valley), all variables were converted into percentages. To allow for non-linear relationships between each variable and the ratio, the variables were further converted from a linear variable, ranging from 1 to 100, into twenty five-percentile categorical variables, i.e., one each for 1–5th percentile, 6–10th percentile, * * * 96th–100th percentile. When all but one of these variables are entered on the right-hand side of a regression with the population-to-physician ratio as the dependent variable, the coefficients on each variable represent the average difference in the adjusted population-to-physician ratio relative to the omitted reference category. In most cases, the omitted reference category is the 1–5th percentile, i.e., the five percent of counties with the lowest values for a particular variable.

Entering highly collinear variables, such as income and poverty, into a single regression model usually results in one coefficient being positive, and the other being negative. In order to develop a “user-friendly” scoring system in which all weights are positive, variables were added sequentially to the regression model, with the effects of previously entered variables constrained to their estimated effects. As a result, coefficients on all variable other than the first represent the “marginal differences” in the ratio, after controlling for all previously included variables.

A decision was made to use a population-to-physician ratio of 3000:1 as a cutoff criterion for designation. The following analysis was restricted to counties with adjusted population-to-physician ratios between 500:1 and 3000:1, for which the dependent variables was not missing (N=2,493).

Income was the single most important correlate of the ratio. It was entered first, and estimates were obtained for each of 19 categories; counties in the 95–100th percentile were the excluded category. Each of the estimated coefficients represents the average difference in the ratio for counties in the respective percentile range relative to the omitted group of counties with the highest income. Coefficients were graphed and examined visually, and differences between the coefficients for “neighboring” categories were evaluated for statistical significance. Categories with no statistically significant differences were combined into single variables. As a result of this process, three categories (plus reference category) remained, one each for the 1–75th, 76–85th, and 86–95th percentiles. The regression was run again, suggesting that counties in these categories had higher ratios by 628, 344, and 216 “units”, respectively. (These units are the average differences in the population-to-physician ratio).

Constraining the coefficients on these variables to these values, 19 percentile ranges for the next-highest correlate of the ratio, population density, were added to the analysis. Visual inspection pointed to clear non-linearities in the relationship. There appeared to be a statistically significant difference between counties in the 95–100th percentile relative to all other counties. Furthermore, the effect was increasing up to the 35th percentile of counties, and then decreased between the 36th and 95th percentiles. *Note that these relationships describe the relationship between population*

density and the population-to-physician ratio after controlling for the effects of income. Consistent with the observed relationship, three variables were defined, a categorical variable for the 1–95th percentile range, and two splines for the 1–35th and 36–95th percentiles, respectively.

These three variables describing population density were entered into the model together with the income variables, and the estimated coefficients were used to analyze the marginal effect of unemployment according to the same method. Relative to the omitted reference group of counties in the 1–5th percentile, counties in the 6–20th and 21–100th percentile ranges had significantly higher population-to-physician ratios, after controlling for income and population density. Consequently, two dummy variables for counties in these categories were entered

into the model. The process was repeated for percent of the population under 200% FPL, which suggested that—after controlling for income, population density, and unemployment—the ratio was lowest for counties with a percentage of the population below 200% poverty around the 20th percentile of all counties. Below this threshold, the average ratio was higher by about 110 “units”, above that, the ratio gradually increased by about 2.5 “units” per percentile increment.

Table 2 shows the results of the final regression model containing the four variables described above. After controlling for these variables, none of the remaining variables was significantly associated with shortage. This finding is consistent with other studies of the effects of community characteristics on access to health care, in

that the economic/barrier variables have been shown to have much greater impact than other characteristics. However, legislation requires the use of selected morbidity and mortality measures such as infant mortality and, even if marginal in their net effect, these measures are tied closely to the logic of need for primary care and access to primary care.

To comply with this requirement, the analysis was repeated for actual/expected deaths, the maximum of low birth weight/infant mortality rate, and the percentage of the population over the age of 65. Table 3 shows the results of the final regression model and the specification of each variable. The coefficient estimates in Tables 2 and 3 were used to create a single table containing the weights associated with each variable, for each percentile increment, usually rounding to the nearest increment of 5.

TABLE 2.—COEFFICIENT ESTIMATES FOR ECONOMIC/BARRIER CORRELATES OF SHORTAGE

Correlate of shortage	Cutoffs (percentiles)	Specification	Coefficient	SE	t
Income	0–74	Dummy Variable	355.9	59.3	5.997
	75–84	Dummy Variable	186.0	59.6	3.121
	85–84	Dummy Variable	69.7	53.6	1.301
Population Density	0–95	Dummy Variable	318.6	51.4	6.197
	0–35	Spline	4.23	0.95	4.432
	35–95	Spline	–3.73	0.84	–4.467
Unemployment	5–19	Dummy Variable	167.8	52.0	3.228
	20–99	Dummy Variable	245.4	48.0	5.110
Below 200% FPL	0–14	Dummy Variable	109.0	38.8	2.807
	15–99	Spline	2.36	0.54	4.406
Constant	732.0	78.7	9.297

TABLE 3.—COEFFICIENT ESTIMATES FOR HEALTH/DEMOGRAPHIC CORRELATES OF SHORTAGE

Correlate of shortage	Cutoffs (percentiles)	Specification	Coefficient	SE	t
Actual/Expected Deaths	6–15	Dummy Variable	66.4	64.0	1.038
	16–55	Dummy Variable	121.6	57.2	2.124
	56–75	Dummy Variable	211.2	59.4	3.554
	76–100	Dummy Variable	278.5	60.2	4.625
Infant Morality	81–100	Dummy Variable	65.73	27.41	2.398
Percent 65+	1–100	Continuous	1.93	0.37	5.161
Constant	1364.4	57.2	23.872

List of Subjects

42 CFR Part 5

Health care, Health facilities, Health professions, Health statistics, Health status indicators, Medical care, Medical facility, Dental health, Mental health programs, Physicians, Population census, Poverty, Primary care, Shortages, Underserved, Uninsured.

42 CFR Part 51c

Grant programs—Health, Health care, Health facilities, Reporting and recordkeeping requirements.

For the reasons set out in the preamble the Department of Health and Human Services proposes to amend parts 5 and 51c of title 42 of the Code of Federal Register as follows:

PART 5—DESIGNATION OF MEDICALLY UNDERSERVED POPULATIONS AND HEALTH PROFESSIONAL SHORTAGE AREAS

1. The heading for part 5 is revised as set forth above.

2. The authority citation for part 5 is revised to read as follows:

Authority: 42 U.S.C. 254b, 254e.

3. The existing text consisting of §§ 5.1 through 5.4 is designated as subpart A and revised to read as follows:

Subpart A—General Procedures for Designation of Medically Underserved Populations (MUPs) and Health Professional Shortage Areas (HPSAs)

Sec.

5.1 Purpose.

5.2 Definitions.

5.3 Procedures for designation and withdrawal of designation.

5.4 Notice and publication of designation and withdrawals.

5.5 Transition provisions.

5.6 Provisions related to Automatic HPSA designation of certain Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC)

Subpart A—General Procedures for Designation of Medically Underserved Populations (MUPs) and Health Professional Shortage Areas (HPSAs)

§ 5.1 Purpose.

This part establishes criteria and procedures for the designation and withdrawal of designations of medically underserved populations pursuant to section 330(b)(3) of the Public Health

Service Act and of health professional shortage areas pursuant to section 332 of the Act.

§ 5.2 Definitions.

As used in this part:

(a) *Act* means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

(b) *Department* means the Department of Health and Human Services.

(c) *Frontier Area* means those areas identified by the Secretary (through the Frontier Work Group of the Office for the Advancement of Telehealth) as frontier areas, or, until an official list of frontier areas is issued, those U.S. counties or county-equivalent units with a population density less than or equal to 6 persons per square mile.

(d) *FTE* means full-time equivalent, and shall be computed using such guidance as the Secretary may provide.

(e) *Governor* means the Governor or other chief executive officer of a State.

(f) *Health professional shortage area* (or HPSA) means any of the following which the Secretary determines in accordance with this part has a shortage of health professionals:

(1) A rational, geographic service area;

(2) A population group; or

(3) A public or nonprofit private medical facility or other public facility that provides primary medical, dental or mental health services.

(g) *Inner portions of urban areas* means core areas of urbanized central places areas as defined by HRSA, based on data from the Bureau of the Census.

(h) *Population Center* means the census area (tract, division, town, etc.) with the largest population within a proposed rational service area.

(i) *Medical facility* (or other public facility that provides primary medical, dental or mental health services) includes:

(1) A health center, as defined in Section 330(a) of the Public Health Service Act, means an entity that serves a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing, by providing, either through the staff and supporting resources of the center or through contracts or cooperative arrangements, required primary health services and, as may be appropriate for particular centers, additional health services necessary for the adequate support of the primary health services required for all residents of the area served by the center (including a community health center, migrant health center, health center for the homeless, or health center for residents of public housing);

(2) Any Federally qualified health center (FQHC), as defined in Section 1861(aa)(4) of the Social Security Act term "Federally qualified health center" means an entity which is receiving a grant under section 330 (other than subsection (h)) of the Public Health Service Act, or is receiving funding from such a grant under a contract with the recipient of such a grant, and meets the requirements to receive a grant under section 330 (other than subsection (h)) of such Act; based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant; was treated by the Secretary, for purposes of part B, as a comprehensive Federally funded health center as of January 1, 1990; or is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an urban Indian organization receiving funds under Title V of the Indian Health Care Improvement Act.

(3) A rural health clinic [RHC] as defined in Section 1861(aa)(2) of the Social Security Act is primarily engaged in furnishing to outpatients services which is located in an area that is not an urbanized area (as defined by the Bureau of the Census) and in which there are insufficient numbers of needed health care practitioners which is located in an area that is not an urbanized area (as defined by the Bureau of the Census) and in which there are insufficient numbers of needed health care practitioners; a public health center or other medical, dental or mental health facility operated by a city or county or State health department; or a community mental health center (see Section 520 of the Act);

(4) An ambulatory or outpatient clinic of a hospital;

(5) An Indian Health Service facility, or a health program or facility operated under the Indian Self-Determination Act by a tribe or tribal organization; or an Urban Indian Health Program; or

(6) A facility for delivery of health services to inmates in a U.S. penal or correctional institution (under section 323 of the Act), or a State correctional institution; or

(7) A State mental hospital.

(j) *Medically underserved population* (or "MUP") means:

(1) The population of a geographic area designated by the Secretary in accordance with this part as having a shortage of personal health services (also called a medically underserved area or MUA); or

(2) A population group designated by the Secretary in accordance with this part as having a shortage of such services.

(k) *Metropolitan statistical area* means an area that has been designated by the Office of Management and Budget as a metropolitan statistical area. All other areas are "micropolitan" or "non-metropolitan" areas.

(l) *Poverty level* means the current poverty threshold as defined by the Bureau of the Census, which uses a set of money income thresholds that vary by family size and composition to determine who is in poverty. If a family's total income is less than the family's threshold, then that family and every individual in it is considered in poverty. The thresholds are updated annually.

(m) *Primary care clinician* means a physician, nurse practitioner, physician assistant, or certified nurse midwife who practices in a primary care specialty as defined in § 5.104(e)(2) of this part, provides direct patient care, and practices in a primary care setting, as defined in paragraph (n) of this section.

(n) *Primary care setting* means a setting where integrated, accessible health care services are provided by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, practicing in the context of family and community, and providing continuity and integration of health care. It includes but is not limited to health centers as defined in § 5.2(i)(2) of this part, health maintenance organizations, generalist physicians' offices, and ambulatory care facilities operated by hospitals including outpatient facilities that are separate but a part of inpatient facilities; it excludes inpatient facilities, non-primary care physician specialist's offices, and facilities for long term care.

(o) *Secretary* means the Secretary of Health and Human Services, or any officer or employee of the Department to whom the Secretarial authority involved has been delegated.

(p) *State* includes the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, Guam, the Northern Mariana Islands, the U.S. Virgin Islands, the Federated States of Micronesia, the Marshall Islands, and the Republic of Palau.

§ 5.3 Procedures for designation and withdrawal of designation.

(a) Any agency or individual may request the Secretary to designate (or withdraw the designation of) an area,

population group, or facility as an MUP and/or as a HPSA. Requests by State agencies participating in the Department's electronic shortage designation system should be made electronically.

(b) The Applicant will forward a copy of (or relevant electronic information on) each such designation request to the officials and entities listed below in each State affected by the request, asking that they review the request and offer their recommendations, if any, to the Secretary within 30 days:

(1) The Governor;

(2) The head of the State health department or State health agency designated by the Governor, or other health official to whom this reviewing authority has been delegated (such as the Director of the Primary Care Office), and the Director of the State Office of Rural Health;

(3) Appropriate local officials within the State, such as health officers of counties or cities affected;

(4) The State primary care association or other State organization, if any, that represents federally qualified health centers and other community-based primary care organizations in the State;

(5) Affected State medical, dental, and other health professional societies; and

(6) Where a public facility (including a Federal medical facility) is proposed for designation or withdrawal of designation, the chief administrative officer of such facility.

(c) The Secretary may propose the designation, or withdrawal of the designation, of an area, population group, or facility under this part. Where such a designation or withdrawal is proposed, the Secretary will notify the agencies, officials, and entities described in paragraph (b) of this section and request comment as therein provided.

(d) Using data available to the Secretary from national and State sources, and based upon the applicable criteria in the remaining subparts and appendices to this part, the Secretary will annually prepare listings (by State) of currently designated MUPs and HPSAs, together with relevant data available to the Secretary, and will identify those MUPs and HPSAs within the State whose designations, because of age or other factors, are required to be updated. The Secretary will provide the listing for each State and a description of any required information to the entities in that State identified in paragraph (b)(2) and (4) of this section, either electronically or in hard copy, and will request review and comment within 90 days.

(e) The Secretary will furnish, upon request, an information copy of a request made pursuant to paragraph (a) of this section or applicable portions of the materials provided pursuant to paragraph (c) of this section to other interested persons and groups for their review and comment. Resulting comments or recommendations may be provided to the Secretary, the Governor, and/or the State health official identified in paragraph (b)(2) of this section.

(f) In the case of a proposed withdrawal of a designation, the Secretary shall afford other interested persons and groups in the affected area an opportunity to submit data and information concerning the proposed action, including entities directly dependent on the designation and primary care associations and State health professional associations, to the extent practicable.

(g) The Secretary may request such further data and information as he/she deems necessary to evaluate particular proposals or requests for designation or withdrawal of designation under paragraph (a) of this section. Any data so requested must be submitted within 30 days of the request, unless a longer period is approved by the Secretary. If the information requested under paragraph (c) of this section or under this section is not provided, the Secretary will evaluate the proposed designation (including continuation of designation) or withdrawal of designation of the areas, population groups, and/or facilities for which the information was requested on the basis of the information available to the Secretary.

(h) After review and consideration of the available information and the comments and recommendations submitted, the Secretary will designate those areas, population groups, and facilities as MUPs and/or HPSAs, as applicable, which have been determined to meet the applicable criteria under this part, and will withdraw the designations of those which have been determined no longer to meet the applicable criteria under this part.

(i) Urgent Review. If a clinician dies, retires, or leaves an area that is not already designated as an MUP or HPSA with no or limited notice, causing a sudden and dramatic change in primary medical care, dental or mental health services available to that area's population, the State health agency or official identified in paragraph (b)(2) of this section may submit an urgent request to the Secretary on behalf of the affected community that the area be immediately designated as an MUP and/

or HPSA. Such urgent requests will be reviewed on an expedited basis, within 30 days of receipt. If

(j) The Secretary fails to complete review of the request within 30 days after receipt, the area as defined by the State agency will be considered designated as an MUP and/or HPSA, as applicable, until and unless subsequent review by the Secretary indicates that inaccurate data were provided or that the situation has changed. Each year, each State may invoke this urgent procedure for processing no more than five percent of the total number of designations the State had at the end of the preceding calendar year.

§ 5.4 Notice and publication of designations and withdrawals.

(a) In the case of a request under § 5.3(a) of this part, the Secretary will give written or electronic notice of the determination made to the individual or agency that made the request. The date of this notice will reflect the actual date of determination.

(b) The Secretary will also give written or electronic notice of a designation (or withdrawal of designation) under this part on or not later than 60 days after the effective date, as noted in paragraph (a) of this section, of the designation (or withdrawal), to:

(1) The Governor of each State in which the designated or withdrawn MUP or HPSA is located in whole or in part;

(2) The State health department or other agency or official identified under paragraph § 5.3(b)(2) of this part of the affected State or States, and any other State agency deemed appropriate by the Secretary; and

(3) Other appropriate public or nonprofit private entities which are located in or which the Secretary determines have a demonstrated interest in the area designated or withdrawn, including entities directly dependent on the designation and primary care associations and State health professional associations.

(c) The Secretary will publish updated lists of designated MUPs and HPSAs in the **Federal Register** after the end of each fiscal year, reflecting designations current at the end of each fiscal year, and make the complete list available on-line, by type of designation and by State, and will maintain a regularly updated Web site of current designations between **Federal Register** list publications. Such listings will distinguish between first and second tier designations as determined pursuant to § 5.103 of this part.

(d) The effective date of the designation of an MUP or HPSA shall be the date of the notification letter or electronic notice provided pursuant to paragraph (a) or (b) of this section, or the date of publication in the **Federal Register**, whichever occurs first.

(e) The effective date of the withdrawal of the designation of an MUP or HPSA shall be the date of the notification letter or electronic notice provided pursuant to paragraph (a) or (b) of this section, or the date on which notification of the withdrawal is published in the **Federal Register**, or the date of publication in the **Federal Register** of an updated list of designations of the type concerned which does not include the designation, whichever occurs first.

§ 5.5 Transition provisions.

(a) Continuation of currently designated MUPs and primary care HPSAs. Except as otherwise provided in this section and § 5.6 of this part, these new criteria for the designation of a MUP or a primary care HPSA will be phased in over a period of three years from the date of publication of the final rule in the **Federal Register**, with the oldest MUP and HPSA designations being reviewed first. Existing designations will remain in effect until reviewed under the new criteria on the schedule set by the Secretary after consultation with State entities as described below.

(b) Revision of MUPs and primary care HPSAs.

(1) The Secretary will, within 90 days after publication of this final rule in the **Federal Register**, submit to the entities in each State identified pursuant to § 5.3(b)(2) and (4) of this part a listing of the adjusted population-to-primary care clinician ratio computed under § 5.104 of this part for each currently designated MUP and primary care HPSA within its boundaries, based on the data and information available to the Secretary.

(2) The State health agency or other designee of the Governor shall have 90 days from receipt of such listing, or such longer time period as the Secretary may approve, to provide comments to the Secretary. Such comments should take into account the effects on local communities and any comments by affected entities and should include recommendations on the following topics:

(i) Where the boundaries of a currently designated MUP and primary care HPSA overlap but do not coincide—

(A) Which service area boundaries the State recommends be continued in effect;

(B) Whether the State proposes to have any remaining area separately designated, either on its own or as part of another service area; or

(C) If the State wishes to identify and consider for designation a new service area instead of either area currently designated, identification of the boundaries recommended.

(ii) Any other service area boundaries (of existing designated areas) that the State recommends be revised;

(iii) The State's suggestions as to which areas should be updated in the first transition year, which in the second, and which in the third;

(iv) The State's recommendations concerning those areas it suggests be updated during the first transition year; and

(v) The accuracy of the FTE primary care clinician data and other data used in scoring.

(3) Where a current MUP and a primary care HPSA designation overlap, and the State makes an election under paragraph (b)(2)(i)(A) of this section, the MUP or primary care HPSA that is not selected will be deemed to be automatically withdrawn.

(4) If part of the area of a currently designated MUP or primary care HPSA is revised under this part and the State does not request designation of the remaining area, the current designation covering the remaining area will be deemed to be automatically withdrawn.

(5) If a State does not provide recommendations to resolve overlapping area situations under paragraph (a) of this section, the Secretary may revise the areas involved, based on the applicable criteria and data and information available.

§ 5.6 Provisions related to Automatic HPSA designation of certain Federally Qualified Health Centers (FQHC) and Rural Health Centers (RHC).

(a) The Health Care Safety Net Amendments of 2002, as amended by Public Law 108–163, provide automatic HPSA designation for at least six years, for all entities that:

(1) Were deemed or certified as an FQHC or RHC, § 5.2(h) of this part, on or after October 26, 2002;

(2) Meet the requirements of section 334 of the Act (concerning the provision of services regardless of ability to pay); and

(3) Do not lose their FQHC or RHC status and/or cease to meet the requirements of section 334 of the Act during that time period.

(b) After the date these regulations take effect, some of the FQHC and RHC

entities with automatic HPSA designation as described under paragraph (a) of this section, [or some of the clinical sites of these entities], may also be found to:

(1) Be located in a geographic area that has been designated under the criteria for geographic primary care designations in Subpart B of this part;

(2) Be located in an area containing a population group that has been designated under the population group criteria in Subpart C of this part and serving the designated population group, as determined by the Secretary (e.g., a migrant health center serving a designated migrant population; a homeless health center serving a designated homeless population; a public housing or community health center serving a designated low-income population group); or

(3) Have met the criteria for designation as a safety-net facility in Subpart D of this part.

(c) A list of FQHC and RHC clinical sites that are automatically designated pursuant to paragraph (a) of this section, excluding any clinical sites that have also been found to be covered by another HPSA designation as set forth in paragraph (b) of this section, shall be maintained. This list of automatically designated clinical sites, with their addresses, shall be appended to each list of designated HPSAs published in the **Federal Register** or posted on the web in accordance with § 5.4 (c) of this part.

(d) To maintain HPSA designation after six years of automatic designation, FQHC or RHC clinical sites remaining on the appended list of "automatic" HPSAs (or the most recent previous date that the HPSA list was published in the **Federal Register** or posted on the web) will be required to demonstrate that their area meets the criteria in subpart B of this part, that they are serving a population group which meets the criteria in subpart C of this part, or that they meet the facility criteria in subpart D of this part. At or near the end of the six-year period of automatic designation, the FQHCs and RHCs involved will be informed of this requirement by mail, and shall then have 90 days to provide evidence that the criteria are met for the sites in question.

(e) If an FQHC or RHC is notified as described in paragraph (d) of this section that it needs to demonstrate that one or more of its clinical sites meet the designation criteria herein, and fails to submit materials in support of such a finding within 90 days, the sites involved shall then be removed from the HPSA list, unless additional time to provide further information is granted

by the Secretary on a case-by-case basis. Sites so removed can reapply for HPSA/ MUP designation under the criteria herein at a later date if their situation changes so that they are able to provide such evidence.

(f) If evidence in support of designation of an FQHC or RHC site under the criteria herein is provided within the 90 day timeframe specified in paragraph (d) of this section, or during such additional time as the Secretary may allow in paragraph (e) of this section, the Secretary will review the evidence submitted and make a determination, within 60 days of receipt. Such sites will remain on the HPSA list until this determination is made.

(g) After review of any information provided as described in paragraph (f) of this section, any FQHC or RHC clinical site which the Secretary determines does not meet the criteria herein shall be removed from the HPSA list. The FQHC or RHC involved will be so notified, and subsequent published or posted HPSA lists will not include such sites.

4. Subpart B is added to read as follows:

Subpart B—Criteria and Methodology for Designation of Geographic Areas as Medically Underserved Areas (MUAs) and Primary Care HPSAs

Sec.

- 5.101 Applicability.
- 5.102 Criteria for designation of geographic areas as MUAs and Primary Care HPSAs.
- 5.103 Identification of rational service areas for the delivery of primary medical care.
- 5.104 Determination of adjusted population-to-primary care clinician ratio.
- 5.105 Contiguous area considerations.

Subpart B—Criteria and Methodology for Designation of Geographic Areas as Medically Underserved Areas (MUAs) and Primary Care HPSAs

§ 5.101 Applicability.

The following criteria and methodology shall be used to designate geographic areas as medically underserved (under section 330(b) of the Public Health Service Act) and as primary care HPSAs (under section 332 of the Act).

§ 5.102 Criteria for designation of geographic areas as MUAs and Primary Care HPSAs.

A geographic area will be designated both as a medically underserved area (pursuant to section 330(b) of the Act) and as a primary care HPSA (under Section 332 of the Act) if it is demonstrated, by such data and information as the Secretary may

require, that the area meets the following criteria:

- (a) The area meets the requirements for a rational service area for the delivery of primary medical care services under § 5.103 of this part; and
- (b) The area's adjusted population-to-primary care clinician ratio/score, computed under § 5.104 of this part, equals or exceeds 3,000:1; and
- (c) In the case of specific types of areas identified in § 5.105 of this part, resources in contiguous areas are shown to be overutilized or otherwise inaccessible, as defined in § 5.105 of this part.

§ 5.103 Identification of rational service areas for the delivery of primary medical care.

(a) General definition: A rational service area (RSA) is a geographically delimited, continuous and cohesive area around one or more population centers within which a preponderance of the population normally seeks and can reasonably expect to receive primary medical care services.

(b) Each rational service area should be large enough to sustain services and small enough to ensure that primary medical care resources within the RSA are accessible to the population of the RSA within a reasonable travel time, assumed to be 40 minutes for a frontier area and 30 minutes for all other areas unless the provisions of paragraph (g) of this section are invoked by a State.

(1) Travel times in most areas shall be measured by the estimated time required to get from point A to point B by principal roads in an automobile traveling at the speed limit, in typical traffic for the area, taking into consideration the area's terrain.

(2) Travel times within inner portions of urban areas may be computed in terms of travel by public transportation, in areas with at least 20% of the population under 100% of the poverty level and/or a significant reliance on public transportation (e.g. at least over 30% dependent according to the U.S. Census.)

(c) Individual RSAs shall be defined in terms of one or more contiguous U.S. Census Bureau geographic units for which census data are available (e.g. counties, census tracts, census divisions (MCDs/CCDs), or zip code tabulation areas (ZCTAs), the boundaries of which do not overlap with the boundaries of another rational service area.

(d) Cohesiveness for paragraph (a) of this section can be established by demonstrating that the area:

- (1) Is isolated from contiguous areas due to topography, market or

transportation patterns or other physical barriers, or

(2) Has a homogeneous socioeconomic composition different from those in contiguous areas, and is isolated from or has limited interaction with contiguous communities and/or access barriers to resources in those areas, or

(3) Has a tradition of primarily internal interaction or independence as defined by transportation or market patterns, or

(4) Is a single whole county.

(e) Size of an RSA shall be limited, where an RSA has more than one population center (towns of equivalent size), by a maximum of 30 minutes travel time between population centers within a single RSA.

(f) Geographic separation of RSAs

(1) Geographic separation of RSAs shall be measured by the travel times between the population center(s) of one RSA and those of contiguous RSAs, normally involving a minimum of 30 minutes travel time between population centers of different RSAs.

(2) Travel time from the population center of an RSA to the population center of a contiguous RSA may be less than 30 minutes within metropolitan statistical areas where established neighborhoods and communities display a strong self-identity (as indicated by a homogeneous socioeconomic or demographic structure and/or a tradition of interaction or interdependence), have limited interaction with contiguous areas, and, in general, have a population density equal to or greater than 100 persons per square mile.

(g) RSA parameters determined by State—

(1) RSA parameters different from those defined in paragraph (f) of this section, but within the ranges defined in paragraph (g)(2) of this section, may be used for RSA delineation within a State if:

(i) Such parameters and the method for defining RSAs to be used with those parameters are adopted by the State through a partnership approach with affected State and community officials/ stakeholders and in consultation with the Secretary, (ii) The RSA parameters and method selected have the approval of the State health department or other designee of the Governor identified in § 5.3(b)(2) of this part, and

(iii) The final RSA approach to be used has been reviewed by the Secretary in advance of the State submitting particular RSA definitions using its approach.

(2) Permissible Ranges for RSA parameters adopted by States:

(i) The maximum travel time to assure access to care within the RSA is set at 30 minutes in paragraph (b) of this section and the maximum travel time between population centers within the RSA, set generally at 30 minutes in paragraph (e) of this section, may be set at any value greater than or equal to 20 minutes but less than or equal to 40 minutes, for non-frontier RSAs.

(ii) Maximum travel time to assure access to care within a frontier or other sparsely-populated RSA, set generally at 40 minutes in paragraph (e) of this section, may be set at any value greater than 30 minutes but less than or equal to 60 minutes, where topography, market, transportation, or other conditions and patterns lead to utilization of providers at greater distances.

(iii) Separation between RSAs—Minimum travel time from the population center(s) of the RSA to the population center of a contiguous RSA may be set at any value greater than or equal to 20 minutes and less than or equal to 40 minutes.

(h) *State-wide system.* Each State is encouraged to develop a State-wide system which divides the territory of the State into rational service areas (RSAs) for the delivery of primary care services within the State.

(1) This may be done all at once or incrementally, by developing State RSA criteria using the parameter ranges defined above and a process for defining the State's RSAs according to those criteria over a period of time. A full statewide plan is encouraged to maximize its effectiveness in improving the designation process.

(2) Each State-wide system of rational service areas or process for developing State RSAs shall be developed in consultation with the Secretary and be approved by the State health department or other designee of the Governor.

§ 5.104 Determination of adjusted population-to-primary care clinician ratio.

The adjusted population-to-primary care clinician ratio is computed as the sum of the "barrier-free" population-to-primary care clinician ratio of an area, calculated as in paragraph (a) of this section, and the area's High Need Indicator score, calculated as paragraph (b) of this section:

(a) *Effective Barrier-Free Population-to Clinician Ratio* for an area is computed as follows:

(1) Estimate the primary care utilization of the area's population if no barriers to accessing health care existed, in total expected visits per year. This shall be done by applying current

national utilization rates for populations without access barriers, to current data on the population composition of each area by age and gender. The national utilization rates to be used for this purpose (in visits per year, by age group and gender) will be published in tabular form by the Secretary from time to time. The utilization rate table applicable at the time of publication of this regulation will be included in the preamble; later updates will be made available periodically but no more often than annually.

(2) Divide the resulting total estimated number of annual barrier-free visits for the area by the national mean utilization rate (consistent with the tabular utilization data used and published along with it) to obtain the area's effective (barrier-free) population.

(3) Where an area has a significant number of migratory workers, homeless persons, or seasonal residents, the effective population calculated in paragraph (a)(2) of this section may be adjusted further by multiplying by the factor [Resident Civilian Pop. + Migratory workers & families + Homeless + Seasonal Residents] / Resident Civilian Pop., where these quantities are defined as in paragraph (c)(1) of this section. The resident-civilian population does include some components of the homeless population, so any additions should avoid duplication.

(4) Calculate the ratio of the final effective population to the area's number of FTE primary care clinicians, calculated as discussed in paragraph (c)(2) of this section, to determine the area's barrier-free population-to-primary care clinician ratio.

(b) *High Need Indicator Score.*

(1) The High Need Indicator score for an area is computed as the sum of the area's partial scores for each of the nine variables listed in this paragraph (b)(1):

- (i) Percentage of population below 200% of the federal poverty level;
- (ii) Unemployment rate;
- (iii) Percentage of population that is non-White;
- (iv) Percentage of population that is Hispanic;
- (v) Percentage of population that is over age 65;
- (vi) Population density;
- (vii) Actual/expected death rate
- (viii) Low birth weight birth rate
- (ix) Infant mortality rate

(2) A current national Percentiles Table IV-6 (relating raw scores for each indicator to the national percentile distribution of that indicator at the county level) shall be used to determine an area's percentile rank for each high need indicator at the time of proposed

designation or update. HRSA will publish revised percentile tables as a Notice in the **Federal Register** if there are significant changes in the indicators in paragraph (b)(1) in this section.

(3) The percentile rank for each indicator shall then be converted to a partial score, using the Scores Table IV-7.

(4) The total High Need Indicator score is computed as the sum of the nine partial scores computed in paragraph (b)(3) of this section for each indicator.

(c) The barrier-free population-to-primary care clinician ratio/score, as computed in paragraph (a) of this section, is added to the High Need Indicator Score, as computed in paragraph (b) of this section, to obtain the final adjusted population-to-primary care clinician ratio.

(d) The threshold for designation is an adjusted population-to-primary care clinician ratio/score that exceeds 3,000:1.

(e) Calculation of specific variables

(1) *Population counts.* The population of an area is the total resident civilian population, excluding inmates and residents of institutions, based on the most recent U.S. Census data, adjusted for increases/decreases to the current year using the best available intercensus projections, and making the following adjustments, as appropriate:

(i) Migratory workers and their families may be added to the adjusted resident civilian population, if significant numbers of migratory workers are present in the area, using the latest Migrant Health Atlas or best available Federal or State estimates. Estimates used must be adjusted to reflect the percentage of the year that migratory workers are present in the area.

(ii) If an area includes significant numbers of homeless individuals not reflected in the census figures, and reasonable estimates of their numbers are available, these data may be submitted for consideration as an adjustment to the population of the area.

(iii) Where seasonal residents significantly affect the effective total population of an area, seasonal residents (not including tourists) may be added to the adjusted resident civilian population, if supported by acceptable State or local estimates. Estimates used must be adjusted to reflect the percentage of the year that seasonal residents are present in the area.

(iv) Significant numbers of these populations are indicated when the numbers are large enough to reflect an additional burden on the health care

system that the census data do not capture effectively.

(2) *Counting of primary care clinicians.*

(i) In determining an area's adjusted population-to-primary care clinician ratio for designation as a tier 1 shortage area, clinicians shall be counted as follows:

(A) All non-Federal doctors of medicine (M.D.) and doctors of osteopathy (D.O.) who provide direct patient care and practice principally in one of the four primary care specialties (general or family practice, general internal medicine, pediatrics, and obstetrics and gynecology), shall be included in clinician counts.

(B) All non-Federal nurse practitioners, physician's assistants, and certified nurse midwives practicing in primary care settings shall be included in clinician counts, but with a multiplier of:

(1) 0.5, or, at the applicant's option,

(2) 0.8 times an additional factor whose value is between 0.5 and 1.0, depending on the scope of practice allowed for each type of non-physician clinician in the State involved. A table of these factors for each State and for each type of non-physician clinician will be provided in the final regulation. HRSA will publish an updated table of these factors as a Notice in the **Federal Register** if such updates become available.

(C) Where clinicians are practicing less than full-time, or have more than one practice address, their contribution to the total count may be reduced based on their estimated full-time-equivalency (FTE) practicing within the area being considered, using available data.

(D) Each intern or resident physician shall be 0.1 FTE physician

(E) Hospital staff physicians practicing in organized outpatient departments and primary care clinics shall be counted only on an FTE basis, based on their time in outpatient/ambulatory settings, not in inpatient care.

(F) The following shall be excluded from primary care clinician counts:

(1) Practitioners who are engaged solely in administration, research, or teaching;

(2) Hospital staff physicians involved exclusively in inpatient and/or in emergency room care; and

(3) Clinicians who are suspended under provisions of the Medicare-Medicaid Anti-Fraud and Abuse Act, during the period of suspension.

(ii) In determining an area's adjusted population-to-primary care clinician ratio for designation as a tier 2 shortage area, clinicians shall be counted as

provided for above, except that the following clinicians shall also be excluded:

(A) Primary care clinicians who are members of the National Health Service Corps (NHSC), established by section 331(a) of the Act, are fulfilling a service obligation incurred under the NHSC Scholarship or Loan Repayment Program (sections 338A and 338B of the Act) or are fulfilling a service obligation incurred under the State Loan Repayment program (section 338I of the Act);

(B) Physicians who are practicing in the United States under a waiver of their J-1 Visa requirements; and

(C) Primary care clinicians who are providing services at a health center receiving a grant under section 330 of the Act and who are not otherwise excluded under paragraphs (e)(2)(ii)(A) or (B) of this section.

(iii) Counting of FTEs.

(A) Clinician count data in the Department's electronic designation database (from national data, augmented by State data where approved by the Secretary) may be used by applicants without adjustments for designation purposes.

(B) If applicants prefer, they may conduct surveys of the clinicians in area(s) requested for designation. When this is done, FTEs shall be computed using such guidance as the Secretary may provide.

(3) *Data Sources for High Need Indicators*

(i) The Unemployment Rate, High Need Indicator at paragraph (b)(1)(i)(B) of this section, shall be calculated based on the latest Bureau of Labor Statistics unemployment data available for the lowest-level area (county, city, place, or other labor statistics area) that comprises or includes the area.

(ii) Data for the percent below poverty and demographic High Need Indicators at paragraphs (b)(1)(i)(A) and (ii) of this section, for an area shall be aggregated from the latest available U.S. Census data for the counties, census tracts, census divisions or ZCTAs which comprise the area, or from more recent updates thereof if available and approved by the Secretary.

(iii) The health status High Need Indicators at paragraph (b)(1)(iii) of this section shall be calculated based on the latest available five-year average data available, from DHHS or the State involved, for the county of which the service area is a part, unless the area is a subcounty area and statistically significant five-year average subcounty data on these variables are available for that subcounty area. For service areas which cross county lines, a population-

weighted combination of the rates for the counties involved shall be used.

§ 5.105 Contiguous area considerations.

(a) An analysis of resources in areas contiguous to the area being considered for designation shall be required only if the State involved has not developed a system of RSAs, or has a partially-developed system which does not include all areas contiguous to the requested area, and the population center of the area for which designation (or update of designation) is sought is less than 30 minutes from the nearest providers.

(b) Where contiguous area analysis is required under paragraph (a) of this section, resources in a particular contiguous area will be deemed to be overutilized or otherwise inaccessible if any of the following conditions exists:

(1) All primary care clinicians in the contiguous area are located more than 30 minutes travel time from the population center(s) of the requested area;

(2) The adjusted (or unadjusted) population-to-FTE primary care clinician ratio within the contiguous area is in excess of 2000:1; or

(3) Primary care clinician(s) located in the contiguous area appear to be inaccessible to the population of the requested area because of specific access barriers, such as:

(i) A lack of economic access to contiguous area resources, particularly where a very high proportion of the requested area's population is poor, and Medicaid-covered or public (sliding-fee-schedule or free) primary care services are not available in the contiguous area; or

(ii) Significant differences exist between the demographic characteristics of the requested area and those of the contiguous area (and its clinicians), indicative of isolation of the requested area's population from the contiguous area, such as language or cultural difference.

5. Subpart C is added to read as follows:

Subpart C—Criteria and Methodology for Designation of Population Groups as MUPs and/or Primary Care HPSAs

Sec.

5.201 Applicability.

5.202 General criteria for designation of specific population groups as MUPs and/or primary care HPSAs.

5.203 Criteria for designation of migratory and seasonal agricultural workers as primary care HPSAs.

5.204 Criteria for designation of homeless populations as primary care HPSAs.

5.205 Criteria for designation of Native American populations as primary care HPSAs and MUPs.

5.206 Requirements for “permissible” designation of other population groups as MUPs.

Subpart C—Criteria and Methodology for Designation of Population Groups as MUPs and/or Primary Care HPSAs

§ 5.201 Applicability.

(a) Certain specific population groups will be designated as both MUPs and primary care HPSAs if it is demonstrated that the criteria in § 5.202 of this part are met when applied to data on these population groups. These specific population groups are:

(1) The low income population, defined as that portion of an area’s population whose incomes are below 200% of the poverty level.

(2) The Medicaid-eligible population of the area.

(3) Linguistically-isolated populations, defined as the Secretary may with reference to census definitions of linguistically-isolated households and/or populations for whom English is not spoken at all or is a second language not spoken well.

(b) Migratory and seasonal agricultural workers and their families within specific service areas are defined in law as “special medically underserved populations”. They will also be designated as primary care HPSAs if it is demonstrated that the criteria in § 5.203 of this part are met.

(c) Homeless populations are defined in law as “special medically underserved populations”. They will also be designated as primary care HPSAs if it is demonstrated that the criteria in § 5.204 of this part are met.

(d) Residents of Public Housing are defined in law as “special medically underserved populations”. They will also be designated as primary care HPSAs if it is demonstrated that the criteria in § 5.202 of this part are met when computed for the low income population group residing in a particular Public Housing community.

(e) Native American population groups (including American Indian tribes or Alaska Native entities) will be designated as both MUPs and primary care HPSAs if it is demonstrated that the criteria in § 5.205 of this part are met.

(f) If an FQHC, RHC, or other public or nonprofit private clinical site has been designated as a safety-net facility primary care HPSA under Subpart D, § 5.301 of this part (based on service to significant numbers of uninsured and Medicaid-eligible patients), the population group of uninsured and Medicaid-eligible patients served by the clinical site shall be considered designated as an MUP.

(g) Other population groups recommended by State and local officials may be designated as MUPs under unusual local conditions which are a barrier to access to or availability of health services, under procedures described in § 5.206.

§ 5.202 General criteria for designation of specific population groups as MUPs and/or primary care HPSAs.

(a) Any of the specific population groups identified in § 5.201(a) of this part may be designated if it is demonstrated, using such documentation as the Secretary may require, that the following criteria are met when applied to data for the population group:

(1) The area in which the population group resides meets the requirements for a rational service area under § 5.103 of this part;

(2) The rational service area in which the population group resides does not meet the criteria for designation as a geographic area under § 5.102 of this part;

(3) There are access barriers that prevent the population group from accessing primary medical care services available to the general population of the area, as demonstrated by an adjusted population-to-primary care clinician ratio computed for the population group that equals or exceeds the 3000:1 designation threshold in § 5.104 of this part.

(b) In calculating the adjusted population-to-primary care clinician ratio for a population group, the methodology described in § 5.104 of this part shall be used, except that:

(1) The group’s population shall be used instead of the area’s population,

(2) The FTE clinicians available to the population group shall be used rather than those available to the area in general (i.e. Medicaid FTE/claims and sliding fee scale FTE for a low income population), and

(3) High Need Indicators shall be calculated based as nearly as possible on their values for the applicable population group within the service area, using such approximations as the Secretary may allow.

§ 5.203 Criteria for designation of migratory and seasonal agricultural workers as primary care HPSAs.

(a) Where data availability permits, the method described in § 5.202 of this part may be used to calculate an adjusted population-to-primary care clinician ratio for a population group composed of migratory and seasonal agricultural workers, and to compare this ratio with the 3000:1 designation

threshold, with these additional conditions:

(1) For a migratory and seasonal agricultural worker population group, an agricultural area (as defined by the Secretary) may be used as a rational service area.

(2) The population of the migratory and seasonal population group identified must be adjusted by a factor representing the fraction of the year that this population is present in the area.

(b) Alternatively, a simplified designation procedure may be used, as follows:

(1) Define the boundaries of the agricultural area or other service area within which the migratory and seasonal agricultural worker population reside or temporarily reside for a portion of the year.

(2) Provide data on the number of individuals in the population group (including workers and their families) and the number of months they are present in the area during a typical year.

(3) If the number of individuals times the number of months divided by 12 exceeds 1000, this special medically underserved population group will also be considered a primary care HPSA, with its population-to-primary care clinician ratio assumed equal to 3000:1.

§ 5.204 Criteria for designation of homeless populations as primary care HPSAs.

(a) Where data availability permits, the method described in § 5.202 of this part may be used to calculate an adjusted population-to-primary care clinician ratio for a homeless population group (or for a combined homeless and other low-income population group), and compare this ratio with the 3000:1 designation threshold. For such population groups, the area in which homeless populations congregate and/or are sheltered may be used as a rational service area.

(b) Alternatively, a simplified designation procedure may be used, as follows:

(1) Define the boundaries of the area in which homeless populations congregate and/or are sheltered.

(2) Provide data on the average number of homeless individuals in the defined area during a typical year, and the average number of months they are homeless.

(3) If the average number of homeless individuals during a typical year exceeds 1000, this special medically underserved population group will also be considered a primary care HPSA, with its population-to-primary care clinician ratio assumed equal to 3000:1.

§ 5.205 Criteria for designation of Native American population groups as primary care HPSAs and MUPs.

(a) Those American Indian tribes or Alaska Native entities identified by the Department of the Interior as federally recognized are automatically designated as population group primary care HPSAs and MUPs and will be given a baseline ratio of 3000:1.

(b) Where data availability permits, the method described in § 5.202(b) of this part may be used to calculate a higher population-to-primary care clinician ratio for a Native American population group and/or to facilitate scoring such a designation for purposes of allocating program resources. For such designations, a reservation may be used as a rational service area.

§ 5.206 Requirements for “permissible” designation of other population groups as MUPs.

The population of a service area that does not meet the criteria at § 5.102 of this part, or a population group that does not meet the criteria in §§ 5.202 through 5.205 of this part, may nevertheless be designated as an MUP if the following requirements are met:

(a) The area or population group is recommended for designation by the Governor of the State in which the area is located and by at least one local official of the area. A local official for this purpose may be—

(1) The chief executive of the local governmental entity which includes all or a substantial portion of the requested area or population group (such as the county executive of a county, mayor of a town, mayor or city manager of a city); or

(2) A city or county health official (such as the head of a city or county health department) of the local governmental entity which includes all or a substantial portion of the requested area or population group.

(b) The request for designation is based on the presence of unusual local conditions, not covered by the criteria at § 5.102 and/or §§ 5.202 through 5.205 of this part, which are a barrier to access to or the availability of personal health services in the area or for the population group for which designation is sought.

(c) The request contains such documentation as the Secretary may require.

6. Subpart D is added to read as follows:

Subpart D—Criteria and Methodology for Designation of Facilities as Primary Care Health Professional Shortage Areas

Sec.

5.301 Criteria for designation of public and nonprofit private medical facilities as safety-net facility primary care HPSAs.

5.302 Criteria for designation of Federal and State correctional institutions as primary care HPSAs.

Subpart D—Criteria and Methodology for Designation of Facilities as Primary Care Health Professional Shortage Areas

§ 5.301 Criteria for designation of public and nonprofit private medical facilities as safety-net-facility primary care HPSAs.

(a) A public or nonprofit private medical facility, or a remote clinical site of such a facility, which is located in a geographic area that is not designated as a geographic primary care HPSA under Subpart B of this part, shall be designated as a “safety-net-facility” primary care HPSA if the following criteria are met:

(1) The facility or site is or is part of an FQHC, RHC or other public or nonprofit private medical facility which provides primary medical care services on an ambulatory or outpatient basis, and

(2) The facility or clinical site is identifiable as a safety-net facility based on service to significant numbers of uninsured and Medicaid-eligible patients, as determined using payment source data and the minimum requirements by type of area described in paragraph (b) of this section.

(b) *Methodology.* In determining whether public or nonprofit private facilities or clinical sites are safety-net facilities for purposes of this designation, the following methodology will be used:

(1) The facility or particular site for which designation is sought must meet all of the following requirements:

(i) Currently provides full-time ambulatory or outpatient primary medical care;

(ii) Provides services regardless of an individual’s ability to pay for such services; and

(iii) Has a posted, discounted sliding-fee-scale which is available to all uninsured patients with incomes below 200% of the poverty line.

(2) Payment source criteria. Using such documentation as may be required by the Secretary, it must be demonstrated that:

(i) At least 10% of all patients served at each facility or clinical site (or group of such sites, where payment source data are available only for the group) are indigent uninsured, receiving services free or on a discounted sliding fee scale.

(ii) The number of patients served that are paid under Medicaid, plus the number who receive services free or on

a discounted sliding fee scale, as a percentage of all patients served at each facility or clinical site (or group of such sites, where payment source data are available only for the group) must equal or exceed the following:

(A) 40% in metropolitan areas

(B) 30% in non-metropolitan, non-frontier areas

(C) 20% of all patients in frontier, non-metropolitan areas

§ 5.302 Criteria for designation of Federal and State correctional institutions as primary care HPSAs.

(a) Medium to maximum security Federal and State correctional institutions and youth detention facilities will be designated as primary care HPSAs, if both of the following criteria are met:

(1) The institution has at least 250 inmates; and

(2) The institution has no primary medical care clinicians, or the ratio of the number of inmates per year to the number of FTE primary care clinicians, determined in accordance with § 5.104(e)(2) of this part, serving the institution is at least 1,000:1.

(b) For purposes of this paragraph, the number of inmates shall be determined as follows:

(1) If the number of new inmates per year and the average length-of-stay are not specified, or if the information provided does not indicate that intake medical examinations are routinely performed upon entry, then the number of inmates is used.

(2) If the average length-of-stay is specified as one year or more, and intake medical examinations are routinely performed upon entry, then the number of inmates equals the average number of inmates plus 0.3 multiplied by the number of new inmates per year; or

(3) If the average length-of-stay is specified as less than one year, and intake examinations are routinely performed upon entry, then the number of inmates equals the average number of inmates plus 0.2 multiplied by (1 + ALOS/2) multiplied by the number of new inmates per year, where ALOS is the average length of stay, in fraction of a year.

(c) Clinicians permanently employed by the Federal Bureau of Prisons or by States to provide services to Federal or State prisoners shall be counted based on the FTE services they provide, calculated as provided for in § 5.104(c)(2).

7. Subpart E is added to read as follows:

Subpart E—Identification of Primary Care Health Professional Shortage Areas of Greatest Need**§ 5.401 Use of methodology for identification of HPSAs of greatest need.**

The adjusted population to clinician ratios that are the result of the

calculations in the methodology will be used as the relative scores to identify those HPSAs of Greatest Need. Areas will be ranked according to the ratios calculated to determine an area's eligibility for designation.

8. Appendix A to part 5 is revised to read as follows:

Appendix A to Part 5—Scoring Table for High Need Indicators Used in MUP and Primary Care HPSA Designation

TABLE A-1.—SCORES FOR HIGH NEED INDICATORS, GIVEN THEIR NATIONAL PERCENTILES

Percentile	Poverty	Unemp	Elderly	Density	Hispanic	Non white	Death rate	LBW/IMR
0	0.00	0.00	0.00	995.20	0.00	0.00	0.00	0.00
1	3.01	1.18	0.54	831.13	0.81	0.00	0.82	0.72
2	6.04	2.37	1.09	735.15	1.64	0.00	1.65	1.44
3	9.11	3.58	1.65	667.05	2.47	0.00	2.49	2.17
4	12.21	4.79	2.21	614.23	3.31	0.00	3.33	2.91
5	15.34	6.02	2.77	571.07	4.15	0.00	4.19	3.65
6	18.50	7.26	3.34	534.58	5.01	0.00	5.05	4.40
7	21.70	8.52	3.92	502.98	5.88	0.00	5.93	5.17
8	24.93	9.79	4.51	475.10	6.75	0.00	6.81	5.93
9	28.20	11.07	5.10	450.16	7.64	0.00	7.70	6.71
10	31.50	12.37	5.69	427.59	8.53	0.00	8.60	7.50
11	34.84	13.68	6.30	407.00	9.44	0.00	9.52	8.29
12	38.22	15.00	6.91	388.05	10.35	0.00	10.44	9.10
13	41.64	16.35	7.53	370.51	11.28	0.00	11.37	9.91
14	45.10	17.70	8.15	354.18	12.21	0.00	12.32	10.73
15	48.59	19.08	8.78	338.90	13.16	0.00	13.27	11.57
16	52.13	20.46	9.42	324.55	14.12	0.00	14.24	12.41
17	55.71	21.87	10.07	311.02	15.09	0.00	15.22	13.26
18	59.34	23.29	10.72	298.22	16.07	0.00	16.21	14.12
19	63.00	24.73	11.39	286.08	17.07	0.00	17.21	15.00
20	66.72	26.19	12.06	274.53	18.07	0.00	18.22	15.88
21	70.48	27.67	12.74	263.52	19.09	0.00	19.25	16.78
22	74.29	29.16	13.43	253.00	20.12	0.00	20.29	17.68
23	78.15	30.68	14.12	242.92	21.17	0.00	21.34	18.60
24	82.06	32.21	14.83	233.26	22.23	0.00	22.41	19.53
25	86.02	33.77	15.55	223.98	23.30	0.00	23.49	20.48
26	90.03	35.34	16.27	215.04	24.39	0.00	24.59	21.43
27	94.10	36.94	17.01	206.43	25.49	0.00	25.70	22.40
28	98.22	38.56	17.75	198.13	26.61	0.00	26.83	23.38
29	102.40	40.20	18.51	190.10	27.74	0.00	27.97	24.38
30	106.64	41.86	19.28	182.34	28.89	0.00	29.13	25.39
31	110.95	43.55	20.05	174.83	30.05	0.00	30.30	26.41
32	115.31	45.27	20.84	167.54	31.23	0.00	31.49	27.45
33	119.74	47.01	21.64	160.47	32.43	0.00	32.70	28.50
34	124.24	48.77	22.45	153.61	33.65	0.00	33.93	29.57
35	128.80	50.56	23.28	146.94	34.89	0.00	35.18	30.66
36	133.44	52.38	24.12	140.46	36.14	0.00	36.45	31.76
37	138.15	54.23	24.97	134.15	37.42	0.00	37.73	32.88
38	142.93	56.11	25.83	128.00	38.72	0.00	39.04	34.02
39	147.79	58.02	26.71	122.00	40.03	0.00	40.37	35.18
40	152.74	59.96	27.61	116.16	41.37	0.00	41.72	36.36
41	157.76	61.93	28.51	110.46	42.73	1.39	43.09	37.55
42	162.87	63.94	29.44	104.89	44.12	2.81	44.48	38.77
43	168.07	65.98	30.38	99.44	45.53	4.25	45.90	40.01
44	173.36	68.06	31.33	94.12	46.96	5.71	47.35	41.27
45	178.75	70.17	32.31	88.92	48.42	7.20	48.82	42.55
46	184.24	72.33	33.30	83.83	49.90	8.72	50.32	43.86
47	189.83	74.52	34.31	78.85	51.42	10.27	51.85	45.19
48	195.52	76.75	35.34	73.97	52.96	11.85	53.40	46.54
49	201.33	79.03	36.39	69.18	54.53	13.46	54.99	47.92
50	207.25	81.36	37.46	64.50	56.14	15.10	56.60	49.33
51	213.29	83.73	38.55	59.90	57.77	16.77	58.25	50.77
52	219.45	86.15	39.66	55.39	59.44	18.48	59.94	52.24
53	225.75	88.62	40.80	50.97	61.15	20.22	61.66	53.74
54	232.18	91.15	41.96	46.62	62.89	22.00	63.41	55.27
55	238.75	93.73	43.15	42.36	64.67	23.82	65.21	56.83
56	245.47	96.36	44.37	38.17	66.49	25.68	67.04	58.43
57	252.34	99.06	45.61	34.05	68.35	27.58	68.92	60.07
58	259.38	101.82	46.88	30.01	70.26	29.53	70.84	61.74
59	266.59	104.65	48.18	26.03	72.21	31.53	72.81	63.46
60	273.97	107.55	49.52	22.11	74.21	33.57	74.83	65.21
61	281.54	110.52	50.89	18.27	76.26	35.67	76.89	67.02
62	289.30	113.57	52.29	14.48	78.36	37.82	79.02	68.87

TABLE A-1.—SCORES FOR HIGH NEED INDICATORS, GIVEN THEIR NATIONAL PERCENTILES—Continued

Percentile	Poverty	Unemp	Elderly	Density	Hispanic	Non white	Death rate	LBW/IMR
63	297.28	116.70	53.73	10.75	80.52	40.03	81.19	70.76
64	305.47	119.92	55.21	7.08	82.74	42.30	83.43	72.71
65	313.89	123.22	56.73	3.47	85.02	44.63	85.73	74.72
66	322.56	126.63	58.30	-0.09	87.37	47.03	88.10	76.78
67	331.49	130.13	59.91	-3.60	89.79	49.50	90.54	78.91
68	340.69	133.74	61.58	-7.06	92.28	52.05	93.05	81.10
69	350.18	137.47	63.29	-10.46	94.85	54.68	95.64	83.36
70	359.98	141.32	65.06	-13.82	97.51	57.39	98.32	85.69
71	370.12	145.30	66.90	-17.13	100.25	60.20	101.09	88.10
72	380.61	149.41	68.79	-20.40	103.10	63.11	103.95	90.60
73	391.49	153.68	70.76	-23.62	106.04	66.12	106.92	93.19
74	402.77	158.11	72.80	-26.79	109.10	69.24	110.01	95.87
75	414.50	162.72	74.92	-29.93	112.27	72.49	113.21	98.67
76	426.70	167.51	77.12	-33.02	115.58	75.87	116.54	101.57
77	439.43	172.50	79.42	-36.08	119.03	79.39	120.02	104.60
78	452.72	177.72	81.83	-39.09	122.63	83.07	123.65	107.76
79	466.63	183.18	84.34	-42.07	126.39	86.93	127.45	111.08
80	481.22	188.91	86.98	-45.01	130.35	90.97	131.43	114.55
81	496.55	194.93	89.75	-47.92	134.50	95.21	135.62	118.20
82	512.72	201.28	92.67	-50.78	138.88	99.69	140.04	122.05
83	529.81	207.98	95.76	-53.62	143.51	104.42	144.70	126.11
84	547.94	215.10	99.03	-56.42	148.42	109.44	149.65	130.43
85	567.23	222.68	102.52	-59.19	153.65	114.79	154.92	135.02
86	587.86	230.77	106.25	-61.93	159.23	120.50	160.56	139.93
87	610.02	239.47	110.26	-64.63	165.23	126.64	166.61	145.21
88	633.95	248.87	114.58	-67.31	171.72	133.26	173.15	150.90
89	659.97	259.08	119.28	-69.95	178.76	140.47	180.25	157.10
90	688.47	270.27	124.43	-72.57	186.48	148.36	188.04	163.88
91	719.97	282.63	130.13	-75.15	195.02	157.08	196.64	171.38
92	755.19	296.46	136.49	-77.71	204.56	166.84	206.26	179.76
93	795.11	312.13	143.71	-80.24	215.37	177.89	217.16	189.27
94	841.20	330.23	152.04	-82.75	227.85	190.66	229.75	200.24
95	895.72	351.63	161.89	-85.23	242.62	205.75	244.64	213.21
96	962.43	377.82	173.95	-87.68	260.69	224.23	262.86	229.10
97	1048.45	411.58	189.50	-90.11	283.99	248.05	286.36	249.57
98	1169.68	459.18	211.41	-92.51	316.83	281.62	319.47	278.43
99	1376.93	540.53	248.87	-94.89	372.97	339.02	376.07	327.76

9. The heading for Appendix B to part 5 is revised to read as follows:

Appendix B to Part 5—Criteria for Designation of Areas Having Shortages of Dental Professionals

* * * * *

Appendices D, E, F, G [Removed]

10. Appendices D, E, F, and G of part 5 are removed.

PART 51c—GRANTS FOR COMMUNITY HEALTH SERVICES

11. The authority citation for part 51c is revised to read as follows:

Authority: 42 U.S.C. 216, 254c.

12. Section 51c.102 is amended by revising paragraph (e) and adding paragraph (k) to read as follows:

§ 51c.102 Definitions.

* * * * *

(e) *Medically underserved population* means the population of an urban or rural area which is designated as a medically underserved population by

the Secretary under part 5 of this chapter.

* * * * *

(k) *Special medically underserved population* means a population defined in section 330(g), 330(h), or 330(i) of the Act. These include migratory and seasonal agricultural workers, homeless populations, and residents of public housing. A special medically underserved population is not required to be designated in accordance with part 5 of this chapter.

13. Section 51c.104 is amended by revising paragraph (b)(3) and adding paragraph (d) to read as follows:

§ 51c.104 Applications.

* * * * *

(b) * * *

(3) The results of an assessment of the need that the population served or proposed to be served has for the services to be provided by the project (or in the case of applications for planning and development projects, the methods to be used in assessing such need), utilizing, but not limited to, the

factors set forth in § 5.104 of this chapter.

* * * * *

(d) If an application funded under this part demonstrates that the grantee would serve a designated medically underserved population at the time of application, then the grantee will be assumed to be serving a medically underserved population for the duration of the project period, even if the designation is withdrawn during the project period.

14. Section 51c.203 is amended by revising paragraph (a) to read as follows:

§ 51c.203 Project elements.

* * * * *

(a) Prepare an assessment of the need of the population proposed to be served by the community health center for the services set forth in § 51c.102(c)(1), with special attention to the need of the medically underserved population for such services. Such assessment of need shall, at a minimum, consider the factors listed in § 5.103(b) of this chapter.

* * * * *

Dated: May 23, 2005.

Betty Duke,

*Administrator, Health Resources and Services
Administration.*

Approved: March 26, 2007.

Michael O. Leavitt,

*Secretary, Department of Health and Human
Services.*

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