Designation of Medically Underserved Populations
And Health Professional Shortage Areas
Supporting Statement

A. Justification

1. Circumstances of Information Collection

This is a request for OMB approval of the information collection requirements contained in the Notice of Proposed Rulemaking (NPRM) for the designation of Medically Underserved Areas and Populations (MUA/Ps) and Health Professional Shortage Areas (HPSAs). The Health Resources and Services Administration (HRSA), within the Department of Health and Human Services (HHS), is responsible for making these designations.
The proposed rule for which the clearance is requested revises:

(a) existing regulations at 42 CFR Part 5 that currently govern the designation of HPSAs, as legislatively mandated by Section 332 of the Public Health Service (PHS) Act, and

(b) existing regulations at 42 CFR Part 51 c.102(e) that currently govern the designation of MUA/Ps, as legislatively mandated by Section 330(b)(3) of the PHS Act.

The regulations being revised have been in force since the late 1970s, however, because HRSA did not believe that the regulations mandated the collection of new information, no prior OMB approval was requested. At this time, HRSA recognizes that the provision of information for designation falls under the requirements of the Paperwork Reduction Act, and is submitting this Information Collection Request (ICR) in compliance.

Background and Relevant Statutes

The current HPSA criteria date back to 1978, when they were issued under Section 332 of the 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 National Health Service Corps (NHSC). Section 332(b) of the PHS 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 PHS Act defines "medically underserved population" as the population of an urban or rural area designated by the Secretary of HHS 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.

The Health Care Safety Net Amendments of 2002, P.L. 107-251, as amended by P.L. 108-163, included modification of Section 332 to require the "automatic" designation as HPSAs of all Federally Qualified Health Centers (FQHCs) and Rural Health Centers (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.

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 goals of revising the designation process were to:

(a) consolidate the existing procedures, 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.

The revised methodology and designation process proposed in the NPRM offers a significant improvement in the identification of communities experiencing limited access to primary care services. These revisions will assist the Department in targeting key resources more effectively to areas of greater relative need for assistance.

A number of significant HHS-administrated programs and some other Federal and State programs utilize the MUA/P or HPSA designation as a requirement for program participation.

Specifically:

- MUA/P designations are used as one basis for eligibility for grant funding of health centers under sections 330(c) and (e) of the PHS Act, which requires that these health centers serve medically underserved populations.

- Other health centers not funded by Section 330 grants but otherwise meeting the definition of a health center in Section 330(a), including service to a MUA/P, may be certified by the Centers for Medicare & Medicaid Services (CMS) (upon the recommendation of HRSA) as federally qualified health center (FQHC) look alikes, thus becoming eligible (like those health centers funded under Section 330) for cost-based Medicaid and Medicare reimbursement (Section 1861(aa)(4) of the Social Security Act (SSA)).

- Health professionals placed through the National Health Service Corps (NHSC) may only be assigned to designated HPSAs (section 333 of the PHS Act).

- Physicians practicing in areas designated as geographic HPSAs are eligible for Medicare incentive payments of an additional 10 percent above the rate they would otherwise receive (Section 1833(m) of the SSA). More information is available on the CMS website at: http://www.cms.hhs.gov/HPSAPSAPhysicianBonuses/.

- Clinics in rural areas designated either as an MUA or as a geographic or population group HPSA, and which use nurse practitioners and/or physician assistants, may be certified by CMS as rural health clinics (RHCs) (Section 1861(aa)(2) of the SSA); these RHCs are also eligible for cost-based Medicaid and Medicare reimbursement.

- A number of HRSA health professions programs funded under Title VII of the PHS Act are required to give preference to applicants placing graduates in medically underserved communities, defined to include both HPSAs and MUA/Ps.

It is necessary for the Department to have a process for designation of MUA/Ps and HPSAs in order to establish what areas, population groups and facilities are eligible for resources dispensed through the various programs listed above.

The proposed revised process for designation of MUA/Ps and HPSAs is described in detail in the attached NPRM. Briefly, any agency, individual or community group can request the designation of an area, population group, or facility at any time. 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. All such requests are required to be sent to officials at the State level and other

interested parties for a 30-day review and comment period. No action is taken until this review period is over, in order to ensure that State agencies and others have had an opportunity to provide any supportive or conflicting data or comments. A thorough review is conducted and a decision is made based on all available data.

In the past, nearly all applicants have been required to furnish data showing that their area, population group, or facility met the published criteria for designation. The proposed new process will allow applicants for geographically-based designations to simply specify the geographic area whose designation is requested. Data from national data bases (including census data, health status data, and data on locations of providers) can then be used to initially evaluate the requested area against the established criteria.

In making decisions about whether an area qualifies for designation as an MUA/P and/or HPSA, the agency will calculate a "barrier-free" population-to-primary care clinician ratio and adjust this ratio further for community characteristics by adding partial scores for each of several variables.

This approach requires data on the following variables:

- Number of Primary Care Clinicians (including primary care physicians, nurse practitioners, physicians assistants, and certified nurse-midwives)
- Percent of population below 200% of poverty
- Unemployment rate
- Infant mortality rate or low birth weight rate
- Actual-to-Expected Death Rate
- Population density per square mile
- Percent of population that is non white
- Percent of population that is of Hispanic ethnicity
- Percent of population that is elderly

In some instances the available national data may not be completely current and thus may not accurately reflect local conditions. In such cases, particularly if the national data suggest that the area will not qualify for designation, corrected local data may be provided by the applicant if the applicant wishes to obtain designation. Most of the variables listed above depend on census or health status data which is available on a current basis from national sources. The variable for which corrected local data is most often required is the number of primary care clinicians. The national data base for physicians alone contains practice locations for over 250,000 primary care physicians and is not completely current for all physicians at all times.

As indicated above, the new criteria consider non-physician clinicians as well as physicians in counting primary care clinicians. Although the Agency will make available national data on these non-physician clinicians, the effort required to provide local data on this variable could increase the overall effort and burden for designation. Applicants will have the option of accepting the Agency's data on non-physician providers, or using corrected local data for physicians and/or non-physicians.

If an area does not qualify for designation as a geographic area, it may be that a population group within the area qualifies for designation. In such cases, in order to obtain a designation, the applicant will need to define the population group and provide data on the number of people in the population group and the number of primary care practitioners serving it.

The Health Care Safety Net Amendments of 2002 included a provision for the automatic designation of FQHCs and eligible RHCs until October 26, 2008. As a result, many sites which previously had to submit data to become or remain designated will no longer have the requirement to provide information.

The collection of information for which approval is requested is required in order to make possible designation of areas, population groups and facilities as MUA/Ps and/or HPSAs, and thus become eligible for the benefits of certain HHS and other federal programs.

2. Purpose and Use of Information

The purpose of the data collection is so that medically underserved areas and populations and health professional shortage areas may be identified and appropriately designated by HRSA. The various programs using these designations were listed in the preceding section. Through appropriate designations, a broad range of federal programs can target medically underserved areas, population groups, and facilities.

Users of the MUA/P and HPSA designations include: community groups seeking the resources of the various programs mentioned above; State agencies; program officials at HRSA, CMS, AHRQ, DA, and USIA; and foreign physicians seeking waivers of their J-1 visa return-home requirements. The list of designations will be published annually in the Federal Register and posted at HRSA's website and can be found on: http://hpsafind.hrsa.gov. .

Section 332 of the PHS Act requires that HPSA designations be reviewed annually by the Secretary and revised as necessary. This requirement has been met in the past by annually providing State agencies and other interested parties with a listing showing the information in the database for all counties and designated subcounty areas, population groups and facilities. State agencies and other interested parties are then asked to provide updated data for any areas where significant changes have occurred, with a minimum requirement of providing current data on those areas, population groups or facilities whose designations were made or last updated three years (or more) previously.

Section 4205 of the Balanced Budget Act of 1997 revised the authority for Rural Health Clinic Services (Section 1861(aa)(2) of the SSA) to require that RHCs serve areas whose designation (MUA/P, HPSA, or other) was made or updated within the previous 3-year period. Under the proposed rule, the current HPSA annual review approach would essentially be extended to MUA/Ps. The Agency would annually provide data from its database on all designated MUA/Ps and HPSAs to the States and other interested parties. Each year, they will be asked to verify those designations that are older than three years or more. However, because of the almost complete overlap in definition between MUA/Ps and HPSAs under the proposed new criteria, it is not anticipated that this will significantly impact the annual workload of a State agency. Review of those MUA/Ps whose designations have not been updated in a number of years will be phased in over a three-year period, together with a review of existing HPSAs. The proposed regulations include a process for reconciling overlapping boundaries of existing designated HPSAs and MUA/Ps.

Under the new system, States and other partners in the designation process will have the option of accepting the national data rather than using local data. They would only have to obtain data in those cases where the national data do not indicate a shortage or underservice.

Because the development and maintenance of an accurate list of shortage areas (and of accurate data on those areas) depends on the participation of State and local entities, the application process has been made as simple as possible. No application form is currently used. Rather, applicants and/or State entities representing them are asked to make their requests by letter, with attachments providing relevant maps and documentation.

When the proposed new process is implemented, the application and update process will be simplified even further. In the case of required updates, the Agency's Bureau of Health Professions (BHPr) will perform the necessary calculations using national data and provide the results to the State and other interested parties for verification. In the case of new applications, a State or other applicant will have the option of simply requesting a designation by specifying the area boundaries.

3. Use of Improved Information Technology

The revised designation process will allow for computation by HRSA of the adjusted population-to-clinician ratio (and its components, including the barrier free population-to-clinician ratio and score contribution from indicators of community characteristics), both for new areas defined by applicants and in updating previously-defined areas. These computations will be automated. A master database of national data for use in these computations will be maintained and regularly updated, using electronic inputs from a variety of sources.

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.

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.

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.

To expedite the provider updating process, States may submit their own provider data in electronic form, by county or other service area or census identifier, so that these data may be substituted for the national data where appropriate.

An automated management information system (MIS) for designation calculations has been developed and will allow for on-line submission of designation requests and updates. The HPSA and MUA/P lists are currently available from the HRSA web site at: http://bhpr.hrsa.gov/shortage. .—

4. Efforts to Identify Duplication

The request and the information necessary for the designation of HPSAs and MUA/Ps is a unique activity, specific to HRSA's responsibility under the PHS Act. Duplication of effort will be avoided by making national data available for use in requests for and updates of designations. If the available national data will result in an approved designation, there is no need for an applicant to provide any further information. These data are required in order to make possible the designation of areas, population groups, and facilities as MUA/Ps and/or HPSAs, and thus become eligible for the benefits of certain HHS and other federal programs.

5. Involvement of Small Entities

This activity does not have a significant impact on small entities.

6. Consequences if Information Is Collected Less Frequently

The legislative requirements for HPSAs involve an annual review, and the Balanced Budget Act requires that Rural Health Clinics serve MUA/Ps or HPSAs whose designations have been made or updated within the previous three years. 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). Information will be collected every three years for existing designations and as needed when new applications are submitted. If this information were to be collected less frequently, legislative requirements would not be met and accuracy of the designations would suffer.

7. Consistency with the Guidelines in 5 CFR 1320.5 (d)(2)

This data collection fully complies with 5 CFR 1320.5 (d)(2).

8. Consultation Outside the Agency

Public comment is being solicited in the Notice of Proposed Rulemaking published in the *Federal Register* on February 29, 2008 (Vol. 73, pages 11232-11281).

On September 1, 1998, a notice of proposed rulemaking was published, revising the designation methodology. Due to the large volume of public comment, it was determined that the impact of the proposal as published would need to be more carefully tested, possible revisions and alternative approaches developed as necessary, and a new notice of proposed rulemaking (NPRM) would then be published. A notice was published in the *Federal Register* on June 3, 1999, announcing that further analysis would be conducted on the impact of the proposed approach. HRSA obtained the necessary components of the national databases required for impact testing and began working with researchers to develop the specifics of analytic plan for testing the methodology. The Cecil G. Sheps Center of the University of North Carolina was funded to conduct the national testing of the proposed methodology in the 1998 NPRM and

alternative methods, and to coordinate efforts by other research groups for State or regional testing.

In January, 2000, a group of sixteen State Primary Care Office (PCO) representatives provided consultation in a series of conference calls, meetings, and discussions, resulting in recommendations for a revised designation approach. Following these recommendations, a comprehensive database for impact testing was established, and a revised methodology was developed based on a conceptual framework of access and under-service using statistical methods.

In May, 2003, a notice was published in the *Federal Register* describing the current shortage criteria to determine HPSAs of greatest shortage for primary care, dental, and mental health (Vol. 68, pages 32531-32533).

The proposed methodology for this NPRM was 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.

In addition, the designation process is discussed on a regular basis with the State Primary Care Offices (PCOs) and State Primary Care Associations (PCAs). These discussions include quarterly meetings with regional representatives (the PCA/PCO Workgroup) and an annual meeting with the entire group (the PCO/PCA Symposium). There is also a monthly conference call with a subgroup which is particularly interested in the designation process (the Designation Issues Group). These discussions were reflected in the efforts to revise and simplify the designation process described in the attached NPRM. Discussions were held with PCO representatives of several States in developing the estimates of data collection burden and cost described below.

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality

This activity does not collect personally identifiable information on individuals; therefore, the Privacy Act of 1974 is not applicable.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden

The estimated respondent hour and labor cost burden is:

Designation Type	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Cost per Hour	Total Burden	Total Cost
MUA/P HPSA Metro Area	54	7.24	391	27.4	$18.00	10,713	$192,834
MUP/HPSA Non-Metro Area	54	16.83	909	10.9	$18.00	9,908	$178,344
Facility Designations	25	2.8	70	2.6	$18.00	182	$ 3,276
Total	79		1,370			20,803	$374,454

These estimates were determined based upon previous experience in the designation of MUA/Ps/ and HPSAs as required by the current 42 CFR Part 5. Additional information and input was gathered from informal telephone interviews with various officials responsible for the processing of applications. The hourly cost estimates are based on approximate hourly rates for a mid-level State employee.

13. Estimates of Annualized Cost Burden to the Respondents

There are no significant capital or start-up costs for the applicants.

14. Estimates of Annualized Cost to the Federal Government

Oversight and analysis will be done by program staff and consultants at an estimated average annual cost of $860,000 based on the Shortage Designation Branch salary, plus an additional $140,000 for data acquisition and maintenance. The total estimated annual cost is approximately $1,000,000.

15. Changes in Burden

This is a new request.

16. Time Schedule, Publication, and Analysis Plan

Requests for designation will be reviewed at both the 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 will be 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.

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 of the NPRM). 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.

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 P.L. 108-163, will be implemented. 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 ttthen 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 of the NPRM.

It is the Agency's intent to implement these regulations after review of public comments on the NPRM, and when final regulations are approved and published. Following publication of a Final Rule, the Secretary will consult with State partners as to which area and population group designations within their State are to be reviewed under the new criteria during the first few

transition years. The list of designated MUA/Ps and HPSAs will be published annually in the Federal Register and periodically posted on the web, together with a list of those additional FQHC and RHS sites that are automatic HPSAs.

17. Exemption for Display of Expiration Date

No exemption is requested.

18. Certifications

This data collection activity meets the requirements of 5 CFR 1320.9. The required certifications are included in the package.