

**Congress of the United States**  
**U.S. House of Representatives**  
**Committee on Small Business**  
2361 Rayburn House Office Building  
Washington, DC 20515-6315

STATEMENT

of the

Honorable Nydia M. Velázquez, Chairwoman  
House Committee on Small Business

Hearing on Competitive Bidding for Clinical Lab Services: Where is it Heading and  
What Small Businesses Can Expect  
July 25, 2007

Clinical laboratory services are an essential component of quality health care. They provide physicians with objective data needed to help them diagnose, treat and monitor diseases and other medical conditions. Often, laboratory testing is done on the same day the specimen is received and the results reported on the following day.

As with many parts of our health care system, small businesses play a critical role in this area. The laboratory industry is dominated by small businesses who work with hospitals, nursing homes, and health facilities to provide care. In fact, nearly ninety percent of the industry is made up of small firms.

The clinical lab industry is a highly complex and integrated structure. Numerous relationships exist between diverse small and large firms, which rely on one another to ensure high quality lab services are provided. The industry did not develop quickly and the market has allowed for labs providing differing services to thrive.

Today, we will hear how CMS's competitive bidding project threatens to dismantle this system overnight. It seems that CMS has ignored congressional intent and moved forward with a project that creates a cumbersome bureaucracy. As proposed, it could make it impossible for small labs to survive.

CMS argues that small businesses are protected because labs with less than \$100,000 of Medicare business are exempted from the project. This threshold will not save small businesses – to suggest otherwise is disingenuous.

In practical terms, virtually all independent and most hospital labs doing business in the demonstration area will exceed the limit. Even the smallest labs have business revenue of at least \$1 to \$2 million annually. And for those that are below the threshold, the new payment structure will mean that they are paid Medicare fees that simply won't cover costs.

➤ Despite pleas from labs both big and small, CMS has ignored the concerns of these businesses. We heard a similar tale last week. CMS failed to solicit the input of small pharmacists when developing the price formulation for generic drugs. The result will be the same in that small health care providers cannot survive.

When small labs go out of business, they stay out of business. Because of the investment in equipment and specially trained personnel, a laboratory cannot shut its doors temporarily and start up again when circumstances change. This will leave vulnerable patient populations with compromised access to lab services.

In short, instead of competition deciding market share, CMS will determine market share winners and losers, and the losers are small local businesses. It is apparent from the written testimony that the agency has not engaged them adequately. While CMS will say that Congress mandated the action, it clearly never ordered them to ignore the input of the stakeholders.

Competitive bidding for laboratory services in any form could have wide reaching implications for the healthcare industry. Medicare beneficiaries receive over 250 million laboratory tests each year. And while these services account for less than 2 percent of Medicare spending, they impact an estimated 60 percent of all medical decisions.

Given this broad impact, important questions must be answered today on whether this project will actually work. I look forward to today's testimony and thank the witnesses for their participation.