AMERICAN SOCIETY FOR CLINICAL LABORATORY SCIENCE

June 19, 2006

Office of Strategic Operations and Regulatory Affairs
Centers for Medicare and Medicaid Services
Division of Regulations Development-C
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: Bonnie L. Harkless

Re: CMS-10193 and CMS 10133

The American Society for Clinical Laboratory Science (ASCLS) is writing to comment on the April 21, 2006 *Federal Register* notice, "Agency Information Collection Activities: Proposed Collection; Comment Request," regarding the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project Bidding Form (CMS-10193, OMB#: 0938), the instructions to be used to complete the form and the Supporting Statement.

ASCLS is the nation's oldest and largest non-registry professional association for non-physician clinical laboratory professionals. The Society's mission includes promoting high standards of practice in the workplace and ensuring professional competence, while its ultimate goal is to ensure excellent, cost-effective laboratory services for consumers of health care. Our membership of nearly 11,000 includes clinical laboratory directors, managers, administrators, supervisors, and staff at all levels of practice in all disciplines.

ASCLS has a number of general questions about this process that we believe must be answered before this project commences:

- How will CMS handle the laboratory service needs of nursing homes if the small, local laboratories (either hospital outreach or privately owned) are not among the winners since these are the only laboratories that currently service this sector of health care?
- Physician office laboratories comprise the largest number of laboratories in this country with a 25-30% market share. How does their exemption impact the total savings anticipated from this demonstration project? How will those that are in the CBA be paid during the period of the project?
- How will quality of service be monitored during the project? ASCLS believes that the ombudsman role should be filled by a committee because the

- complexities of laboratory services are beyond the expertise of any one person. Will the monitoring be done through a Medicare contractor? The contractor must then comprise both the fiscal intermediary and the carrier functions so the contractor is knowledgeable of all types of laboratories

Supporting Statement

#12. Burden Estimates (Hours & Wages)
The number of hours per bidder is grossly underestimated. Responding to this bid will require at least twice the upper limit of the estimate (i.e. twice the 100 hours).

The annualized cost is based on the salary of a staff scientist/techonologist. This is not the level of laboratorian needed to assemble the information for this bid. The laboratory will have to dedicate a management position and enlist aid from the legal, financial, and information technology departments. The salaries for individuals from each of these departments will exceed the $23.66 per hour CMS has factored into the cost of this burden.

#3. Use of Information Technology
We believe that this section needs clarification. What is the intent of the section? Is it supposed to explain how to submit the application electronically? What is meant by "collection"; is this supposed to be the application? Does CMS have the ability to accept an electronic signature?

Bidding Instructions

A. Bidding Status

Under the "Rules", the definition of "Required bidders" should include the exclusions (physicians' office laboratories, hospital outpatients, etc) as CMS cannot assume that every laboratory in the bidding area will already know about the exclusions.

ASCLS requests that CMS clarify in the instructions that laboratories that don't bid do not jeopardize hospital outpatient and physician office patient reimbursement.

CMS should explain the "pre-determined cap on total Medicare demonstration test revenue" for the non-required bidders. Is this different than the $100,000? What happens when the non-required bidder exceeds the cap - $100,000? If the annual cap is reached in year one of the project, is the lab able to participate the second year or is the lab excluded for both years two and three.

C. GEOGRAPHIC COVERAGE AND TEST MENU

#3 The instructions need to explicitly state how to add information for the all of the specimen collection locations if the application is submitted in hard copy or electronically.

The amount of information required to be submitted with the entire application will be volumes; in hard copy, for instance, it could fill multiple binders. The instructions do not standardize the organization of all of the material so that CMS can readily compare the submitted information. If the application can be submitted electronically, what software must be used, should the files be submitted on CD ROMs, or a different hardware?

#6 This question requests the types of expansion plans CMS expects a required bidder to provide if they are to win the contract. The announced start of the first demonstration project is April 2007. It will be impossible for most hospital laboratories who would qualify as required bidders to build and install the information system, construct specimen collection sites, etc. in the time left between now and the beginning of the project. This requirement effectively excludes this type of laboratory and restricts participation to laboratories that already have the infrastructure in place. Thus CMS has fewer bidders from which to choose.

Bidding Form

In 1998, CLSI (then NCCLS), published a guideline to follow when choosing a referral laboratory, *"Selecting and Evaluating a Referral Laboratory; Approved" GP9-A, ISBN 1-56238-357-4*. The criteria in this document outline the process that a laboratory conducts to choose such services. This document is the product of a CLSI consensus using input from laboratorians in government agencies, commercial and state referral laboratories, hospitals and accrediting bodies. ASCLS believes that CMS should use the same criteria to identify winners under the bidding competition. We are concerned that this form does not ensure that the winning laboratories are efficient and effective at delivering quality laboratory services. However, since CMS did not follow this document, ASCLS has the following questions and concerns:

A. BIDDING STATUS

The major question is whether this form will be filled out in an electronic format that will allow for the expansion of answers. ASCLS believes the form should be available in an electronic format.

B. APPLICANT INFORMATION

The financial information, business relations, etc that are being requested in this section will not be consistent from bidder to bidder. The information provided by Hospital outreach laboratories will not reflect the capitalization of the laboratory but rather that of the parent institution or system. This doesn't tell CMS whether the laboratory is viable enough to finish the demonstration project. The way these questions are crafted seems more focused on independent laboratories and possibly presents these laboratories with an unfair advantage.

C. GEOGRAPHIC COVERAGE AND TEST MENU

#5 Subcontracting

Most laboratories do not have letters of agreement with all of the reference laboratories that are used, with the exception of the major subcontractor. Will the lack of letters of agreement preclude the bidding laboratory from sending the tests from this project to a referring laboratory with which they have no letter of agreement?

It is not clear whether new agreements can be made during the demonstration project if, for example, a participating laboratory gets a request for a new test and needs to find a new referring laboratory.

#6 Expansion

Since CMS has not indicated the volume that a winning laboratory can anticipate, it is difficult to describe the degree to which additional staff, instrumentation, facilities, etc should be added. CMS must make it clear before the bidding takes place whether a laboratory can subcontract after the winning bids have been awarded if volume exceeds their capacity?

D. CAPACITY AND BID PRICE INFORMATION

#4 Test Capacity and Bid Price

We recommend that the application form comes pre-populated with the HCPCS codes and the test names to standardize the bid. A pre-populated list would remove ambiguity as to which tests were included in the bid. This is particularly important because many of the HCPCS and CPT codes are not analyte specific. They are general codes for a method, such as immunoassay,and the tests performed by this method can stand vary

dramatically in price. Therefore CMS will have to list what tests they want for these method codes.

We do not believe that CMS has made clear what is wanted in Column E – Test Weight in this section of the application. There needs to be a better description as to how to calculate the test weight if the bidding laboratory is supposed to do that. ASCLS suggests that CMS calculate the Test Weight since that would standardize the results and not leave the calculation to the interpretation of each bidder.

E. QUALITY

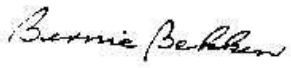
#2 Laboratory Registry
The question for this item asks for any affiliated laboratory. We urge CMS to define "affiliated" in the instructions. Does affiliated mean laboratories in your company or health system or the subcontractors of the bidding laboratory?

The only information in this section related to evaluating the quality of the laboratory is proficiency testing. The measurement of quality laboratory services is far more complex than proficiency testing results. Those results do not measure the laboratory's ability to provide the right information on the right patient at the right time. Therefore, ASCLS believes that CMS is not asking the appropriate questions to ensure that the winners can and do provide quality service. We again refer CMS to the CLSI document "Section 3 Criteria for Selection", which recommends that **before** entering into a contract for laboratory services, the purchaser of the services should have information about:

- 3.2.4 Turnaround times, including references from clients that document that laboratory's "compliance with its stated policy."
- 3.2.5 Communication systems that use "a standardized order entry or results reporting communication protocol.
- 3.2.6 Efficiency and timeliness of reporting results and the effectiveness of interpretations. Reports should include "age and sex adjusted reference ranges and/or other therapeutic and diagnostic reference ranges, where possible". The laboratory's turnaround time for reporting critical values, handling Stat tests, being available to answer questions about results, and responsive to handling "inappropriate/compromised" specimens are all criteria that should be queried before awarding any contracts.

The ASCLS recommends that CMS hold a working meeting soon to discuss the many open issues surrounding this process so they can be addressed in real time if this demonstration project is to move forward by the dates previously announced. ASCLS and its members thank you for your attention to these concerns and suggestions and reaffirm our willingness to work with you, your colleagues, the chosen contractor, and other stakeholders to ensure that the results of this demonstration project are as sound and definitive as possible.

Sincerely,



Bernadette Bekken, President
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