

**United States 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**

**Testimony of
Ronald Weiss, M.D., M.B.A.
President, ARUP Laboratories
Chairman of the Board, American Clinical Laboratory Association**

Chairwoman Velazquez, Congressman Chabot, members of the committee, I thank you for this opportunity to testify on an issue that has great importance and significant ramifications for patients.

I am Ronald Weiss, president of ARUP Laboratories, a large commercial reference laboratory at the University of Utah serving hospital and independent laboratories across the country. As a pathologist and physician, I am a fellow in the College of American Pathologists and in the American Society for Clinical Pathology. I am President-Elect of the American Pathology Foundation, a past member of the Executive Council of the Academy of Clinical Laboratory Physicians and Scientists, and have twice served as Chairman of the Board of the American Clinical Laboratory Association (ACLA). It is my honor to testify today on behalf of ACLA.

More pertinent to the subject at hand, I have served on CMS’ Technical Expert Panel for the demonstration project.

Madam Chairwoman, the concept of competitive bidding for laboratory services is not a new idea. The Department of Health and Human Services has struggled for almost two decades to develop a competitive bidding demonstration project. It is not an idea that has improved with time. Repeated attempts to move in this direction have each failed because of the complexity of the task, because of the huge destabilizing and anti-competitive effect it will have on the laboratory industry and, most importantly, because it would severely undermine the quality and access of laboratory services to Medicare beneficiaries.

The competitive bidding model being considered will take a huge toll on small business operations and vulnerable populations including nursing home residents and home-bound patients.

This point of view has unanimity within the clinical laboratory community – small labs, large commercial labs, niche service labs and hospital-based labs. It speaks volumes that, when the Centers for Medicare and Medicaid Services released the 75-page Bidders Package last week, there were over 80 people present at the open door meeting and another 400 on the call-in line. All of those who made statements at the forum were opposed to the demonstration project. This unanimity exists because all sectors of the laboratory industry play a role in providing Medicare beneficiaries approximately one million clinical laboratory tests every single day, and they understand that no competitive bidding design can accommodate the complexities involved in keeping this service seamless and exemplary.

There is a clear contradiction in terms at work here. This is called a competitive bidding model, but it is clearly anti-competitive and it will drive a significant number of clinical labs out of business.

Competitive bidding in the private sector establishes service commitments and acceptable prices through negotiation. For laboratory services, this depends upon a clear knowledge of the volume of needed services, streamlined submission and payment processes, and consistency in lab-to-lab referral arrangements, none of which exist in this demonstration project.

Extensive analysis of this demonstration project by the American Clinical Laboratory Association yields a number of clear conclusions. Let me briefly mention five of the most striking.

Number one, all laboratories, especially small, local, independent and hospital outreach laboratories with limited resources, will find it impossible to deal with the extraordinary complexity of the bidding process. This flawed design will prove fatal to them as they will likely lose their Medicare reimbursement and be forced out of business.

Number two, many of those small labs who – and I use the term very loosely – “win” the bidding process will lose because they will be forced to accept bids well below their already-conservative profit margins, forcing them to close their doors.

Number three, as more labs have difficulty staying in business, vulnerable patient populations will find access to laboratory services seriously compromised.

Number four, the demonstration could severely disrupt the existing complex web of arrangements between local labs that service Medicare patients by performing many common tests, and reference labs, such as ARUP, that perform many of the more complex tests for them.

Some of these high complexity, esoteric reference labs are thousands of miles from the demonstration area, yet they will have to bid in the demonstration area if they provide more than \$100,000 in services. It is not clear that these labs will even know that they are required to bid and win in order to continue to be reimbursed by Medicare for services provided in the demonstration area.

And, finally, number five, other reference labs may choose not to bid, or may not be selected as winners if they do. This would disrupt existing, complex lab-to-lab referral arrangements and create a situation in which local labs simply cannot put together a winning bid on all 358 tests specified in the project, leaving them out of business and beneficiaries without access to these medically important tests.

In the final analysis, Madam Chairwoman, one has to ask the question: is there a compelling need for such a demonstration project? Medical laboratory services account for only 1.7 percent of Medicare spending and payments for those services have already been reduced by roughly 40 percent in inflation-adjusted terms between 1984 and 2004. If the goal is to seek savings, those savings have already been realized and this model will only add a substantial and cumbersome administrative burden for CMS while disadvantaging beneficiaries and their health care providers.

America's clinical labs have a simple objective – to provide accessible, quality medical services to patients and to the health care community. Laboratory medicine is a value proposition, driving 70 percent of medical decision-making at two to three percent of total health care costs. As a complex medical service provided by specialized physicians and laboratory professionals, it is not a commodity. This demonstration project clearly does not help us achieve the goal of preserving this service objective, and should be repealed before it is allowed to begin. The Medicare Physician Fee Schedule is not competitively bid, nor should it be, and the Clinical Laboratory Fee Schedule should not be either. I would not like to look back and take any solace in the fact that Medicare beneficiaries' laboratory services went to the lowest bidder, while the true cost was poorer quality and limited access.

Thank you for this opportunity and I look forward to your questions.