

## **SUMMARY MEETING MINUTES**

September 22 – 24, 2010

The Negotiated Rulemaking Committee (hereafter the “Committee”) was convened for its first meeting at 9:34 A.M. on September 22, 2010 at the Legacy Hotel, Rockville, Maryland. The meeting was facilitated by Lynn Sylvester and Dan LeClair of the Federal Mediation and Conciliation Service.

### **Committee members present:**

Marc Babitz\*  
Andrea Brassard  
Roy Brooks  
Jose Camacho\*  
Kathleen Clanon  
Beth Giesting  
David Goodman  
Daniel Hawkins  
Sherry Hirota  
Steve Holloway  
Barbara Kornblau  
Tess Kuenning  
Nicole Lamoreux  
Alice Larson  
Tim McBride  
Lolita McDavid  
Alan Morgan  
Ron Nelson  
Charles Owens  
Robert Phillips\*\*  
Alice Rarig  
Patrick Rock  
Edward Salsberg  
William Scanlon  
John Supplitt  
Don Taylor  
Elisabeth Wilson

\* Participation via teleconference

\*\* Represented by a designated alternate for all or parts of the meeting

## **WELCOME AND INTRODUCTIONS**

Dr. Marcia Brand, Deputy Administrator of the Health Resources and Services Administration (HRSA), welcomed the Committee and commended the members' agreement to participate at this meeting, on what she noted was the eve of the six month anniversary of the enactment of the Patient Protection and Affordable Care Act. She said HRSA hopes and believes this Committee can succeed where other efforts have failed to develop a revised, improved Designation Rule. The Committee contains the best and most qualified to accomplish this. She stated that the new Rule needs to be fair, flexible, clear, and appropriate.

Dr. Brand also asked the Committee to formally approve the facilitators engaged by HRSA, Lynn Sylvester and Dan LeClair of the Federal Mediation and Conciliation Service. The Committee approved these facilitators without objection.

Lynn Sylvester introduced herself and Dan LeClair and gave a brief overview of the Federal Mediation and Conciliation Service. In addition, Ms. Sylvester addressed some administrative matters, including hotel information for subsequent meetings, daily sign-in information for the Committee and members of the public, and the accessibility of handouts and documents following each meeting.

Eric Turer of John Snow, Incorporated (JSI), introduced himself and JSI staff present, and covered JSI's roles/involvement with HRSA and the Committee. JSI is handling presentation of technical aspects/options for defining MUPs and HPSAs, and will be conducting analyses requested by (or of interest to) the Committee, as well as handling logistics of the meetings.

Committee members introduced themselves, describing their relevant education and/or experience and their overall interests and concerns of the organizations they represent regarding the designation of medically underserved areas/populations and health professions shortage areas. Notable in these introductions were the commitments expressed to reach a satisfactory consensus and the recognition by the Members of the importance of the effort.

As the Federal representative on the Committee, Edward Salsberg expressed that HRSA does not think it "has all the answers" about how to do this and that HRSA really needs the Committee's help.

## **OVERVIEW OF THE NEGOTIATED RULEMAKING PROCESS**

Ms. Sylvester gave a presentation entitled "An Introduction to Negotiated Rulemaking." (Attachment 1) She discussed the differences between traditional rulemaking and negotiated rulemaking. As she noted, negotiated rulemaking

brings interested parties together to form a committee, discuss, and reach a consensus on a proposed or interim rule. Ms. Sylvester presented the Negotiated Rulemaking Statue definition of consensus as meaning a “unanimous concurrence on the interests represented” She suggested a working definition of “consensus” to mean that each Member is at least 70% comfortable with the consensus reached, and is 100% committed to that consensus. Once a consensus, is reached by the committee, the agency then agrees to publish a Notice of Proposed Rulemaking or as in this case, an Interim-Final Rule incorporating the Committee’s consensus. In turn, the committee members and the organizations they represent agree not to submit any adverse comments to the rule.

If a consensus is not reached on all issues, the agency should incorporate any areas of consensus in developing a proposed or interim-final rule. Additionally the agency will better understand the areas where consensus was not reached.

Committees established for negotiated rulemaking committees are governed by provisions of the Federal Advisory Committee Act (FACA) which, in part, requires, that all meetings be open to the public and all working papers, studies, agendas, meeting minutes, etc. made available to the full Committee are also available for public inspection.

## **REVIEW AND ADOPTION OF COMMITTEE GROUND RULES**

Dan LeClair provided “Draft Negotiated Rulemaking Committee Ground Rules” to the Committee for discussion, as well as “Sample Negotiated Rulemaking Committee Ground Rules and Protocols.” (Attachments 2, 3)

Some Members of the Committee were unaware that their participation meant that the organizations or interest groups they were asked to represent on the Committee would refrain from filing adverse comments to a proposed or interim final rule if a consensus was reached. After considerable discussion, the Committee came to a consensus that the committee members would consult with the constituents before the October meeting to clarify this requirement. The Committee agreed to come to the October meeting with a list of organizations they formally represent. The Committee also agreed that a “consensus” on a particular issue achieved at one Committee Meeting would be considered “tentative” and made final at the subsequent meeting (allowing for conferral with constituents.) In addition, the Committee confirmed the Agency would issue an Interim Final Rule, as opposed to a Notice of Proposed Rule Making (consistent with the FACA). The Committee also came to a consensus that the facilitators “shall” develop draft agendas.

There was also discussion over whether the Committee’s focus includes oral and behavioral health in addition to primary care. Mr. Salsberg, the Federal Representative, said that the intent is for this Committee to focus on primary

care-relevant designations. Future efforts could apply the lessons learned here to develop revised HPSA criteria for oral and behavioral health. While the Committee could theoretically agree to include oral and behavioral health in this effort, HRSA does not recommend it; in large part because the Committee, as established, does not include representation from the oral and behavioral health professional communities and there is insufficient time to address those issues.

Mr. LeClair and Ms. Sylvester agreed to revise the ground rules based on the Committee's input and provide the revised copy at the following day's meeting.

## **CURRENT APPROACH, LEGISLATION AND RULEMAKING HISTORY**

Mr. Turer, JSI, gave a presentation entitled "Current Approach, Legislation and Rulemaking History." (Attachment 4) The designations for Health Professional Shortage Areas (HPSA) and Medical Underserved Areas/Populations (MUA/P) were established in the 1970's. They are currently used by dozens of federal programs, as well as state and other non-federal programs. As Mr. Salsberg noted, dental care and mental health HPSAs are not intended to be considered by the committee. In addition, the Governor's Certified designations of Shortage Areas for Rural Health Clinic purposes does not fall within the purview of the legislation authorizing HPSA or MUA/P designations and thus is not to be considered by the Committee. Those designations specifically for the Rural Health Clinic program under State-specific criteria will exist regardless of the Committee's consensus.

Mr. Turer also briefly described the current methodologies for both HPSAs and MUA/Ps. In addition, he discussed the legislative requirements for HPSAs and MUA/Ps. Noting that the Committee was not convened simply to revisit or reconsider past attempts, but to develop a consensus new approach with the benefit of the experience of those past attempts, Mr. Turer gave a brief overview of the two previous Proposed Rulemaking efforts. Finally, he described to the Committee some of the preparatory work done thus far by HRSA and JSI to develop possible measures, approaches and options.

\*\*\*\*\*Day Two\*\*\*\*\*

## **OVERVIEW OF THE INTEREST BASED NEGOTIATION MODEL**

Mr. LeClair gave a presentation entitled "Interest-Based Problem Solving." (Attachment 5) This problem-solving model involves identifying relevant issues, interests, options, positions and criteria. The following definitions apply:

- "issue" is at the problem to be solved;
- "interest" is a concern or need behind an issue;
- "option" is often one of many possible solutions that satisfy interests, as opposed to a "position" which is a party's solution to the issue; and
- "criteria" which are objective standards to compare and judge options.

In examining options, there is a three- stage factor analysis to apply. Stage I examines the “feasibility factor”: whether the option is capable of being carried out. Stage II analyzes the “benefit factor”: whether the option satisfies or harms any important interests. Stage III examines the “acceptability factor”: whether the option will be received favorably by constituents of all parties and if not, whether the option can be modified to make it favorable. Mr. LeClair concluded his presentation with the thought that if the Committee cannot reach an agreement, they look at the “WATNA: the Worst Alternative To a Negotiated Agreement.” He observed that by failing to achieve a consensus the Committee leaves it up to HRSA to write the Rule without their guidance.

The Committee agreed to use the interest-based problem-solving model suggested and explained by Mr. LeClair

## **REVIEW OF POTENTIAL NEGOTIATED RULEMAKING ISSUES**

Mr. Turer, JSI gave a presentation entitled “Preliminary Presentation on Purpose, Principles, Issues and Process for Revised Rules.” (Attachment 6) He first identified the required principles for a revised designation rule based on statutory language, followed by proposed principles for a revised designation rule. In addition, he proposed two phases in the rule development framework. Phase I would include component identification, component measurement, combining components and preliminary designation thresholds. Potential issues to consider in Phase I include: need/demand measurement; capacity/supply measurement; high need/indirect/non-provider options; sub-population approaches; service area definition; HPSA-MUA/P distinction; and thresholds for designation. Phase II would include initial impact testing, refinement and final impact test and review. Potential issues to be considered in Phase II include alternate designations (safety net/facility), governor’s/exceptional process and implementation issues.

## **DISCUSSION OF REVISED GROUND RULES AND FUTURE MEETINGS**

Ms. Sylvester and Mr. LeClair provided the Committee with the red-line draft of the ground rules. The Committee made a few more edits to the ground rules. Because the Committee wanted to consult with their constituents before the October meeting, the ground rules will not be finalized until that time.

The Committee agreed for subsequent meetings to be only two days in length. Day one will begin at 9:30 a.m. and end at 6:00 p.m. Day two will begin at 8:00 a.m. and end at 4:30 p.m. The October and November meetings will be in Rockville, Maryland; however, HRSA will explore other location options for subsequent meetings, such as downtown Washington, DC.

## **APPLICATION OF THE INTEREST-BASED NEGOTIATION MODEL**

The Committee agreed to use the list of potential issues in Phase I as proposed by Mr. Turer. However, the Committee added nine additional (potentially overlapping) issues: underservice, access, barriers, facilities definition, impact testing, shortage, exceptions, renewal and do-no-harm. In addition, the Committee reached a consensus to remove “demand” from the issue of “need/demand requirement.”

The Committee agreed to prioritize the list of issues using a facilitation technique, employing paper dots. Each Committee member had three dots to use to identify their top priorities. The top three issues are to be discussed at the October meeting. Issues that receive no dots are still to be discussed but at some later date. The issues were prioritized as follows:

- Need measurement (19 dots)
- HPSA-MUA/P distinction (16 dots)
- Underservice (15 dots)
- Access (13 dots)
- Sub-population approaches (13 dots)
- Capacity/supply measurement (8 dots)
- Service area definition (8 dots)
- Barriers (5 dots)
- High need/Indirect/Non-provider options (1 dots)
- Facilities definition (1 vote) dots
- Thresholds (no dots)
- Impact testing (no dots)
- Shortage (no dots)
- Exceptions (no dots)
- Renewal (no dots)
- Do-no-harm (no dots)

With regard to the issue of need measurement, the Committee requested JSI to prepare a presentation on criteria for measuring need and the availability of data sources for doing so.

With regard to the issue of HPSA-MUA/P distinction, the Committee requested HRSA to prepare a presentation on each federal program using HPSAs or MUA/Ps and how resources flow from each program.

With regard to the issue of underservice, the Committee recognized the discussion is closely related to the discussion of need measurement.

The Committee would also like JSI to provide a list of data sources by the October meeting.

Minutes Approved on October 13, 2010

The Committee agreed to discuss the top three issues in the following order:  
HPSA-MUAP distinction, underservice and need measurement.

\*\*\*\*\***Day Three**\*\*\*\*\*

**DEVELOP AGENDA FOR OCTOBER MEETING**

The Committee agreed to have the HRSA and JSI presentations on the top three issues given before the Committee discusses each issue. Under each issue, the definition, methods and data will be discussed.

The next meeting will be held on October 13-14, 2010 in Rockville, Maryland.

**PUBLIC COMMENT**

Andrea Weddle, Executive Director of the HIV Medical Association (HIVMA), introduced herself and explained that the HIVMA has a number of HIV Medical Providers and Ryan White Providers. The Severity of Need Index recently developed in collaboration with HRSA has been critical in informing the Ryan White work, and she suggested it may be useful for the Committee to use as one resource for indicators/data potentially useful as part of MUP-HPSA designation.

Dr. Ernest Brown, a family physician, introduced himself and explained that his patients are primarily in Wards 7 and 8 of the District of Columbia; areas where medical need is great. Dr. Brown makes house calls to his patients and would like to ensure that individual physicians like him, and other physicians practicing in similar settings, are considered in the designation process.

**SUGGESTIONS TO MAKE FUTURE MEETINGS MORE SUCCESSFUL**

At Mr. LeClair's suggestion, the Committee made a number of recommendations to make subsequent meetings more successful. They include having a means of tracking and recording Committee consensus, doing a better job about checking with the rest of the Committee before implementing a suggestion made by one member, forming subcommittees, attempting to secure a better phone conferencing system, utilizing the "parking lot", brainstorming, getting more input from the subject-matter experts, and getting more input from the interest groups.

The meeting adjourned on September 24, 2010 at 10:20 a.m.

**SEPTEMBER 22-24, 2010 SUMMARY MEETING MINUTES  
ATTACHMENTS**

1. An Introduction to Negotiated Rulemaking (PowerPoint)
2. Draft Negotiated Rulemaking Committee Ground Rules
3. Sample Negotiated Rulemaking Committee Ground Rules and Protocols
4. Current Approach, Legislation, and Rulemaking History (PowerPoint)
5. Interest Based Problem Solving (PowerPoint)
6. Preliminary Presentation on Purpose, Principles, Issues and Process for Revised Rules (PowerPoint)