

CLINICAL LABORATORY COALITION

Committed to Ensuring Access to Quality Laboratory Services

September 7, 2006

Mr. Timothy P. Love
Director
Office of Research, Development and Information
Centers for Medicare and Medicaid Services
Room C3-20-11
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Mr. Love:

The Clinical Laboratory Coalition ("CLC"), a coalition of organizations representing the many sectors of the clinical laboratory, has prepared the attached paper that sets forth our collective areas of concern with the imminent implementation of the demonstration of competitive bidding in the first Metropolitan Statistical Area ("MSA"). This paper is being sent because the Centers for Medicare and Medicaid Services ("CMS") has provided no public forum since August 2005 for CLC members to comment on the implementation of the demonstration of competitive bidding.

When we met face-to-face with Mark B. McClellan, MD, Administrator, Centers for Medicare and Medicaid Services in early 2005, we were promised that the clinical laboratory community would have multiple opportunities to meet with CMS as the demonstration progressed. To date, CMS has provided only two opportunities in a public forum for the members of the CLC to learn about the proposed demonstration, to seek clarification of various aspects of the proposed demonstration and to express our areas of concern. The last public forum was held approximately one year ago. As recently as March 17, 2006, the CLC sent a letter to Dr. McClellan requesting a further opportunity to meet with Dr. McClellan to clarify CMS's intent to move forward with the demonstration. The CLC never received a response to our March 17, 2006 letter..

While the opportunity to comment on the application form for required and non-required bidders is appreciated by the CLC, we are confined to commenting on the details of the application form, the accompanying instructions and the Supporting Statement for Paperwork Reduction Act. Meanwhile, CMS released Publication 100-19, Demonstration, Transmittal 48, Change Request 5205 (July 28, 2006) that contains many aspects of the proposed bid design and implementation of competitive bidding. As you will see in the attached paper, CR 5205 has raised many issues for CLC members that could have been addressed through a face-to-face meeting or public forum, but no such opportunity was provided to CLC members.

If we understand CR 5205 correctly, CMS is planning to select the MSA, release the bid design and identify bid winners by January 1, 2007. Thus, we are concerned that there may be little or no time for CLC members to seek answers to the questions that we raise in the attached paper. We urgently request a meeting with CMS, after you have reviewed our attached paper, but before the first MSA is announced, to discuss these issues with you so that they can be resolved and our members can be adequately informed.

Thank you for your attention to this request.

Sincerely,

Advanced Medical Technology Association

American Association for Clinical Chemistry
American Association of Bioanalysts
American Clinical Laboratory Association
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Clinical Pathology
American Society for Microbiology
Clinical Laboratory Management Association
College of American Pathologists
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