

CLINICAL LABORATORY COALITION

Committed to Ensuring Access to Quality Laboratory Services

September 28, 2005

Ms. Linda Lebovic
Program Specialist
Mailstop C4-17-27
Demonstrations Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Lebovic:

The Members of the Clinical Laboratory Coalition (“CLC”)¹ would like to express our appreciation to the Centers for Medicare and Medicaid Services (“CMS”) for holding its recent Open Door Forum to present, and provide the public with a brief opportunity to comment on, the draft design for the Medicare Clinical Laboratory Competitive Bidding Demonstration. We also appreciate that the draft design took into consideration some of the clinical laboratory community’s recommendations, including requiring entities bidding in the demonstration areas to bid on all clinical laboratory tests available on the Medicare test menu.

As we stated when we met with you and Dr. McClellan in January, we believe that the active involvement of the clinical laboratory industry will ensure that the competitive bidding demonstration implementation is fair and that the results and conclusions derived from the demonstration project are fully reflective of all of the information generated by the demonstration. At that meeting, we were pleased to hear CMS staff say that there will be Open Door Forums “at every critical juncture of the project,” and that RTI will be present.

While RTI was present at the August Open Door Forum, the draft design was released to the public only four working days prior to the Forum. Given the tremendous level of interest in the demonstration project among members of the laboratory community, this short period of time was not sufficient to fully analyze the document. Moreover, allowing only one hour of questions at the Forum for 190 participants did not provide enough time for the level of interaction required to dissect the complexities of the issues involved.

¹ The Clinical Laboratory Coalition is comprised of organizations committed to ensuring access to quality laboratory services for all Americans. These organizations include: Advanced Medical Technology Association (AdvaMed), American Association of Bioanalysts (AAB), American Association for Clinical Chemistry (AACC), American Clinical Laboratory Association (ACLA), American Medical Technologists (AMT), American Society for Clinical Laboratory Science (ASCLS), American Society of Clinical Pathology (ASCP), American Society for Microbiology (ASM), Clinical Laboratory Management Association (CLMA), and College of American Pathologists (CAP).

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Given the above, we strongly urge you to allow another 60 days for the public to give thoughtful consideration to the draft design and submit questions to CMS. At the end of the 60-day period, we recommend that CMS hold another Open Door Forum – well in advance of the December 31st deadline for reporting to Congress – during which CMS would provide complete responses to the questions submitted by the public and allow for a more interactive session.

We sincerely hope that future Open Door Forums will provide us with ample opportunity to make concrete recommendations relative to RTI's proposals. In this instance, more time for preparation would have yielded a more fruitful Forum for both the clinical laboratory community and CMS. If we can be of further assistance to you on this or other clinical laboratory matters, please do not hesitate to contact any of the undersigned organizations.

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 Microbiology
American Society of Clinical Pathology
Clinical Laboratory Management Association
College of American Pathologists
Laboratory Corporation of American Holdings
Marshfield Clinic
Quest Diagnostics
Roche Diagnostics

cc: Mark McClellan
Mark Wynn

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