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CMS
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

To Whom It May Concern,

On behalf of the Department of Pathology at the Virginia Commonwealth University Health System in Richmond, Virginia and as a laboratory professional, I am writing in response to 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 burden estimates provided in the Supporting Statement are grossly underestimated and fail to account for the hourly rates necessary to complete the forms. The estimate of 100 hours to complete the application is unrealistic and will not be sufficient for most laboratories to assess whether their facility is required to bid based on Medicare revenue from the previous year, to assemble a complete financial statement, to negotiate subcontractor arrangements with other laboratories and provide signed agreements, and to determine capacity and bid price for all 1,100 tests on the clinical laboratory fee schedule. Furthermore, laboratories will need the services of individuals responsible for billing, collections, operations, and legal counsel to complete this information. None of these individuals' hourly rates were included in the calculation of the financial burden.

The application does not ask enough questions to correctly ensure that quality laboratory services are maintained throughout the demonstration project, and there is little emphasis in the form on the collection of this information from bidding laboratories. The only information required is for a "Quality Assurance Contact," the laboratory's status under CLIA, and its Proficiency Testing program. These measures are too few. They oversimplify and fall short of determining a laboratory's capacity for quality.

The unresolved issues surrounding implementation of the competitive bidding demonstration project make accurate completion of the application form nearly impossible. For example, there is no clear definition of the terms "face-to-face encounter" or "non-patient" in the application instructions or in the Supporting Statement. There is also no statement regarding whether a bidder can bid separately or form a consortia and also be a subcontractor listed by another primary bidder. These are crucial decisions that will affect how our facility will respond to the competitive bidding demonstration and price services within the demonstration. Finally, CMS requests proprietary information about our facility, which is worrisome, as while there is a statement regarding the protection of confidentiality of the information, there is no statements regarding acceptance of liability if that information is released or disclosed to an unauthorized party.

In addition to the general comments provided above, as a member, I also support the detailed comments submitted by CLMA, the Clinical Laboratory Management Association, and refer you to those comments.

Thank you for the opportunity to comment on this important issue.

Sincerely,

Thomas J. Dilts 6/19/06

Thomas Dilts, Vice Chair-Operations and Administration

NICL LABORATORIES

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19 June 2006

Ms. Michelle Shortt, Director
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
ATTN: 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 NICL Laboratories (NICL), I wish to extend our appreciation to the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the burden estimate and other aspects of the collection of information related to the Medicare Clinical Laboratory Competitive Bidding Demonstration.

NICL Laboratories, headquartered in Northbrook, IL, is a privately owned independent clinical laboratory. NICL specializes in providing comprehensive laboratory services to long term care facilities, physician practices and hospitals. Currently NICL services approximately 200 skilled nursing facilities (SNFs), which is the equivalent of 30,000 beds. We have maintained our service initiatives to the nursing home industry when others have abandoned this market due to cost and labor intensity required to serve the Medicare populations resident within the facilities.

Upon review of the application form, we are concerned that it is not comprehensive enough to illicit information needed from bidders to ensure that the demonstration is consistent with the Medicare statue and ensures Medicare beneficiaries access to quality clinical laboratory testing. While the application form asks question related to geographic coverage and test menu, it is unclear to us how CMS plans to ensure testing for highly vulnerable patients, such as those residing in SNFs. It is not clear from reading the form how CMS intends to prevent laboratories from using strategies to target and serve only the easiest, low-cost, high -volume sectors of the market. Further, the form does not adequately ask bidders for information about the quality of the clinical laboratory services they provide. We feel that CMS must develop a mechanism that will thoroughly assess the quality of the laboratories before the demonstration begins so that appropriate measures of quality improvement or degradation can be made at the conclusion of the demonstration.

Finally, we believe that the burden estimates provided by CMS grossly underestimate the time and cost of completing the forms. A vast array of professionals is required to complete the forms, including financial operations, laboratory operations, billing collections and legal counsel. The hourly rates for these individuals are not included in the calculation of the financial burden.

Thank you for your consideration.

Sincerely,

Mary Ann Appleby, MEd, MJ
Strategic Program Manager