DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Parts 5 and 51c

RIN 0906–AA44

Designation of Medically Underserved Populations and Health Professional Shortage Areas

AGENCY: Health Resources and Services Administration, DHHS.

ACTION: Proposed rules.

SUMMARY: The rules proposed below would consolidate the processes for designating medically underserved populations (MUPs) and health professional shortage areas (HPSAs), designations that are used in several DHHS programs. The purpose is to improve the way underserved areas are designated by incorporating up-to-date measures of health status and access barriers and eliminating inconsistencies and duplication of effort. The intended effect is to reduce the effort and data burden on States and communities by simplifying and automating the design process as much as possible, while maximizing the use of technology. The proposed rules involve major changes to both the MUP and the primary care HPSA designation criteria, which have the effect of making primary care HPSAs a subset of the MUPs. No changes are proposed with respect to the criteria for designating dental and mental health HPSAs. Podiatric, vision care, pharmacy, and veterinary care HPSA designations would be abolished under the rules proposed below.

DATES: Comments on this proposed rule are invited, and, to be considered, must be submitted on or before November 2, 1998.

ADDRESSES: Comments should be submitted in writing to: Office of Policy Coordination, Bureau of Primary Health Care, Room 7–1D1, 4350 East-West Highway, Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Richard Lee, 301–594–4280.

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 of the Public Health Service Act (as amended by the recent Health Centers Consolidation Act of 1996, Pub. L. 104–299), 42 U.S.C. 254c, and for designation of Health Professional Shortage Areas (HPSAs) pursuant to section 332 of the Act, 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 Community Health Center regulations at 42 CFR Part 51c, Subpart A, and implementing **Federal Register** notices. The proposed rules below would replace the existing Part 5 with regulations governing both MUP and HPSA designation, and would make conforming changes to Part 51c. Together, these changes would meet the MUP designation requirements of the new legislation and the HPSA designation requirements of existing legislation, while consolidating the two processes to a great degree.

(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.)

I. Current Uses of Designations

The MUP and HPSA designations are currently used in a number of Departmental programs. MUP designations are used in the community health center (CHC) program as a basis for eligibility for funding under section 330(e) of the Act. Health professionals placed through the National Health Service Corps (NHSC) can be assigned only to designated HPSAs. Other health centers not funded by section 330 grants but otherwise meeting the definition of a community health center, including service to a MUP, may be certified by the Health Care Financing Administration (HCFA) upon the recommendation of the Health Resources and Services Administration (HRSA) as federally qualified health centers (FQHCs), eligible for reasonable cost-based Medicaid and Medicare reimbursement. 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 HCFA as Rural Health Clinics (RHCs); these RHCs are also eligible for reasonable cost-based Medicaid and Medicare reimbursement. Physicians delivering services in areas designated as geographic HPSAs are eligible for Medicare incentive payments of an additional 10 percent above the Medicare reimbursement they would otherwise receive. In addition, a number of health professions programs funded under Title VII of the Public Health Service Act are required to give preference to applicants placing graduates in medically underserved communities, defined to include both HPSA and MUPs. For most of the programs using the 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. Purposes of Revising the Designation Mechanisms

The current HPSA criteria date back to 1978; their predecessor, the ''Critical Health Manpower Shortage Area'' or CHMSA criteria date back to the 1971 legislation creating the National Health Service Corps. The current MUA/P criteria date back to 1973 and 1975, when legislation was enacted creating grants for Health Maintenance Organizations and Community Health Centers, respectively.

The original CHMSA criteria were based on a simple population-to-primary care physician ratio; the HPSA criteria expanded this to require a lower ratio for areas with high needs indicated by high poverty, infant mortality or fertility, 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 with incomes below poverty, population-to-primary care physician ratio, infant mortality rate and percent elderly, but poverty has tended to predominate (partly because it was available at subcounty levels).

Since the time these designations were developed, other programs have been required to use these designations, such as the Rural Health Clinic program, the Medicare Incentive Program, and the J–1 visa waiver program, and various Bureau of Health Professions programs now have preferences for applicants serving designated areas. In addition, 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 and more requests have been received for urban neighborhoods and population group designations. The availability of census data on poverty, race and ethnicity down to the census tract level enabled the delineation of urban service areas based on their economic and race/ethnicity characteristics; thus areas with concentrations of poor, minority and/or linguistically isolated populations could achieve area or population group HPSA designations based on limited access to physicians serving other parts of their metropolitan areas. As a result, many

HPSA designations actually represent underserved populations within larger areas that may have reasonable population-to-practitioner ratios; the distinction between HPSA and MUA/P designations has become less sharp. Furthermore, Congress has explicitly identified indicators for identifying HPSAs with the greatest shortages to include not only provider-to-population ratio but also rates of low birth weight births, infant mortality, and poverty as well as access to primary health services.

Generally, the literature indicates that, despite increases in the total number of physicians practicing in the United States, including increases in numbers of primary care physicians, anticipated ''diffusion'' of these physicians into frontier and other remote rural areas has been limited. At the same time, while some areas have improved their population-to-practitioner ratios, the nature of the unmet need has shifted to populations with certain characteristics. Reflecting this evolution, the combined methodology proposed below includes both population-to-practitioner ratios and demographic and other factors associated with access problems. The designation processes and criteria are being revised to accomplish several goals and alleviate problems associated with the existing methods of designation. These purposes include: (a) To consolidate the two existing procedures, two sets of primary care-related criteria, and two overlapping lists of designations, one of which has been updated regularly while the other has not, into one procedure with consistent criteria that generates an integrated list, updated regularly; (b) to make the system more proactive, better able to identify new, currently undesignated areas of need and areas no longer in need; (c) to 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) to expand the State role in the designation process, with special attention to the State role in definition of rational service areas; (e) to 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; (f) to incorporate better measures or correlates of health status; (g) among the selected indicators of underservice/shortage, to improve equity by more heavily weighting the more common attributes, while giving less weight to factors that apply only to subsets of underserved areas/populations; and (h) to ensure that current services to underserved populations are not disrupted in the transition to a new system. These purposes are explained more fully below.

A. Consolidation and Simplification

The separate statutes authorizing MUP and HPSA designations address fundamentally the same policy concern: that is, the identification of those areas and populations which have unmet needs for personal health services, for the purpose of determining eligibility for certain Federal health care resources. Some of these areas and populations have shortages of health professionals to deliver the health services; in others, the problem is lack of access to existing resources. The legislative requirements for the two are similar in many respects, but the designation processes have, up to now, been largely separate. The rules proposed below attempt to establish a unitary procedure and consistent criteria, insofar as is legally permissible, both to simplify the designation process for agencies, communities, entities, and individuals involved in it and to increase the efficient and effective use of Departmental resources. Thus, all the legislatively mandated elements of both statutes are included in the proposed procedures. Further, in redesigning the criteria, common definitions are used for MUPs and HPSAs. In addition, the criteria are structured so that primary care HPSAs become a subset of MUPs, the subset with particular shortages of health professionals.

B. Proactivity and C. Automation

The proposed methodology is also designed to enable a more automated process for designation, through a simpler method for scoring areas and for updating the scores when data updates occur. 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. The intent is to minimize the effort required by States, communities, and other entities to designate an area or update its designation. It should also enable more universal application of the designation criteria, so that applicant familiarity with the designation process will be less of a factor and independent data collection by applicants will be less of a barrier than previously. At the same time, States and communities will continue to have the opportunity to challenge federally-provided data.

D. Increased State Role

The proposed approach seeks to foster 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 significantly 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 covering its territory. Once developed, these service areas will be used in underservice/shortage area designations unless new census data or other changes require further area boundary changes. It is also the agency's intention to ask States to provide information on their practitioner data sources and their methods for evaluating access to service area and contiguous area resources; where States have reliable data sources and analysis procedures, the time required for case-by-case review will be significantly reduced.

E. 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 low income, racial minority or Hispanic ethnicity, and linguistic isolation. It is hoped that the inclusion of these indicators in the proposed index will reduce the need for specific population group designations for these population groups, by increasing the probability of designation of geographic areas with concentrations of these groups.

F. Incorporate Better Measures or Correlates of Health Status

Both designation statutes speak of inclusion of indicators of health status. However, the only specific measure of health status mentioned in either statute or included in the existing designation criteria is infant mortality rate. Both infant mortality rate and low live birthweight rate are nationally available for all counties and for a limited number of subcounty areas (generally, for places

of population 10,000 or more), and these measures are both incorporated. As discussed further below, other direct measures of health status could not be included at this time; however, a number of indirect measures were included as proxies, because they are correlated with low health status.

G. Improve Equity Through Weighting

Experience in designation of both MUA/Ps and HPSAs has indicated that the most common characteristics of shortage/underserved areas involve high population-to-practitioner ratios and a high proportion of the population in poverty or with low incomes. Both these indicators figure prominently in the current HPSA and MUA/P designation approaches; both were considered logical candidates for high relative weighting in any new index. Other indicators of access barriers and low health status are being included, but with lower weights representing their less general applicability as underservice indicators.

H. Avoid Disruption

An improved system will not generate the exact same designations as the old system, or it would represent no change/improvement. However, in the transition to a new system, which will involve updating many MUP designations that have not been updated for some time, care must be taken to ensure that vulnerable underserved populations, identified under previous criteria and now being served by projects based on the existing designations, do not suffer an inappropriate disruption of services. This involved testing the new criteria against the database of currently-designated service areas and active projects.

III. Development of the New Methodology

The development of the proposed new methodology was initiated in the fall of 1992 through discussions with academic researchers and Federal experts in relevant fields, as well as representatives of State health departments and others involved in and affected by the designation process. These discussions covered problems with the current methods, and issues involved in developing better needs assessment/designation methods; the basic goals listed above were identified. A wide variety of potential shortage/underservice indicators and methodological approaches were discussed.

Particular attention was given to health status indicators. Morbidity and mortality rates, including those relevant to primary health care, are generally available only at the county level. This is a problem, because only about one-third of current designations cover whole counties (40 percent are subcounty areas, 22 percent are population groups, and 6 percent are facilities). Also considered were health status indicators based on ''ambulatory care sensitive conditions.'' However, since such data are currently available for less than half the States, their inclusion was not feasible. Developments in this field will be monitored for possible future inclusion of such indicators.

A third group of health status and utilization indicators identified as potentially useful in designation are those collected as part of the National Center for Health Statistics' Health Interview Survey (HIS). However, the surveying/sampling techniques used in collecting these data were originally designed to obtain conclusions valid at national, not local, levels. Efforts to develop a method to allow prediction of the indicators from local demographic data are underway, but have not yet been successful.

Based on the recommendations of various experts consulted and the gaps in data availability noted above, it was decided to pursue development of a new index using demographic proxies for those access and health status indicators that are not yet widely available. The literature was reviewed to identify additional candidate variables, potential variables were evaluated to establish a test data base, and correlation analysis was applied to identify which indicators could be treated as independent variables and which combinations of indicators would tend to over-represent the same underlying variables.

As a result of this process, some indicators considered were not selected for inclusion in the proposed new methodology. For example, the percentage of the population with incomes below 100 percent of the poverty level is not used as an indicator of ability-to-pay; instead, the percentage with incomes below 200 percent of poverty (which is very highly correlated with the proportion below poverty) was selected, since this low-income population is the prime target population of the CHC and NHSC projects which use the designations. Another indicator not ultimately included was educational level. Educational level is quite highly correlated with income; since percent of population with low income is being included in the new methodology, and is highly weighted, it was felt that educational level need not also be included. The percentage of the population which is uninsured was not included, because these data are generally available only at the State level. An indicator of health status, trimester of entrance into prenatal care, was likewise not used, because of concerns that these data are often unreliable.

Impact testing and analysis were conducted to ensure that variables most indicative of need were incorporated, that the scaling and relative weighting of the indicators identified areas of known high need, and that the transition to the new methodology would cause minimal disruption to projects already serving the underserved based on past designation methods. The proposed new methodology was discussed with a variety of academic and government experts and State partners in the designation process during 1995 and revised. As revised, the proposed methodology has been outlined in presentations to national and regional meetings of State and community primary care organizations and others.

IV. Description of the Proposed Regulations

A. Procedures

The proposed approach to processing both MUP and HPSA designation requests, set forth in proposed Subpart A below, is an adaptation of the HPSA designation procedures currently in effect, as codified at 42 CFR Part 5. The proposed 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 procedures involve an interactive process between the Secretary, the States, and individual applicants. Any individual, community group or 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 primary care associations (*i.e.* organizations representing community health centers and other providers of primary care), and appropriate medical, dental or other health professional societies.

Annually, the Secretary will review all designations, with emphasis on those for which new data have not been submitted during the previous three years; this extends to MUA/Ps the review process previously used for HPSAs. In such reviews, the latest data from national sources on already-designated areas are provided by the Secretary to State entities and others for review and correction; if no corrections are provided, the national data are used as the Secretary's basis for decisions. The national data will normally be used for census-collected variables, and for infant mortality and low birth weight rates, but national data for practitioner counts and for population groups is typically updated during the designation process using State and local sources. State and local data are normally more up-to-date and accurate regarding provider locations and are the only source for accurate full-time-equivalency data on those practitioners practicing less than full time or splitting their time between two or more different areas.

There is also a section describing procedures that would operate during the transition from the current system to the new system. These procedures include a process for resolution of any overlapping boundaries that may exist between currently-designated HPSAs and MUA/Ps at the time the new regulations go into effect, and allow that any HPSA or MUA/P designation for which new data was submitted and approved under the old criteria may continue in effect for three years from the approval date. This is to relieve States, communities and others from having to provide updated data on all designations during the first year the new regulations go into effect.

B. MUP Criteria

The criteria for designating MUPs are set out in Subpart B. In brief, areas to be designated must be rational areas for the delivery of primary care services. For each area so defined and considered for designation, the Secretary will determine the area's score on its Index of Primary Care Shortage (IPCS). As discussed below, the IPCS is a composite of partial scores on a number of variables that reflect and incorporate statutory requirements. An area may be designated if its composite score for all variables equals or exceeds the designation threshold determined by the Secretary. (This approach is structurally quite similar to the approach previously used to designate MUA/Ps.)

C. Rational Service Areas

The proposed rules would continue to require that each area proposed for designation be a rational area for the delivery of primary care services. *See*, proposed § 5.103(a). Optimally, each State will develop a State-wide system that subdivides the territory of the State into rational service areas; criteria for such a State-wide system are specified. A definition of the term rational service area is included which allows for considerable flexibility of interpretation by States. Until a State develops such a State-wide system of areas, provisions for determining individual rational service areas would apply. These provisions allow for inclusion of service areas currently designated, whether made up of whole counties or portions thereof; of counties or county-equivalents; and of other areas meeting the regulation's definition of a rational service area. To deal with cases where the boundaries of currently designated MUA/Ps and HPSAs overlap but do not coincide, transition procedures allow the appropriate State official to define which area will be considered to be the rational service area for designation purposes.

D. IPCS Approach

The proposed rules provide that, for each area defined as a rational service area and considered for a primary care shortage/underservice designation, the Secretary will determine the area's score on a new Index of Primary Care Shortage (IPCS). *See*, proposed § 5.103(b). The IPCS is a composite of seven variables that reflect need for and lack of access to primary care services, including those factors that are legislatively mandated: (1) The population- to-primary care practitioner ratio, (2) the percentage of the population with incomes below 200 percent of the poverty level, (3) the infant mortality or low birthweight rate, (4) the percentage of the population that is racial minority, (5) the percentage of the population of Hispanic ethnicity, (6) the percentage of the population that is linguistically isolated, and (7) low population density. The basis for inclusion of these variables in the index is discussed below.

1. Population-to-Primary Care Practitioner Ratio

This ratio is the best available measure of primary care resources available within a particular area, is historically accepted as the prime indicator of primary care practitioner shortage, and reflects the resource decisions central to the NHSC and CHC programs. Also, inclusion of this measure is legislatively required for HPSAs, and meets the MUP legislative requirement for a measure of availability.

2. Percentage of the Population With Income Below 200 Percent of the Poverty Level

This variable represents the economic access barrier faced by many underserved populations, including Medicaid-eligibles and those working poor and Medicaid-ineligibles who tend to be uninsured or underinsured. It also closely approximates the target population of CHC/NHSC projects, which are required to provide care on a sliding fee scale to patients with incomes below 200 percent of poverty level, and fulfills the legislative requirement for a factor indicative of ability-to-pay. Furthermore, low income is highly correlated with low health status. *See*, for example, George Davey Smith, et al., ''Socioeconomic Differentials in Mortality Risk among Men Screened for the Multiple Risk Factor Intervention Trial,'' Am. J. Public Health, 1996:86:486–504.

3. Infant mortality rate or low birthweight rate

These two variables are both indicators of adverse birth outcomes. Consideration of infant mortality rate (deaths per thousand live births) is statutorily required; it has also been used historically as a measure of negative health status, and/or as an indicator of inadequacy of the health care system. Low live birthweight rate (percentage of live births below 2500 grams) is a statistically more robust indicator, since there are more events, and it better reflects access to prenatal care. The highest of the partial scores for each of these two indicators would be used in computing an area's overall IPCS score.

4. Percentage of the Population That Is a Racial Minority

This variable (defined in the census as including blacks, Asian and Pacific Islanders, Native Americans, and other non-whites) is included partly because various minority groups display higher prevalence of certain diseases than the population at large, and lower health status generally, and partly because of access barriers due to discrimination in some cases and cultural barriers in others. The literature indicates that these effects are independent of income. (*See*, for example, Gornick et al., ''Effects of Race and Income on Mortality and Use of Services among Medicare Beneficiaries,'' *New England*

Journal of Medicine, Vol. 335, No. 11, pp. 791–799, Sept. 12, 1996; Commonwealth Fund, National Comparative Survey of Minority Health Care, 1995.) Also, a high percentage of the CHC/NHSC patient population are minorities.

5. Percentage of the Population of Hispanic Ethnicity

This census variable is included because many persons of Hispanic ethnicity experience negative health status effects and discriminatory and cultural barriers, independent of income, while persons of Hispanic ethnicity are not included in the census variable ''racial minority'' unless they self-identify themselves as ''other non-white.'' (For reference relevant to both indicators (4) and (5), see, for example, Lillie-Blanton and Alfaro-Correa, Joint Center for Political and Economic Studies Project on the Health Care Needs of Hispanics and African-Americans, 1995.) Also, a high percentage of the underserved populations served by existing CHC/NHSC programs is Hispanic.

6. Percentage of the Population That Is Linguistically Isolated

This variable (defined in the census as the percentage of the persons in households in which no one over the age of 14 speaks English well) is used as a direct measure of those persons with a severe language barrier, as distinct from those of foreign origin who speak English well.

7. Low Population Density

This variable is included as a proxy for the long distances and high travel times to care experienced by frontier and other isolated rural communities.

E. Scoring

For a given area, partial scores are computed for each of the above variables; these partial scores are then summed to obtain the total IPCS score. An area will receive non-zero partial scores only for those variables which have, in that area, values worse than a normative level for that variable, if available, or the 1996 national rate, where no norm was available.

In the case of the population-to-primary care practitioner ratio, the normative floor level for scoring being used is 1250:1. This corresponds to the lower end of the acceptable range for supply of primary care providers recognized by the Council on Graduate Medical Education (COGME) after adjusting for inclusion of obstetrician-gynecologists and nonphysician providers. A range of 60–80 ''generalist'' physicians per 100,000 population was recognized by the Council on Graduate Medical Education (COGME) as adequate for primary care in its Eighth Report (see U.S. DHHS Report No.HRSA–P–DM 95–3, revised Nov. 1996, pp. 8–12). Since COGME's definition of ''generalist'' physicians encompasses only those physicians in Family Practice, General Practice, General Internal Medicine and Pediatrics, while the definition of Primary Care Practitioners (PCPs) in the MUP/HPSA criteria proposed herein also includes physicians in Obstetrics and Gynecology as well as nurse practitioners, physician assistants and certified nurse midwives, the COGME lower level of 60 per 100,000 was adjusted upward by the ratio of all U.S. PCPs to all U.S. generalists, yielding a level of 80 PCPs per 100,000 population or 1250 persons per PCP.

In the case of infant mortality and low live birthweight, the normative floor levels correspond to the Healthy People 2000 national targets of no more than 7 infant deaths per thousand live births and no more than 5 percent low birthweight births, respectively. In the case of the census-related variables, the 1996 national rates are used as the floor for scoring.

There is a maximum number of points for each variable, and scales for each variable have been devised which relate to its distribution across all U.S. counties. (For example, for a census variable given a maximum score of five points, the values of the variable which divide all counties above its national rate into five equal groups are used as breakpoints.) The scales proposed to be used are shown in Tables 1–7 below; following consideration of comments, they will be republished (with any changes made in response to comments) with the final rule.

The IPCS approach provides that certain variables are more heavily weighted than others, in determining an area's IPCS score. *See*, § 5.103(b). The weighting scheme chosen was designed to enhance equity by more heavily weighting common attributes of shortage areas, while giving less weight to factors that identify population subgroups with particular access problems. The population-to-primary care practitioner ratio and percentage of population with incomes below 200 percent of the poverty level variables are most heavily weighted (maximum 35 points each). The percentage of population that is linguistically isolated, percentage minority and percentage Hispanic variables are less heavily weighted (maximum 5 points each). Similarly, the infant mortality rate and low birthweight rate variables are scored at a maximum of 5 points each; the highest of these two scores is included in the total IPCS score. To address the isolation and distance-related access problems of rural populations, the low-population-density variable is weighted on a 10-point scale. These seven partial scores are combined to obtain the total IPCS score, which thus has a maximum value of 100 points.

TABLE 1.—IPCS PARTIAL SCORE FOR POPULATION-TO-PRIMARY CARE PRACTITIONER RATIO (R) [1]

Range	Partial score
R ≥ 9,000:1	35
9000:1 > R ≥ 7000:1	34
7000:1 > R ≥ 5000:1	33
5000:1 > R ≥ 4500:1	32
4500:1 > R ≥ 4000:1	31
4000:1 > R ≥ 3800:1	30
3800:1 > R ≥ 3500:1	29
3500:1 > R ≥ 3400:1	28
3400:1 > R ≥ 3300:1	27
3300:1 > R ≥ 3200:1	26
3200:1 > R ≥ 3100:1	25
3100:1 > R ≥ 3000:1	24
3000:1 > R ≥ 2800:1	23
2800:1 > R ≥ 2600:1	22
2600:1 > R ≥ 2500:1	21
2500:1 > R ≥ 2400:1	20
2400:1 > R ≥ 2300:1	19
2300:1 > R ≥ 2200:1	18
2200:1 > R ≥ 2100:1	17
2100:1 > R ≥ 2000:1	16
2000:1 > R ≥ 1950:1	15
1950:1 > R ≥ 1900:1	14
1900:1 > R ≥ 1850:1	13
1850:1 > R ≥ 1800:1	12
1800:1 > R ≥ 1750:1	11
1750:1 > R ≥ 1700:1	10
1700:1 > R ≥ 1650:1	9
1650:1 > R ≥ 1600:1	8
1600:1 > R ≥ 1550:1	7
1550:1 > R ≥ 1500:1	6
1500:1 > R ≥ 1450:1	5
1450:1 > R ≥ 1400:1	4
1400:1 > R ≥ 1350:1	3
1350:1 > R ≥ 1300:1	2
1300:1 > R ≥ 1250:1	1
R < 1250:1	0

[1] For areas or population groups where the number of FTE primary care practitioners equals zero, the appropriate ratio R for entering this table is computed as follows: R = adjusted population + 1250.

TABLE 2.—IPCS PARTIAL SCORE FOR PERCENT OF POP. WITH INCOMES BELOW 200% OF POVERTY LEVEL (P)

Range	Partial score
P ≥ 65%	35
65% > P ≥ 60%	34
60% > P ≥ 57%	33
57% > P ≥ 55%	32

TABLE 2.—IPCS PARTIAL SCORE FOR PERCENT OF POP. WITH INCOMES BELOW 200% OF POVERTY LEVEL (P)—Continued

Range	Partial score
55% > P ≥ 52%	31
52% > P ≥ 50%	30
50% > P ≥ 49.5%	29
49.5% > P ≥ 49%	28
49% > P ≥ 48.5%	27
48.5% > P ≥ 48%	26
48% > P ≥ 47%	25
47% > P ≥ 46%	24
46% > P ≥ 45%	23
45% > P ≥ 44.5%	22
44.5% > P ≥ 44%	21
44% > P ≥ 43.5%	20
43.5% > P ≥ 43%	19
43% > P ≥ 42%	18
42% > P ≥ 41%	17
41% > P ≥ 40%	16
40% > P ≥ 39.5%	15
39.5% > P ≥ 39%	14
39% > P ≥ 38.5%	13
38.5% > P ≥ 38%	12
38% > P ≥ 37%	11
37% > P ≥ 36%	10
36% > P ≥ 35%	9
35% > P ≥ 34.5%	8
34.5% > P ≥ 34%	7
34% > P ≥ 33.5%	6
33.5% > P ≥ 33%	5
33% > P ≥ 32.5%	4
32.5% > P ≥ 32%	3
32% > P ≥ 31%	2
31% > P ≥ 30%	1
P < 30%	0

TABLE 3.—IPCS PARTIAL SCORE FOR INFANT MORTALITY RATE (IMR)—OR—LOW BIRTH WEIGHT RATE (LBWR)

Range	Partial score
Deaths/1000 Birth	
IMR ≥ 15.0	5
15.0 > IMR ≥ 12.0	4
12.0 > IMR ≥ 11.0	3
11.0 > IMR ≥ 10.0	2
10.0 > IMR ≥ 7.0	1
IMR < 7.0	0
LBW births as % of live births	
LBWR ≥ 9.0	5
9.0 > LBWR ≥ 8.0	4
8.0 > LBWR ≥ 7.5	3
7.5 > LBWR ≥ 7.0	2
7.0 > LBWR ≥ 5.0	1
LBWR < 5.0	0

The highest of the IMR and LBWR scores is to be used.

TABLE 4.—IPCS PARTIAL SCORE FOR PERCENT POP. RACIAL MINORITY (M)

Range	Partial score
M ≥ 50%	5
50% > M ≥ 40%	4
40% > M ≥ 30%	3
30% > M ≥ 25%	2
25% > M ≥ 20%	1
M < 20%	0

TABLE 5.—IPCS PARTIAL SCORE FOR PERCENT POP. OF HISPANIC ETHNICITY (H)

Range	Partial score
H ≥ 40%	5
40% > H ≥ 25%	4
25% > H ≥ 15%	3
15% > H ≥ 11%	2
11% > H ≥ 8.8%	1
H < 8.8%	0

TABLE 6.—IPCS PARTIAL SCORE FOR PERCENT OF POP. LINGUISTICALLY ISOLATED (LI)

Range	Partial score
LI ≥ 10.0	5
10.0 > LI ≥ 7.0	4
7.0 > LI ≥ 5.0	3
5.0 > LI ≥ 4.0	2
4.0 > LI ≥ 3.0	1
LI < 3.0	0

TABLE 7.—IPCS PARTIAL SCORE FOR POPULATION DENSITY (D)

[persons/sq. mi.]

Range	Partial score
D < 3	10
3 ≤ D < 7	9
7 ≤ D < 10	8
10 ≤ D < 15	7
15 ≤ D < 20	6
20 ≤ D < 25	5
25 ≤ D < 30	4
30 ≤ D < 35	3
35 ≤ D < 40	2
40 ≤ D < 50	1
D ≥ 50	0

F. Designation Threshold

A county or other rational service area will be designated if its composite IPCS score for all variables equals or exceeds the designation threshold determined by the Secretary. This rule proposes to set this threshold at a level which does not cause a major disruption at the time of implementation in the number of counties with some designation, reduces the total population in designated areas somewhat, and, by keeping the threshold constant, allows for future decreases in the number and population of designated areas as conditions improve. The threshold level proposed is 35, approximating the current median of all U.S. county IPCS scores—i.e., the score which would, based on 1996 data, separate the highest-scoring 50 percent of counties nationwide from the remaining counties.

Use of a designation threshold set at the median county value is consistent with past practice for designating MUA/Ps, and testing indicates it would result in a total U.S. underserved population of about 64 million, approximately 10 percent lower than the unduplicated population of currently-designated MUA/Ps and HPSAs, 72 million. The difference is primarily attributable to improvements since the time of the last major MUA/P update.

G. Degree of Shortage; Relationship of Designations to Interventions; Types of Shortage Lists

An important issue in the preparation of these regulations was whether those practitioners who are present in designated areas as a result of interventions based on the designations should be included in computations when updating the designations. One school of thought emphasizes concerns about potential ''yo-yo'' effects, in which an area is designated, 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. Another school of thought reflects concerns about carrying on the list of designations areas whose needs have been met through CHC and/or NHSC interventions. This can lead to such eventualities as waiver of J–1 visa physicians' return-home requirements in return for service in a designated area or certification of a new Rural Health Clinic in a designated area, although that area's needs are already being met by CHC, NHSC, and/or previously waived J–1 visa providers.

To deal with these concerns it is proposed to publish a two-tiered list of designations. Each designated MUP or HPSA will be identified as having either a first or second degree of shortage. First degree of shortage designations will be those which continue to be designatable even when resources placed in the area through CHC and/or NHSC interventions are counted; second degree of shortage designations will be those which are designatable only when

resources placed through CHC and/or NHSC interventions are excluded. Both types of designations would be eligible for CHC and NHSC resources, but other programs would be encouraged to concentrate their resources on first degree of shortage areas. For primary care HPSAs, these two degrees of shortage would replace the previously defined degree of shortage groups.

Some have suggested that the second group should also include areas that would remain designatable if physicians whose J–1 visa return-home requirements have been waived were not counted. This has not been done, since J–1 waiver physicians are not equivalent to those placed or supported by HRSA: they are not required to serve patients regardless of ability to pay, and for many, there is no monitoring system in place. However, public comment on this issue is invited.

H. Data Definitions

The proposed rules spell out the data needed to determine the score for each of the IPCS variables for an area. *See*, proposed § 5.103(c).

1. Population and Practitioner Counts

The population and practitioner count variables are to be calculated in essentially the same way as now provided for HPSAs under the existing Part 5. Like the present Part 5, the proposed rules anticipate adjustment of population by age/sex; however, rather than including these adjustments in the regulation as before, the proposed rules provide that the table for making such adjustments will be published by notice from time to time in the **Federal Register**, so that updated data on age/sex utilization rates can be used as it becomes available. The age-adjustment table proposed to be used initially is shown as Table 8 below; it will be republished (with any changes made) in the preamble to the final rules.

TABLE 8.—AGE ADJUSTMENT OF POPULATION

[Based on 1992 Health Interview Survey data]

Number of physician contacts =
malepop < 1 yr * 5.9 + femalepop < 1 yr * 5.9
malepop 1–4 * 5.9 + femalepop 1–4 * 5.9
malepop 5–17 * 3.0 + femalepop 5–17 * 3.0
malepop 18–44 * 3.5 + femalepop 18–44 * 5.4
malepop 45–64 * 3.5 + femalepop 45–64 * 5.4
malepop 65–74 * 5.5 + femalepop 65–74 * 7.1
malepop > 74 * 11.1 + femalepop > 74 * 11.1

TABLE 8.—AGE ADJUSTMENT OF POPULATION—Continued

[Based on 1992 Health Interview Survey data]

Adjusted population = Number of physician contacts/5.3 (here, 5.3 is the national average number of physician contacts per year)
Population-to-primary care practitioner ratio (R, for Table 1) = Adjusted population / number of FTE primary care practitioners

The practitioner count requirements are similar to those in the current Part 5, although they are reorganized for clarity and some important changes have been made. Foreign medical graduates who are citizens or permanent residents or are on J or H visas are to be fully counted unless they have restricted licenses. Practitioners providing medical services under a federal service obligation or as an employee of a federal grantee are counted for first degree of shortage designations but are excluded for second degree of shortage designations; see, discussion above. It should be noted that, although the proposed rules would allow NHSC and grant-hired practitioners to be excluded from the practitioner count for second degree of shortage designation purposes, these practitioners are included by the Department in making decisions as to how to allocate additional NHSC assignees 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; experience has shown that this provision is not useful as a practical matter.

2. Non-Physician Primary Care Practitioners

Significant interest has been expressed in including nurse practitioners (NPs), physician assistants (PAs), and certified nurse-midwives (CNMs) in counts of primary care practitioners for designation purposes, particularly where they practice as effectively independent providers of care and particularly given the role of these practitioners in the Rural Health Clinic program. However, controversy exists as to whether the available data will 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 modes of practice allowed for these practitioners, including the extent to which they are allowed to work independently, and what medical tasks they are legally allowed to perform. This means that it has been difficult or impossible to incorporate their contributions in a consistent way across all States. Second, there are significant limitations to the national databases currently available on these practitioners as compared with the national data available for M.D.s and D.O.s. While some States have accurate data on the number, location and practice characteristics of these practitioners, others do not; however, if incorporation of these practitioners were made dependent on use of State data, those States willing and able to provide the data would effectively be penalized relative to those States which could not or did not provide it, since inclusion of more practitioners decreases the likelihood of designation. Finally, for those States in which nonphysician practitioners 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, is not well-defined.

The proposed rules below include these nonphysician practitioners by requiring that all of them be counted as equivalent to 0.5 FTE. Some have suggested that different equivalencies be used in different States, depending on the degree of independence allowed by the different State laws, or that the equivalency be different in areas without physicians as compared to areas where physician and nonphysician providers are teamed together. This has not been done, both to avoid further complexity and to avoid penalizing those States where nonphysician providers are effectively used; however, public comment on the equivalency issue is solicited. The rules provide that the proposed relative weight of 0.5 may be revised upward by **Federal Register** notice, if the Secretary determines that national practice data support a higher weight. Please note that the 0.5 relative weighting is proposed only for purposes of estimating primary care practitioner counts for shortage area designation purposes; it should not be construed as representing the relative cost of these providers' services compared to physician services. However, its use is consistent with productivity standards currently used by HCFA for RHCs and FQHCs, which are 2100 visits per year for NPs and PAs as compared with 4200 visits per year for physicians.

A national database for these practitioners will be constructed from those data available from national sources on NPs, PAs and CNMs. Data from this national database will be used

as a first approximation, but States will be encouraged to provide more accurate State data, if available. In this way, States with better data should not be penalized.

Methods for computing the remaining IPCS variables are also included in Subpart B below. The proposed rules specify the type of data to be used, so as to achieve, insofar as possible, uniformity and comparability of designations. It should be noted that HRSA plans to initially compute the IPCS scores for county-equivalents and existing HPSAs and MUPs from national data, providing them to the States and other interested parties for review.

I. Population Group Designations

The inclusion in the proposed IPCS of a number of variables representing the access barriers and/or negative health status experienced by certain at-risk populations, and its use in geographic area designations, is likely to decrease the need for specific population group designations, which are more difficult procedurally for both applicants and reviewers to deal with. However, the proposed rules continue to provide for population group designations within geographic areas which, taken as a whole, do not meet the criteria for designation. *See*, proposed § 5.104(a). These generally build on the criteria for designating geographic areas, with several key differences. First, the proposed rules recognize certain additional types of areas as rational areas for the delivery of primary care services for specific population groups (*e.g.*, reservations for Native American population groups). *See*, proposed § 5.104(a). Second, there are particular minimum population size requirements applicable to the designation of low income population groups. *See*, proposed § 5.104(b). Finally, each variable in the IPCS 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. *See*, proposed § 5.104(a). However, where the definition of a population group requested for designation essentially coincides with one of the variables used in the index (*e.g.*, a low-income population group, defined as the population with incomes below 200 percent of the poverty level), the total IPCS score could be distorted by automatically assigning the maximum possible score to one variable. To avoid this, it is proposed that the variable involved not be considered in scoring the requested population group; instead, its weight would be distributed among the other variables.

J. Designation of Primary Care HPSAs

1. Criteria and Procedures

The criteria and procedures for designating primary care HPSAs are set out in proposed Subpart C. They build upon and are integrally related to the criteria and procedures for designating MUPs set out in Subpart B; to be considered for primary care HPSA designation, areas and population groups must first achieve the same minimum IPCS score used in MUP designation. However, to clearly identify those underserved areas and population groups with practitioner shortages, consistent with past HPSA practice the proposed new primary care HPSA designation criteria also require a specific minimum population-to-practitioner ratio, not required for designation of an MUP. *See*, proposed §§ 5.202(c) and 5.203(b)(4). Thus, under the rules proposed below, the geographic area and population group primary care HPSAs will be a subset of the MUPs.

2. HPSA Designation Threshold

The threshold population-to-primary care practitioner ratio for primary care HPSA designation of this subset (within the group of all areas above the threshold for MUA/P designation) is proposed to be set at 3,000:1. In effect, this maintains current practice with regard to the HPSA threshold. A threshold of 3,000:1 is currently used for HPSA designation of population groups and of ''high need'' geographic areas, which are identified based on criteria including proportion of the population with low incomes, infant mortality and fertility rates, and indicators of insufficient primary care capacity. Under the proposed regulation, all areas considered for HPSA designation will first have been identified as ''high need'' by achieving an IPCS score of 35 or more, using similar criteria which include proportion of the population that is low income or minority, infant mortality or low birthweight rates and low population density.

Public comments are specifically requested on whether the proposed 3,000:1 threshold or some alternative threshold would best serve to identify those areas and population groups with shortages of primary care health professionals.

As with the other thresholds mentioned above, there are no plans to change this level once set; therefore, the number of designated areas should decrease as the national provider distribution improves. Note also that this level is not being identified as an adequacy level but as a shortage level.

3. HPSA Designation of ''Special Medically Underserved Populations.''

The proposed provisions for population group HPSAs allow for HPSA designation of the ''special'' populations defined by section 330 of the PHS Act (as recently amended by Pub. L. 104–299), which are not required to be designated as MUPs. For example, the provisions for designation of migrant/seasonal farmworker population groups as primary care HPSAs allow the use of agricultural areas as the service area unit of analysis. Although no particular special requirements are specified for designation of homeless populations as primary care HPSAs, they can be considered for designation either in similar fashion to or in combination with poverty or low-income populations, i.e. by utilizing the ratio of the total number of persons in the population group to the total FTE primary care practitioners serving them, together with data for the other IPCS variables representing as closely as possible their values for the population group being considered. Similarly, a project serving a public housing project can be considered for primary care HPSA designation by either assessing its geographic area for a geographic area HPSA designation or assessing its low income population for a population group HPSA designation.

K. Designation of Facility Primary Care HPSAs

1. Correctional Facility HPSAs

The criteria and methodology for designating correctional facilities as primary care HPSAs are essentially unchanged from the current Part 5. They have no MUP counterpart, since the statute does not provide for designation of facility MUPs.

2. Other Public or Private Non-Profit Facilities as HPSAs

These criteria are proposed to be simplified. Under the proposed rules, such a facility will be considered for primary care HPSA designation only if it is serving one or more designated geographic or population group HPSAs but is not located within a designated geographic HPSA or within the area of residence of a designated population group HPSA. To be designated, the facility would then need to demonstrate from patient origin data that a majority of its services are being provided to residents of designated areas or to designated population groups; travel

time would not be a consideration. Second, as before, the facility would need to show that it has insufficient capacity to meet the primary care needs of the designated areas or population groups served. However, instead of showing that two of four criteria for insufficient capacity are met, as in the past, only one criterion would be used: more than 6,000 outpatient visits per year per FTE primary care physician on the staff of the facility. The two previously-used waiting time criteria were difficult to document but almost always automatically met, while the indicator ''excessive use of emergency rooms for non-emergent care'' was not well-defined.

L. 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. Appendix B (dental HPSAs) would be redesignated as Appendix A, and Appendix C (mental health HPSAs) would be redesignated as Appendix B, but no other changes to the appendices are proposed at this time.

M. Podiatry, Vision Care, Pharmacy and Veterinary Care HPSAs

The HPSA regulations now in use 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 were originally developed for use in student loan repayment programs for individuals in those health professions which are no longer authorized or funded. Consequently, the proposed rule would abolish these types of designation by revoking these appendices.

N. Transition provisions

The proposed rules also include transition provisions. *See,* proposed § 5.5. These would allow existing designations of MUA/Ps and primary care HPSAs which were made or updated under the previous criteria within the past three years to remain in effect while older designations are updated under the new criteria, unless the State itself indicates that it would like to revise them earlier. The intent is to review all designations under the same schedule used under the previous HPSA procedures; i.e., each year those designations which are more than three years old must be updated, while review of more recent designations is optional. The proposed rules also set out a procedure for resolving situations where MUA/P and primary care HPSA boundaries overlap.

O. HPSAs of Greatest Shortage Determinations

Section 333A of the Public Health Service Act provides that priority in the assignment of NHSC members be given to entities that, in addition to meeting certain other requirements, serve HPSAs ''of greatest shortage,'' and lists the factors to be used in determining which HPSAs qualify as such. At present, the ''HPSA of greatest shortage'' score is calculated under criteria published in the **Federal Register**, 56 FR 41363–41365, Aug. 20, 1991, and uses population-to-primary care physician ratio, percent of population below the poverty level, infant mortality rate or low birthweight rate, and travel time or distance to care.

Although the regulations proposed below were developed to implement requirements of sections 330 and 332 of the Act and thus do not directly address the additional ''HPSA of greatest shortage'' determinations required by section 333A, the agency's intent is to use the new IPCS variables in making those determinations for geographic and population group primary care HPSAs in the future. Section 333A(b) requires that certain exclusive factors be considered in determining HPSAs of greatest shortage: the ratio of available health professionals to the population, the rate of low birthweight births, the infant mortality rate, the ''rate of poverty,'' and ''access to primary health services, taking into account the distance to such services.'' In the agency's view, these required factors are captured by the proposed IPCS. ''Rate of poverty'' in the statute is represented by the percent of the population with incomes below 200 percent of the poverty line, and ''access to primary health services, taking into account the distance to such services' in the statute is represented by the combination of four access variables—percent linguistically isolated, percent minority, percent Hispanic ethnicity, and low population density. All these factors represent access barriers; furthermore, the low population density variable in particular represents and is correlated with excessive travel distance to care. Therefore, the agency intends to use the IPCS variables in determining relative shortage for the purposes of making HPSA of greatest shortage determinations under section 333A for primary care HPSAs. The precise method for doing so will be published following publication of the final rules.

P. Impact Analysis

The agency has conducted an analysis of the impact of the new designation methodology on counties, existing geographic HPSAs, and existing MUAs. It is important to note that the agency's impact analysis was done using national data for all variables in the IPCS; therefore, it could not reflect the use of State and local data which is normally obtained during the back-and-forth activity of the actual designation process. Accordingly, the results of the impact analysis for particular areas are not definitive; in fact, the scoring based on national data would represent only the first step in an exchange with State and local partners in the actual designation process. However, the aggregate results of this impact analysis (in terms of total numbers of areas designated or dedesignated nationally) represent a conservative approximation to the likely results of the real designation process—conservative since more corrective feedback is likely to be received from areas which the national data would tend to dedesignate than from areas which it would newly designate or continue in designation.

The U.S. has 3,141 counties (including D.C., but excluding Puerto Rico and other non-States). Under the existing designation system, 703 counties have been wholly-designated as both MUA and HPSA; 700 others as whole-county MUAs; and 202 others as whole-county HPSAs, for a total of 1,605 counties wholly-designated. In addition, 1,063 other counties contain either a part-county MUA designation, a part-county geographic HPSA designation or both. The 35 unduplicated population of all designated HPSAs and MUAs is 72 million.

The agency's impact analysis indicates that, under the new system, approximately 1,600 counties would be wholly designated, and about 750 other counties partially designated, with a total designated population of 64 million. Thus, there would be a net decrease of about 300 counties with some designation, and 8 million fewer persons living in designated areas. The percentage of counties containing some type of designation would decrease from 85 percent to 76 percent.

The impact analysis also indicates that nationally 23 percent of existing MUAs (counting each designated whole county and each separate subcounty area as one MUA) would lose their designation, while only nine percent of existing HPSAs would lose designation. Most of the anticipated net decrease in counties wholly or partially designated

corresponds to the anticipated old MUA dedesignations, which in turn relates to the fact that many MUAs have not been updated for 15 years and underservice-relevant conditions in some of these have improved.

Of the 3,141 U.S. counties, 2,134 are rural, while 1,007 are urban; 447 have large minority (non-white) populations, while 260 have large Hispanic populations. As shown in Table 9, the impact analysis indicates that approximately 78 percent of the rural counties, 65 percent of the urban counties, 92 percent of the high-minority counties, and 88 percent of the high-Hispanic counties would continue to be at least partially designated. The table shows other relevant statistics for these groups of counties; for example, two percent of both rural and urban counties would gain designation, while 11 percent of rural counties and 12 percent of urban counties would lose their designation. Another nine percent of rural counties and 21 percent of urban counties which previously contained no designations would remain undesignated.

TABLE 9.—IMPACT BY TYPE OF COUNTY

[in percents]

	Total (3141)	Rural (2134)	Urban (1007)	High Minority (447)	High Hispanic (260)
Remain Designated	74	78	65	92	88
Gain Designation	2	2	2	1	6
Lose Designation	11	11	12	5	3
Remain Undesignated	13	9	21	2	3

It should be emphasized that these numbers approximate the national overall impact, based on the use of national data only. It is impossible to predict the actual final impact on specific communities and States because of the iterative process built into the system. As described in section IV.A 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 provider 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.

The impact of the proposal on projects and providers in existing MUPs and HPSAs has also been considered by HRSA. Estimates indicate that most of the former MUA/Ps that would be dedesignated are not ones that are currently served by CHCs. This is because the CHC grant program employs further tests of need in the grant application process; current grantees are generally serving areas and population groups which would remain designatable under the new process. In those few cases where a grantee is serving an area which would be dedesignated under the new process, it is anticipated that an appropriate population group will be designatable under the new process.

Although it is estimated that the total number of HPSAs will not change appreciably, some particular HPSAs will lose designation either because their IPCS score does not reach 35 or because the counting of NPs, PAs and CNMs results in their population-to-practitioner ratio falling below 3,000:1. The effect on existing NHSC sites will be muted because NHSC assignees serving HPSAs that are dedesignated after they arrive are allowed to complete their tours of duty; however, such sites would not be able to ''backfill'' such assignees once they leave. HRSA will examine this effect in more detail during the comment period.

No national database on location of physicians who have obtained J–1 visa waivers currently exists, so a detailed analysis of the potential impact on that program is not immediately available. However, once such physicians obtain waivers, they can complete their obligation in the area for which they were waived even if the area loses its designation.

HRSA and HCFA will collaboratively analyze the combined impact of the proposed new criteria and relevant provisions of the Balanced Budget Act of 1997 on Rural Health Clinics during the comment period. (See also section V below.)

Public comments on the anticipated effects of the proposal on these various programs are specifically solicited.

Q. 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 Pub. L. 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.

V. 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 ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, budgetary impact, or 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 and does not otherwise 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 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 relevant to this regulation would be the Community Health Center grantees. While we cannot predict actual impact at the community level, for reasons discussed in section IV.P above, the similarity between the need component of the funding criteria for CHCs and the elements of the new designation methodology suggest that very few CHC service areas would lose designation. In addition, because of the provision that projects whose designation is lost will nevertheless be considered as serving an MUA/P for the duration of the project period, any negatively affected CHC will have time to submit an alternate type of designation request (such as population group or Governor's) or to make the transition to unfunded status.

With regard to small businesses, while the designation process may affect some small profit-making health care-related businesses, it is unlikely that it could have a significant economic impact (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 HPSAs; however, this would be unlikely to amount to five percent of their total revenues.

Rural Health Clinics already certified based on an MUA or HPSA designation have not been adversely affected by dedesignations in the past since the legislative authority for them has had a grandfather clause; once certified, the RHC certification could not be withdrawn based on loss of designation. However, recent legislation (the Balanced Budget Act of 1997) has changed that; effective January 1, 1999, RHCs in areas that have lost designation may lose their RHC certification. On the other hand, the same legislation also provides that RHC certifications can be retained if it is determined that the RHC is essential to the delivery of primary care services in its area. Therefore, dedesignation will not automatically decertify an RHC.

''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. Of the 3,141 counties in the U.S., 2,134 are rural and 1,007 are urban. Our impact analysis indicated that 11 percent of all counties could lose a designation, including 12 percent of urban counties and 11 percent of rural counties. This would suggest that a substantial number of small government jurisdictions could be affected. However, it is unlikely that the economic impact on these 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. (941 counties have CHC and/or other BPHC funding, and/or have NHSC resources.) The first of these types of impact would occur only in the case of a Community Health Center (CHC) which, at the beginning of a new project period, had been unable to identify a Medically Underserved Population in the area it proposed to serve. Typically, grant funding forms 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 would 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. Given that the area will have recently been dedesignated, there must have been an increase in the number of 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.

The third type of impact applies in the case of FQHCs and/or RHCs which lose eligibility for cost-based reimbursement, 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 benefits available in a particular fiscal year 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.

VI. 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. The 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 recordkeeping on designations previously made or commented upon by the State. These requirements apply under both current rules and the proposed rule.

Once a designation 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 together with any additional, more current or 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 the areas involved, especially for subcounty areas, since only county-level physician data have been available from national sources; national population data have been largely limited to decennial census data and official Census Bureau intercensus 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 may be used without further collection and analysis if acceptable to the State and community involved. This should reduce 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 still need to obtain local data to support continued designation. In such cases the inclusion of nonphysician providers under the proposed new rules will increase the 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 are therefore eligible for the 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 information to DHHS are the State Primary Care Offices (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 reduced 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, and will also require MUA/Ps to undergo an updating process which was not previously required, it eliminates the 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 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.

The resulting burden estimates are as follows:

Type of request	Average time to compile (in hours)
Current system:	
MUA/P application—urban area/pop group	11.5
MUA/P application—rural area/pop group	4.7
HPSA application—urban area/pop group	44.9
HPSA application—rural area/pop group	14.9
HPSA facility application	2.6
Average time per application—all types	24.5
New system:	
MUA/P/HPSA application—urban area/pop group	27.4
MUA/P/HPSA application—rural area/pop group	10.9
HPSA facility application	2.6
Average time per application—all types	15.4

Thus the reporting burden per application is reduced by 9.1 hours, or 37 percent.

Purpose of comments: Comments by the public on this proposed collection of information 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: Any public comments specifically regarding these information collection requirements should be submitted to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Washington, DC 20503, Attn: Desk Officer for DHHS, and to Susan Queen, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. 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.

List of Subjects

42 CFR Part 5

Health facilities, Health professions, Health statistics, Manpower, Mental health programs, Reporting and recordkeeping requirements.

42 CFR Part 51c

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

Dated: December 16, 1997.

Claude Earl Fox,

Acting Administrator, Health Resources and Services Administration.

Approved: April 6, 1998.

Donna E. Shalala,

Secretary, Department of Health and Human Services.

For the reasons set out in the preamble, parts 5 and 51c of title 42, Code of Federal Regulations, are proposed to be amended 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. 216, 254c, 254e.

3. The table of contents for part 5 is revised to read as follows:

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

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.

Subpart B—Criteria and Methodology for Designation of Medically Underserved Populations

5.101 Applicability.
5.102 Criteria for designation of populations of geographic areas as MUPs.
5.103 Methodology for designation of geographic areas as MUPs.
5.104 Criteria for designation of population groups as MUPs.
5.105 Requirements for designation of MUPs recommended by State and local officials.

Subpart C—Criteria and Methodology for Designation of Primary Care Health Professional Shortage Areas

5.201 Applicability.
5.202 Criteria for designation of geographic areas as primary care HPSAs.
5.203 Criteria for designation of population groups as primary care HPSAs.
5.204 Criteria for designation of medical and other public facilities as primary care HPSAs.

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

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

4. The existing text is designated as subpart A; a subpart heading is added; and newly designated subpart A is revised to read as follows:

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

§ 5.1 Purpose.

This part establishes criteria and procedures for the designation and withdrawal of designations of medically underserved populations pursuant to section 330 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) *FTE* means full-time equivalent.

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

(d) *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) An urban or rural area;

(2) A population group; or

(3) A public or private nonprofit medical facility or other public facility.

(e) *Medical facility* means a facility for the delivery of health services and includes:

(1) A health center (such as a community health center, migrant health center, health center for the homeless, or a health center for residents of public housing), public health center, facility operated by a city or county health department, outpatient medical facility, or a community mental health center;

(2) A hospital, State mental hospital, facility for long-term care, or rehabilitation facility;

(3) An Indian Health Service facility, or a health program or facility operated under the Indian Self-Determination Act by a federally recognized tribe or tribal organization;

(4) 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;

(5) Any medical facility used in connection with the delivery of health

services under section 320, 321, 322, 324, 325, or 326 of the Act;

(6) Any other federal medical facility.

(f) *Medically underserved population* or *MUP* means:

(1) The population of an urban or rural 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.

(g) *Metropolitan statistical area* means an area which has been designated by the Office of Management and Budget as a metropolitan statistical area. All other areas are ''non-metropolitan areas.''

(h) *Poverty level* means the current poverty line issued by the Secretary pursuant to 42 U.S.C. 9902.

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

(j) *State* includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, Palau, the U.S. Outlying Islands (Midway, Wake, *et al.*), the Marshall Islands, and the Federated States of Micronesia.

§ 5.3 Procedures for designation and withdrawal of designation.

(a)(1) Any agency or individual may request the Secretary to designate (or withdraw the designation of) a particular area, population group, or facility as an MUP or HPSA, as applicable. The Secretary will forward a copy of each such request to the agencies, officials, and entities listed below, with a request that they review the request and offer their recommendations, if any, to the Secretary within 30 days:

(i) The Governor;

(ii) The appropriate State health agency or agencies;

(iii) Appropriate county or other local health officials within the State;

(iv) The State primary care association or other State organization, if any, that represents a majority of community health centers in the State;

(v) State medical, dental, or other appropriate health professional societies; and

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

(2) 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 (a) of this section and request comment as therein provided.

(b) 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, relevant data available to the Secretary, and an identification of those MUPs and HPSAs within the State whose designations, because of age or other factors, are required to be updated. Such listings shall distinguish between first and second degree-of-shortage MUPs and HPSAs, as determined in accordance with § 5.103. The Secretary will provide the listing for the State and a description of any information needed to the appropriate entities described in paragraphs (a)(1) (ii) and (iv) of this section in each State and request review and comment within 90 days.

(c) The Secretary will furnish, upon request, an information copy of a request made pursuant to paragraph (a) of this section or the materials provided pursuant to paragraph (b) of this section to other interested persons and groups for their review and comment. Comments or recommendations may be provided to the Secretary, the Governor, the appropriate State agency(ies), or any other contact designated by the Governor.

(d) In the case of a proposed withdrawal of a designation, the Secretary shall afford, to the extent practicable, 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.

(e)(1) The Secretary may request such further data and information deemed 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 therefor, unless a longer period is approved by the Secretary.

(2) If the information requested under paragraph (b) or (e)(1) of 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.

(f) 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 designation of those which have been determined no longer to meet the applicable criteria under this part.

§ 5.4 Notice and publication of designations and withdrawals.

(a) In the case of a request under § 5.3(a)(1), the Secretary will notify the individual or agency requesting the designation or withdrawal of designation of the determination made.

(b) The Secretary will give written notice of a designation (or withdrawal of designation) under this part on, or not later than 60 days from, the effective date 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 of the affected State or States and any other State agency(ies) 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 periodically, but not less than annually, publish updated lists of designated MUPs and HPSAs in the **Federal Register**, by type of designation and by State. Such listings shall identify the degree-of-shortage of each MUP or HPSA 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 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 provided pursuant to

paragraph (a) or (b) of this section, 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) *Revision of MUPs and primary care HPSAs.* (1) The Secretary will, after [date of publication of final rule in the **Federal Register**], submit to the entities in each State identified pursuant to § 5.3(a)(1) and (2) a listing of the Index of Primary Care Services (IPCS) scores computed under § 5.103(b) 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 may 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)(*1*) Which area boundaries the State recommends be continued in effect; and

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

(B) If the State wishes to designate a new area instead of either area currently designated, a request for such designation in accordance with the applicable subpart or appendix of this part;

(ii) Any other area boundaries that the State recommends be revised; and

(iii) Accuracy of the FTE primary care practitioner data and other data used in scoring.

(b) *Continuation of currently designated MUPs and primary care HPSAs.* (1) Except as otherwise provided in this section, the designation of a MUP or a primary care HPSA designated in the period up to three years prior to [the date of publication of the final rule in the **Federal Register**] will remain in effect for three years from the date of designation, unless part of the area covered by the designation is revised under this part.

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

(3) 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.

(4) 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) Subparts B and C are added to read as follows:

Subpart B—Criteria and Methodology for Designation of Medically Underserved Populations

§ 5.101 Applicability.

The following criteria and methodology shall be used to designate populations of geographic areas and population groups as medically underserved populations (or ''MUPs'') under section 330(b) of the Act.

§ 5.102 Criteria for designation of populations of geographic areas as MUPs.

The population of an urban or rural area will be designated as a medically underserved population, pursuant to section 330(b) 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(a); and

(b) The area's Index of Primary Care Shortage (IPCS) score, computed in accordance with § 5.103(b), equals or exceeds the designation threshold specified under § 5.103(b)(4).

§ 5.103 Methodology for designation of geographic areas as MUPs.

(a) *Rational service areas for the delivery of primary care services*—(1) *State-wide system.* Each State is encouraged to develop a State-wide system which divides the territory of the State into rational service areas for the delivery of primary care services within the State.

(i) A ''rational service area'' is a geographic area that—

(A) Is composed of one or more contiguous census tracts (CTs), block numbering areas (BNAs), or census divisions and does not include partial CTs or BNAs;

(B) The boundaries of which do not overlap with the boundaries of another rational service area defined by the State;

(C) In which travel time from the population center of the area to the population center of each contiguous area is typically greater than 30 minutes but less than 60 minutes, except where the circumstances in any of the following subparagraphs of this paragraph are shown to exist:

(*1*) Travel time from the population center of the area to the population center of a contiguous area may exceed 60 minutes in a frontier or other sparsely populated area, where topography, market, transportation, or other conditions and patterns lead to utilization of providers at greater distances;

(*2*) Travel time from the population center of the area to the population center of a contiguous area may be less than 30 minutes where established neighborhoods and communities within metropolitan statistical areas 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; or

(*3*) The State has defined a different travel time standard for use in its State, has provided a rationale for use of this travel time standard, and the travel time standard proposed is accepted by the Secretary as reasonable; and

(D) In which contiguous area resources are not reasonably available to the population of the area at the time of submission of the area for consideration as a rational service area. Contiguous area resources are deemed not reasonably available if any of the following conditions exists:

(*1*) Primary care practitioner(s) in the contiguous area are more than 30 minutes travel time from the population center(s) of the area;

(*2*) The contiguous area population-to-FTE primary care practitioner ratio is in excess of 1,500:1; or

(*3*) Primary care practitioner(s) in the contiguous area are inaccessible to the population of the area because of specific access barriers, such as—

(*i*) Significant differences between the demographic (or socio-economic) characteristics of the area and those of the contiguous area indicative of isolation of the area's population from

the contiguous area, such as language differences; or

(*ii*) A lack of economic access to contiguous area resources, particularly where a very high proportion of the area population is poor (*i.e.*, where more than 20 percent of the population or the households have incomes below the poverty level or more than 40 percent have incomes below 200 percent of the poverty level), and Medicaid-covered or public primary care services are not available in the contiguous area.

(ii) Each State-wide system of rational service areas shall be developed in collaboration with the Secretary and be approved by the State health department or other designee of the Governor.

(2) *Non-statewide system*. Until a State develops a State-wide system of rational service areas pursuant to paragraph (a)(1) of this section, the following areas will be considered to be rational service areas for the delivery of primary care services:

(i) Currently designated HPSA or MUP service areas, consistent with the requirements of § 5.5;

(ii) A county or a political subdivision equivalent to a county, such as a parish in Louisiana; and

(iii) Any other area that the Secretary determines meets the requirements set out at paragraph (a)(1)(i) of this section.

(b) *Index of Primary Care Shortage (IPCS).* (1) The IPCS score for an area is the sum of the area's score with respect to the scales for each of the following seven variables, with the following maximum scores:

(i) Population-to-primary care practitioner ratio (35 points);

(ii) Percentage of the population with incomes below 200 percent of the poverty level (35 points);

(iii) Percentage of the population consisting of racial minorities (5 points);

(iv) Percentage of the population that is Hispanic (5 points);

(v) Percentage of the population that is linguistically isolated (5 points);

(vi) The greater of the area's score for—

(A) Infant mortality rate (5 points); or

(B) Low birthweight births rate (5 points);

(vii) Low population density (10 points).

(2) Scales for each variable comprising the IPCS are determined by giving zero points to areas having values for the variable below a normative level for that variable, or below the 1996 national rate, where no norm is available, and allocating breakpoints between zero and the above maximum scores proportionally based on the number of counties with values above the norm or national rate.

(3) IPCS scores will be computed in accordance with paragraph (c) of this section and will be determined on both a first degree-of-shortage basis and a second degree-of-shortage basis.

(4) The threshold for designation of an MUP is an IPCS score of 35.

(c) *Calculation of specific IPCS variables*—(1) *Population count.* The population of an area is the total resident civilian population, excluding inmates 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) Adjustments to the population for the differing health service requirements of various age/sex population groups of the area shall be computed using a table based on national utitilization rates by age/sex provided by the Secretary and published from time to time in the **Federal Register**.

(ii) 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.

(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, Chamber of Commerce, or other local estimates. Estimates used must be adjusted to reflect the percentage of the year that seasonal residents are present in the area.

(2) *Counting of primary care practitioners.* (i) In determining an area's IPCS for designation as having a first degree-of-shortage, practitioners shall be counted as follows:

(A) *Practitioners included.* 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 counted in terms of FTEs, to the extent possible. In computing the number of FTE primary care physicians, the following adjustments shall be made:

(*1*) Each intern or resident counts as 0.1 FTE physician;

(*2*) Each graduate of a foreign medical school who is a citizen or lawful permanent resident of the United States but does not have an unrestricted license to practice medicine counts as 0.5 FTE physician;

(*3*) Hospital staff physicians practicing in organized outpatient departments and primary care clinics, shall be counted on an FTE basis, calculated as provided for in paragraph (c)(2)(iii) of this section;

(*4*) Practitioners who are semi-retired, who operate a reduced practice, or who provide patient care services to the residents of the area only on a part-time basis shall be counted on an FTE basis, calculated as provided for in paragraph (c)(2)(iii) of this section; and

(*5*) Each nurse practitioner, physician's assistant, or certified nurse midwife counts as 0.5 FTE. The Secretary may revise this weight upward if, based on such national practice data as the Secretary considers reliable, the Secretary determines that a higher weight better represents the average contribution of such practitioners.

(B) *Practitioners excluded.* The following shall be excluded from primary care practitioner counts under paragraph (c)(2)(i) of this section:

(*1*) Physicians 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*) Physicians 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 IPCS for designation as having a second degree-of-shortage, practitioners shall be counted as provided for under paragraph (c)(2)(i) of this section, except that the following practitioners shall also be excluded:

(A) Primary care practitioners who are providing medical services pursuant to a federal scholarship or loan repayment program obligation, such as obligations under sections 338A, 338B, 338I, and 338L of the Act; and

(B) Primary care practitioners who are employed by a federal grantee under section 330 of the Act.

(iii) *Counting of FTEs.* FTEs shall be computed as follows: for practitioners working less than a 40-hour week, every four hours (or ½-day) spent providing patient care, in either ambulatory or inpatient settings, counts as 0.1 FTE, and each practitioner providing patient care 40 or more hours a week counts as 1.0 FTE. Numbers obtained for FTEs shall be rounded to the nearest 0.1 FTE.

(3) *Computation of other variables.* (i) Data for the IPCS variables at paragraphs (b)(1)(ii) through (b)(1)(v) of this section

for an area shall be aggregated from the most recent available U.S. Census data for the counties, census tracts, and/or census divisions which comprise the area; more recent national updates thereof may be used, if available.

(ii) The IPCS variables at paragraph (b)(1)(vi) of this section shall be calculated based on the latest available five-year average 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 the subcounty area. For service areas which cross county lines, a population-weighted combination of the rates for the counties involved shall be used.

(iii) The IPCS variable at paragraph (b)(1)(vii) of this section shall be calculated using U.S. Census TIGRE data or the equivalent for the specific service area involved.

§ 5.104 Criteria for designation of population groups as MUPs.

(a) A population group may be designated as an MUP under section 330(b) of the Act, if it is demonstrated, by such data and information as the Secretary may require, that the following criteria are met, as applicable:

(1) The area in which the population group resides—

(i) Meets the requirements for a rational service area under § 5.103(a); or

(ii) In the case of a American Indian or Alaska Native population group, is an Indian reservation; or

(iii) In the case of a health center population group, is the catchment area of the health center, as defined by its application under section 330 of the Act;

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

(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 IPCS score for the population group that equals or exceeds the currently applicable designation threshold, as provided for by § 5.102(b). In calculating the IPCS score for a population group:

(i) The IPCS variables shall be calculated based as nearly as possible on their values for the applicable population group and service area, using such methodology as the Secretary may require; and

(ii) If the type of population group for which designation is sought is one for which one variable automatically achieves the maximum possible score, the point value assigned to that variable shall be distributed among the other variables, using such methodology as the Secretary may require.

(b) The following types of population groups may be designated as MUPs only if the applicable criteria of this section are met, as shown by such data and information as the Secretary may require:

(1) *Low income population group:* at least 1,500, or 30 percent, of the area's population, whichever is less, have annual incomes below 200 percent of the poverty level;

(2) *American Indian or Native Alaskan tribal population group:* the tribe is listed in the current listing of **Federal Register** by the Department of the Interior.

§ 5.105 Requirements for designation of MUPs recommended by State and local officials.

The population of a service area that does not meet the criteria at § 5.102(b) or § 5.104 may be designated as an MUP, if the following requirements are met:

(a) The area 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(b) and 5.104, 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 for designation contains such documentation as the Secretary may require.

Subpart C—Criteria and Methodology for Designation of Primary Care Health Professional Shortage Areas

§ 5.201 Applicability.

The following criteria and methodology in this subpart shall be used to designate geographic areas, population groups, and facilities as primary care HPSAs under section 332 of the Act.

§ 5.202 Criteria for designation of geographic areas as primary care HPSAs.

An urban or rural geographic area may be designated as a primary care HPSA where the following criteria are met:

(a) The area is a rational service area under § 5.103(a);

(b) The area's IPCS score equals or exceeds the designation threshold specified under § 5.103(b)(4); and

(c) The area's population-to-primary care practitioner ratio, as determined in accordance with § 5.103(c), equals or exceeds 3,000:1.

§ 5.203 Criteria for designation of population groups as primary care HPSAs.

(a) The following types of population groups may be designated as primary care HPSAs:

(1) A population group designated under § 5.104;

(2) A migrant and/or seasonal farmworker population, as defined in section 330(g) of the Act;

(3) A homeless population, as defined in section 330(h) of the Act; and

(4) A public housing resident population, as defined in section 330(i) of the Act.

(b) A population group specified in paragraph (a) of this section may be designated as a primary care HPSA where the following criteria are met:

(1) The area in which the population group resides—

(i)(A) Meets the requirements for a rational service area under § 5.104(a); and

(B) In the case of a public housing resident population group, the rational service area includes public housing, as defined under section 330(i)(1) of the Act; or

(ii) In the case of a migrant and/or seasonal farmworker population group, is an agricultural area, as defined by the Secretary;

(2) The area in which the population group resides does not meet the criteria for designation as a geographic area HPSA under § 5.202;

(3) The criteria in § 5.104, as appropriate to the type of population group under consideration, are met; and

(4) The population-to-primary care practitioner ratio determined in accordance with § 5.104(a)(3) equals or exceeds 3,000:1.

§ 5.204 Criteria for designation of medical and other public facilities as primary care HPSAs.

A public or private nonprofit medical facility or other public facility will be designated as a primary care HPSA, if the following criteria are met:

(a) *Federal and State correctional institutions.* (1) 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:

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

(ii) The ratio of the number of internees per year to the number of FTE primary care practitioners, determined in accordance with § 5.103(c)(2)(iii), serving the institution is at least 1,000:1. For purposes of this paragraph, the number of internees shall be determined as follows:

(A) 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 internees equals the number of inmates;

(B) 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 internees equals the average number of inmates plus the product of 0.3 multiplied by the number of new inmates per year; or

(C) 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 internees equals the average number of inmates plus the product of 0.2 multiplied by (1 + ALOS/2) multiplied by the number of new inmates per year. ''ALOS'' is the average length of stay, in fractions of a year.

(2) Physicians 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 § 5.103(c)(2)(iii).

(b) *Public or non-profit private medical facilities*—(1) *Criteria.* Public or non-profit private medical facilities will be designated as primary care HPSAs, if the following criteria are met:

(i) The facility is providing primary medical care services to one or more areas and/or population groups designated under this subpart as a primary care HPSA but is not located within a designated geographic area HPSA or within the rational service area for a designated population group HPSA; and

(ii) The facility has insufficient capacity to meet the primary care needs of the designated area(s) or population group(s) served.

(2) *Methodology.* In determining whether public or non-profit private medical facilities or other public facilities meet the criteria established by paragraph (b)(1) of this section, the following methodology will be used:

(i) A facility will be considered to be providing services to one or more designated areas or population groups, if a majority of the facility's primary care services are being provided to residents of geographic areas designated as primary care HPSAs under this subpart or members of population groups designated as primary care HPSAs under this subpart.

(ii) A facility will be considered to have insufficient capacity to meet the primary care needs of the designated area(s) and/or population(s) it serves, if there are more than 6,000 outpatient visits per year per FTE primary care physician on the staff of the facility.

Appendices A, D, E, F, G [Removed]

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

Appendix B [Redesignated as Appendix A and Amended]

7. Appendix B of part 5 is redesignated as new Appendix A of part 5 and the appendix heading is revised to read as follows:

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

Appendix C [Redesignated as Appendix B and Amended]

8. Appendix C of part 5 is redesignated as new Appendix B of part 5.

PART 51c—GRANTS FOR COMMUNITY HEALTH SERVICES

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

Authority: 42 U.S.C. 216, 254c.

10. 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. A special medically underserved population is not required to be designated in accordance with part 5 of this chapter.

11. 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 § 5.103(b) 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.

12. 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.

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