AMERICAN SOCIETY FOR CLINICAL LABORATORY SCIENCE

August 28, 2006

OMB Human Resources and Housing Branch
New Executive Office Building, Room 10235
Washington, D.C. 20503

Attention: Carolyn Lovett
Delivered by fax: (202) 395-6974

Re: CMS-10193 (OMB # 0938-New)

The American Society for Clinical Laboratory Science (ASCLS) is writing to comment on the July 28, 2006 *Federal Register* notice, "Agency Information Collection Activities: Submission for OMB Review; Comment Request," regarding the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project Bidding Form (CMS-10193, OMB#: 0938), the instructions for completing 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 is alarmed by the lack of time left for laboratories to effectively, efficiently and accurately submit a bid for this demonstration project. Contracting with vendors in today's post-HIPAA climate is arduous and time-consuming, typically taking 4 to 6 months to complete. Information Technology (IT) changes to run the zip code reports needed to determine status, to accommodate billing revisions, input from new contractors, and new patient electronic record creation will be expensive and protracted, as the new software will have to be tested at every turn.

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

- CMS should bear in mind that not all Medicare beneficiaries are mobile. Therefore when considering access issues, CMS needs to consider nursing home patients. 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?

- 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)
While we are heartened that CMS has recognized the number and complexity of individuals who will be needed to respond to this bid request, we believe that the estimate is still not realistic. The number of hours per required bidder is still grossly underestimated. Responding to this bid will require at least twice the upper limit of the estimate (i.e. twice the 100 hours).

Instructions for Completion

A. BIDDING STATUS

The instructions indicate that laboratories will determine whether they are required to bid based on the tests provided to Medicare Part B beneficiaries residing in the CBA. The only way to determine if the beneficiary resides in the CBA would be to sort them by their residential zip codes. Clinical laboratories can track patients based on insurance provider, not zip code. Medicare currently distinguishes patients based on the location of the ordering or referring provider and not by the residence of the beneficiary. Therefore the use of this criterion, just to determine if the laboratory is required to bid, will require a significant investment to modify the billing information technology. ASCLS believes that CMS should calculate the financial impact of modifying clinical laboratory billing systems to track beneficiaries by their residence, rather than by the location of the ordering physician, as part of the administrative burden of this demonstration project.

The instructions also indicate that, to determine bidding status, hospital laboratories should use tests provided to hospital non-patients. However, there is no clear definition of what is a hospital non-patient. The CMS Internet Only Manuals list multiple definitions of who is a hospital "non-patient." Some of the definitions focus on who draws the specimen from the patient; others focus on the fact that the patient is neither an inpatient nor an outpatient, while another definition focuses on the fact that the patient is not physically present in the hospital when the service is provided. Resolving this issue is crucial for hospitals to count the right patients for inclusion in the demonstration.

Unless this is clarified, hospitals may be unable to determine if they exceed the $100,000 in Medicare Part B revenues and are considered required bidders since they may not be able to identify whether a patient is an outpatient or non-patient. Therefore, it is essential that CMS decide and publish the definition of a non-patient that should be used for purposes of calculating Medicare Part B services covered under the demonstration before the project proceeds.

C. GEOGRAPHIC COVERAGE AND TEST MENU

#5.c. With this question, CMS is requiring the bidding laboratories to report the prices it receives from its designated subcontractor/reference laboratories. We question why CMS is requesting this information since the contractual relationship is between CMS and the bidding laboratory, not any of the subcontractor or referring laboratories. How is this information pertinent to the demonstration project?

#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 or modify existing information systems, 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. Not only is this exclusion wrong, it results in fewer bidders from which CMS can 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 the CMS form does not require the submission of any quality data with the application to 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:

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

#6 Expansion
Since CMS has not indicated the volume that a winning laboratory can anticipate, laboratories cannot realistically describe the degree to which additional staff, instrumentation, facilities, etc should be added. It will also be difficult to accurately state how the laboratory will meet the volume of service when no data is provided on what that volume will be. Therefore, 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 its capacity.

B2. QUALITY

9. Proficiency Testing
The only information in this section, in fact on the entire application, related to evaluating the quality of the laboratory is proficiency testing. The measurement of quality laboratory services is far more complex than proficiency testing (PT) results and additional quality measures were discussed by CMS in the Open Door Forum on competitive bidding in August 2005. PT 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 and handling Stat tests, availability to answer questions about results, and responsiveness to handling "inappropriate/compromised" specimens are all criteria that should be queried before awarding any contracts.

With these comments, the ASCLS reiterates its concerns about the viability of this demonstration project. We again want to express our extraordinary concern about the lack of time left for laboratories to effectively, efficiently and accurately submit a bid for this demonstration project. We recommend again 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 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,

Shirlyn B. McKenzie

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