American Association of Bioanalysts/

National Independent Laboratory Association

WRITTEN TESTIMONY SUBMITTED TO THE

HOUSE SMALL BUSINESS COMMITTEEE

Competitive Bidding for Clinical Lab Services: Where's It Heading and What Small Businesses Can Expect

Mark S. Birenbaum, PhD

Administrator

AAB/NILA

906 Olive Street, Suite 1200

St. Louis, MO 63101-1434

(314) 241-1445

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Where's It Heading and What Small Businesses Can Expect
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The American Association of Bioanalysts ("AAB") and the National Independent Laboratory Association ("NILA") appreciate the opportunity to submit testimony to the House Committee on Small Business about the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project. We thank the Committee for holding a hearing on this important issue for Medicare beneficiaries and urge Congress to repeal Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that requires the Centers for Medicare and Medicaid Services ("CMS") to conduct this demonstration.

AAB is a national professional association whose members are directors, owners, managers, supervisors, technologists, and technicians in community clinical laboratories. NILA is a specialized membership section of AAB that is comprised of the owners of community laboratories. NILA is focused on small business issues, quality testing, best business practices, managing growth, expanding test menus, improving service, and acting on legislative and regulatory issues facing the laboratory industry. AAB/NILA and the major laboratory associations remain united in our opposition to this demonstration project.

Background

After nearly two decades and three major consulting projects, CMS still is unable to answer some of the most fundamental questions and concerns about competitive bidding for clinical laboratory services. The agency has failed to provide specific plans and assurances as to how:

- The quality of laboratory testing, and thus the accuracy of disease detection and diagnosis for senior citizens, will be safeguarded;
- Access to clinical laboratory testing for Medicare beneficiaries will be guaranteed, particularly for the most vulnerable populations, such as nursing home residents; and
- Market competition will be enhanced, not undermined.

CMS set aside two hours last week to meet with interested stakeholders. This was the first time in almost two years that CMS had conducted an open interactive meeting with our organizations. Over 400 individuals attempted to participate. However, there was only time for about 30 questions. CMS was unable to answer many of the fundamental issues regarding the project design. AAB/NILA provided a formal list of questions as long ago as October of 2005. We have yet to receive a substantive response.

CMS's inability to answer these questions and concerns in its latest draft "Bidders' Package" shows what we have known for a long time: CMS has been unable to design a bidding model for clinical laboratory services, whether limited regionally or nationwide, that will meet the objective of providing clinical laboratory services at fees below current Medicare reimbursement

rates, while simultaneously maintaining quality and access to care. There is no reason to proceed with a fundamentally flawed project. The CMS design will irrevocably alter the structure of the laboratory market in the test area, reduce provider choice, and is likely to curtail rather than enhance competition. ***It is therefore difficult to understand why the government is moving full-steam ahead with this health care project. Our senior citizens should not be forced to participate in an ill-designed experiment.***

"Competitive" Bidding is a Misnomer

The CMS project applies to independent clinical laboratory testing. The market for these services is highly concentrated. There are two giant national laboratories and a lot of small community laboratories. The CMS design is likely to further concentrate the market and reduce competition in a manner that might otherwise be prohibited by the Federal Trade Commission ("FTC") and the Justice Department ("DOJ"). If implemented nationwide, it is likely to accelerate the consolidation of the laboratory field and reduce rather than enhance competition.

In order to understand the impact of the proposed Medicare project, it is essential to understand the structure of the independent laboratory market. The Institute of Medicine highlighted this issue in its 2000 report, Medicare Laboratory Payment Policy. The report notes that:

> Market consolidation has radically changed the face of the independent laboratory sector. In 1990, no single laboratory company had a major market share; rather the eight largest companies accounted for 47 percent of the nationwide independent laboratory market. By 1999, two companies, Quest Diagnostics and LabCorp, largely through mergers and acquisitions, [now] account for 61 percent of the testing conducted by independent laboratories.

NILA has updated the distribution of market shares and converted this data into a pie chart that appears as Attachment A. This chart dramatically illustrates the highly concentrated nature of the laboratory market. Two large laboratories now control over 65 percent of all independent laboratory testing. The remaining community laboratories continue to be locally viable and provide essential services, but they are particularly vulnerable when the playing field is not level. The competitive bidding demonstration designed by CMS could irrevocably shift the remaining market shares to the two dominant laboratories. The government should not further fuel the fire of market concentration. It should be investigating strategies to create a more diversified and competitive market.

In 2003, the FTC and DOJ intervened in a merger between Quest and Unilab in California because of their concerns regarding market concentration and required Quest to divest a substantial number of patient service centers to maintain the competitive nature of the local independent laboratory market. Ironically, CMS may end up through this project creating the very type of dominant laboratory that the FTC and DOJ opposed.

A poorly designed project will further reduce competition in the communities selected. The federal government should not be allowed to redesign market shares in a manner that would have been prohibited if it was occurring as a result of a private merger or acquisition. If the market is further concentrated there may only be one dominant provider in each community. That provider will be able to control the supply of testing in the target region and the only constraint will be the Medicare fee schedule. Right now the laboratories compete with each other on quality and service. CMS's design will result in a market where there is no competition at all. One or two dominant providers will be established by the government and there will be significant barriers for new labs to enter the market. ***The result of this project could easily be government-sanctioned oligopolies, duopolies, or monopolies.***

National Labs, Not Community Labs, Will Be Able to Shift Costs to Other Areas

Small and regional laboratories will begin the bidding process on an uneven playing field. The demonstration then will exacerbate this situation further due to the fact that all, or nearly all, of an affected community or regional lab's Medicare business will be located in the selected Metropolitan Statistical Area ("MSA"). That means that the bid a community lab submits represents *all* of its Medicare work. In contrast, the large national laboratories can discount their bids in the demonstration zone and compensate for these "temporary discounts" through their work in other parts of the country, effectively shifting their costs elsewhere. There is nothing in the CMS design that would prevent large labs from submitting inordinately low bids in these test markets to gain market share. The bids they submit may bear no relationship to the price they would accept for all of their Medicare work.

The CMS Definition of a "Small Business" Exception is a Mirage

Given that the demonstration project threatens small community and regional clinical laboratories with extinction, it had been our hope that CMS would consult with the Small Business Administration ("SBA") to determine how to define the term "small business" for purposes of this demonstration. Unfortunately, CMS did not do so.

CMS's draft bidder's package indicates that CMS has established $100,000 in annual Medicare revenue as the outer limit for a small laboratory business that would be exempt from bidding. However, the SBA defines a "small business clinical laboratory" as one which has no more than $12.5 million in annual overall revenue. Typically, small laboratories depend on Medicare for at least 40 percent of their revenues, which would mean that a small business laboratory might have as much as five million dollars in annual Medicare revenue, not $100,000. CMS's flawed definition of a small business lab therefore leaves many community clinical laboratories unduly exposed in the demonstration project. ***To meet CMS's definition, a lab cannot just be "small," it must be nano-size.*** There are likely to be few if any community based laboratories in the demonstration area that can provide a full service menu of testing and meet the CMS definition. While there may be larger laboratories outside of the testing area that provide less than $100,000 worth of Medicare testing in the demonstration area, their businesses are not local. Ironically,

they will be favored over a smaller locally-controlled business that does all of its work within the demonstration area.

In addition, the CMS exception for small laboratories is far from an exception. These labs with less than $100,000 in Medicare business will be not be required to bid. However, they will be required to accept the bid winning price. This is particularly unreasonable. Out-of-state laboratories often avoid high cost local work such as nursing home testing. Applying their winning bid price to the community laboratories that have made a commitment to servicing all aspects of their local market is not fair. The CMS small laboratory exception is a mirage.

Small Business Laboratories Have Not Had a Seat at the Table

Not only does it appear that CMS did not consult with the SBA, the agency did not seek technical assistance from the small business laboratory community. At the beginning of the design phase, CMS established a Technical Expert Panel ("TEP"), selected by the agency to provide technical support for the demonstration project. While AAB/NILA understands the challenges of composing a panel with representation from all relevant sectors of the clinical laboratory community, we were disappointed that none of the selected TEP advisors represented the views of the truly local, independent community laboratory. Moreover, there was not a single non-physician laboratory director on the TEP. Given these facts, at the end of 2004, AAB/NILA sent a letter to CMS requesting that the agency consider adding one or more additional representatives to the TEP to ensure that the panel reflected the full range of clinical laboratory stakeholders. Unfortunately, the agency did not follow through on this request.

Serving a Resource-Intensive Population: Nursing Home Residents

Nursing home patients are particularly at risk in this demonstration. The large publicly traded national laboratories have largely withdrawn from this work. The high cost of sending in personnel to draw blood and deliver results within several hours, and the limited Medicare reimbursement for on-site services and travel, have driven the national labs to seek high profit margins elsewhere. If community and regional clinical laboratories are driven from the market by the government, there will be no labs remaining that are interested in servicing nursing homes and their vulnerable residents.

CMS's draft design does not indicate that the agency will force winning bidders to service particular nursing homes. While the bid design may ultimately suggest or even require service to all sites in the area, there is no clear mechanism for enforcing this type of requirement. To subject this vulnerable population to a new laboratory that is not committed to the nursing home community is a serious design flaw. The bidding design must include a mechanism to ensure that this patient population is protected. The ability to provide immediate turnaround, STAT testing is critical. That is exactly the type of resource-intensive service that many nursing home residents need and is provided by community laboratories.

Preserving Community and Regional Laboratories as Critical Health Infrastructure

Without the continued presence of community and regional laboratories, there also would be a significant additional problem: the ability of the nation's local laboratory infrastructure to respond to infectious disease outbreaks, bioterror events, and natural disasters would be seriously compromised. While a distant laboratory may have the ability to process tests, it might not have the infrastructure or local resources to maintain the same level of service with regard to the collection or processing of the specimens. Moreover, a distant laboratory will simply not be available if our transportation systems become impaired due to natural disasters such as hurricanes or terrorist attacks like on September 11th.

Administrative Burden for Small Laboratories

The design complexity of the bidding process and the reporting to CMS required of winning lab bidders will require a large investment in personnel and infrastructure, potentially making it cost prohibitive for even the "winners" of the bid process, particularly if they are community laboratories. CMS significantly underestimates the time and cost of completing the forms. Laboratories will have 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 almost every test on the clinical laboratory fee schedule. Moreover, the individuals needed to complete the forms would include those responsible for billing, collections, operations, and legal counsel. The bid design requires community laboratories to submit audited financial reports to CMS. It is estimated that the cost of completing such an audit could be as much as $25,000. This is a small amount for a large laboratory but it is a significant burden on a small business.

Conclusion

AAB/NILA respectfully requests that Members of the House Small Business Committee work with their colleagues on the Ways and Means and Energy and Commerce Committees to halt the competitive bidding demonstration for Medicare clinical laboratory services. We again thank the Committee for the opportunity to submit this testimony.

For more information, please contact AAB/NILA Administrator Mark Birenbaum at (314) 241-1445.