THE SECRETARY OF HEALTH AND HUMAN SERVICES
Washington, D.C. 20201

CHARTER

Negotiated Rulemaking Committee on Designation of Medically Underserved Populations and Health Professional Shortage Areas

AUTHORITY

Use of the Negotiated Rulemaking process to establish a comprehensive methodology and criteria for designation of Medically Underserved Populations (MUPs) and Health Professional Shortage Areas (HPSAs) was specifically mandated by Section 5602 of the Patient Protection and Affordable Care Act of 2010.

The Negotiated Rulemaking process is described at 5 U.S.C. §§ 561-569, the Negotiated Rulemaking Act of 1990, Public Law 101-648. Each Negotiated Rulemaking Committee is also governed by the provisions of Public Law 92-463 (5 U.S.C., App.), which sets forth standards for the formation and use of advisory committees generally.

OBJECTIVES AND SCOPE OF COMMITTEE ACTIVITIES

The purpose of the Negotiated Rulemaking Committee on Designation of MUPs and HPSAs is to provide advice and make recommendations to the Secretary of Health and Human Services, through the Administrator, Health Resources and Services Administration (HRSA), with respect to developing a new rule containing a revised methodology, criteria and process for such designations.

Programs Involving Designation: Entities wishing to apply for Health Center funding (under Section 330 of the Public Health Service Act) must show that they will serve a designated MUP. Communities seeking placement of a National Health Service Corps clinician (under Section 331) must show they are in a designated HPSA. In addition, certification by the Centers for Medicare and Medicaid Services (CMS) as a Rural Health Clinic (RHC) is available to entities located in a primary care HPSAs or geographic MUP or Governor-designated area, and otherwise meeting the RHC definition, while certification by CMS as a Federally Qualified Health Center (FQHC) is available to entities located in or serving an MUP and otherwise meeting the Health Center definition in Section 330 (but not receiving Section 330 grant funding). Other Federal programs also use these designations, such as the CMS program of Medicare Incentive (or bonus) Payments to physicians providing Medicare services in HPSAs. The programmatic responsibility for designation is delegated to the Office of Shortage Designation within HRSA's Bureau of Health Professions.

Reasons for Developing Revised, Comprehensive Methodology: The existing criteria for designation of MUPs and HPSAs date back to the 1970s, when they were developed to implement the provisions in Sections 330 and 331-2 of the Public Health Service Act. Some indicators are common to the two sets of criteria, but some are not, and the methods for taking into account the indicators considered are different in each. The list of designated HPSAs is required by statute to be updated on a regular basis, but no such statutory requirement exists for MUPs, and many MUP designations are now significantly outdated; to properly update them requires reexamining the criteria, since benchmarks for the various indicators involved have changed over time. Because the two lists of designated areas/populations are used by a number of Federal programs, it is important that they both be kept reasonably current; it is also important that the criteria used for both types of designation reflect underservice/shortage indicators currently relevant and available. Some find it confusing to have two sets of primary-medical-care-related shortage/underservice criteria, one for primary care HPSAs and the other for MUPs, so there is a need to either combine them or clarify how the two differ and make them more consistent. For these reasons, HRSA has been trying to develop a revised, more coordinated MUP and primary care HPSA designation methodology and procedure that would, at a minimum, define consistently the indicators used for both designation types; clarify the distinctions between MUPs and primary care HPSAs; and update both types of designation on a regular, simultaneous basis.

Previous Rulemaking efforts: Previously, attempts were made to revise the MUP and primary care HPSA criteria using the standard rulemaking procedures. One NPRM on this subject was published for public comment on September 1, 1998 (at 63 FR 46538-46555). Following HRSA review of the extensive public comments submitted on that NPRM, a totally new approach was developed with expert input. This second version was published February 29, 2008 (at 73 FR 11232-11281). Extensive numbers of public comments with multiple concerns were again received, resulting in a HRSA decision (announced in the *Federal Register* on June 23, 2008) to further reconsider the proposal; no final rule has yet been published. In an apparent effort to bring this rulemaking effort to a satisfactory conclusion, Congress in P.L. 111-148 mandated the use of the Negotiated Rulemaking process.

DESCRIPTION OF DUTIES

The Negotiated Rulemaking Committee on Comprehensive Methodology and Criteria for Designation of MUPs and HPSAs shall, with the assistance of a neutral facilitator, attempt to reach consensus on the content of a revised rule, including both the criteria and process for making such designations. (Consensus here is defined as unanimous concurrence, unless the Committee agrees to a different definition at its first meeting.) If the Committee reaches consensus on some or all aspects of a proposed revised rule, the Committee will recommend, through the HRSA Administrator, that the Secretary adopt the Committee's consensus as the basis for an Interim Final rule to be published in the *Federal Register*.

Following the public comment period, Committee members may also be asked to assist in recommending what further changes to the rule (if any) should be made in response to the public comments received. Final decisions will then be made by HRSA and the Secretary. A final rule is to be published within one year of the end of the public comment period.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Committee will provide advice to the Secretary of Health and Human Services through the Administrator, Health Resources and Services Administration.

SUPPORT

Management and support services for Committee activities will be provided by the Health Resources and Services Administration through the Bureau of Health Professions.

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

Estimated cost for operating the committee (over a period of one year: the last quarter of FY 2010 and the first three quarters of FY 2011) is $672,347. Estimated person-years of staff support required is a total of 3.3 FTE staff years, at an estimated total cost of $525,869.

Committee members who are not full-time Federal employees shall be responsible for their own expenses of participation in the Committee, except for those who are located outside the Washington DC metropolitan area and request reimbursement of travel expenses in order to participate on the Committee, and whose participation the Health Resources and Services Administration has determined is necessary to assure adequate representation of the interest or expertise involved. Such members may be reimbursed for travel expenses in accordance with Standard Government Travel Regulations.

DESIGNATED FEDERAL OFFICER

HRSA will select a (full-time or permanent part-time) Federal employee to serve as the Agency and Department representative on the Committee and as the Designated Federal Officer (DFO) for the Committee. The DFO will attend each Committee meeting, and endeavor to ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. Between meetings, the DFO will consult with officials of HRSA and other HHS components and officials any other Federal programs that may be affected by new MUP/HPSA Designation rules, to ensure that their concerns are taken into consideration. The Committee, including the DFO, will schedule or approve all Committee and subcommittee meetings.

The Secretary, through the HRSA Administrator and the DFO, will select a neutral Committee facilitator, who must be approved by the Committee, to Chair the Committee. Meeting agendas

will be prepared by the facilitator and JSI staff based on Committee discussion and consultation with the DFO, but must also be approved by the Committee.

In the event that, for whatever reason, the DFO is unable to fulfill some (or all) of the Committee responsibilities assigned to the DFO during part (or all) of the period during which the Committee is meeting, then the HRSA Administrator will temporarily appoint one or more permanent HRSA program staff members to assist in carrying out the duties involved.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings shall be held according to a schedule agreed upon by the Committee including the DFO, anticipated to be approximately once a month for a period of about six months. Notice of all meetings will be given to the public.

Meetings will be open to the public, except when determined otherwise by the Secretary or her designee, in keeping with guidelines under the Government in the Sunshine Act, 5 U.S.C. 552b(c).

DURATION

The Negotiated Rulemaking Committee will continue to operate until consensus is reached, or it becomes apparent that consensus cannot be reached prior to the target date of July 1, 2011 (or later date set by the Secretary), or is terminated according to the termination provisions below.

TERMINATION

The Committee shall terminate upon promulgation of the interim-final rule, or at an earlier date specified by the HRSA Administrator after consulting with the Committee, or by the Committee itself in the event that consensus is not achieved. The Committee may be reconvened following the receipt of public comments on the interim-final rule, at the option of the HRSA Administrator (and with approval by the Secretary), if deemed helpful to resolve outstanding issues raised by the comments. Alternatively, Committee members may be asked to comment in writing or by Conference Call.

MEMBERSHIP

The Committee shall be limited to 25 members, unless it is determined that a greater number of members is necessary for the functioning of the Committee or to achieve balanced membership, including the one government employee acting as DFO and representing HRSA/DHHS. A neutral facilitator, approved by the Committee, shall act as Chair. Members shall be chosen for their ability to represent the various interests that will be significantly affected by the rule, and/or for technical expertise related to indicators and methodologies potentially useful in defining medical underservice and health professions shortage. Members shall be invited to serve for the duration of the Committee.

SUBCOMMITTEES

The Committee may establish subcommittees that are composed of some members of the parent committee together with other individuals who have relevant expertise. The HRSA Committee Management Office will be notified upon establishment of each subcommittee, and will be provided information on its name, membership, function, and estimated frequency of meetings.

Any subcommittee must report back to the Committee, rather than providing advice or work products directly to the Secretary or her designee, since it is the Committee as a whole that is chartered to reach consensus.

RECORDKEEPING

Meetings will be conducted and records of the proceedings kept, as required by applicable laws and Departmental regulations. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. § 552.

FILING DATE

June 29, 2010

APPROVED:

June 29, 2010 /S/

Date Secretary of Health and Human Services