

Quest Diagnostics Incorporated

815 Connecticut Avenue NW
Suite 330
Washington, DC 20006
202.263.6260
www.questdiagnostics.com



U.S. House of Representatives
Committee on Small Business
Hearing

***“Competitive Bidding for Clinical Lab Services;
Where’s it Heading and What Small Businesses can Expect”***

July 25, 2007

Statement of Quest Diagnostics

Quest Diagnostics is pleased to submit comments to the House Small Business Committee on the hearing “Competitive Bidding for Clinical Lab Services: Where’s it Heading and What Small Businesses can Expect.”

Quest Diagnostics is the nation’s leading provider of diagnostic testing, information and services that patients and doctors need to make better healthcare decisions. The company offers the nation’s broadest access to diagnostic testing services through its network of principal laboratories in more than 35 major metropolitan areas across the United States and in Mexico and the United Kingdom, and provides interpretive consultation through its extensive medical and scientific staff. In addition, the company operates 150 smaller, rapid-response laboratories and 2100 Patient Service Centers. On a typical workday, the company processes approximately 550,000 test requisitions – each containing orders for multiple tests. The company performs testing ordered on more than 150 million requisitions each year.

Quest Diagnostics has extensive experience with the Medicare program and is familiar with the proposed competitive bidding demonstration project. Quest Diagnostics strongly opposes the CMS competitive bidding demonstration project for many reasons and has serious concerns regarding the negative impact competitive bidding will have on small businesses, including those that compete with Quest Diagnostics, such as small laboratories and hospital laboratories. Despite being the largest laboratory business in the United States, Quest Diagnostics does not compete in every market or in every category of laboratory services. For example, Quest Diagnostics is not as active as local laboratories in providing services to nursing home residents or home bound patients. The company has serious concerns about how vulnerable Medicare patients in these settings will obtain services if local laboratories are not winners. Furthermore, since very few laboratories will be winners and because Medicare is an important payer for all laboratories, some laboratories that are excluded from performing demonstration tests may begin to close patient service centers and rapid-response laboratories or close down altogether. As a direct result, competitive bidding administered by CMS for clinical laboratory services would decrease Medicare beneficiaries’ access to laboratory services, by forcing patients to travel longer

distances for the collection of their specimens. Alternatively, physicians may be burdened with collecting specimens in their own offices, adding to their cost of providing health care services.

We do not dispute the possibility that competitive bidding can work in the private payer market. However, the Medicare program has not listened to input from laboratories and has designed a demonstration that is so flawed that it should not be permitted to proceed. Just a few of the many problems with the design are highlighted below:

- 1) CMS cannot commit to providing any specific volume of testing to winners, because it does not know and will not be able to determine the true volume of demonstration tests (due to excluded laboratories and service areas) and because it does not know in advance of the bidding how many winners it will award. How can a bidder bid without knowing the volume of tests at stake – so it can estimate its costs?
- 2) CMS has not defined in advance the level or scope of services but indicates that it will negotiate these issues with the winners as part of determining the “terms and conditions.” How can a bidder bid without knowing all the terms and conditions in advance, such as whether it must respond to nursing home requests or calls to collect and test specimens from a home bound patient at 3 AM?
- 3) CMS keeps changing the model on how a bidder must bid and how CMS will pay for tests performed by reference laboratories – a sizable percentage of the testing offered by most laboratories – particularly smaller laboratories. It is impossible to create a financial model under the circumstances.
- 4) CMS pricing for the demonstration tests will be calculated using an algorithm of the winning bidders’ bid prices. Yet CMS does not consider what happens if the pricing is based on bids submitted by reference laboratories or new labs that must substitute for initial winners that might drop out of the demonstration or be forced out due to quality concerns. How will CMS account for higher costs of these laboratories compared to the initial bids? Moreover, CMS pricing for reference tests does not appear to deal with repricing the demonstration fee schedule, if the reference laboratory is not a winner and the winning bidder has to find another supplier for esoteric tests.

Clearly, no laboratory can submit a bid without knowing such basic facts as volume, service levels, and lab-to-lab referral arrangements, none of which have been clarified by CMS or its contractor.

A competitive bidding model for Medicare beneficiaries is particularly complex because of the nature of the beneficiaries and the complexity of Medicare coverage rules, which CMS indicates will still remain in place during the demonstration. Experts who have studied competitive bidding for clinical laboratory services, such as the Institute of Medicine (IOM), considered competitive bidding for laboratory services and specifically did not recommend it. They recognized that it would severely undermine the quality and access of important laboratory services to vulnerable Medicare patients.

CMS seems to be willing to overlook the potential – some would say likely - risk to quality and access for its vulnerable Medicare beneficiaries in order to proceed with this test, seemingly without recognizing that the face of competition will be irrevocably changed in the demonstration sites within just a few months of the commencement of the demonstration. Today’s laboratory market is healthy and competitive. National laboratories compete with

hospital laboratories, independent privately owned laboratories and physician office laboratories. At the same time, these different laboratories bring diverse strengths and capabilities to the market that are critical to the overall complex service delivery system and that ensure all Medicare beneficiaries have adequate access to vital laboratory testing. However, CMS appears almost exclusively focused on price and capacity, though it claims it will consider other factors when selecting winners. Even if CMS does take additional factors into account, most laboratories will not be winners and many of the small laboratories that are not winners will not be able to sustain themselves following the loss of Medicare revenue. We join with small laboratories, hospital laboratories, and esoteric and niche laboratories in calling for repeal of this flawed clinical laboratory services competitive bidding demonstration project.

We thank the House Small Business Committee for its attention to this important matter and for their actions to repeal the demonstration project.