CLINICAL LABORATORY COALITION

Committed to Ensuring Access to Quality Laboratory Services

December 14, 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:

Thank you for meeting with representatives of the Clinical Laboratory Coalition ("CLC"), a coalition of organizations representing the many sectors of the clinical laboratory industry, on November 15, 2006 to discuss our collective areas of concern regarding the imminent implementation in the first Metropolitan Statistical Area ("MSA") of the demonstration of competitive bidding. Please express our appreciation to Bill Saunders, Linda Magno, Mark Wynn and Linda Lebovic for participating in the meeting. We very much appreciate the amount of time you gave to us on this matter of utmost importance to clinical laboratories and Medicare beneficiaries.

As you know, the CLC submitted a list of questions and concerns to the Centers for Medicare and Medicaid Services ("CMS") on September 13, 2006 which outlined the specific areas of our greatest interest and the basis for our concerns. The CLC is still waiting for a response from CMS to the September 13th letter.

The meeting on November 15th was very helpful in providing clarification regarding some of the issues raised in the September 13th letter. However, yet further questions emerged. We will not cover each and every issue in this letter that we addressed in our September 13th letter to you. However, we have identified the following additional issues as a result of our most recent meeting. First and foremost, we are concerned about the timing that was outlined by CMS for the implementation of demonstration of competitive bidding. Your comments in the meeting suggested that the posting by CMS of the Metropolitan Statistical Area selected for the demonstration triggers a process that begins with an Open Door Forum in the MSA and leads to a Bidders Conference sixty to ninety days later. Moreover, the bidding process will begin with the Bidders Conference and conclude with winning bidders selected within sixty to ninety days. CMS acknowledged at the meeting that it went through a six to nine month process to develop and implement the IT changes necessary to implement competitive bidding, inform its contractors and administer a "dummy" competitive bidding process to identify problems with the software.

The timing for implementation is insufficient to review the bid solicitation package, assess which tests will be performed in-house, identify and negotiate agreements for the provision of the other tests with reference laboratories, and develop pricing for each of these services. In contrast, DME suppliers were given more than a year after the release of the bid solicitation package to formulate and submit a bid. Due to the number of tests on the clinical laboratory fee schedule ("CLFS") and the fact that no one clinical laboratory will provide all services reimbursed under the CLFS, the process will be imminently more complex than the DME competitive bidding demonstration. Further, clinical laboratories will encounter the same IT issues encountered by CMS while still ensuring that quality clinical laboratory services are provided to Medicare beneficiaries and other patients. We believe that twelve months from the selection

of the first MSA is the minimum time needed for clinical laboratories to complete the process of responding to the demonstration and developing a responsive bid.

Second, the task of bidding is complicated by tracking services by the zip code of the Medicare beneficiary. This is not a field normally captured by clinical laboratories since it is not relevant to payment by most payers, including Medicare. System changes will have to be made to establish a field in order to collect this information prior to the development of a bid proposal. Further, clinical laboratories typically bid based on covered lives, types of services, physicians that are part of the contract and with a clear understanding of anticipated volume. Providing this information by zip code only identifies the Medicare beneficiaries being served but does not indicate which providers are being served within the zip code or the volume per beneficiary. This greatly hinders the ability of clinical laboratories to bid with any level of confidence which will hinder the quality and accuracy of the bids.

Third, the CLC and our member organizations are committed to providing quality care. Under competitive bidding, though, clinical laboratories may submit unrealistically low bids that could jeopardize patient care. We are concerned that the lack of information on the impending demonstration and its unrealistic timeframes will not provide clinical laboratories with sufficient time to develop financially viable bids. This may increase the likelihood that the quality of clinical laboratory services could suffer. Given that approximately 70 percent or more of patient diagnoses are based on a clinical laboratory test result, we are concerned that there is an increased likelihood of testing error that could result in delayed patient care or adverse consequences for a beneficiary.

Fourth, we remain concerned about access to services for Medicare beneficiaries. Identifying Medicare Beneficiaries by zip code does not indicate if they are residing in a skilled nursing facility (SNF), receiving home health care, a patient of a physician office, or require STAT tests. Each of these environments has very different service characteristics. Further, the cost of servicing each of these environment varies with SNFs requiring the greatest intensity of service due to the fact that most SNF residents are infirm, and require frequent phlebotomy services that are usually provided by the performing clinical laboratory on-site. This is in contrast to Medicare beneficiaries that have services ordered by a physician's office where specimens are frequently drawn at service centers maintained by the clinical laboratory service provider. Thus, the cost of providing clinical laboratory services can be substantially different within the same zip code. Further, CMS has paid scant attention to the long-term impact on Medicare beneficiaries if there are fewer providers of clinical laboratory services potentially resulting in all patients experiencing diminished access to care.

Due to these concerns, as well as those raised in our September 13th letter, we are once again making a request that an Open Door Forum be held prior to the selection of the MSA. This will allow for a full discussion of these issues and enable CMS to develop an approach that fully considers all of the issues and the potential consequences prior to identifying the MSA and releasing the bid solicitation package. Once the MSA is selected and the process has begun, delaying an Open Door Forum until later in the process will result in many unintended consequences that will have potentially grave impacts on Medicare beneficiaries as well as clinical laboratories.

Sincerely,

American Association of Bioanalysts
American Association for Clinical Chemistry
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
Laboratory Corporation of America Holdings
Mayo Clinic
Quest Diagnostics

Cc: The Honorable Charles Grassley
The Honorable Max Baucus
The Honorable Joe Barton
The Honorable John Dingell
The Honorable William Thomas
The Honorable Charles Rangel
The Honorable Nancy Johnson
The Honorable Fortney H. Stark
Keith Fontenot, Office of Management and Budget

4225104_v4