



# AMERICAN ASSOCIATION OF BIOANALYSTS

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June 20, 2006

Ms. Michelle Shortt  
Director  
Centers for Medicare & Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development-C  
Attention: Bonnie L. Harkless  
Room C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**RE: CMS-10193 and CMS-10133, Agency Information Collection Activities: Proposed Collection; Comment Request (Medicare Clinical Laboratory Competitive Bidding Demonstration)**

Dear Ms. Shortt:

On behalf of the American Association of Bioanalysts ("AAB"), I would like to thank the Centers for Medicare and Medicaid Services ("CMS") for the opportunity to submit written comments on the burden estimate and other aspects of the collection of information related to the Medicare Clinical Laboratory Competitive Bidding Demonstration. We appreciated the Open Door Forum that CMS held in Baltimore last August and were pleased that CMS incorporated a number of recommendations made by the laboratory community in its draft design, such as requiring bidders to bid on the full range of tests on the Medicare test menu and to submit multi-year bids.

As you know, AAB represents the owners, directors, supervisors, and technologists of community clinical laboratories. An improperly designed demonstration could irreparably disrupt existing laboratory markets and have a particularly negative impact on community-based clinical laboratories and the Medicare populations they serve. There are major segments of the laboratory market that are served almost exclusively by community laboratories. Nursing home patients are a leading example.

## **Application Form**

A properly designed demonstration begins with an application form that is designed to illicit the information needed from bidders to ensure that the demonstration is consistent with the Medicare statute and ensures Medicare beneficiary access to clinical laboratory testing. Unfortunately, CMS's application form is not as comprehensive as it should be to capture such information.

First, while it asks a number of questions related to geographic coverage and the test menu, the form does not ask any questions that suggest how CMS plans to ensure access to testing for highly vulnerable patients, such as those residing in skilled nursing facilities (SNFs). It is not

Page Two

clear from reading the form how CMS intends to prevent laboratories from using marketing and service strategies to target and serve only the easiest, low-cost, high-volume segments of the market.

Second, the form includes a "Subcontracting" section in which the applying laboratory would list any other laboratories with which it is establishing a subcontracting agreement. The form requires very little information to be provided under this section. Does CMS intend to provide bidders with a set of guidelines about the types of discussions they can have with other laboratories in developing a consortium? Has CMS identified specific individuals within the Department of Justice or the Federal Trade Commission assigned to monitor compliance with fair competition and antitrust laws during this demonstration?

Third, the form does not adequately probe bidders for information about the quality of the clinical laboratory services they provide. The form merely asks the laboratory to designate a "quality assurance staff member to serve as a point of contact," inquires as to the laboratory's status under the Clinical Laboratory Improvement Act program (CLIA), and requests the laboratory to list the CLIA-approved Proficiency Testing programs in which it participates. It does not provide a mechanism by which to thoroughly assess the quality of the laboratories before the demonstration begins so that an accurate measure of quality improvement or deterioration can be made at the end of the demonstration.

### **Burden Estimates**

In addition, AAB members are concerned that the burden estimates provided by CMS significantly underestimate the time and cost of completing the forms. The estimate of 100 hours is not sufficient for most laboratories to assess whether the facility is required to bid based on Medicare revenue from the previous year; assemble a complete financial statement; negotiate subcontractor arrangements with other laboratories and provide signed agreements; and determine capacity and bid price for all 1,100 tests on the clinical laboratory fee schedule. Moreover, the individuals needed to complete the forms include those responsible for billing, collections, operations, and legal counsel. None of the hourly rates for these individuals are included in the calculation of the financial burden.

As a professional association that cares deeply about the quality and accuracy of laboratory testing, AAB welcomes the opportunity to contribute to the success of the demonstration project. We look forward to hearing your responses to our questions and concerns. Thank you for your consideration.

Sincerely yours,



Mark S. Birenbaum, Ph.D.  
Administrator

cc: AAB Board of Directors