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House Small Business Committee

Hearing on Competitive Bidding for Clinical Lab Services

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Testimony of

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Chairwoman Velazquez, Ranking Minority Member Chabot and Congressman Braley, thank you for the opportunity to testify today on behalf of the Clinical Laboratory Management Association (CLMA) regarding the proposed demonstration project to utilize competitive bidding to procure clinical laboratory services for Medicare Beneficiaries covered under Medicare Part B. CLMA's membership is comprised of approximately 4,300 clinical laboratory managers and supervisors serving in hospitals, independent clinical laboratories, skilled nursing facilities, physician offices and research facilities, as well as representatives from the medical device industry and consultants that serve all sectors of the clinical laboratory industry. While the majority of CLMA's members are hospital-based, we do attempt to present a perspective that is shaped by all sectors of the clinical laboratory industry.

The Competitive Bidding Demonstration Project was mandated by Congress as part of the Medicare Modernization Act (MMA) in 2003. Competitive Bidding for clinical laboratory services has been proposed for over 20 years and CMS has made multiple attempts to design a workable demonstration. All previous attempts failed, not for lack of trying, but because of the enormous complexity of the project and the inability to guarantee the quality of the clinical laboratory services and ensure patient access to health care.

We understand that the Centers for Medicare and Medicaid Services (CMS) is mandated by the MMA to implement the Competitive Bidding Demo and that the agency is obligated to again attempt the demo. The MMA stated that the purpose of the demo is to "test whether competitive bidding can be used to provide Part B lab services at cost savings to the Medicare program while maintaining quality and access for Medicare Beneficiaries". While this may sound like a good idea and appear to be reasonable, the demo project as designed by CMS is flawed and if allowed to proceed will be devastating to the clinical lab industry and will result in quality and access issues for our Medicare beneficiaries.

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Following the CMS Open Door Forum on Monday, July 16th, intended to inform the clinical laboratory industry regarding the proposed Bid Design and to respond to our concerns, we concluded the session with more questions than answers and a firm conviction by **all labs** –large, small, national, regional, urban, and rural- that this project has to be stopped before great harm is done both to Medicare Beneficiaries and to the clinical lab industry as we know it.

My perspective on competitive bidding is shaped by my current role as a lab manager and my 35 years experience at a small, community based independent lab in Dubuque, Iowa serving hospitals and physicians in a 50 mile radius of Dubuque. United Clinical Laboratories (UCL) is the consolidation of laboratory services at 2 competing hospitals, one with a small rural hospital 25 miles from Dubuque, and a pathologist owned independent laboratory. United Clinical Laboratories was formed in 1986 after almost 10 years of knowing it was the "right thing to do", but difficult because of the competitive mind-set of the hospitals. UCL is jointly owned by the two hospitals and the pathology group. We have just celebrated our 20th anniversary as a very successful, nationally recognized, joint-venture laboratory system. The consolidation of laboratory services in Dubuque resulted in overall cost reductions for both hospitals, expanded lab services to the community, allowed for more specialized testing to be done in Dubuque rather than referred out of town, allowed for the purchase of highly sophisticated equipment and made better use of highly skilled and hard to find technologists… all with no loss of jobs. Our non-hospital clients range in size from a large, multi specialty clinic in Dubuque with 100 physicians and 7 satellites in rural areas to office practices of 1 or 2 physicians. We have built our business, not on price, but on our recognized quality and service. We are neither the cheapest nor the most expensive option, but we have been deemed the BEST option for clinical lab services by our almost 200 clients. One Joint Commission inspector recently told us he considered our laboratory a "gold standard" and one of the best labs he'd ever seen. If you've ever been through a grueling Joint Commission inspection, you know that was a supreme compliment.

As far as breakdown of our patient mix, since we are owned by the hospitals and provide all hospital laboratory services, the majority (65%) of our testing and revenue comes from hospital inpatient work. The remaining 35% is from our successful outreach testing. Of the outreach testing, 38% of the test volume is from Medicare patients.

Competitive Bidding would be bad for all labs -large, national, publicly traded labs (Quest, LabCorp), small and large hospital labs, large regional labs (Marshfield Clinic, Cleveland Clinic), but most of all, the small, community labs like mine, many of which will be put out of business. I would like to focus on just what could happen to United Clinical Laboratories under competitive bidding. The current demo requires all labs receiving at least $100,000 in revenue from Part B Medicare reimbursement to bid. My laboratory would definitely qualify as a required bidder……the ONLY laboratory in Dubuque that would have to bid. What's concerning to me is that there will be drastic consequences if I am a "bid loser" and also significant consequences even if I am a "bid winner."

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If United Clinical Laboratories is a bid winner, I am guaranteed less reimbursement than I currently receive for the same testing as a result of the design of the demonstration. (Winning bids must by definition be lower than the current reimbursement under the Medicare Part B fee schedule....some projections assume a winning bid must be at least 5-10% below current reimbursement.) With already extremely small profit margins, what will this do to my bottom line? Even if I win, can I afford to do testing if reimbursement, in some cases, is below my costs to do the test? The bottom line is, can my laboratory survive? There is a high possibility it cannot.

If I am not a bid winner and local physicians and clinics can't use my laboratory for Medicare testing, I will also lose their non-Medicare testing. It is too difficult to divide work between multiple labs based on payer...different requisitions, reports, bills. One-stop-shopping is the name of the game.

I currently use an Mayo Medical Labs, an out of state reference lab, for specialized testing that I am unable to do in my lab. My bid also has to include a bid for these tests. What if my preferred reference lab is not a bid winner? This 30-year relationship with Mayo will have to be severed. This 30-year relationship provides not only testing services, put physician consulting services and support for my community outreach services. I will have to establish a relationship with a new laboratory, arrange for courier service, perhaps pay for and wait for a laboratory results interface to my information system and at the same time, not allow service interruptions to any of my clients. My bid must include pricing for tests I purchase from my current reference lab. If they are not a bid winner, I won't know what my referral expenses are since I must choose a new reference lab. All this impacts my bottom line and my labs profitability.

Competitive Bidding has the potential to take the joint venture lab system we have developed in Dubuque as a well respected, cost effective, community based health system and change it forever. If the outreach testing goes away and UCL is left with only inpatient work, the consolidated lab is in jeopardy. Currently the cost to provide lab services at the two Dubuque hospitals is the third lowest among twenty-six tri-state (IA-WI-IL) hospitals. If the consolidated lab is dissolved, the 2 competing hospitals will go back to just that...competing. There will again be duplication of testing, services and personnel. All resulting in increased cost to the hospitals, physicians and patients. If competitive bidding saves dollars for Medicare Part B lab services, but causes an increase in hospital Part A costs, what has been gained?

Quality:
Quality cannot be assumed. CMS defines quality as "meeting CLIA guidelines". Anyone in the lab industry knows that quality cannot be assumed just because a lab has a CLIA certificate. CLIA is the minimum standard and most labs perform far above the CLIA standards. There **is** a difference in quality. When we look at quality, we look not only at the quality of the test result, but the quality of the service provided. A correct lab result reported hours after it was critically needed by the physician is not a quality result, even if it is the right result. If testing cannot be done my local, community laboratory because we are not a "bid winner" and must be sent to out of town, turn around time will increase and the quality of patient care suffers. I can get a test

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result to a physician in minutes or hours, not the next day. The Competitive Bidding Demonstration as designed, guaranteeing "bid losers, means that this **will** happen and patient care will be adversely affected.

Access:

When considering the impact on access to health care, it is important to look at the issue in two different areas. First, from the perspective of a Medicare Part B beneficiary seeking access to clinical laboratory services, there are a number of scenarios that must be considered. For example, if the Medicare patient has to travel to a laboratory to have a specimen drawn or to obtain services, how far are we willing to have them travel before we can say that there is an access problem? In Dubuque, if I am not a "bid winner", the next closest bid winner could be 60 miles away in Cedar Rapids or 70 miles away in the Quad Cities. Those laboratories will most likely not set up expensive courier service to Dubuque to expand their business to get more Medicare business, contrary to CMS's notion that a winning bidder has the opportunity to get more business. This scenario will play out all over the country, not just in Dubuque. I strongly believe that this **IS** an access issue waiting to happen. Also, if the Medicare beneficiary's physician collected the specimen and has to send it to a "winning" lab, how long is too long to wait for results? What about long standing relationships that are now severed because the laboratory the physician is familiar with is not a winning lab? Will they still have the automatic transfer of results into the patient's EMR? Will there be a difference in normal ranges from the new reference lab, affecting how they interpret results? Will consultation with medical experts developed over the years be lost? Finally, the impact on nursing home patients must be considered. My laboratory is the ONLY laboratory that provides a phlebotomist to go to the nursing homes to draw blood. A large percentage of my Medicare testing comes from Nursing Homes. If I am not a bid winner, who will provide lab services to these nursing homes? Nursing home patients today are much sicker than in the past and require more lab tests and require the results within minutes or hours….not the next day. This is one of my biggest concerns with competitive bidding…what happens to these patients? This is not just a Dubuque problem…it's a problem that will occur nationwide.

A second concern relates to physician and patient access to clinical laboratory results. Currently all of the laboratory results released by my laboratory are sent directly to the patient's electronic medical record if one is available. Lab work done as part of a patient's inpatient stay is also sent to the physician office medical record. I believe Dubuque is a leader in the clinical laboratory industry when it comes to community electronic sharing of medical records. My laboratory has developed a community wide inquiry program that allows any physician with internet access the ability to access a patient's complete laboratory record whether that testing was done in the hospital, at any UCL laboratory or a local clinic or at Mayo Medical Laboratories, our current reference lab. If I am not a bid winner and testing has to be done by another laboratory, this capability-not available in most cities the size of Dubuque-is lost. How many out of town or out of state winning labs will agree to the expense of providing an interface to our lab's information system to continue this service, especially if I am not their client? The answer: NONE.

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As I look at Quality and look at Access, isn't limiting access to laboratory services a quality issue? And isn't a physicians inability to have quality lab services furnished by a laboratory they are familiar with an access issue? Quality and access are intertwined. The ability of the Medicare beneficiary and their physician to access quality laboratory services is imperative for a Medicare beneficiary's continuity of care. Competitive Bidding will severely harm both patient access and quality despite the measures identified by CMS because the measures selected by CMS do not address the relationship and trust that is built over time between the patient, physician and clinical laboratory.

It's clear to me and to the laboratory community that this CMS Demonstration Project cannot be carried out without a guaranteed negative effective on **both** quality and access. If CMS Competitive Bidding saves the Medicare program money at the cost of compromising a Medicare beneficiary's access to quality lab services and ultimately their healthcare, what have you really saved?

It is critically important that our members of Congress hear the voices of all stakeholders and that the Competitive Bidding Demonstration project be stopped. Thank you, once again, Chairwoman Velasquez, Ranking Minority Member Chabot and Congressman Braley for allowing me to be part of this hearing.