FULL COMMITTEE HEARING ON COMPETITIVE BIDDING FOR CLINICAL LAB SERVICES: WHERE IT IS HEADING AND WHAT SMALL BUSINESSES CAN EXPECT

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FULL COMMITTEE HEARING ON COMPETITIVE BIDDING FOR CLINICAL LAB SERVICES: WHERE IT IS HEADING AND WHAT SMALL BUSINESSES CAN EXPECT

Wednesday, July 25, 2007

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The Committee met, pursuant to call, at 10:00 a.m., in Room 2360 Rayburn House Office Building, Hon. Nydia Velázquez [Chairwoman of the Committee] presiding.

Present: Representatives Velázquez, Cuellar, Braley, Ellsworth, Sestak, Chabot, Heller and Davis.

OPENING STATEMENT OF CHAIRWOMAN VELÁZQUEZ

ChairwomanVELÁZQUEZ. This hearing on competitive bidding is now called to order. 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 90 percent of the industry is made up of small firms. The clinical lab industry is 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 different services. Today we will hear how CMS 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 be make 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 particular 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 million 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 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 especially trained personnel, a laboratory cannot shut its door 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 health care industry. Medicare beneficiaries receive over 250 million laboratory tests each year and while these services account for less than two percent of Medicare spending, they impact on estimated 60 percent of all medical decisions.

Given this broad impact, an important question 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. I now yield to Mr. Chabot for his opening statement.

OPENING STATEMENT OF MR. CHABOT

Mr.CHABOT. Thank you, Madam Chair. Good morning and thank you all for being here as we examine the Centers for Medicare and Medicaid Services, Medicare Clinical Laboratory Competitive Bidding Demonstration Project. It's a mouthful. I would like thank Chairwoman Velázquez for holding this hearing and each of the witnesses for taking the time to provide this Committee with testimony.

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug Improvement and Modernization Act of 2003. The legislation produced the largest overhaul of Medicare in the public's health program 38 year history. Among other things, the legislation required CMS to run a demonstration using competitive bidding and performance-based contracting procedures when entering into contract for the administration of benefits under Medicare Part B.

Before this legislation, Medicare contracting was not subject to competition. Between 2005 and 2009, CMS will be conducting full and open competitions to replace the contractors that currently perform claims processing and related functions for the Medicare program. The legislation requires the competition and resulting con-

tracts be in accordance with the Federal Acquisition Regulation or FAR.

FAR Part 19 implements federal government policy to provide maximum practicable opportunities in its acquisitions to small businesses, veteran owned small business, service disabled veteran small businesses, HUB Zone small businesses, small disadvantaged businesses and women-owned small business concerns. Such concerns must also have the maximum practicable opportunity to participate as subcontractors in the contracts awarded by any executive agency consistent with efficient contract performance.

The legislation also requires CMS to conduct demonstration projects on the application of competitive acquisition for durable medical equipment, prosthetics, orthotics and supplies and for payment for clinic laboratory diagnostic tests that would otherwise be made under Medicare Part B, Clinical Laboratory Fee Schedule. The latter competitive demonstration project is the subject to today's fact-finding hearing to acquire a better understanding of the CMS demonstration project's definition and impact on small business clinical laboratory.

In developing demonstration project procedures relating to competitive bidding and the awarding of contracts, the CMS is required by legislation to take appropriate steps to ensure that small business clinical laboratories have an opportunity to be considered for participation. Unlike the contracting for administration of benefits under Medicare Part B, the legislation does not require the demonstration of the subject to the FAR.

Competition is the foundation of capitalization. Competition stimulates innovation, encourages efficiency and drives down prices savings taxpayer dollars. Small business has historically been the engine of innovation and a catalyst for competition. They also employ more than 50 percent of all employees in this country.

While I support competition and the outcomes it normally produces, I want to ensure that the demonstration project design methodology meets the intent of the Small Business Act by providing small business clinical laboratories the maximum practicable opportunities to participate in the demonstration as both prime contractors and sub-prime contractors.

It is also critical to the success of the demonstration project that CMS' demonstration's project design maintains or enhances the current competitive environment, service accessibility and service quality. The demonstration's project design should not result in fewer small business clinical laboratories leading to increased prices, reduced service accessibility and a deterioration of service quality over the long run.

We have excellent witnesses here today to provide us with insight into the rationale behind the demonstration project's definition of a small business clinical laboratory and how the demonstration project's competition methodology ensures maximum practicable opportunities for that. We look forward to hearing from all the witnesses here today and I want to again thank you, Madam Chair, and I yield back the balance of my time.

ChairwomanVELÁZQUEZ. Thank you. Our first witness is Mr. Timothy Love. Mr. Love is the Director of the Office of Research, Development and Information at the Centers for Medicare and

Medicaid Services. The Office of Research, Development and Information at the Center of CMS, the main role is to lead the agency in providing information on expertise to shape the current and future directions of CMS programs or to cooperate all demonstration activities including the project being discussed today.

Mr. Love, you're welcome and you will have basically five minutes and your entire testimony will be entered in the record.

STATEMENT OF TIMOTHY P. LOVE, DIRECTOR, OFFICE OF RESEARCH, DEVELOPMENT AND INFORMATION, CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr.LOVE. Thank you, Madam Chair.

Good morning, Madam Chairwoman and Distinguished Ranking Member and Members of the Committee. I'm pleased to be here today to discuss the clinical laboratory competitive bidding administration mandated by the Medicare Prescription Drug Improvement and Modernization Act of 2003, also known as the MMA.

Mr.CHABOT. Excuse me. Could you pull that even a little closer?

Mr.LOVE. I'm sorry.

Mr.CHABOT. That's all right. Just kind of hard to hear in the room if you don't have—You have to speak right into it.

Mr.LOVE. I'll try to project a bit better, sir.

Mr.CHABOT. Thanks.

Mr.LOVE. Certainly. As you know, the Medicare Program expenditures are expected to grow significantly in coming years. Medicare costs including clinical lab expenditures are increasing much faster than the rate of inflation and our program is particularly vulnerable because the number of beneficiaries will spike with the impending Medicare eligibility of baby boomers.

In the past three decades, Congress has directed our agency to conduct demonstrations that have saved Medicare tens of billions of dollars and extended the life of the trust funds. The advantage of a demonstration is that we can learn something on a small scale before going program wide. Of course, any decision to go beyond the limited scope of this demonstration would be up to the Congress.

Medicare payments to clinical laboratories are significant. Madam Chairwoman mentioned that it is two percent of the program, but that does translate into $6.7 billion a year and Congress clearly saw this as an opportunity to investigate more efficient payment in competitive market-based demonstration as an alternative to the status quo which is a centralized, one-size-fits-all administrative pricing program.

With regard to the particular interests of the House Small Business Committee, I want to assure you that CMS has worked diligently to implement the law while treating smaller laboratories fairly. For example, we will choose multiple winners and even the smallest, local clinical labs will be allowed to participate in the demonstration as opposed to a winner-takes-all approach favoring large national laboratories.

CMS will not require the smallest laboratories to bid, though they will have that option. These non-bidding labs will, however,

have to accept competitively set market prices. Bidders that are not selected will still be able to receive Medicare payment for provision of services to Medicare outside of the competitive bidding area and outside of the Medicare fee-for-service program. This certainly doesn't affect any labs that are providing services to beneficiaries under Medicare Managed Care.

In response to comments from smaller labs, we have simplified the bidding process so that only one-third of the existing fee schedule still covering 99 percent of cost and volume are up for bid. Our goal is to assure that small businesses can participate in the demonstration on a level playing field and have an equal opportunity to win a place in the demonstration. Small laboratories that want to use the demonstration as an opportunity to expand their market may do so by competing for additional Medicare business.

In closing, I would like to make a final point regarding the essential role of quality assurance in performing clinical laboratory tests for Medicare beneficiaries in this demonstration. We are not interested in conducting a demonstration that establishes a more efficient price at the expense of quality. In the law, Congress directed us to apply all the current protections available under the Clinical Laboratory Improvement Act, also known as CLIA. In the demonstration design, however, we have gone beyond the CLIA regulations. Winning laboratories will be required to supply quality data throughout the demonstration in such critical areas such as tests, turnaround time, log-in error rates and unusable or lost specimens. At CMS, we think of quality assurance as a stewardship issue, equal in importance to our stewardship responsibilities to promote trust fund solvency.

I thank you again for inviting me to speak with you today and, Madam Chairwoman, you've raised a number of points that I didn't get to in my opening remarks and I will be happy to answer any or all of those questions. Thank you.

[The prepared statement of Mr. Love may be found in the Appendix on page 39.]

ChairwomanVELÁZQUEZ. Thank you.

Mr. Love, CMS estimated the cost to small businesses of submitting bids will be approximately $4,000. According to numerous comments CMS received at the July 16, 2007 Open Door Forum, potential bidders estimated that the cost will significantly exceed that amount. Can you tell the Committee how did you, CMS, estimated the cost to small businesses?

Mr.LOVE. The projection of demonstration participation costs or bidding costs, we had established by our contractor or our economic experts who developed the bidding schedule and although I cannot provide you that technical detail, I would be happy to submit that for the record.

ChairwomanVELÁZQUEZ. But can you talk to us as to how did you get to that figure of $4,000?

Mr.LOVE. It is a projection of the level of effort and opportunity costs put into submitting a bid for consideration in the competitive bidding process. There is a—We've actually created a specific software—

ChairwomanVELÁZQUEZ. Okay.

Mr.LOVE. —that is we think quite user friendly and we really did try to limit the opportunity costs of the bidders having to pull that information out.

ChairwomanVELÁZQUEZ. So how could you explain such a disagreement between those who participated in the Open Door Forum and your technical experts?

Mr.LOVE. Madam Chairwoman, I would say that there are a number of legitimate disagreements and you mentioned a number of them in your opening remarks and this may be one of those situations where we would have to agree to disagree on the outcome. But we would be happy to support that methodology establishing the $4,000 figure.

ChairwomanVELÁZQUEZ. Can you tell us who was the contractor who did the analysis?

Mr.LOVE. Yes. That is RT International, Research Triangle International. It's a very well regarded economics research firm.

ChairwomanVELÁZQUEZ. Once the bidder's package is final, will CMS re-estimate the actual cost of bidding? Will it consult with the laboratories themselves on the true cost of bidding?

Mr.LOVE. I'm sorry. I didn't understand the question.

ChairwomanVELÁZQUEZ. Once the bidder's package is final, will CMS re-estimate the actual cost of bidding.

Mr.LOVE. No Madam. We are going to evaluate the bids on price and non price criteria. But we will evaluate it based on the prices submitted.

ChairwomanVELÁZQUEZ. Isn't the $4,000 an estimate?

Mr.LOVE. No. I think the $4,000 may be referring to the logistical costs of assembling the bid where the actual price bid to participate in the demonstration, that would be the result of the bidding process that the bid evaluation panel would establish and we will be happy for both the winning and non winning labs to debrief them as to the process that produces the demonstration participants.

ChairwomanVELÁZQUEZ. The clinical laboratory industry describes competitive bidding as a misguided approach to the reimbursement of laboratory services. What are your thoughts about this observation?

Mr.LOVE. I think it's important as you will know that our job is to implement the law as decided by Congress and signed by the President.

ChairwomanVELÁZQUEZ. But we didn't tell you what type of approach or model you would apply, did we?

Mr.LOVE. No, certainly—Excuse me. Certainly the Congress gave us some —

ChairwomanVELÁZQUEZ. Latitude, yes.

Mr.LOVE. —parameters. Exactly. Is your question relating specifically to the competitive nature of it?

ChairwomanVELÁZQUEZ. Yes.

Mr.LOVE. The competitive nature, and I heard some of these arguments at last week's Open Door Forum among other places, and I'm frankly a bit puzzled by it in that the status quo is an administrative pricing system established by my very capable colleagues in Baltimore, but it is an administrative, centralized pricing system.

The demonstration has a market driven method for establishing a price. But equally important, there are non price features where

I think really provides some opportunities for smaller businesses and those opportunities are being able to provide faster turnaround time, better customer service to physicians, to beneficiaries, and certainly a level of market-specific savvy that some of the larger labs simply will not have.

ChairwomanVELÁZQUEZ. Mr. Love, when you met with the industry, especially those small labs, did they provide you any other alternative in terms of input and why did you choose only the competitive bidding as the only approach? Why did you decide that was the best model?

Mr.LOVE. Well, on the competitive bidding, we had no discretion there. Congress by law, we did have to do it in a competitive bidding structure. It's how we configured the competitive bidding within that overall structure that we did have some discretion.

ChairwomanVELÁZQUEZ. Okay, and did you get any input from the industry as to how—

Mr.LOVE. Yes. Certainly we did.

ChairwomanVELÁZQUEZ. And did you consider any of those? Let me ask you. How many times did you meet with those stakeholders?

Mr.LOVE. We met—Well, in differing categories, well over a dozen times. We had four Open Door Forum. If I may, I could give you a specific answer to that. We had the Open Door Forum that you referred to last Monday, I believe. That was actually the third Open Door Forum we've had which is a public forum for interested parties to give input to the process.

In addition, shortly after becoming Director of the Office of Research, Development and Information two years ago, I had my first meeting with representatives of the lab industry. I've since had two others. Former Administrator McClellan has met with these representatives. Staff have spoken each year at industry conferences to explain this and we have been very much in the sunshine on this issue.

ChairwomanVELÁZQUEZ. Just not to explain. I'm talking to you about input.

Mr.LOVE. Yes. Input certainly, and I can give you several examples of where we have accepted input from—

ChairwomanVELÁZQUEZ. As a result of the Open Door last week, are you planning to revise your model?

Mr.LOVE. We have—There are three issues, one of which was addressed in the Open Door Forum last week and that is there are, as you know, both the bidding lab itself and the referral lab. You referred in your opening remarks to the interaction between labs to produce their results and the referral labs in our original design, we only had the bidding lab able to bill Medicare and we got input from a number of stakeholders that said, "Logistically, this is just not how the industry works." And as one modification, we are allowing either the bidding lab or the referral lab to submit bills to Medicare.

We had some visits about a year ago, a meeting I attended with representatives that included the ASRD Laboratory industry who made a fairly compelling case, I think, for their particular issues with the design of the demonstration and we have created modi-

fications in demonstration design for that as well. A year ago (Inaudible.)

ChairwomanVELÁZQUEZ. Okay. For small businesses to have a real opportunity to compete, I think this is a fair questions. What are the metrics for non price features of a competitive bidding?

Mr.LOVE. The non price features will—The evaluation features are going to be on quality, the quality and the ability to perform the tests on access to ensure that Medicare beneficiaries, particularly our most vulnerable beneficiaries in nursing homes and rural areas who may otherwise have access problems. That is a criteria we are going to consider very carefully.

Gaming, quite frankly, and more specifically our economic experts at RTI had some concerns that the larger labs could low-ball and price some of the small labs out of the market and that's something we're going to look at very carefully in the business.

ChairwomanVELÁZQUEZ. Okay. That's one of our concerns. Because in 2000, the Institute of Medicine stated that the nation's two largest laboratories, Quest and LabCorp, controls 61 percent. That was in 2000. Do you know what is the percentage today that they control in 2007 between those two?

Mr.LOVE. Not offhand, Madam Chairwoman.

ChairwomanVELÁZQUEZ. So then how can you effectively guarantee that there is going to be competition?

Mr.LOVE. That really comes into the $100,000 price threshold that you referred to and what we've done, had that threshold been higher, it frankly would have left not quite a monopoly, but certainly a very small number of large players driving the bids. By lowering it, we will have at least ten bidders competing for Medicare business in the market area and that in our mind is fairly robust competition.

ChairwomanVELÁZQUEZ. I'm going to get back to this question again. But I am going to recognize Mr. Chabot.

Mr.CHABOT. Thank you very much, Madam Chair. Mr. Love, just a few questions. First of all, Congress told you to do a demonstration project and the idea as you stated in doing a demonstration project is perhaps learning, getting, the bugs out before you do it broadly at which time it would have a greater impact and cost a lot more and that sort of thing. Is that correct?

Mr.LOVE. Yes sir.

Mr.CHABOT. Now it's my understanding that the clinical laboratory industry currently is composed of a few large players that together have a very large market share and a large number of smaller laboratories that together have a much smaller market share. How was this addressed in the demonstration project's design?

Mr.LOVE. We really looked at the markets under consideration and we looked at the status quo and the markets that are eligible for the demonstration based on the criteria. For example, we are not looking at metropolitan service areas that span states, for example, the New York Metropolitan Service Area which includes New Jersey and Connecticut as well as New York. That would not make sense in terms of the participation in the demonstration.

So we looked at specific within state metropolitan service areas, MSAs, and determined the number of bidders that would be re-

quired for an authentic market competition and these are labs that are viable and functioning in that market now, although they may not be covering the entire market area, if that's your question sir, regarding the market penetration, say, and the market made up of inclusive zip codes.

And under the demonstration, they will not have to cover that entire area. We will certainly make sure that in the aggregate all winning bidders are able to cover that and ensure access for our Medicare beneficiaries. But there will be certainly opportunities for smaller labs to prosper or to bid in their current market or, if they choose, expand into greater service areas within the bidding area.

Mr.CHABOT. And what outreach efforts are being done by CMS and the clinical laboratory community to ensure that the community is aware of the demonstration project?

Mr.LOVE. I would defer to the second panel to refer to industry outreach. For CMS in addition to the Open Door Forum, every document, again getting back to the demonstration development and the sunshine issue, that we have been able to make public is currently available on our web site.

Open Door Forum are either in person or by phone. Folks are able to participate. We are going to have an ombudsman for the project. We're working with the carriers who are associated with paying the bills in these districts to make sure they are informing beneficiaries as well as lab participants, bidding labs, about the development of the demonstration.

Mr.CHABOT. Okay. Let me ask one more questions. Has CMS considered two partial small business clinical laboratory set-asides for services they normally perform for the local community?

Mr.LOVE. I'm sorry. There are two specific services that Congress had exempted in the Medicare Modernization Act. I'm not sure if that's what (Inaudible.)

Mr.CHABOT. Okay. I'll yield back the balance of my time. Thank you.

ChairwomanVELÁZQUEZ. Mr. Cuellar.

Mr.CUELLAR. No questions.

ChairwomanVELÁZQUEZ. I do have more questions. Mr. Love, you mentioned in your testimony that your multiple bid winner approach will ensure small lab participation. Other than having one more than, yes, one more bid winner, what are your assurances or what assurances can you provide to this Committee that small business or small labs will be winners?

Mr.LOVE. I'm sorry, Madam, if I used the word "ensure." That was not my attention. We're going to offer them the opportunity to compete with a number of the provisions that I stipulated to ensure that it is a level playing field both on price and non price criteria.

ChairwomanVELÁZQUEZ. Would you agree that this method in no way provides really real opportunities for small labs to survive and isn't it true that many labs will be forced to close their doors under this model?

Mr.LOVE. No, madam. I would not agree with that. We would—The outcome of the demonstration, I didn't have an opportunity to mention it, but we do have an rigorous evaluation in place that will look to that among the several issues that you have mentioned

which would inform the Congress and other policy makers before we went any further with this.

ChairwomanVELÁZQUEZ. Were you at the Open Forum last week?

Mr.LOVE. Yes, madam, I was.

ChairwomanVELÁZQUEZ. Okay. A number of lab providers indicated that the $100,000 Medicare revenue threshold was unreasonably low. How did CMS calculate the threshold and did it reconsider the impact that it will have a small business lab?

Mr.LOVE. Yes, we did consider quite carefully and there really were two considerations. One is again ensuring a robust market competition. If the threshold were set too high, you would just have the big players driving a price quite frankly. So when it's lower, there would be more opportunities for bidders to participate making more robust competition.

But the other feature quite frankly was a small business consideration. Those below the threshold have the option of playing or being what we call passive labs. They still would be subject to the fee schedule, but they would not be involved in the bidding process. And our view was that for smaller labs to really be playing in this demonstration, they should have every opportunity to have a voice in the bidding process.

ChairwomanVELÁZQUEZ. The Small Business Administration defines a small business laboratory as generating revenue of $12.5 million. Were you aware of that?

Mr.LOVE. Yes, madam, I was.

ChairwomanVELÁZQUEZ. So given that Medicare usually accounts for 40 percent of revenues for a small lab, it seems a more reasonable threshold for a small lab will be near $4.8 million. How do you explain this enormous discrepancy?

Mr.LOVE. Again, within the market area, it is just Medicare fee-for-service business in the market area, not necessarily the Medicare fee-for-service business outside the market area or Medicare managed care service within the market area. It really doesn't have to do with the Medicare managed care part of the program. But again, it really did come down those features of how do we ensure robust competition which was our understanding of the intent of Congress as well as allowing these smaller labs to have a bid, a voice and the bid, rather than just being swept along as the passive bidder.

ChairwomanVELÁZQUEZ. As I mentioned to you before, a lot of the people that participated, the small labs, they say that the $100,000 Medicare revenue threshold was unreasonably low. Are you planning to re-evaluate?

Mr.LOVE. No, madam, we're not. We have consulted and we went back after our Open Door Forum last week and went back with our economic experts and considered that very issue and we ran into the same problem. By raising it, we are really concerned that it will be too exclusive to the benefit of the larger national labs.

ChairwomanVELÁZQUEZ. My understanding is that you will be contracting a research company to evaluate the success of the demonstration project.

Mr.LOVE. Correct. There are actually—If I could, there are three parties in the evaluation. That would be CMS, of course, our economic experts at the Research Triangle Institute as well as the

folks at Palmetto which is a carrier that's responsible for the operational end of the implementation.

ChairwomanVELÁZQUEZ. Who will be writing the check for the private research company?

Mr.LOVE. That is funded by the Center for Medicare and Medicaid Services.

ChairwomanVELÁZQUEZ. But do you think that some people will call into question their findings?

Mr.LOVE. Our agency has a long, and I would argue, distinguished record in the independence of our findings and certainly, I've had no indication that it would be otherwise and I'm speaking as the director of the agency's R&D shop right now.

ChairwomanVELÁZQUEZ. Yes.

Mr.LOVE. We live and die by the ability to be credible in our findings.

ChairwomanVELÁZQUEZ. Well, last week we held a hearing in this Committee with CMS where we were discussing generic drugs reimbursement and the IG and the General Accounting Office called into question their finding. So that's why I'm asking the question of questioning the company's research finding that you are hiring. Let me ask you. Would you agree that a General Accounting Office study requested by Congress may help ensure more accuracy and independence?

Mr.LOVE. I'm certainly—and the GAO is a great source, I think, for helping us better understand and improve our programs and I would be very supportive of GAO looking into this issue.

ChairwomanVELÁZQUEZ. Very good. Any other member who wishes to ask questions? Mr. Chabot.

Mr.CHABOT. I don't have any more additional questions, but if you—Are there any points that you think might have been unclear or anything that you would like to expound upon to clear up anything that you think wasn't perfectly clear?

Mr.LOVE. Just that I appreciate that this is very sensitive. It is a bread-and-butter issue for a lot of small labs and we appreciate that and we have tried to be sensitive to that in the development of the demonstration. We are implementing the law to the best of our ability considering all stakeholder interests particularly those of small businesses.

Mr.CHABOT. Thank you. I yield back.

ChairwomanVELÁZQUEZ. I have two more questions.

Mr.LOVE. Yes madam.

ChairwomanVELÁZQUEZ. Even though laboratories with less than $100,000 in business are not required to bid, it is my understanding that they must live with the bid, the winning price. This will place a severe hardship on small laboratories that service the more challenging areas of the local market where operating costs can be higher. Why should they be required to accept this price and how can labs be expected to survive under those conditions?

Mr.LOVE. The small labs below the $100,000 threshold actually have the option. They can bid if they choose to. They may also, particularly if they're interested in expanding their business beyond $100,000 during the three years of the demonstration, they would be required to bid. But it is—I'm sorry. I forgot the second part of your question.

ChairwomanVELÁZQUEZ. Why should they be required to accept this price?

Mr.LOVE. There essentially would really, I think, eviscerate our ability to have competition in the market if you really excluded a significant and important part of the market and our understanding is that would be inconsistent with the direction of Congress.

ChairwomanVELÁZQUEZ. But you don't think that isn't fair if they have no participation or input into the bidding process and then they will have to accept whatever price is imposed.

Mr.LOVE. They do have the option to participate if they choose. We just—We certainly have no indication from Congress that we could accept or exempt participants from a market. It is market-specific and inclusive.

ChairwomanVELÁZQUEZ. Mr. Love, if winning bidders drop out of the demonstration for quality or other reasons, what is CMS' plan to recalculate that demonstration prices?

Mr.LOVE. I'm sorry.

ChairwomanVELÁZQUEZ. If winning bidders drop out of the demonstration for quality or other reasons, what is CMS's plan to recalculation the demonstration prices?

Mr.LOVE. We actually will not recalculate the demonstration prices. What we will do is as part of the bid evaluation panel as well as the terms and conditions of the demonstration, we will ensure that there is a safety net to provide access to quality lab services for Medicare beneficiaries.

ChairwomanVELÁZQUEZ. We're going to call—Do you have staff here with you?

Mr.LOVE. Yes, madam, I do.

ChairwomanVELÁZQUEZ. Who are they?

Mr.LOVE. I have with me the lead technical analyst who is really the woman who has done much of the presenting at the national conferences.

ChairwomanVELÁZQUEZ. Okay, and she will be staying here to listen to the other panel.

Mr.LOVE. I will be staying also. This is a very interesting issue for me and I think an important one.

ChairwomanVELÁZQUEZ. Okay. Thank you very much.

Mr.LOVE. Thank you.

ChairwomanVELÁZQUEZ. You are excused.

And now I will ask that the witnesses of the second panel to please come forward and take your seats.

(Pause.)

ChairwomanVELÁZQUEZ. Our first witness is Mr. Thomas, and I'm going to try very hard, Bejgrowicz.

Mr.BEJGROWICZ. Perfect.

ChairwomanVELÁZQUEZ. Thank you.

Mr. Bejgrowicz is the Client Account Manager for AccuLabs, a laboratory services nursing homes in New Jersey. He has held administrative positions at a number of facilities and is a licensed nursing home administrator. AccuLabs has been in business for over 35 years. Mr. Bejgrowicz is here testifying on behalf of the American Health Care Association that is the nation's leading long-term care organization representing 11,000 industry members.

Mr. Bejgrowicz, welcome and you have five minutes to make your presentation and your entire testimony will be entered into the record.

STATEMENT OF THOMAS S. BEJGROWICZ, M.S., L.N.H.A, CLIENT ACCOUNT MANAGER, ACULABS,ON BEHALF OF THE CLINICAL LABORATORY MANAGEMENT ASSOCIATION

Mr.BEJGROWICZ. Thank you. Good morning. On behalf of American Health Care Association, its nursing home members and many small businesses throughout the country, I thank you, Madam Chair, Mr. Ranking Member and other Members of the Committee for giving me the opportunity to testify. My name is Tom Bejgrowicz.

For as long as I can remember, I've always been drawn to health care. The quintessential moment that I decided to dedicate my life to helping others is when my grandfather was a resident in a nursing home. Now I am a licensed nursing home administrator and over the past 17 years, I have worked for small facilities, large corporation and hospital-owned not-for-profit centers.

American Health Care Association and I am concerned that Medicare beneficiaries in nursing homes will no longer have access to quality laboratory services if CMS continues to implement competitive bidding. Quality of care could be jeopardized and many residents like my grandfather could be negatively impacted if competitive bidding comes to fruition. At best, competitive bidding will put small labs out of business. At worst, it will restrict access to quality health care for Medicare beneficiaries, limit choice, disturb the continuity of care and ultimately increase the cost to Medicare.

Federal law requires nursing home residents to receive the necessary care and services in accordance with comprehensive assessment and plan of care. Many relatively small independent clinical labs such as AccuLabs where I am currently employed have supported nursing homes in meeting this requirement by tailoring their services to go beyond that of simply analyzing a blood specimen. Thus, nursing homes rely on these services to provide the highest level of care.

For example, phlebotomists, the people who draw your blood, very often travel many miles from facility to facility collecting specimens from bed-bound patients. Often, these laboratories will provide a testing menu that is highly focused to ensure rapid turnaround time of critical testing, will often develop normal ranges centered around specific age groups and utilize certain testing methodology to ensure continuity of care. Our experience is that why the larger labs will in some cases in doing the test, they are not interested in providing tailored services.

Continuity of care for patients at smaller nursing homes may also suffer. Smaller labs that are not able to participate in competitive bidding may be required to close due to decreased business and nursing facilities will be required to find another laboratory to provide services. Not only will the facility and the patient have to adjust to a new laboratory service provider, but it also may take some time to find an alternative provider.

Should the small lab be forced out of the market by competitive bidding, access to care will be severely hindered. CMS assumes the

winning labs are interested in servicing all Medicare beneficiaries which is simply not the case. Historically, the large laboratories have shifted their focus from long-term care to the more lucrative physicians' offices. As such, termination notices were issued to many long-term care and assisted living facilities.

At present, there are two major labs that command nearly 70 percent of the market and once competitive bidding is in place, they will likely have an even greater percent of the market in that competitive bid area. Under those circumstances, it is not likely that the large labs will have more motivation to service the nursing home population than they have now.

Another area of concern is that not only will competitive bidding create barriers to access to laboratory services, but also it will cause a decline in the quality of laboratory service.

CMS has not released detailed specification for the indicators that it will use to measure laboratory service quality of care, although it plans to implement this demo in less than one year. The health care community has asked CMS repeatedly for these performance measures, but CMS has not developed them. On July 16, 2007, an Open Door Forum was held during which CMS stated the quality measures will be standardized across all laboratories. This one-size-fits-all mentality does not apply to the dynamic field of laboratory medicine.

In closing, with competitive bidding in place, CMS will tie the hands of the facilities. The choice of which laboratory provider a nursing facility can use will be limited. There will fewer laboratories to choose from after the demonstration project is implemented. Those that remain will be the larger national laboratories that have focused their attention on markets on other than nursing facilities.

It is with the best interest of all long-term care residents and all Medicare beneficiaries that I ask Congress to re-examine this ill-conceived plan and repeal competitive bidding legislation. The potential impacts on access and quality of care as well as the increases of Medicare costs go against AHCA's mantra of performance excellence and commitment to affordable, healthy and ethical long-term care.

Thank you for your consideration in this important matter.

[The prepared statement of Mr. Bejgrowicz may be found in the Appendix on page 49.]

ChairwomanVELÁZQUEZ. Thank you, Mr. Bejgrowicz. And now I recognize Mr. Braley for the purpose of introducing his constituent.

Mr.BRALEY. Thank you, Madam Chairwoman. It is my honor and privilege to introduce one of my constituents, Mary Jo Bonifas, who is here to share her testimony with us today. Mary Jo is a certified medical technologist and has over 36 years of experience in the clinical lab. She is currently the Manager of Laboratory Services for United Clinical Laboratories, Inc., a foresight joint venture laboratory system based in Dubuque, Iowa. She has been with the Dubuque lab system for over 30 years and a laboratory manager for 26 years.

Mary Jo is a member of the board of directors of the Iowa Chapter of Clinical Laboratory Management Association (CLMA) and is

also president of the board of directors for the National CMLA Advocacy Group. It is my distinct privilege and pleasure to welcome her to this hearing.

STATEMENT OF MARY JO BONIFAS, MANAGER OF LABORATORY SERVICES, ON BEHALF OF THE CLINICAL LABORATORY MANAGEMENT ASSOCIATION

Ms.BONIFAS. Thank you. Madam Chairwoman Velázquez, Congressman Chabot and Congressman Braley, thank you for the opportunity to testify today on behalf of Clinical Laboratory Management Association on this very important issue.

CMLA's membership is comprised of approximately 4300 clinical laboratory managers serving in hospitals, independent labs, skilled nursing facilities, physician offices, research facilities as well as representatives from medical device industry. While the majority of CMLA's members are hospital based, we attempt to present a perspective that is shaped by all sectors of the clinical lab industry.

My perspective on competitive bidding is shaped by my current role as a lab manager and over 35 years of experience at a small, community-based laboratory in Dubuque, Iowa, serving hospitals and physicians within a 50 mile radius of Dubuque. United Clinical Laboratories is a consolidation of laboratory services at two Dubuque hospitals and a pathology-owned independent laboratory.

We have built our business in a very competitive market, not on lowest price, but on a 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. The competitive bidding project as designed by CMS is flawed and, if allowed to proceed, will be devastating to the clinical lab industry especially 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 my lab under competitive bidding. Because I receive at least $100,000 in revenue from Medicare B reimbursement, I qualify as a required bidder, the only laboratory in Dubuque required to bid. What concerns me is there will be drastic consequences if I'm a bid loser and also significant consequences even if I'm a bid winner.

If I am bid winner, I am guaranteed at least five to ten percent less reimbursement for my Medicare work simply based on the design of the demonstration. 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 cost to do the test?

If I'm not a bid winner and local physicians and clinics can't use my lab for Medicare testing, I will also lose their non Medicare testing. It is just too difficult to divide work between multiple labs based on payor and one-stop-shopping is the name of the game. The bottom line is can my lab survive. There is really a high possibility it cannot.

I currently use Mayo Medical Labs for specialized testing that I am unable to do in my lab and my bid must also include a bid for these tests. What if Mayo, 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,

but also consulting services to local physicians. 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 computer system and at the same time not allow service interruptions to any of my clients.

Let's also look at quality and access. Quality cannot and should not be assumed just because a lab has a CLIA certificate. There is a difference in quality. Quality is not just 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 a physician is not a quality result even if it is the right result.

If testing cannot be done by my community laboratory because we are not a bid winner and must be sent out of town, test results will be back the next day rather than in hours or minutes and this impacts the quality of patient care. The competitive bidding demonstration as designed guaranteeing there will be bid loser means that this will happen and patient care will be adversely affected.

Access. Access includes both the patients and a physician's access to quality lab services and to testing results. If I am not a bid winner and the Medicare patient has to travel to a laboratory for services, how far are we willing to have them travel before we say there is an access problem? In Iowa, a bid winning lab may be 50 miles away. If the Medicare beneficiary's physician collects a specimen and has to sent to a winning lab out of town, how long is too long to wait for results?

And what about Dubuque nursing homes? My laboratory is the only lab providing services to 20 local nursing homes. If I am not a bid winner, who will provide their lab services?

Nursing home patients today are much sicker than in the past. They require more lab tests and they require these results within minutes or hours, not the next day. This is not a Dubuque problem. It's a problem that will occur nationwide.

Access also includes physician access to lab results. My laboratory has developed an inquiry program used community wide 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 site, at a local clinic or even Mayo. If I'm not a bid winner and testing has to be done by another laboratory, this capability not available in most cities the size of Dubuque will be lost.

To summarize as we look at quality and look at access, isn't limiting access to laboratory services a quality issue and isn't a physician's inability to have lab services furnished by a laboratory they trust and are familiar with an access issue? Quality and access are intertwined. It's clear to me and to the lab community that this CMS demonstration project cannot be carried out without guaranteed negative effect on both quality and access.

CMS, if the competitive bidding demo saves the Medicare program money at the cost of compromising a Medicare beneficiary's access to quality lab services and ultimately their health care, what have you really saved?

Madam Chairwoman and Committee Members, I thank you once again for allowing me to be part of this hearing. It's critically important that you, our members of Congress, hear the voices of all

stakeholders and that this competitive bidding demonstration project be stopped. Thank you.

[The prepared statement of Ms. Bonifas may be found in the Appendix on page 66.]

ChairwomanVELÁZQUEZ. Thank you very much. Our next witness is Mr. Tod Schild. Mr. Schild is representing Schild Medical Laboratory as the Senior Vice President.

Schild Laboratories employs over 350 people and is located in Brooklyn, New York. Mr. Schild is testifying here today on behalf of the National Independent Laboratory Association.

Welcome.

STATEMENT OF TOD SCHILD, VICE PRESIDENT SALES & MARKETING, SHIEL MEDICAL LABORATORY, ON BEHALF OF NATIONAL INDEPENDENT LABORATORY ASSOCIATION

Mr.SCHILD. Thank you. Good morning. I want to thank the Chair, the Ranking Member and the other Members of the Committee for the opportunity to testify before you today. As you mentioned, I am the Senior Vice President of Schild Medical Laboratory headquartered in the Brooklyn Navy yard and an active member of the National Independent Laboratory Association. Schild employs 360 people. Our business provides service to private physician practices and nursing home throughout the New York metropolitan area.

I am not an expert in legislative matters, but I think rarely in our history has been there been Congressional legislation that although well intended was planned in such a way as to devastate the industry that is critical to the health and well-being of the American public.

The clinical laboratory project designed by CMS will irrevocably alter the market for laboratory services, reduce patient choice and limit access to quality testing. The program has critical flaws and missing pieces. Rather than fostering competition, it will create government sponsored oligopolies. Instead of reducing laboratory costs for Medicare, it will increase costs. Rather than improve the quality of health care, it will diminish patient access and stifle lifesaving innovation. We all agree that overall Medicare costs reductions are desirable, but this is not an appropriate way to achieve that goal.

The CMS proposal is opposed by all major professional groups involved in the clinical laboratory services industry. It was strongly opposed at the most recent CMS Open Door Forum by almost every person who commented on the proposed design. Over 400 individuals tried to participate in that forum and only a fraction of the questions asked were answered.

By its design, the effect of the demonstration will be to reduce the number of labs permitted to perform Medicare work in the demonstration area. Loss of the ability to perform and bill tests to Medicare patients would most assuredly be a death sentence for the vast majority of non-winning bidder laboratories. Quality and service of the remaining labs will decrease from the strain of their additional volume.

Medicare is just over 30 percent of Schild's work. For some labs, the portion of Medicare work might be as high as 70 to 80 percent. Under the demonstration, there will only be a handful of winners. Non-winners will be out of the program for three years before they get a chance to bid again. Very few non-bidders will survive. Schild operates at only a five to seven percent profit margin. I know that we cannot survive beyond a year with the loss of 30 percent of our revenue.

Given that the demonstration project is fraught with danger for small labs, it had been our hope that CMS would have consulted with representatives of the small business community and the Small Business Administration to determine how to design this project. Unfortunately, CMS did not do so. CMS did not even use the established SBA definition of small laboratories being classified as $12.5 million or less. The technical expert panel selected by the Agency did not include a single representative of the small community lab market.

The independent laboratory market while still competitive is dominated by two national labs holding approximately 65 percent of the market. The extent of this concentration is illustrated by the chart in my written testimony. The large national labs can discount their bids in the demonstration zone and compensated for these temporary discounts through their work in other parts of the country. Labs like Schild that operate in only one or two of the 22 metropolitan statistical areas identified by CMS will not have that advantage. Schild or other labs like us will be the losers in the bidding process.

Let me add that in no way do any labs large or small see any benefit to the American public coming out of this ill-conceived plan. We are all united in our objective to stop this demonstration from proceeding. The difference is that large labs in the demonstration are fighting for their bottom line and the smaller labs are fighting for their existence.

Medicare competitive bidding for laboratories is the opposite of what it purports to be. It is clearly anti-competitive. The demonstration will permanently alter the market of any metropolitan statistical area that has the misfortune of being chosen. Long-time quality laboratories will be forced out of business and new start-up laboratories will be a thing of the past.

Nursing home residents are particularly vulnerable and will suffer the most under this demonstration. Only local and regional lab service nursing homes, the high cost of sending in personnel to draw blood and deliver results within several hours and the limited Medicare reimbursement for onsite services and travel have driven many labs to seek higher profit margins elsewhere.

Medicare's competitive bidding will eliminate the existence of many of the labs that are willing to take on the high operating costs to provide quality care for our aging population in long-term care facilities. At last week's Open Door Forum, CMS was not able to adequately respond to our questions and concerns regarding how these facilities can continue to receive the level of service required.

Additionally, the design complexity of the bidding process and the reporting to CMS required of winning bidders will require a large investment in personnel and infrastructure potentially mak-

ing it cost prohibitive for even the winners in the demonstration area. CMS itself will have to take on administration costs far beyond what they are anticipating. It only takes a review of the bidder's package draft to see how CMS is over-complicating an already expensive and complicated process. Any savings that they would have hoped to realize by a slightly reduced fee schedule will be consumed by their own additional overhead.

In conclusion, there are no laboratory winners in the Medicare competitive bidding demonstration, only losers and bigger losers. Our industry and the American public will be worse off and no savings will result. The only result will be diminished quality, limited access, stifled innovation, lost jobs, poorer health, lost lives and further crippling of our already crippled national health care system.

On behalf of Schild Medical Laboratory, NILA and laboratory professionals across the country, I urge you to repeal the authority for CMS to move forward with this project. There are simply too many unanswered questions and too many risks associated with this ill-designed experiment.

[The prepared statement of Mr. Schild may be found in the Appendix on page 71.]

ChairwomanVELÁZQUEZ. Thank you, Mr. Schild.

Our next witness is Dr. Ronald Weiss, M.S., M.B.A. Dr. Weiss is President and COO of ARUP Laboratories. Dr. Weiss is Board certified in Anatomic and Clinical Pathology, Medical Microbiology and Hematology.

ARUP Laboratories is a national laboratory and an enterprise of the University of Utah and its Department of Pathology. He is here today on behalf of the American Clinical Laboratory Association, a group of national and regional laboratories across the country.

Welcome sir.

STATEMENT OF RONALD WEISS, M.D., PRESIDENT & COO, ARUP LABORATORIES, INC., ON BEHALF OF THE AMERICAN CLINICAL LABORATORY ASSOCIATION

Dr.WEISS. Thank you.

Chairwoman Velázquez, Congressman Chabot, Members of the Committee, I thank you for this opportunity to testify on an issue as you've heard that has great importance and significant ramification for our patients.

As you indicated, my name is Ronald Weiss. I am President of ARUP Laboratories in Salt Lake City. I am a pathologist and a physician practicing laboratory medicine and I've twice served as chairman of the board of the American Clinical Laboratory Association and it's my honor to testify on behalf of ACLA and all of its members, small and large. More pertinent to the subject at hand, I have also served on CMS's 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 that 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 as you've heard and on vulnerable populations including nursing home residents and homebound patients. This point of view has unanimity within the clinical laboratory community, small laboratories, large commercial laboratories, niche service laboratories and hospital based labs and it speaks volumes that when the Centers for Medicare and Medicaid Services released the 75 page bidder's 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 between all sectors of the laboratory industry because all of these sectors 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 both seamless and exemplary.

There is a clear contradiction in terms at work here and this is called a competitive bidding model, but it is clearly anti-competitive and it will drive a significant number of clinical laboratories out of business. Competitive bidding when done in the private sector establishes service commitments and acceptable prices through a negotiation process. For laboratory services, this depends upon a clear knowledge of the volume of those needed services, a streamline submission and payment process and consistency in laboratory to laboratory referral arrangements, none of which exists in this demonstration project.

Extensive analysis of the demonstration by the ACLA yields a number of clear conclusions and I would like to briefly mention five of the most striking ones now.

1. 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.

2. Many of those small laboratories who are perhaps fortunate to win the bidding process will actually lose because they will be forced to accept bids well below their already conservative profit margins, forcing them to close their doors.

3. As more labs have difficulty staying in business, the vulnerable patient populations I've mentioned will find access to laboratory services seriously compromised.

4. The demonstration could severely disrupt the existing complex web of arrangements between the local laboratories that service Medicare patients by performing many common laboratory tests and reference laboratories such as ARUP that perform many of the more complex tests for them.

Some of these high complexity esoteric reference laboratories 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's not even clear that these labs will know that they are required to bid and win in order to continue to be reimbursed by Medicare for services provided in that area.

5. Other reference laboratories may choose not to bid or may not be selected as winners if they do so. This would disrupt existing complex laboratory to laboratory referral arrangements, previously described by my colleague, Ms. Bonifas and create a situation in which local laboratories 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, complex tests.

In the final analysis, Madam Chairwoman, one has to ask the question, is there really 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 laboratories have one simple objective and that is 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 product. This demonstration project clearly does not help us achieve the goal of preserving this service objective and should be repelled 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 an solace in the fact that Medicare beneficiaries' laboratory services went to the lowest bidder while the true cost was poor quality and limited access.

And if I may have a moment, I would like to clarify the market size and share numbers that have been repeatedly mentioned this morning. When you look at the entirety of medical laboratory services, hospital laboratories provide approximately 60 percent by volume of total laboratory services, physician office laboratory is approximately ten percent and independent laboratory is about 30 percent. The two largest laboratories in that independent laboratory sector account for 60 percent of that sector which is approximately 18 to 20 percent overall, not the 70 percent number that had been mentioned.

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

[The prepared statement of Dr. Weiss may be found in the Appendix on page 76.]

ChairwomanVELÁZQUEZ. Thank you, Dr. Weiss. Dr. Weiss, you mentioned that basically in the meetings that had been held between the industry and CMS and the most recent one last week on the Open Door Forum there was basically people were united in terms of their objection to the use of the competitive bidding to de-

termine pricing for lab services. However, you also indicated that it is important for CMS to gather information on lab pricing. If competitive bidding is not an effective mechanism for capturing information about market pricing, what alternative exists to capture accurate data?

Dr.WEISS. Thank you, Madam Chairwoman. As I mentioned, medical laboratory services is a professional medical service and certainly competitive bidding is not the answer. The IOM study looked at several different options when they published their results in 2000. One of those was actually to just continue to use the current clinical laboratory fee schedule and in fact one recommendation was to set it at the national limitation amount.

It's true that the CLFS is not a perfect system for reimbursing for these services, but it's one that laboratorians in the laboratory industry have worked with now for over 20 years and I think it would be far better to continue to try and improve that system rather than to make a drastic change and do something like competitive bidding which I believe is a flawed concept.

ChairwomanVELÁZQUEZ. Dr. Weiss, you mentioned that you took part of the technical expert panel. Were there—Can you talk to us about how much sensitivity there was in their discussion regarding the impact that this will have on small businesses represented by small labs?

Dr.WEISS. The technical expert panel that was established by CMS and RTI we only met once face to face in Baltimore on, I believe it was May 25, 2005. That was an all-day meeting. There were no minutes from that meeting, but I can tell you that there were far-ranging discussions that touched upon many of the issues we've talked about this morning and including the impact on smaller laboratories.

We only had one other interaction as the TEP and that was on a conference call to review the draft bidder application form and that was held almost to the day a year later in 2006 and we've not had any other request to provide input since then.

ChairwomanVELÁZQUEZ. Was there sharing information regarding data collected or impact analysis based on—

Dr.WEISS. There was no impact analysis of the kind we've talked about this morning, certainly, to look at the impact on quality and access. No such analysis has been done to my knowledge and at least published and shared with the TEP.

ChairwomanVELÁZQUEZ. Thank you. Ms. Bonifas.

Ms.BONIFAS. Bonifas.

ChairwomanVELÁZQUEZ. A nationally-recognized accreditation group has cited United Clinical Laboratories as a gold standard laboratory and the best laboratory they have ever seen. However, competitive bidding prices places an emphasis on obtaining the best price over quality. How will a competitive bidding program affect your gold standard service and will it reward such a service?

Ms.BONIFAS. The effect of competitive bidding on my laboratory as I said in my remarks, even if I win, I'm going to have to accept less Medicare reimbursement. That's going to impact my already small profit margins. If I'm a bid loser, there will be a significant community impact in Dubuque. Where will Medicare beneficiaries? What about turnaround time? What about nursing homes?

There will be a major impact on the service delivery system that we have set up and that's one of the things we're recognized for in that the Joint Commission Inspector when he called us a gold standard laboratory. It has a chance to jeopardize the system that we've put in place in Dubuque which is recognized in the community as a very beneficial service to the community. We've provided cost savings to all patients in Dubuque because of the joint venture system that we've set up and that's been in place for over 20 years and that whole consolidated lab system is in jeopardy.

If I'm going to lose my outreach market, United Clinical Labs is the merger of two hospital and the independent lab. We service the local physicians. If I lose that outreach testing, then it puts more of a burden on my inpatient and outpatient costs because the outreach testing is what allows me to offset some of the costs of my inpatient and outpatient work. So the consolidated lab as we know it, I don't think, would survive and that would have a significant impact on the community of Dubuque.

ChairwomanVELÁZQUEZ. Thank you. Mr. Bejgrowicz, one of the problems with this project is that it doesn't account for the highly unique nature of the tests required by skilled nursing facilities. How confident are you that the bid demo will be able to arrive at an accurate and fair price for the tests?

Mr.BEJGROWICZ. First of all, Madam Chair, quality is what drives nursing home care. So looking at price, looking at quality, looking at the number of tests, a lot of the tests are very, very specialized tests that the nursing home patients require.

Physicians are looking for quick turnaround times. The physicians are looking for results within six to eight hours. These are the necessary goals to which the laboratories really need to adhere in order to provide services to the long-term care residents.

ChairwomanVELÁZQUEZ. I would like to ask this question to each one of you. Is it true that different labs may use unique testing procedures for a specified lab test? Can lab tests be fairly compared under the CMS demo if lab use different testing procedures?

Mr.SCHILD. I would like to address that first.

ChairwomanVELÁZQUEZ. Sure

Mr.SCHILD. There are often more than one way to perform the same test and it was brought up today about continuity of care. There are different methods and different reference ranges for many of the tumor markers that are run like CA125 and CEA and those are used to monitor patients who are being treated for cancer. If a lab that a hematology/oncology uses does not win the bid process and can no longer process Medicare specimens, those physician practices will be forced to go another lab.

When, believe it or not, we obtain a new account from some of our competition, they often don't shift over all of their business because patients that they started testing at one lab they don't want to move over to another lab. So, yes, it could have a big impact. There is different equipment. There is different methodologies. There are different reference ranges and it will affect the continuity of care.

Ms.BONIFAS. I would just like to echo what Mr. Schild has said. What my laboratory has done when, for example, we brought CEA

testing, one of the tumor marks. We used to send it to Mayo. We now do it in our lab.

Before we started releasing results to the physicians, we did baseline studies on all their patients, both at Mayo and in our lab so we could see if there was any difference in the results and so that the physicians would be able to monitor them and there was a difference in the reference range and the difference in methodology. So there was a chance that there would be some difference in interpretation of the results.

Now we didn't get paid for doing the test twice. We only got paid once, but those are the things that we did in order to make sure that the physician interpretation was correct and the patients were correctly monitored and we could bring the testing in-house. So, yes, different testing methodologies, different reference ranges, can cause a difference in interpretation and patients would have to be studied. Yes, it will impact.

ChairwomanVELÁZQUEZ. Let me recognize. Dr. Weiss, do you want to—

Dr.WEISS. I just wanted to echo those comments and say that we work in a very dynamic and innovative medical laboratory community in the United States and inherent in your question is the fact that there are constant endeavors to improve not only the quality but the timeliness of individual laboratory tests and the cost of doing those tests. So manufacturers of test kits and test instruments are constantly trying to improve that. So we do end up with a situation where for each individual HCPCS Code on that list there may be several different methodologies that have inherently different costs.

ChairwomanVELÁZQUEZ. Thank you. Mr. Chabot

Mr.CHABOT. Thank you very much, Madam Chair. Mr. Bejgrowicz, I'll being with you if I can. Would you please tell us again why you believe, or expound upon it, the CMS's demonstration project's design will at best put smaller laboratories out of business and at worst restrict access to quality health care for Medicare beneficiaries and limit choice and disrupt the continuity of care and ultimately increase the cost to Medicare?

Mr.BEJGROWICZ. Congressman, again, the first priority for a nursing home owner, a nursing home operator, a nursing home administrator, is quality of care. When we look at this demonstration project, we look at the quality. We look at the access to care. Nursing home residents, again, need specific access. They need service.

For example, we're talking about laboratories that will provide phlebotomy services. Again, I explained phlebotomy services as the people that will come in and draw your blood. A lot of times these larger laboratories don't have phlebotomy services. They require the nursing staff to draw the blood.

Again, we're looking at the test methodologies, the test ranges. The smaller independent laboratories specialize in long-term care. The larger laboratories have pulled out of providing care to the nursing homes.

Mr.CHABOT. Thank you very much. Ms. Bonifas, let me turn to you next if I can. If the demonstration project isn't ended or stopped as you, I believe, had suggested that you would prefer, what changes would you recommend in the demonstration project

that would make it fairer and would remedy some of the problems that have been raised by the panel members?

Ms.BONIFAS. Well, when I asked for the project to be stopped, I meant to be stopped and not change it. I don't think—I agree with Dr. Weiss. There are other ways if CMS and Congress is looking to save money in the Medicare program in clinical lab services. I think the competitive bidding demo is not the way to do it and there are some alternatives to look at.

I think the competitive bidding demo as presented is flawed and I'm not sure there's anything that could be done to fix it that would make it a successful demonstration project. I think as Dr. Weiss said it's simply complex. It's been tried.

I mean, I've been in this industry a long time. We've been talking about competitive bidding for over 20 years. It's not something that has been tried and failed. It's been something that can't even be tried because the issue is some complex we can't even figure out how to try it. And to go forward with the demo and saying that, "Well, it's just a demo. Let's see what happening," to proceed with a demo when there are these many problems with it, what happens if you proceed with the demo just because it's a demo and businesses like mine go out of business. We're not going to be able to re-enter the market.

Let's stop looking at competitive bidding as a way to save money in the clinical lab field for Medicare and look at some other alternatives. The Institute of Medicine recommended a revision to the clinical lab fee schedule. The clinical lab industry is dealing with a Medicare fee schedule that was developed in 1984. Everyone including CMS recognizes that it's archaic, it's irrational and it's out of date. Other physicians, radiologists, ambulance have all revised their fee schedule. Let's take a look at that as an option and stop competitive bidding.

Mr.CHABOT. Thank you. Mr. Schild, would you explain how the demonstration project that we're referring to here today would irrevocably alter the market for laboratory service resulting in reduced patient choice and limited access and resulting market concentration?

Mr.SCHILD. Congressman, I think that's relatively easy to answer. I could use the New York area as an example and I know it was indicated that we wouldn't be the first, but there are 30 laboratories approximately operating in lower New York serving New York Metro. Even if 15 laboratories were selected as winners out of the 30 that had to bid, there are 15 labs that will close.

Schild Medical Laboratory has a dozen patient service centers throughout the boroughs of New York City and Long Island and Lower Westchester. All of those would close and the patients would have to seek having their blood drawn at another patient service center. A lot of the larger labs, they have a very, very big network, but there is no much need out there the wait times there are already extremely long. If you limit the number of labs in the marketplace, there is the answer to your access question, where do they go.

What this demonstration project is all about is government reshaping a free market and I really don't think that that's what our country is about and I think it's going to have devastating implica-

tions and labs will close and labs that leave the marketplace will not be able to re-enter.

Again, we have very narrow margins, somewhere between five and seven percent, depending on the year. Medicare is 30 percent of our revenue. Remove that. I don't think we could go beyond the year in existence, plus it will stifle innovation because new players can't enter into the market. How can Medicare create a system that will stop new businesses from forming and that's where we say it will irrevocably reshape the marketplace. All you'll have is the existing player and they'll just keep dwindling and dwindling down until everybody realizes that this was a mistake and you start over again.

Mr.CHABOT. And finally, Dr. Weiss, would you explain again in your statement that you made in your testimony that the CMS demonstration project will cause a huge destabilizing and anti-competitive effect on the clinical laboratory community?

Dr.WEISS. Thank you, Congressman. As my other colleagues on the panel have indicated, the complexity of what we are dealing with in terms of the relationships between laboratories functioning in communities is such that disrupting that will create major impacts not only on those laboratories but the patients they serve.

And if I can use my organization as an example, we have recognized that a laboratory like ours is not suited to providing clinical laboratory services to a number of the segments of the patient population. It's truly the independent and hospital based laboratories in communities and in regions that could be affected by this demonstration project. Those are the entities that are best suited to provide these services.

So we have this complex relationship between laboratories at several different levels, all of us trying our best to provide high quality services to patient populations like those in Medicare and competitive bidding will throw a tremendous monkey wrench, if you will, into that process and be extremely disruptive in my opinion.

Mr.CHABOT. Thank you, Doctor. I yield back the balance of my time.

ChairwomanVELÁZQUEZ. Mr. Braley.

Mr.BRALEY. Madam Chairwoman, Ranking Member Chabot, I have only served on this Committee with you for six months, but I am fairly confident in saying that only CMS could create a competition where if you win you lose.

(Laughter.)

Mr.BRALEY. It's very disturbing to those of us who have recently come to Congress to be sitting here week after week talking about CMS driven decisions that have an adverse impact on the people we represent in our districts.

And, Ms. Bonifas, I want to start to talking to you about your comment that 20 local nursing homes in your area are served only by your laboratory. Do you remember making that comment? Last week, another one of my constituents from Maqueketa, Iowa, a family pharmacist was here, talking about some of the extraordinary things that people in his profession had done above and beyond the call of duty to help people coup with the new Medicare

D requirements, that they received no compensation for but felt that they were obligated to do as a sense of professional calling.

And what I would like you to do is help us put a human face on the type of services you and your employees provide above and beyond what's normally expected just in order to get an reimbursement from Medicare serving the needs of all the patients who are currently in those 20 nursing homes. What type of experiences are typical to the people who work in your laboratory?

Ms.BONIFAS. Thank you, Congressman Braley. I wasn't always the only laboratory that provided services to the Dubuque nursing homes. A large multi-physician clinic also used to send phlebotomists to the nursing homes and after awhile, they just stopped and basically United Clinical Labs was left with the business.

We don't do nursing home business because we make money on it. Most of it is out of a sense of obligation and if we don't do this, who is going to do this? We have three phlebotomists who go to the nursing homes. They used to go every day. As long as the nursing home called, we would send them. Now they go—The nursing homes have been put on a schedule. Certain nursing homes are only visited on certain days. We've worked with the homes to teach them how to draw their own blood. Our couriers pick it up.

But our employees that are going out to the nursing homes do that not because they get paid well for that because they don't and the reimbursement to go out to the nursing home to do that work is not much. But our employees that do that do it because they like to do it. They enjoy working with the older people and one of them in particular who has been a nursing home phlebotomist for over 25 years said even when she retires she would still do it and do it for nothing because she just likes the people in the nursing homes.

So, as I said, we don't do it because we make money on it. We feel there's a sense of obligation because if we don't do it, I don't know who will.

Mr.BRALEY. Isn't it true that given the age of the patient population in those nursing homes you're more likely to encounter patients who have compromised immune systems where these access to laboratory services can have a dramatic impact on their health outcomes?

Ms.BONIFAS. Yes, I think that would be true.

Mr.BRALEY. One of the things you talked about was some of the innovative things you were doing with electronic management of medical records and I guess my question for you is in this competition that CMS set up were there any points or positive awards made for people who were taking innovative approaches in EMR like you described your laboratory was doing?

Ms.BONIFAS. No, not to my knowledge. I don't think the bidding demonstration even requires that you transmit results electronically. But we were very innovative in Dubuque. I think if you talk to any of the Dubuque physicians, they will tell you one of the things they really like is this program that our in-house computer programmers wrote that allows them anywhere to access the result and it also saves money. Someone who is being seen in the hospital who also may have just been seen in the doctor's office rather than

ordering the test again, they can look and see "Oh, this person had this test. We don't need to order it. Here are the results." They can print that result. They can chart that result. It is a very innovative program and like I said, not available in most cities the size of Dubuque.

Mr.BRALEY. If a competitive bidding program were to be enacted in the Dubuque area, what can Medicare beneficiaries that rely upon United Clinical Laboratories for lab service expect to happen in terms of their care?

Ms.BONIFAS. Well, it depends if we're a winner or a loser or a winning loser maybe is the right.

Mr.BRALEY. I'm not sure if you win you really win.

Ms.BONIFAS. Exactly. Medicare beneficiaries are used to using our facilities and it's not just the Medicare beneficiaries. It's their physicians who are used to using our laboratory. If I'm a bid winner, then I'm going to get less reimbursement. If I'm not a winner, I'm not sure where they're going to go. I'm not sure where the physicians are going to have to send their testing. All of those, that infrastructure that we've built, that service delivery system, is going to be lost.

And because of the consolidated lab in Dubuque, physicians, even the large multi-physician clinic with over 100 physicians and the large internal medicine practice, they rely on us. Most of them don't do Medicare testing if they know we do it because they would rather send it to us and not lose money on it.

Mr.BRALEY. Thank you for sharing those insights and thank you for holding the hearing.

ChairwomanVELÁZQUEZ. Mr. Davis.

Mr.DAVIS. Thank you, Madam chairwoman and I thank the panelists for being with us today. I actually come out of the background of health care before I came to Congress. I understand CMS very well. I've dealt with them for almost 30 years either in the hospital setting or in an outpatient setting. Thank you for what you do.

One thing that I found and I would like to know if this is what you've seen in your experiences that bigger is not always best, farther away is not always best. Do you see in your judgment and experience having local access to physicians and clinical lab and home health care and pharmacies and those things that make for an integrated health system are done better at the local level or is it better done at some far away, out of sight resource and anyone could just answer that for me.

Mr.SCHILD. I would like to respond because New York is a unique market. Both the large players and the small players provide local service. So in New York, that isn't as much of a factor but the whole concept of just reducing the number of laboratories will have a significant impact on an already very, very crowded marketplace where access is key. We serve so many millions of people that we can't afford to reduce the number of players in the marketplace.

Mr.DAVIS. Anyone else?

Dr.WEISS. Health care is local and it's critically important that health care be delivered to patients by physicians and health care providers in the local areas. In our circumstance, we're a laboratory

located in Salt Lake City and we provide services to hospital laboratories and independent laboratories around the country. But we provide that in a very, very narrow niche of very unusual testing.

We don't attempt nor should we to provide services that are best delivered at the local level and to the populations in particular that we've been talking about, nursing home and homebound patients, it would be impossible for a laboratory like ours if we were required to bid and to bid on those services to provide those services in an effective way. It is really most important that those services be provided locally.

Ms.BONIFAS. I would also like to say that the service needs to be local. There is a place for both. There is testing that needs to be done in the community and it's the rapid turnaround time, the things that are needed right away, the easier things to do. That needs to be done in the community lab. Those tests shouldn't be sent to a large national reference lab.

There is a place for all labs. We need the national reference labs. We need the Mayos and the ARUPs and the Quests and the LabCorps. We need them to do the esoteric tests that we can't do because we don't have the technology or the expertise or the volume to do effectively. So we need everybody. We need the community-based laboratory and we need regional labs. We need national labs. We need everybody and we don't need to exclude anybody from that market.

Mr.DAVIS. In most industries in America, competition is a good thing. If you have more competition, it breeds better quality and it also breeds lower cost. Do you see that in health care?

Mr.SCHILD. It's an absolute in health care. The more players in the market, the more new ideas and concepts get introduced and sometimes the smallest labs in the industry have contributed technology that was adopted by all. So if you start reducing the number of small clinical laboratories that will disappear.

One example I could give you of technology that has impacted the whole industry is one of my competitors, Sunrise Medical Labs in Hophog Long Island, introduced the first computer system that helped distinguish a patient's insurance and which plan it had to go to because of some exclusionary decisions that were made by managed care organizations. Schild Medical Laboratory is working on introducing a new cardiac risk assessment test that we think is going to revolutionize the marketplace. So it is so important for there to be small players in the market because they, too, can reshape health care in a positive way.

Mr.DAVIS. Let me ask one last question. What will happen if a physician orders a stat test and you've gone to a national health system, basically what I see this coming to, and there's not that local competition there available and for the other members on the panel stat means immediate? Anyone like to take that as to what would happen?

Mr.BEJGROWICZ. Congressman, if I can. That resident would be shipped to the hospital incurring large costs while if we had that test performed in the nursing home, the physician then could treat the resident. Frankly, I'm very worried about the residents in the nursing homes. I really am.

Mr.DAVIS. Thank you. I yield.

ChairwomanVELÁZQUEZ. Mr. Sestak.

Mr.SESTAK. Thank you, Madam Chair. I probably only have one question but a couple of observations. I think this hearing is tremendous for a number of reasons. First, I was taken that CMS has absolutely ignored the Institute of Medicine's recommendation a few years ago that if it were to do this competitive bidding it was to be focused on gaining accurate information about market pricing by its purchase of service. They completely ignored that recommendation.

Second, every hearing I've been to has always talked about health care in terms of affordable, accessible, quality of care. For some reason, they've decided to talk about the affordability here. In lieu of the third point and missed so much else where affordability could be gained, you brought it up. One area would be preventive care. Heaven forbid if we ever looked at preventive, early diagnosis. Twenty-two percent of our payments out of Part B go to 67 percent of Medicare recipients because they had five more chronic disease, fee for service and you kind of looked at that management of that care and early diagnosis and continuing to help prevent it from getting worst, the savings would be enormous. And then we narrow down in this small area instead of going for the big prize.

And, finally, and most importantly is my own experience. You said it so well. But for me when my four-year-old daughter had her malignant brain tumor and was given three to nine months to live a year and a half ago, I can't tell you how helpful community-based system was and it was in the Navy. Tragedy struck us and I have to tell you as we hunted for the right labs because much of this stuff is done at home, you can, the right place that can do the right blood tests for tumors. Staying up throughout the night to administer stuff they give us, but always there on call because they had a great relationship with the patients and a great relationship with the hospitals.

I am quite taken that the quality of affordable, accessible health care goes a long way towards this type of community-based approach. I don't have the statistics to prove it, but I am quite taken as we came to know the small labs as we switched from brain surgeries to chemo to radiation to work on future hopefully quality of life. That's more of a comment.

But I was taken and if each of you would, in matter of fact, if you don't, if one or two just might, this community-based relationship you spoke about, I see it everywhere during my exposure there. It prevented the seams in which so much happens at the worst moment of time that if you have that kind of community-based relationship things don't get dropped through the crack. They can have some impact on your care. Would you can expound on that if you care? I made more of a statement because it was very personal to me. But there is something more to add on this community-based I think will go away with the focus upon larger rather than smaller.

Mr.SCHILD. I guess what I could add to that is our lab is very often willing to take on work that is a little bit more labor intensive and results a lower profit because we have to survive. So sometimes a tiny, tiny profit is better than none at all and we also

recognize that we live in a community and one of our contracts is with the visiting nurse service and we have an army of phlebotomists that go out on a daily basis and go to very homebound and ill patients and draw their blood and we deliver a quality result the very next morning or if it's stat, the same day and a lot of labs aren't willing to do that.

We agree with your statement and that's just why it's so important that we maintain our current system and re-examine other ways to reduce our Medicare expenditures.

Mr.SESTAK. And there are other ways.

Mr.SCHILD. There are so many.

Mr.BEJGROWICZ. Congressman, if I can just make a statement. From a nursing home perspective, the residents' lives are very scheduled and honestly the nursing home residents almost look forward to that visit from that phlebotomist. They become friends with that phlebotomist and that would disappear.

Mr.SESTAK. People can dismiss that easily but there are studies, statistical studies, that show the relationship that someone can have doing health care goes a long way to their health achievement. It's absolutely a fact. Thank you.

ChairwomanVELÁZQUEZ. Mr. Love, I noticed that you're still here and I'm glad that you decided to stay here. While I know that it is the policy of CMS to not testify on panels with industry, I just would like to ask you to please come to the table to answer just one question. Would you please come forward, Mr. Love? Fine.

Mr.LOVE. Yes madam.

ChairwomanVELÁZQUEZ. Mr. Love, given what you heard here today, will there be time for input by the industry before the implementation of the demonstration and when will the demonstration program start?

Mr.LOVE. Thank you. First, Mr. Sestak, I'm very sorry to hear about that. We have taken extensive input, some of which we got as recently as last week as you know from the Open Door Forum and we are not at the point where we are actually announcing a site and we are continuing to evaluate that input not only from the Open Door Forum, but at our web site we have received comments since the Open Door Forum, some of which I was reading well into last evening. We will continue to consider that information as we move forward.

ChairwomanVELÁZQUEZ. Well, the Committee still has a number of questions after we listened to the witnesses on the second panel and I would like to ask unanimous consent that we are going to send to you questions in writing and we expect those questions to be submitted to the Committee before you implement the program.

Mr.LOVE. We will certainly be responsive to the Committee's questions.

Mr.CHABOT. Madam Chairwoman.

ChairwomanVELÁZQUEZ. Yes

Mr.CHABOT. I assume you mean the answers to the questions.

ChairwomanVELÁZQUEZ. Yes, the answers to the questions before he implements the program.

Mr.CHABOT. Thank you.

ChairwomanVELÁZQUEZ. Thank you. And the gentleman is excused.

Mr.LOVE. Thank you.

ChairwomanVELÁZQUEZ. Let me just say that it is obviously that this is a very complex issue and I think every witness had provided compelling arguments here as why they feel that this project, this demonstration project, could put them out of business, compromising not only the free market system that we have but the quality of care that we are providing to the American people. So this is an issue that is important to this Committee in the sense that we have to make sure that every federal agency when they are creating rules, issuing rules, or creating new demonstration projects that they really take into account the impact that such a project will have on the small businesses.

We will continue to monitor this situation. We will ask CMS to continue to have meaningful meetings with the industry and to take into account those input provided for those small businesses that will impacted by this demonstration project.

I ask unanimous consent that members have five legislative days to enter them into the record without objection. So order and this hearing is now adjourned. Off the record.

[Whereupon, at 11:56 a.m., the Committee was adjourned.]

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.

Opening Statement

Hearing Name	Competitive Bidding for Clinical Lab Services: Where is it Heading and What Small Businesses Can Expect
Committee	Full Committee
Date	7/25/2007

Opening Statement of Ranking Member Chabot

Good morning and thank you all for being here as we examine the Centers for Medicare & Medicaid Services (CMS) Medicare Clinical Laboratory Competitive Bidding Demonstration Project. I would like to thank Chairwoman Velazquez for holding this hearing and each of the witnesses for taking the time to provide this committee with testimony.

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug Improvement and Modernization Act of 2003 (P.L. 108-173). This legislation produced the largest overhaul of Medicare in the public's health program's 38-year history.

Among other things, the legislation required CMS to run a demonstration using a competitive bidding and performance-based contracting procedures when entering into contracts for the administration of benefits under Medicare B. Before this legislation, Medicare contracting was not subject to competition. Between 2005 and 2009, CMS will be conducting full and open competitions to replace the contractors that currently perform claims processing and related functions for the Medicare program. The legislation requires the competition and resulting contracts be in accordance with the Federal Acquisition Regulation (FAR). FAR Part 19 implements Federal government policy to provide maximum practicable opportunities in its acquisitions to small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns. Such concerns must also have the maximum practicable opportunity to participate as subcontractors in the contracts awarded by any executive agency, consistent with efficient contract performance.

The legislation also requires CMS to conduct demonstration projects on the application of competitive acquisition for durable medical equipment, prosthetics, orthotics and supplies and for payment of clinical laboratory diagnostic tests that would otherwise be made under Medicare Part B clinical laboratory fee schedule. The latter competitive demonstration project is the subject of today's fact finding hearing to acquire a better understanding of the CMS demonstration project's definition and impact on small business clinical laboratories. In developing demonstration project procedures relating to competitive bidding and the awarding of contracts, the CMS is required by legislation to take appropriate steps to ensure

that small business clinical laboratories have an opportunity to be considered for participation. Unlike the contracting for administration of benefits under Medicare Part B, the legislation does not require the demonstration to be subject to the FAR.

Competition is the foundation of capitalism. Competition stimulates innovation, encourages efficiency, and drive down prices saving taxpayer dollars. Small Business has historically been the engine of innovation and a catalyst for competition. They also employ more than 50% of all employees.

While I support competition and the outcomes it normally produces, I want to ensure that the demonstration project's design methodology meets the intent of the Small Business Act by providing small business clinical laboratories the maximum practicable opportunities to participate in the demonstration as both prime contractors and subcontractor. It is also critical to the success of the demonstration project that CMS's demonstration project design maintain or enhance the current competitive environment, service accessibility, and service quality. The demonstration's project design should not result in fewer small business clinical laboratories leading to increased prices, reduced service accessibility, and a deterioration of service quality over the long-term.

We have excellent witnesses here today to provide us with insight into the rational behind the demonstration project's definition of a small business clinical laboratory and how the demonstration project's competition methodology ensures maximum practicable opportunities for them. I look forward to their testimony. Thank you Madam Chairwoman and I yield back the balance of my time.

Statement of The Honorable Jason Altmire
House Committee on Small Business Hearing
"Competitive Bidding for Clinical Lab Services: Where It's Heading
and What Small Businesses Can Expect"
July 25, 2007

Thank you, Chairwoman Velazquez, for calling today's hearing to examine the Center for Medicare and Medicaid Services' (CMS) plans to develop a new system to reimburse lab providers for Medicare services. While the goal to reduce payments for clinical laboratory services is laudable, I am worried that the proposed changes could restrict access to these services by harming small labs.

I am concerned that the competitive bidding demonstration program will have a harmful impact on small clinical labs that specialize in certain services and, in many cases, are the only labs that have the ability to serve small local communities. Despite receiving input from a number of small lab owners and industry representatives citing the negative impacts the program could have on small clinical labs, CMS evidently plans to go through with their proposed demonstration program.

I believe that CMS should reevaluate their proposed plan and take into consideration the cost their proposal will have on the future of clinical labs, both large and small.

Madam Chair, thank you again for holding this important hearing today. I yield back the balance of my time.

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Prepared Statement of Honorable Yvette D. Clarke, a Representative in Congress From the State of New York on "Competitive Bidding for Clinical Lab Services: Where's it Heading and What Small Businesses Can Expect"

July 25, 2007

I am pleased that this Committee is examining the laboratory competitive bidding demonstration project proposed by the Center for Medicare and Medicaid Services (CMS). Congress enacted the "Medicare Prescription Drug, Improvement and Modernization Act of 2003," authorizing CMS to design a competitive bidding demonstration project that will reimburse lab providers for Medicare services. As you know, Medicare is the single largest third-party payer of healthcare services, including clinical laboratory services, in the United States. Medicare also constitutes a significant portion of the work most labs perform.

CMS does this country a huge disservice by experimenting with a policy approach that not only adversely affects small businesses in their ability to operate and offer services, but it severely reduces an industry's overall quality and access. I do not believe CMS when they allege that during the demonstration project, quality and access will be protected for beneficiaries. The agency's failure to prove this viewpoint will almost certainly negatively impact the 11th Congressional District that I represent. Since Medicare reimbursements can represent 40 percent or more of the revenues for local laboratories, many small laboratories will most likely be forced out of business if this revenue is lost. The reduction of these laboratories will ultimately leave many patients in my district compromised to decent access, since many clinical labs may no longer be able to participate in Medicare under this extremely imperfect project. Additionally, small laboratories serving nursing homes, home health agencies, and public clinics will suddenly close and my constituents holding technical and non-technical jobs in those facilities suddenly will become unemployed.

I want to also make it very clear to CMS that their inadequate competitive bidding demonstration project will impact the nursing and long-healthcare industry, which is also critical to my district. Nursing facilities need a stable and highly qualified workforce. There are many highly qualified nurses and home healthcare workers in my district who provide quality care to our most vulnerable population of seniors and persons with disabilities. Unfortunately, this industry is struggling because of a shortage of workers to care for a rapidly aging population. This workforce shortage is only projected to get worse as we move forward in the 21st Century and this nation's population continues to age. The end game to the competitive bidding demonstration project is a ripple effect into diminishing the continuity of care for patients at smaller nursing homes in Brownsville, Crown Heights, Flatbush and Park Slope, just to name a few neighborhoods that elected me to protect their interests.

In conclusion, I urge this Committee to continue to reiterate to CMS the negative impact their proposed demonstration project will have on small clinical laboratories, which are one of the many economic engines that drives this country to success.

TESTIMONY OF

TIMOTHY P. LOVE

DIRECTOR FOR THE OFFICE OF RESEARCH,

DEVELOPMENT AND INFORMATION,

CENTERS FOR MEDICARE AND MEDICAID SERVICES

BEFORE THE

COMMITTEE ON SMALL BUSINESS

ON

CLINICAL LAB COMPETITIVE BIDDING

July 25, 2007

Testimony of

Timothy P. Love
Director, Office of Research, Development and Information
Centers for Medicare and Medicaid Services

Before the
Committee on Small Business
On
The Medicare Clinical Laboratory Competitive Bidding Demonstration
July 25, 2007

Good morning distinguished members of the Committee. I am pleased to be here today to discuss the clinical laboratory competitive bidding demonstration project mandated by the Medicare Modernization Act (MMA) of 2003.

In addition to basic demonstration requirements set forth by Congress, the Centers for Medicare and Medicaid Services (CMS) has adopted several features, outlined in greater detail in this testimony, in order to assure that smaller laboratories are treated fairly in the bidding process. A summary of key features includes:

- CMS will choose multiple winners, thus even small businesses will be allowed to participate in the demonstration, as opposed to "winner take all" selection in which only a large laboratory could be selected;
- CMS will exempt small laboratories with less than $100,000 annual business in the competitive bidding area from being required bidders. Those laboratories will be allowed to provide laboratory services to Medicare beneficiaries in the bidding area, but must accept payment at the competitive bid rate;
- The bidders will not be required to provide services to the entire metropolitan service area. Bidders with less capacity will be allowed to specify smaller areas

of service that they propose to cover. In order to protect beneficiaries, bidders will not be allowed to select customers who require less service; and

- Bidders that are not selected are able to continue providing laboratory services in areas outside of the competitive bidding area.

Overview: The Clinical Laboratory Competitive Bidding Demonstration

CMS is seeking to enhance its role as a prudent purchaser of clinical laboratory services, while maintaining a strong focus on beneficiary access and quality of care. Toward that end, Congress mandated a competitive acquisition demonstration project for clinical laboratory tests in the MMA. The clinical laboratory competitive bidding demonstration, consistent with other MMA- mandated programs, employs market-based competition to increase efficiency in Medicare. In requiring the demonstration, Congress determined that competitive pricing for clinical laboratories warranted consideration to make best use of Medicare resources.

Section 302(b) of the MMA set forth basic requirements for the clinical laboratory competitive bidding demonstration. The demonstration applies to services that would otherwise be paid under the Medicare Part B Clinical Laboratory Fee Schedule except for pap smears and colorectal cancer screening tests, and tests furnished by an entity that had a "face to face encounter" with the patient (for example, a physician office laboratory or hospital outpatient department laboratory, when conducting testing for its own patients). Hospital inpatient testing is covered by Medicare Part A and is therefore exempt from the demonstration. The clinical laboratory competitive bidding demonstration is, like all

demonstrations, a small scale experiment to scientifically evaluate a new approach and inform Medicare policy deliberations on a national scale.

Although the statute does not designate specific protections for small clinical laboratory business, CMS believes it is important to ensure that small suppliers have an opportunity to participate. Toward that end, CMS is taking extensive steps to ensure that the project is applied fairly to these small entities.

The MMA specifies that the quality standards established under the Clinical Laboratory Improvement Amendments (CLIA) apply to tests performed under the demonstration. Only CLIA-certified laboratories will be allowed to participate. The demonstration will rely on existing program policies and procedures, wherever possible.

The program will include multiple winners in each competitive bidding area and will achieve budget savings. The Secretary must submit an initial report to Congress, and subsequent progress and final reports as appropriate. The statute did not specify a starting date for the demonstration or the number or location of demonstration sites, CMS hopes to announce a finalized package and the first of two chosen sites for competitive bidding areas (CBAs) later this summer.

In September 2004, CMS contracted with RTI International (and their subcontractor Palmetto GBA, LLC) to assist in designing and operating the demonstration. To further support the project's development and gather input at an early stage of the design, CMS

held a Special Open Door Forum in August 2005, and RTI International convened an on-going Technical Expert Panel. The demonstration design takes careful steps to make sure small business players are treated fairly.

Small business laboratories are defined as those supplying less than $100,000 annually in demonstration tests (paid under the Part B Clinical Laboratory Fee Schedule) to Medicare fee-for-service beneficiaries residing in the CBA. Small business laboratories are not required to submit a bid in order to continue to receive Medicare payment for demonstration tests; however they will be paid under the competitively set fee schedule established for services provided to beneficiaries residing in the CBA. A laboratory that chooses not to bid under this small business provision will have its Medicare payment capped at $100,000 per year for demonstration tests for the duration of the demonstration. Laboratories that are not required to bid but choose to bid will be subject to the same demonstration rules as required bidders.

In April 2006, CMS submitted an Initial Report to Congress on the Medicare Clinical Laboratory Competitive Bidding Demonstration, as directed by the MMA. That report summarized the proposed design for the demonstration, which includes the following elements:

- Two demonstration sites will be selected within competitive bidding areas defined by Metropolitan Statistical Areas (MSAs). The demonstration will last for three years in each site, with staggered starting dates.

- Quality and access will be protected in demonstration for beneficiaries. For example, there are no out of pocket lab expenses for the beneficiaries under the demonstration. In addition, winning laboratories will be required to supply laboratory quality information throughout the demonstration. Further, quality measures will be required as part of the terms and conditions of the agreement. These include performance measures, which will be standardized for laboratories participating in the demonstration and detailed specifications for each of the quality measures will be made available to the laboratories prior to the start of the demonstration. CMS will provide a toll free number specifically established for questions and/or complaints regarding laboratories participating in the demonstration.

- Multiple "winner" laboratories will be selected based on price and non-price criteria, such as quality, capacity, and geographic coverage. Physicians and beneficiaries will have the choice of multiple winners competing with each other on the basis of quality testing and service.

- Further selection criteria for the demonstration sites include the potential for program savings, administrative feasibility, being representative of the laboratory market, and the ability to generalize results to other MSAs. The design contractor recommended the selection of MSAs with moderately large Medicare populations, and neither very low nor very high Medicare managed care penetration. While these criteria were

described in the April 2006 Report to Congress, specific sites have not yet been announced.

- The demonstration will apply to tests provided to beneficiaries enrolled in traditional fee-for-service Medicare whose permanent residence is in a competitive bidding area. Tests provided by independent clinical laboratories, and hospital and physician office labs performing tests for non-patients will be subject to the demonstration.

- CMS has taken steps to avoid having the competitive bid fee schedule be driven by only the largest labs in the area and intends to engender healthy competition among the largest possible number of suppliers. Laboratories with $100,000 or more in annual Medicare payments for demonstration-covered tests within the competitive bidding area will be required to submit bids if they want to continue to have the opportunity to provide demonstration-covered tests to Medicare beneficiaries.. As mentioned earlier, small labs (under the $100,000 threshold) will not be required to bid; however, they will be paid the competitively bid fee schedule amount for demonstration-covered tests (with annual payments capped at $100,000).

- Laboratories that are required to bid and choose not to do so will be ineligible for Medicare Part B payment for demonstration tests provided to beneficiaries residing in the competitive bidding area during the demonstration period.

Laboratories that bid and do not win will also be ineligible for Medicare payment for the demonstration tests for the duration of the demonstration.

- Laboratories that bid and win will be paid under a competitively set fee schedule established for the demonstration area. Fees for tests not covered by the demonstration will be unaffected by a lab's participation or non-participation in the demonstration. Such tests will continue to be paid under the regular Medicare Part B clinical laboratory fee schedule.

- As a beneficiary protection, beneficiaries who travel outside a CBA during the demonstration period and require laboratory services will still be able to receive services from most laboratories in the United States. Laboratories providing services to beneficiaries with permanent residence in the CBA who do not ordinarily serve the CBA, or who have little Medicare Part B revenue paid under the Clinical Laboratory Fee Schedule, will be paid the competitively set fee schedule rate, similar to a small business laboratory that ordinarily serves the CBA. Only a laboratory that was declared a non-winner under the demonstration, or those that were required to bid and did not bid will be denied payment for demonstration tests provided to a beneficiary with permanent residence in the CBA.

The key design elements for the demonstration have been approved by the Office of Management and Budget (OMB). Further operational details are under development within CMS.

Communication with Potential Bidders and Other Stakeholders

In an effort to proactively respond to questions and specific concerns from potential bidders and other stakeholders, CMS has been accessible to any interested individual or organization through Open Door Forums, the CMS website, and phone and email communications throughout the project's development. CMS staff has presented the project's status at numerous professional organization meetings and teleconferences, and have been available for interviews with the press.

Key demonstration design elements, products and dates have been presented to the public through the project webpage, which includes a project summary, a roster of the Technical Expert Panel, the Report to Congress, the October 2006 Proposed Demonstration Design (slides used in various public presentations),, the tentative demonstration test list, and handouts from several Open Door Forums. Information has also been widely distributed through the demonstration's listserv.

In addition, a draft Bidders' Package was posted on July 3, 2007 and announced via CMS' listservs, and a Special Open Door Forum (ODF) was held on July 16, 2007. The purpose of the ODF was to walk through the draft Bidders' Package and expected timeline as well as to address questions and comments about the demonstration. The

ODF also served to inform the larger stakeholder community about the demonstration, providing all potential bidders with the same data and information. After release of a final Bidders' Package, a Bidders' Conference will be held for potential bidders to learn more about the bidding process in the first selected competitive bidding area (CBA).

Conclusion

Thank you again for the opportunity to speak with you today and to continue fostering dialogue among small businesses as the demonstration is developed. I look forward to answering your questions.

American Health Care Association

Statement of

Tom Bejgrowicz

Licensed Nursing Home Administrator

on behalf of the

American Health Care Association

Before the

House Committee on Small Business

"COMPETITIVE BIDDING FOR CLINICAL LAB SERVICES: WHERE IT'S HEADING AND WHAT SMALL BUSINESSES CAN EXPECT"

JULY 25, 2007

Chairwoman Velazquez, Ranking Member Chabot, and all members of the House Small Business Committee, I appreciate the opportunity to testify before you today concerning the impact of the Center for Medicare and Medicaid Services' (CMS) clinical laboratory competitive bidding demonstration project on small businesses on behalf of the American Health Care Association (AHCA).

I am Tom Bejgrowicz, and I am a licensed nursing home administrator in the state of New Jersey. I am currently a Client Account Manager for Aculabs, a laboratory that services primarily nursing homes, and I have been an operations and management consultant for nursing homes for several years. I am a member of the Health Care Association of New Jersey (HCANJ), an association for long term care facilities, which is a member of the national AHCA. I was also a member of HCANJ's Regulatory Affairs Committee, and I am a member of the Society of Licensed Nursing Home Administrators of New Jersey.

AHCA is the nation's leading long term care organization representing nearly 11,000 non-profit and proprietary facilities, including nursing facilities, assisted living residences, subacute centers, and homes for people with developmental disabilities ranging from small, independent-owner facilities to regional, multi-facility chain corporations. The association recognizes that a majority of Americans – because of social needs, disability, trauma, or illness – will require long term care services at some point in their lives. AHCA member facilities are dedicated to continuous quality improvement and provide professional, compassionate care for millions of Americans.

For as long as I can remember, I have always been drawn to health care. From my father who is a physician, to my role as an emergency medical technician, to being a nursing home administrator, healthcare is in my blood. Over the past 17 years I have worked for privately held facilities, large corporations, and hospital owned not for profit centers. The quintessential moment that I decided to dedicate my life to helping others was when my grandfather was a resident in a nursing facility.

Since that time, I have become acutely aware of the vast number of federal and state regulations with which nursing facilities must comply. This oversight system was developed with a laudable goal in mind – to be resident-centered, outcome-oriented, and consistent. However, today's system bears little resemblance to the original intent and oftentimes, puts paperwork before quality patient care. The same illogical thought process is in place with the competitive bidding process for clinical lab services that I am here to discuss today. At best, the demonstration project may put smaller labs out of business. At worst, it may restrict access to quality health care for Medicare beneficiaries, limit choice, disrupt the continuity of care, and ultimately increase costs to Medicare.

The *Medicare Modernization Act of 2003* (MMA) required CMS to conduct a demonstration project to determine if competitive bidding can be used to provide Medicare beneficiaries with quality laboratory services at prices that are lower than current reimbursement rates under Medicare Part B. On July 3, 2007, CMS released a draft bidder's package, but this still did not answer a number of serious issues and concerns that have been raised. AHCA is concerned that Medicare beneficiaries at skilled nursing facilities (SNFs), in particular smaller facilities, will no longer have access to quality laboratory services if CMS continues with its plan to implement competitive bidding. I am here to tell you that the quality of care could be jeopardized and many residents, like my grandfather, could be negatively impacted if competitive bidding comes to fruition.

According to the *Omnibus Budget Reconciliation Act in 1987*, in a SNF, "each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being in accordance with the comprehensive assessment and plan of care." (42 C.F.R. § 483.5) One critical service provided to many SNF patients is clinical laboratory testing which is instrumental in providing accurate and appropriate medical care. According to the Department of Health and Human Services, Office of Inspector General (OIG), 81 percent of SNF residents receiving Medicare Part B services in 2002 also received clinical laboratory tests (approximately 1.4 million residents). SNFs depend on clinical laboratories to perform these tests on their residents and provide the results to the ordering physicians.

In addition to performing necessary tests, the clinical laboratories also provide SNFs with complimentary service delivery components. These tailored services go beyond that of simply analyzing a blood specimen to fulfill mission-critical needs nursing facilities require. Often for smaller nursing homes, these services are provided by relatively small, independent clinical laboratories.

Many tests for patients in long term care facilities, including protimes and therapeutic drug levels for drugs such as Vancomycin, Gentamycin, Dilantin, and Digozin, must be performed quickly with the results returned to the physician within the same day, in order to effectively treat and manage the patient's medical needs. In many cases, it is necessary for the SNF to receive test results back within hours of drawing the blood in order to ensure the patient receives the proper dosage of the necessary medication. An example is that many SNF patients are on blood thinner drugs for various reasons, including pulmonary embolism, atrial fibrillation, mechanical prosthetic valves, recent stroke and many other life threatening diseases. The protime test, which measures the time required for clotting, is essential to monitor the blood thinning drugs and assist the physician in maintaining them at therapeutic levels in order to prevent serious negative health consequences. Therefore, it is critical to have this test performed on a regular and timely basis. This is just one of many medically necessary examples of laboratory services that patients require.

In addition, STAT tests are needed immediately to diagnose and evaluate patients who are in a critical situation. Obviously, it could be life threatening to administer the wrong amount of a drug or to hold administration of a drug dose because the nursing facility is not able to have the blood drawn or receive the laboratory results in a timely manner.

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Some laboratories, particularly those that are smaller, independent laboratories, provide a quick turn-around time by providing a mobile phlebotomy staff that is available 24-hours a day, 365 days a year. These individuals come to the facility to draw blood and then deliver it to the testing facility to ensure the quickest and most efficient turn around time. Some laboratories also have laboratory personnel available 24-hours a day to perform tests (such as STAT tests), time draws and same-day requests. Often, these laboratories will provide a testing "menu" that is highly focused to ensure rapid turn around time of critical testing, will often develop "normal ranges" centered around specific age groups, and utilize certain testing methodology to ensure continuity of care. Our experience is that while the larger labs will in some cases do the tests, they are not interested in providing the tailored services including necessary phlebotomy and "turnaround" transport to long term care facilities.

I strongly believe that this competitive bidding demonstration will jeopardize laboratory services for SNF residents. Because the competitive bidding demonstration program will have the most impact on smaller SNFs, residents of these facilities are most at risk. According to data from National Center for Health Statistics, in 2004 more than 50 percent of SNFs nationwide had fewer than 100 beds. There will be fewer laboratories to choose from after the demonstration project is implemented, and those that remain are likely to be the larger, national laboratories because they will most likely be the low bidders. The larger laboratories will probably outbid smaller laboratories because of their economies of scale and coverage area. They generally provide a higher volume of services and will be able to make up the profit in other areas, whereas smaller laboratories may not have these options. These larger laboratories have generally focused their attention on more lucrative markets, such as physician offices.

There are no guarantees in the draft bidder's package that the competitive bidding "winner" will be forced to provide any level of testing to the long term care setting. CMS assumes that the winning laboratories are interested in servicing all Medicare beneficiaries. This is simply not the case. At times, larger laboratories have reduced services to long term care facilities when they decided to shift their priority and focus efforts on the more lucrative physician office. For example, in the 1990's a larger laboratory bought a smaller laboratory that serviced SNFs. The new owner decided that the smaller laboratory would no longer service SNFs and would instead provide other kinds of services. This happened again in 2007 when another larger laboratory acquired a different smaller laboratory. I would be happy to provide the Committee with documented examples.

At present, there are two major laboratories that command 60 to 70 percent of the market, and once competitive bidding is in place, they will likely have an even greater percent of the market in that competitive bid area (CBA). Under those circumstances, it is not likely the large labs will have more motivation to service the SNF population than they have now. Also, hospital outreach laboratories market mainly to larger, more lucrative nursing homes and those nursing homes that are in close proximity to the hospital.

The competitive bidding process will exclude other laboratories from entering the market for three years, and will stall the introduction of new laboratories into the market. With fewer laboratories to choose from, especially laboratories that service nursing homes, SNFs will not have access to services such as a mobile phlebotomy staff, and may instead have to arrange to have blood draws performed and transported, and test results are not likely to be returned in a timely manner. If physicians treating SNF patients are unable to receive results in a timely manner, they will either have to make a best guess of the drug levels that are needed or send the patients to the hospital via ambulance to have the tests preformed at a cost to the Medicare program. Neither solution is tenable - one possibility may lead to medication errors and the other comes at a significant cost to taxpayers.

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AHCA understands that the quality of care provided in our nation's skilled nursing facilities is incumbent upon a stable, well-trained workforce. Moreover, the continued success of the long term care profession's quality improvement initiatives also is contingent upon adequate, stable funding levels – as well as the ability to boost the actual supply of long term caregivers relative to demographic trends – a growing concern as 77 million baby boomers are virtually on America's retirement doorstep.

Frontline caregivers – including nurses and certified nursing assistants – are indispensable to our collective mission to provide quality care to our most vulnerable population of seniors and persons with disabilities. Unfortunately, long term care facilities face a dire need for additional caregiving staff. The current long term care workforce shortage is only projected to get worse over the next decade as the population ages. In fact, the Bureau of Labor Statistics predicts a 45 percent increase in demand for new long term care workers between 2000 and 2010 alone – the equivalent of approximately 800,000 new jobs. Therefore, it is not realistic to expect nurses, who are already overworked and burdened with regulatory mandates to care for their residents, to perform the additional task of providing phlebotomy services. There are not enough man-hours to allow a nurse to draw blood while performing other duties. Nursing facilities would then incur additional costs associated with increased staffing, training, and education.

Not only will access to laboratory services be seriously curtailed, but the quality of laboratory services could also be impacted. CMS has not yet released detailed specifications for the indicators that it plans to use to measure laboratory quality of care, although it plans to implement the demonstration project in less than a year. The health care community has asked CMS repeatedly for the performance measures that will indicate quality of care, but CMS has not yet developed them. On July 16, 2007, CMS held an Open Door Forum regarding the draft bidder's package, during which agency staff indicated that it would create these performance measures, but did not give a time line as to when that would be done. As well, on page 50 of the draft bidder's package, CMS states that quality measures will be standardized across all laboratories. This "one size fits all" mentality does not apply to the dynamic field of laboratory medicine. Consider the 90 year old nursing home resident with congestive heart failure versus a healthy individual going for a routine checkup. Based on CMS' guideline, two different laboratories testing these patients will be held equally accountable. Without clearly defined performance measures, such as turn around time, log-in error rates, and lost specimens, there is no guarantee that winning laboratories will provide high quality of care that SNF residents require.

Also, an important consideration not to be overlooked is cost. The cost to provide Medicare services to SNF residents is significantly higher then to provide services to other populations. SNFs are increasingly caring for much sicker, costlier Medicare beneficiaries, who require more frequent laboratory testing. While laboratory costs associated with SNF care have risen somewhat, it is important to note that according to the June 2007 Medicare Payment Advisory Commission (MedPAC) report, Medicare spent only approximately 2 percent of its total program expenditures on clinical laboratory services. Clinical laboratory services include services for SNFs, assisted living facilities, physicians, and hospitals.

Another cost consideration involves the lack of competition, as mentioned above, and the "opportunity cost." Without fully being able to predict the short and long term impact of the demonstration project, it can be expected that small independent laboratories will be eliminated. Due to the restrictively high cost of re-entry into the laboratory field, there will be fewer laboratories when re-bidding commences. Once the demonstration project goes into effect, it will not be possible for a "new" laboratory to perform services within the demonstration area. Both new and existing laboratories, who are interested in expanding their territory, will be excluded from Medicare payment system, even if their charges could be lower than laboratories currently providing services under competitive bidding.

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Continuity of care for patients at smaller nursing homes may also suffer. Smaller laboratories that are not able to participate in competitive bidding may be required to close due to decreased business, and SNFs will be required to find another laboratory to provide services. Not only will the SNF and the patient have to adjust to a new laboratory service provider, but also it may take the SNF some time to find an alternate provider.

CMS has been repeatedly informed of the negative impact of the proposed demonstration on nursing home residents. We submitted a number of recommendations that we believe would better able to protect this population, and these recommendations are attached. Some of these recommendations include the following for inclusion in the bid evaluation mechanisms and criteria:

a. Evidence of established service capability for patients residing in nursing home facilities and at home, requiring that results for tests be provided as follows:

    i. Protime; results early in the same day venipuncture is performed in the early morning.
    ii. Chemistry testing, therapeutic drug testing, CBC, Urinalysis testing; results later the same day if venipuncture is performed in the early morning.
    iii. All STAT tests; results consistently within 4 ½ hours of request.
    iv. All other non-STAT tests performed in-house (Thyroid tests, HgbA1c, etc.), except for cultures; results the same day if venipuncture is performed before noon.

b. As part of the bid, each laboratory must provide the name and contact information for each nursing home facility that it has an existing contract with and additional proof of the contract. The demonstration must include a substantial number of the clinical laboratories that have existing nursing home facility contracts to provide STAT and same day test services to nursing home facilities in the demonstration area. "Substantial number" means the number of clinical laboratories that combined together have over 80% of the existing contracts with nursing home facilities located in the demonstration area.

c. For smaller laboratories, including those laboratories that primarily service nursing home and home-bound patients residing in the demonstration area, limit a laboratory's requirement to bid to all of the laboratory test codes that a laboratory has performed in-house and billed to Medicare Part B (without a 90 modifier) and included under a National Provider Number.

d. Exclude the venipuncture fee from competitive bidding; or, in the alternative, separate the bid for venipunctures from the bid for the other laboratory tests and establish a "floor" price; or, in the alternative, separate the bid for venipunctures from the bid for the other laboratory tests and permit bidding for two different venipuncture fees in order for the true cost of these fees to be included in the price of laboratory services: a nursing home and home-bound venipuncture fee and a patient service station venipuncture fee.

However, when CMS recently published its draft bidders' package, it did not include any of these recommendations. Rather, CMS responded by stating that it would consider the "ability [of the bidding labs] to provide or arrange for needed services to special populations and provider types." While we appreciate that CMS recognizes nursing home residents have special needs, the CMS bidding documents

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do not require labs to provide information about how or even whether the laboratory will provide services to these and other vulnerable populations. So, we are very skeptical that there is a way in the proposed demonstration for CMS to protect the care and services required by nursing facility residents. It will be too late if nothing is done until after the demonstration is implemented because the smaller labs that service these facilities will not be able to survive losing their Medicare business.

On behalf of AHCA, I appreciate the opportunity to testify before you concerning this pressing health issue. This decrease may impact access and quality care, as well as potential increase in cost to Medicare goes against AHCA's mantra of performance excellence and commitment to affordable, healthy, and ethical long term care. It is with the best interest of all long term care residents and all Medicare beneficiaries that I ask Congress to re-examine this ill-conceived plan and repeal the competitive bidding legislation.

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Re: Medicare Clinical Laboratory Competitive Bidding Demonstration: Impact of Medicare Clinical Laboratory Competitive Bidding Demonstration on Skilled Nursing Facility Beneficiaries

Dear Ms. Norwalk:

I am writing on behalf of the American Health Care Association (AHCA) regarding the pending Medicare Clinical Laboratory Competitive Bidding Demonstration. AHCA, and its members, are committed to performance excellence and Quality First, a covenant for healthy, affordable and ethical long term care. AHCA represents more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

AHCA is very concerned about the impact on skilled nursing facility (SNF) residents of the proposed Medicare Clinical Laboratory Competitive Bidding Demonstration (the Demonstration). We have reviewed a paper that we understand was submitted to the Centers for Medicare and Medicaid Services (CMS) on December 15, 2006 by a Coalition of Clinical Laboratories Serving Nursing Home and Homebound Patients that requests CMS to provide special consideration to the nursing home laboratories required to participate in the Demonstration. We have attached the Coalition paper for your convenience.

Essentially, we are requesting that if CMS includes these laboratories in the demonstration then CMS should also establish specific bid award criteria, consistent with the Coalition's request, to ensure that quality laboratory services continue to be provided in a demonstration area to SNF patients.

Background

AHCA has many concerns about the impact and effect of competitive bidding overall on the ability of SNFs to continue to provide high quality care. Our concerns first focused on competitive acquisition of certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). On June 28, 2006, AHCA filed comments on the proposed rule on DMEPOS.

We argued that CMS must balance its proposed policy changes with the existing federal requirements mandating that SNFs assume responsibilities that "each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care (42 CRF 483). We feared that altering the acquisition of DMEPOS services could affect the ability of facilities to meet their regulatory obligations.

CMS had recognized such obligations in the implementation of Medicare Part D. This lead CMS to adopt special rules for pharmacy procurement to beneficiaries in long term care facilities and we concluded that this should apply to other items and services provided to residents. Accordingly, we urged CMS to exclude SNFs from the scope of the competitive bidding process or at a minimum, study the affects that competitive acquisition will likely have on patients and institutions before extending the demonstration to include long term care facilities.

We argued that SNFs should be able to select the supplier of services for patients within the SNF. Most SNFs have established relationships with suppliers of covered products and supplies that are built on trust, service and responsiveness. Some SNFs obtain a supplier number and bill for the services directly. Other SNFs obtain a supplier number and employ a third-party to bill for the services. SNFs have an obligation to be responsive to clinical needs in a very timely manner. Absent the ability use suppliers that offer the type of services and performance necessary for patients within SNFs, we feared that facilities would be at risk without market choices.

In the final rule, we were not able to achieve exclusion of SNFs but did at least achieve their ability as suppliers to continue to supply to their own residents.

It has now been brought to our attention that some of the same problems that we feared regarding competitive bidding for DMEPOS are also raised by the application of competitive bidding to laboratory services to SNF residents.

Impact of Medicare Clinical Laboratory
Competitive Bidding Demonstration on SNF Beneficiaries

Section 302 (b) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 requires the Secretary of Health and Human Services to conduct a demonstration project to determine whether competitive bidding can be used to provide quality laboratory services at prices below current Medicare reimbursement rates.

In a recent report, the OIG stated that in 2002, 81 percent of SNF residents receiving Medicare Part B services also received clinical laboratory tests (approximately 1.4 million residents). We understand that the large national laboratories have a demonstrated disinterest in servicing the labor intensive and higher cost SNF populations, having historically discontinued those services when they acquire small laboratories. In one small state a predominant large national laboratory has terminated contracts with several SNFs.

The large laboratories will have even less incentive to service the SNF population if there are fewer laboratories permitted to provide services. The demonstration will lead to further consolidation of the marketplace to the detriment of the SNF community and their patients.

Relatively small independent clinical laboratories serve primarily a SNF or home bound population, and their services are tailored to the needs of this population. These laboratories provide rapid turnaround and same-day results for these critical care patients, many of whom are senior citizens. To support the needs of these at-risk patients, the laboratories provide a mobile phlebotomy staff that is available 24hours a day, 365 days a year to make face-to-face encounters in the same manner as physician office laboratories (POL) and hospital laboratories. And what is critical -- they value providing services to this population and do not abandon them. The quality of care provided in SNFs and at home would be seriously impaired by disinterested laboratories and inadequate clinical laboratory services and testing.

The clinical laboratory competitive bidding demonstration plan does not protect Medicare patients who reside in long-term care settings and who need a higher level of care, which is not provided by the larger laboratories that are likely to be the low bidders in the demonstration. Failure to address this problem in the demonstration can portend deteriorating laboratory services for residents in SNFs.

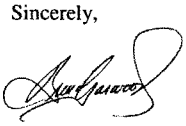
As with DMEPOS, competitive bidding for laboratories deprives the SNFs of their ability to choose high quality laboratories dedicated to SNF resident laboratory services. Again, federal requirements mandate that SNFs assume responsibilities that "each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." (42 CRF 483) Putting small dedicated long term care laboratories in jeopardy makes it increasingly difficult for SNFs to meet these obligations regarding laboratory services.

AHCA, therefore, supports the Coalition's request that if CMS includes these laboratories in the demonstration project then it should also establish specific bid award criteria consistent with the Coalition's request set forth in its December 15, 2006 paper. Inclusion of these criteria will help to ensure that quality laboratory services continue to be provided in a demonstration area to SNF patients. These laboratories need special consideration so that patients in nursing homes continue to receive the high quality, cost-effective laboratory tests and services that are provided to this patient population today.

The long term care profession has made tremendous strides to improve the quality of care and the quality of life of the nearly three million Americans who require critical SNF care and services every year. At no time in the long term care profession's recent history has the

commitment to quality been greater. I ask your help in sustaining our momentum and preserving our ability to choose the highest quality providers of SNF laboratory services.

Sincerely,



Bruce Yarwood
President and CEO

cc: Timothy P. Love, Director
Medicare Demonstrations Program Group
Office of Research, Development, & Information
Centers for Medicare & Medicaid Services

ATTACHMENT

Impact of Medicare Clinical Laboratory Competitive Bidding Demonstration on Beneficiaries Residing in Nursing Facilities or at Home; Recommendations to CMS for Bid Evaluation Mechanisms and Criteria

1. **Clinical Laboratories Critical Role of Supporting the Care of Medicare Patients Residing in Nursing Facilities or Their Homes.**

Kilbourne Medical Laboratories ("Kilbourne") and Clinical Health Laboratories ("Clinical Health") are relatively small, independent clinical laboratories located in and serving primarily the residents of Ohio. Neither laboratory would qualify to be a "passive lab" under the proposed demonstration. These laboratories fill a specific niche by specializing in providing services to patients who reside either at home or in the nursing home. Each laboratory provides 85% to 95% of its laboratory services to this patient population. These independent regional laboratories provide a significant and specialized service that is not readily available or performed by large national laboratories or hospital outreach laboratories. The large national laboratories have shown their disinterest in serving the nursing home business and have focused their attention on the more lucrative physician office market (See attached Memorandum from the Ohio Academy of Nursing Homes; and Letters from a large national laboratory terminating services to nursing homes in the Columbus, Ohio area). The hospital outreach laboratories are strategic players, and market mainly to larger, more lucrative nursing homes and those nursing homes that are in close proximity to the hospital.

There is a distinct difference between **laboratory testing** and **laboratory services**. Standard laboratory testing cannot be compared to the services that are provided by independent laboratories servicing nursing home and homebound patients. It is important to understand that there are a number of additional service delivery components for testing that are provided by these independent clinical laboratories.

First, all clinical laboratories perform tests and provide results to the ordering physician. For nursing home or homebound patients, laboratories provide primarily 100 commonly ordered tests from the possible array of tests, which represent 98% of all tests ordered. The laboratories may provide other tests but these tests are the most common. While providing the test has been "standardized" to a great extent, making sure that the results are delivered in a timely manner is heavily dependent on the service delivery capabilities of the clinical laboratory provider. Many tests (for example, protimes and therapeutic drug levels for drugs such as Dilantin, Digoxin, Vancomycin and Gentamycin) must be performed quickly with results returned to the physician the same day in order to effectively treat and manage the patient. In order to properly dose the patient, it is necessary for the nursing facility to receive test results back on the same day, and in many cases, hours after venipuncture. For example, the protime test measures the

amount of time required for a plasma specimen to clot. Many nursing facility patients are on blood thinner drugs for various reasons like pulmonary embolism, atrial fibrillation, mechanical prosthetic valves, recent stroke and many other life threatening diseases. The protime test is used to monitor the blood thinning drugs and assist the physician in keeping them at therapeutic levels to prevent serious negative health consequences. Therefore, it is critical to have this test performed on a regular and timely basis. This is just one of many medically necessary examples of what these laboratories do for nursing home patients. There are many other critical tests that need to be performed in a timely manner: electrolytes, BNP, glucoses, urinalysis to determine if there is an infection, CBC to test anemia, blood levels for cancer patients, and thyroid levels for critical patients. In addition, STAT tests are needed immediately to diagnose and evaluate patients who are in a critical situation. Obviously, it could be life threatening to administer the wrong amount of a drug or to hold administration of a drug dose because the nursing facility is not able to have the venipuncture performed or receive the lab results in a timely manner.

Second, beyond adhering to the necessary turnaround times for providing these test results, these laboratories provide critical access to laboratory services for nursing home and homebound patients, which typically are a much sicker and frailer population. These services are otherwise limited and difficult for nursing homes to perform. If not performed by these laboratories, the nursing home must arrange to have the blood draws performed and transported, and the test results returned in a timely manner. This is difficult in an environment where nurses are in short supply and other laboratories are less able to return test results in a timely manner. This service and access is what differentiates these labs from laboratories with the "just a lab" mentality of producing test results. These laboratories provide rapid turnaround and same-day results for these critical care patients, many of whom are senior citizens. To support the needs of these at-risk patients, the laboratories provide a mobile phlebotomy staff that is available 24hours a day, 365 days a year to make face-to-face encounters in the same manner as physician office laboratories (POL) and hospital laboratories.

A majority of Kilbourne and Clinical Health's phlebotomy staffs start their day early in the morning (between 1:00 and 4:00 AM). The phlebotomist drives to each location, properly identifies the patient or patients, and performs the specimen collection (as many specimens as needed, which could be as few as one specimen collected). Laboratory staff pick-up specimens like urine, stool or wound cultures at nursing facilities, as well. Even if there are no draws to be performed, collected samples (like urine) will be picked-up at no charge to Medicare, the nursing facility or the insurance company. The specimens are transported back to the lab for testing. It should be emphasized that when staff performs a homebound draw it is for a single patient at one location.

Third, laboratory personnel are available 24/7 to perform STAT tests, time draws and same-day requests. Besides laboratory technician and phlebotomy staff, these laboratories have a team of professionals that take orders from nursing facilities and other clients and review the medical necessity of the tests and all other proper billing, HIPAA and CLIA requirements. They dispatch staff to perform venipunctures or specimen collections that are necessary to maintain quality healthcare. The largest line item

expense for these independent labs is people because these laboratories require both mobile staff to execute all orders, perform blood draws, and transport the samples, and on-site technical and service personnel to perform the tests and return the results (including providing information technology support). While providing a high level of service, these laboratories provide tests that are reimbursed at the lower end of the Medicare fee schedule versus the much higher payments for reference and esoteric tests provided by the larger laboratories.

Kilbourne and Clinical Health perform these services because of the increased number of Medicare beneficiaries and other patients who are transferred from hospitals to nursing home facilities based on the financial pressures of shortened authorized lengths of stay and the enhanced clinical benefits for patient. These patients tend to require a high level of care, need a larger number of STAT tests than the typical nursing home patient, and are generally the most vulnerable Medicare patients. While the needs of the nursing home patient have increased, this patient population has been virtually abandoned by the national laboratories that have decided to focus their services on the more lucrative physician market.

The nursing home labs get results back in the early afternoon every day plus perform STAT testing 24/7, same day service, and timed draw service. Without receiving results in a timely manner, either physicians will make a best guess of the drug levels that are needed or they will be forced to send their patients to a hospital via ambulance, which would be extremely expensive.

We feel that the nursing home laboratories under this demonstration raise issues similar to those confronted by long term care pharmacies under Medicare Part D. But in the proposed demonstration, a nursing home lab will not be able to participate if its bid is not accepted. At least under Part D the standard terms and conditions of the Part D plan's pharmacy contract are required to be offered to the long term care pharmacy. (42 CFR 423.120(a)(5)) There does not appear to be any similar "leveling of the playing field" for specialized providers like those laboratories servicing nursing facility and home-bound patients under the proposed demonstration.

2. Recommendations to CMS for Bid Evaluation Mechanisms and Criteria to Protect Residents of Nursing Homes and Home-Bound Patients.

Kilbourne and Clinical Health request that CMS consider the following recommendations together for inclusion in the bid evaluation mechanisms and criteria:

d. Evidence of established service capability for patients residing in nursing home facilities and at home, requiring that results for tests be provided as follows:

i. Protime; results by 1:00 PM of the same day venipuncture is performed in the early morning.

ii. *Chemistry testing, therapeutic drug testing, CBC, Urinalysis testing; results before 4:30 PM if venipuncture is performed in the early morning.*
iii. *All STAT tests; results consistently within 4 ½ hours of request.*
iv. *All other non-STAT tests performed in-house (Thyroid tests, HgbA1c, etc.), except for cultures; results the same day if venipuncture is performed before noon.*

Rationale: Nursing home and home bound patients need to have laboratory service that provides timely return of test results to the physicians. Evidence required to meet these criterion would be submission of documentation showing the laboratory's substantial experience working with nursing home facilities and an adequate number of phlebotomists on staff in the metropolitan statistical area ("MSA").

e. *As part of the bid, each laboratory must provide the name and contact information for each nursing home facility that it has an existing contract with and additional proof of the contract. The demonstration must include a substantial number of the clinical laboratories that have existing nursing home facility contracts to provide STAT and same day test services to nursing home facilities in the demonstration area. "Substantial number" means the number of clinical laboratories that combined together have over 80% of the existing contracts with nursing home facilities located in the demonstration area.*

Rationale: Nursing home facility and home bound patients need to have laboratory services that provide timely return of test results. Ensuring that a substantial number of these laboratories are included in the demonstration will maintain the access and quality of care required to serve the most vulnerable Medicare population.

f. *For smaller laboratories, like Kilbourne and Clinical Health, including those laboratories that primarily service nursing home and home-bound patients residing in the demonstration area, limit a laboratory's requirement to bid to all of the laboratory test codes that a laboratory has performed in-house and billed to Medicare Part B (without a 90 modifier) and included under a National Provider Number.*

Rationale: Because much of the test menu is out of the control of the nursing home labs, these labs must rely on reference labs to perform and price well over 90% of the other tests on the Medicare fee schedule. To date, both of the large national laboratories have been approached by Kilbourne and Clinical Health, separately, and neither is interested in providing a bid to the nursing home labs for the demonstration. Even if they did provide Kilbourne or Clinical Health with a bid, these labs have no leverage with the large national labs. The large labs would likely

submit a high test price to the independent labs so that they have a greater advantage to win the bid. CMS is asking regional labs to bid on a substantial number of tests that they do not perform in-house as a condition for these labs to be able to continue to service Medicare beneficiaries in the demonstration area. These outsourced tests on average are at least twice as costly as the tests which nursing home labs perform.

These facts put the nursing home and other smaller labs, like Kilbourne and Clinical Health, at a significant disadvantage:

1) If the national labs do not provide these labs with test prices for the demonstration then these independent labs will not be able to bid for the demonstration; or

2) If the national labs provide test prices to these independent labs, then those prices will likely be higher than the national labs own bid to CMS because the national labs have no incentives to provide lower prices to labs that they are competing against in the demonstration. These higher prices will likely result in "pricing" the nursing home and other small independent laboratories out of the competition.

Either way, the effects will likely be higher prices for the tests that are provided by the large labs and elimination of the nursing home and smaller independent labs from the competition by increasing their aggregate bid price to a point that exceeds the "pivotal" bid. It is not clear how either of these events benefit CMS.

Limiting bids to those laboratory test codes that are billed to Medicare by the laboratory will permit these labs to bid for the services that they perform and control, without the need to subcontract high price tests to a party that has no interest in giving them a competitive price. In order to protect the Medicare Program, we recommend including the other bidding labs average bid price for the tests that are not bid by these smaller laboratories in order to determine a composite bid price for each smaller laboratory. This will have the effect, we believe, of ensuring a competitive bid by these laboratories. The laboratories will then also be able to refer tests to a large laboratory that will be paid under the competitively bid fee schedule.

d. *Exclude the venipuncture fee from competitive bidding; or, in the alternative, separate the bid for venipunctures from the bid for the other laboratory tests and establish a "floor" price; or, in the alternative, separate the bid for venipunctures from the bid for the other laboratory tests and permit bidding for two different venipuncture fees in order for the true cost of these fees to be included in the price of laboratory*

services: a nursing home and home-bound venipuncture fee and a patient service station venipuncture fee.

Rationale: Other larger laboratories will likely bid venipunctures based on patient service station costs, not the higher cost of performing venipunctures in a nursing home or home-bound setting. The Medicare venipuncture fee is already low and has not been updated since 1984 when it was introduced. The salary and benefit cost alone for employing phlebotomists has obviously increased over this 20 year time frame. The long established venipuncture fee of approximately $3 does not cover the costs (the venipuncture fee would be approximately $5.82 if it were simply updated based on increases in the Consumer Price Index (CPI) which distinguishes it from Medicare laboratory test fees that are updated annually using the CPI). Time studies support that the time spent (not including travel time) by the phlebotomist in performing a venipuncture for a nursing home or homebound patient is almost twice as much as that required for performing venipunctures at patient service station visited by a patient. This reflects the time spent identifying the patient, set-up time, the physical environment in which the test is performed, the age and physical characteristics of the patient, and various requirements to venipuncture a specimen such as blood cultures. Further, nursing home and homebound patients require more supplies and time to service because:

i. Both nursing home and homebound patients are often harder to venipuncture requiring at times multiple sticks. This means a new needle, gloves and testing tube for each attempt to venipuncture one patient.

ii. New regulations require laboratories to use safety self-sheathing needles, which cost far more than just a needle. (OSHA - Safe Needle Act). A previous needle cost approximately .058 cents per needle. These laboratories are now paying .235 (a 75% increase in costs) as a result of this requirement alone.

There is no requirement that the specimen venipuncture fee be included in the competitive bidding as it is not a part of the "tests" that are described in the competitive bidding law. (*See* 42 USC 1395w-3(e)(1)) The fee is not part of the Medicare Clinical Laboratory Fee Schedule, but is a separate fee to cover the "appropriate costs" of the collection of the specimen. (*See* 42 USC 1395*l*(h)(3)) This fee is very similar to the travel fee that CMS has said is already excluded from the bidding. Therefore, the venipuncture fee, like the travel fee, should not be included in the bidding as it is not a "test" required to be included and, if included, will likely put these laboratories at a significant disadvantage with respect to servicing nursing home and home-bound patients.

In the alternative, in this demonstration CMS should increase the venipuncture fee to a minimum of $5.82 which reflects what the increase should be if it followed the CPI, and keep separate the bid for venipunctures and separate the bid for venipunctures from the rest of the bid.

Finally, if these alternatives are not acceptable to CMS, consider separating the bid for venipunctures from the bid for the other laboratory tests and permit two different venipuncture fees in order for the true cost of these fees to be included in the price of laboratory services: a nursing home and home-bound venipuncture fee; and a patient service station draw fee. Separate bidding for these different venipuncture services will allow for the true cost to be included in the bid price. This will also allow these labs to compete on the venipuncture fee. As described above, nursing home and home-bound blood venipunctures cost these labs more than the fee that is currently reimbursed under the Medicare Program and differ greatly from the cost of drawing blood at a patient service station.

3. Other Concerns with Demonstration Project

g. Performance Measures. The nursing home laboratories recommend that CMS develop a system to track all laboratories participating in the demonstration to ensure that nursing home and home bound patients are receiving timely venipunctures and results are provided to physicians in a timely manner. The laboratories also recommend that patients and providers have a mechanism to communicate service complaints to CMS. Ideally, a toll free phone number would be established by CMS to permit communication of these complaints. CMS would then have real-time access to significant performance issues of demonstration laboratories, particularly those that impact the vulnerable patient population residing in nursing facilities.

h. Audited Financials. These laboratories are concerned about the bidding requirement to provide CMS with audited financials. Not only is the requirement expensive but it is not clear that there will be sufficient time to have financial statements audited after the application is finally approved by OMB. These laboratories have been in business and billing Medicare for a very long time. It is not clear what additional protection audited financials provide to Medicare that CMS does not already know. The demonstration laboratories will not be paid on a capitation or other risk basis that would require assurance of financial reserves, but rather will continue to bill on a fee-for-service basis. While CMS should be concerned about adequate levels of service and ability to perform, audited financials should not be required for a laboratory that currently provides services in the demonstration area.

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House Small Business Committee

Hearing on Competitive Bidding for Clinical Lab Services

July 25, 2007

Testimony of

Mary Jo Bonifas, Manager of Laboratory Services-United Clinical Laboratories, Dubuque, Iowa

Board of Directors, CLMA-Iowa Chapter

President, Board of Directors, CLMA PAC

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.

Competitive Bidding for Clinical Lab Services:
Where's It Heading and What Small Businesses Can Expect
Hearing of the House Committee on Small Business
2360 Rayburn House Office Building
July 25, 2007

My name is Tod Schild. I am the Senior Vice President of Shiel Medical Laboratory ("Shiel") headquartered in the Brooklyn Navy Yard, which is part of the 12th Congressional District. I am testifying on behalf of our laboratory today, but I also wish to associate myself with the written testimony of the National Independent Laboratory Association ("NILA"), of which our laboratory is a member. Shiel is a commercial clinical laboratory employing 360 employees. 70 percent of our testing volume comes from physician practices, 25 percent from a total of 80 Nursing Homes and 5 percent from institutional accounts.

The demonstration project designed by the Centers for Medicare and Medicaid Services ("CMS") will irrevocably alter the market for laboratory services, reduce patient choice, and limit access to quality testing.

The project has critical flaws and missing pieces. Rather than fostering competition it will create government sponsored oligopolies. Instead of reducing laboratory costs for Medicare, it will increase costs. Rather than improve the quality of healthcare, it will diminish patient access and stifle life-saving innovation. We all agree that overall Medicare cost reductions are desirable, but this is not an appropriate way to achieve that goal.

I. Structure of the Laboratory Market

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. 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 Federal Trade Commission ("FTC") and the Department of Justice ("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.

II. Labs Will Shut Down, Jobs will be Lost

If the CMS proposal is allowed to proceed, hundreds of small and medium sized local and regional labs will shut down. Thousands of technical and non-technical jobs will be lost. This is not rhetoric. It is a fact. Medicare is a significant portion of the work most labs do. At Shiel Medical Lab, it is 30 to 33 percent. It is not uncommon for labs that focus primarily on nursing homes to have 70 to 80 percent Medicare. Furthermore, small and regional laboratories begin the bidding process on an uneven playing field. The two largest providers in the marketplace have the benefit of being able to shift their costs outside of the demonstration zone. The bid we submit will most likely be for all of our Medicare work. 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.

Loss of the ability to perform and bill tests for Medicare patients would most assuredly be a death sentence for the vast majority of non-winning bidder laboratories. The way the demonstration was designed is that only a handful of laboratories will be winners in the demonstration area. Non-winners will be out of the program for three years before they get a chance to bid again. Very few will even be around at that point. I can illustrate this easily using Shiel as an example. Our profit margin, you may be surprised to know, is only between five and seven percent. If we were to lose 30 percent of our total revenue it would be difficult to keep our doors open for even a year, and impossible beyond that. The surviving labs will be the national giants. In lower New York, there are at least 30 labs that would be required bidders. Even if 10 were "winners" (which is unlikely) in the bid process, 20 quality labs will cease to exist. The whole concept of increasing competition that the demonstration hopes to accomplish simply disappears. Fewer players in the marketplace with higher demand for diminished services is the outcome. Over time, the simple economics of supply and demand comes into play, and we all know what the result of that is: higher costs.

III. What is a "Small Business Clinical Laboratory"?

Given that the demonstration project is fraught with danger for small community and regional clinical laboratories, 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.

IV. Small Business Laboratories Have Not Had a Real Voice in the Process

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 I understand the challenges of composing a panel with representation from all relevant sectors of the clinical laboratory community, I was 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, 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 do so.

V. Result: More Market Concentration and Less Competition

It is my fear that CMS's lack of consultation with the SBA and the small business laboratory community now leaves community and regional labs in a particularly vulnerable position in a demonstration project that already promises to leave in its wake a less competitive marketplace. The independent laboratory market, while still competitive, is highly concentrated. The two largest laboratories control more than 65 percent of that market. A poorly designed project will further reduce competition in the communities selected. It is unclear which steps, if any, that CMS has taken to ensure that the net result of this process will not be government-sanctioned oligopolies, duopolies, or monopolies.

In addition, I should note that the large national laboratories have substantially more assets than community and regional laboratories. From reviewing CMS's draft design, I cannot see anything that would prevent the large national labs from using the demonstration as a mechanism to pick up market share. While CMS acknowledges the issue, the agency does not explain how it would take care of this serious potential problem. The agency allowed almost two years to pass between the two Open Door Forums on this issue, yet it still it could not answer this basic question. As someone whose livelihood depends on the survival of community and regional labs, I found this to be extremely frustrating.

VI. Choice of Quality Laboratories will be Limited. Service and Quality Levels will Deteriorate.

Given that there will be fewer laboratories in the demonstration area, the number of walk-in patient service centers will be reduced. Currently, the two largest national labs have overcrowding in most of the Patient Service Centers. One of them has even gone to appointment scheduling, where if you walk in without an appointment the scheduled patients get priority. I have repeatedly heard of patients waiting one and two hours to get their blood drawn at some PSCs. Smaller lab PSCs pick up the slack. We are like a breath of fresh air to patients. I maintain an office in one of our PSCs, and I routinely have patients praise us for our quick service. Bear in mind they have already visited their physician and probably had to wait varying lengths of time for that visit. The last thing they want is to take their laboratory testing prescription and have to wait long periods again that same day, or the next morning if a fasting specimen is required. This does not just affect Medicare patients.

A serious patient care issue also will arise out of the mass closing of laboratories, and that is "continuity of care". Many of the same tests can use different methodologies and varying reference

ranges from lab to lab. Physicians treating patients for acute and/or chronic illnesses will be forced to adapt to a different labs method, and it does not always transcend well. This is true particularly in the case of tumor marker tests for cancer patients. Even when we get a new account from one of our competitors, they will often not switch all of their patients because of the importance of continuity of care. A demonstration design that results in mass laboratory attrition from the Medicare program is a poorly designed and dangerous demonstration.

Then there are the physicians. Currently, all laboratories compete on quality and service. That is why community-based laboratories have flourished. There is a level of service that many physicians seek that, in their experience, is provided by smaller businesses. The forced closing of labs will affect the ability of a physician and patient to choose a quality lab of their choice. There will be a severe lack of access for all.

Another critical point to consider is the stifling of innovation. Many of the groundbreaking, life-saving tests have been developed by small laboratories. Exclusion from Medicare equals forced lab closures; which equal less access; which equals reduction of quality and test turnaround time due to overloading of the "winning" labs; which equals fewer resources and/or businesses that can be devoted to research and development. The domino effect that would occur in this scenario has to be avoided at all costs.

CMS might say that "capacity" of a lab to run each of the tests on the bid list will assure there is ample coverage in an MSA. However, the agency is depending on the bidding labs to accurately reflect their stated capacity for each test, and then CMS will go over by some margin to assure ample coverage. All of us in the industry see the fatal flaw in this approach. Estimated capacity is not a commitment. Laboratories may overstate their ability to service the market. 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. A distant laboratory will simply not be available if our transportation systems become impaired due to natural disasters such as hurricanes or terrorist attacks such as September 11th.

VII. Nursing Home Hardship

Only local and regional labs service nursing homes. The large national laboratories long ago opted out of this market. 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 many labs to seek high profit margins elsewhere. Medicare competitive bidding will eliminate the existence of many of the labs that are willing to take on the high operating costs to provide quality care for our aging population in long-term care facilities. The large labs have admitted that this is not a population that they want to service. CMS implied that this will be a provision of "winner" participation in Medicare. Again, service levels will deteriorate. Inexperienced labs will have to institute nursing home coverage. The health monitoring requirements of the neediest segment of the U.S. population will suffer, and lives will be lost as a result of inadequate nursing home coverage. This is a fact. Delayed results, resulting in delayed medication, could seriously compromise patient care. Nursing home coverage is largely overlooked in the project design and is a major oversight by the authors of the bid process. Others testifying today will be able to provide greater detail regarding the substantial risk this project presents to nursing home patients - the most vulnerable segment of the Medicare population.

VIII. Demonstration Rigged Against Community and Regional Laboratories

The Medicare Competitive Bidding Demonstration discriminates mostly against small and medium sized laboratories operating in a few, or only one, Metropolitan Statistical Area ("MSA"). A national lab may be excluded from one or more MSAs, and it will have some financial impact on them; but a local lab that is excluded from Medicare in the single MSA in which it operates will have to cease all operations. Medicare competitive bidding for laboratories is the opposite of what it portends to be. It is clearly "Anti-Competitive."

Medicare competitive bidding will irrevocably alter the market of any MSA that has the misfortune of being chosen. Long time quality laboratories will be forced out of business, and new start-up laboratories will be a thing of the past. The only type of new lab that would be able to open would be institutional labs that do employee drug testing, or labs that do not do direct patient or insurance billing. I would never have imagined a demonstration project that would make it impossible for a new full-service laboratory to enter the market place, and yet it seems to be happening.

IX. Demonstration Complexities and Unaddressed Aspects of the Program

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. 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 hourly rates for these individuals are not being fully accounted for in calculating the financial burden on laboratories posed by this demonstration project.

In conclusion, there are no laboratory "winners" in the Medicare Competitive Bidding Demonstration, only "losers" and "bigger losers." Our industry and the American public will be worse off, and no savings will result. The only result will be diminished quality, diminished access, diminished innovation, lost jobs, poorer health, lost lives, and further crippling of our already crippled national health care system. On behalf of the 360 employees of Shiel Medical Laboratory, NILA, our industry as a whole, and the citizens of the United States, we urge Congress to repeal Section 302(b) of the Medicare Modernization Act of 2003 that requires CMS to conduct a demonstration of Medicare Competitive Bidding for Part B Fee Schedule Clinical Laboratory Services.

American
Clinical Laboratory
Association

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

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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.

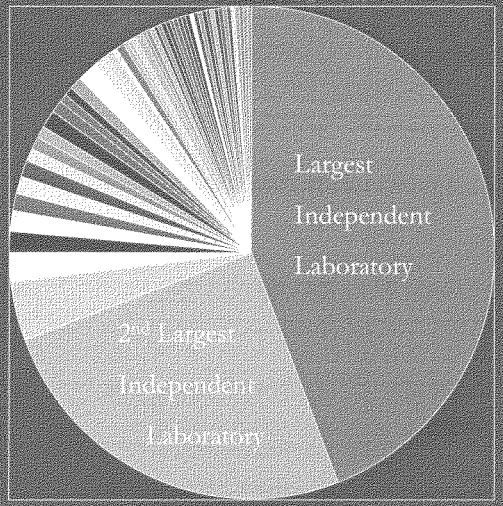
In the final analysis, Madam Chairwoman, one has to ask the question: is there a compelling need for such a demonstration project? Medical laboratory services account for only 1.7 percent of Medicare spending and payments for those services have already been reduced

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.

Estimated Concentration of the Independent Laboratory Market, 2007



Prepared by: National Independent Laboratory Association (2007)
Sources: Washington G-2 (2005), Laboratory Economics (2007), Institute of Medicine (2000)

House Small Business Committee
Hearing on Competitive Bidding for Clinical Laboratory Services
July 25, 2007

Statement of the American Association for Clinical Chemistry

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to offer its views to the Small Business Committee regarding the Centers for Medicare and Medicaid Services (CMS) competitive bidding demonstration project for clinical laboratory services. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care.

AACC strongly opposes the competitive bidding demonstration project. We believe this demo, if it moves forward, will adversely affect competition and the quality of patient care—counter to the objectives of the plan. Few smaller laboratories will be able to compete with larger volume testing facilities based on cost. They simply will not be able to reach the same economies of scale. This will force many small laboratories out of business, thus reducing competition and concentrating testing services among a smaller pool of laboratories.

The CMS 'bidding package' for the competitive bidding process does mention, however, that 'smaller' laboratories can forego the bidding process and accept the lower 'winning price' if they choose to do so. However, this option is not feasible for many low-volume testing facilities because the threshold for this exception is unrealistically low. According to CMS, only laboratories billing less than $100,000 in Medicare revenues annually can avail themselves of this non-bidding option. The industry consensus is that few laboratories will be able to utilize this option.

AACC is particularly concerned with the impact of the loss of these small businesses on patient care. Many of the smaller 'niche' laboratories provide care to underserved patients in need of immediate care, such as seniors in skilled nursing facilities. If these laboratories go out of business, access to care, as well as the timeliness of that care, may be reduced. Further, patients in more remote regions of the demonstration may have to travel further to obtain testing services and wait longer to get their results—thus delaying treatment and potentially affecting patient outcomes and health care costs.

House Small Business Committee
July 25, 2007
Page Two

Finally, we are troubled that CMS has yet to do an impact analysis of the possible consequences of the demonstration, particularly given the concerns expressed by the Institute of Medicine regarding competitive bidding in its 2000 study on the clinical laboratory payment system. The independent research body concluded that that "the disadvantages of competitive bidding outweigh its advantages for use as the basis of payment," adding that "the impact of competitive bidding could disproportionately disadvantage certain segments of the laboratory industry." We think an evaluation of the potential financial and health consequences of the demonstration on the selected site(s), prior to implementation of the demo, should be integral part of any proposed CMS plan.

AACC appreciates the chance to provide input on this important issue. We believe competitive bidding, if adopted, will inhibit competition by putting many small laboratories out of business, while creating a potentially harmful situation for Medicare beneficiaries. Therefore, AACC urges that the authority for conducting the competitive bidding demonstration be repealed.

AACC is the principal association of professional laboratory scientists. Our more than 9,000 members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. If you have any questions, please call me at (504) 568-4281, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Larry Broussard, PhD
President-Elect, AACC

STATEMENT OF AMERICAN MEDICAL TECHNOLOGISTS IN CONNECTION WITH HEARING ON "COMPETITIVE BIDDING FOR CLINICAL LAB SERVICES: WHERE'S IT HEADING AND WHAT SMALL BUSINESSES CAN EXPECT"

Before the Committee on Small Business
United States House of Representatives

July 25, 2007

American Medical Technologists (AMT) appreciates the opportunity to provide this statement for the record of the Small Business Committee's hearing on competitive bidding for Medicare clinical laboratory services. AMT is a national, non-profit organization providing professional certification and membership services to members of the clinical laboratory and related allied health professions. Founded in 1939, AMT currently has over 38,000 active members in good standing. AMT's certification and membership categories include Medical Technologists, Medical Laboratory Technicians, Registered Phlebotomy Technicians, Certified Office Laboratory Technicians, Registered Medical Assistants, and Certified Medical Administrative Specialists, among others. AMT's certification programs, including its competency-based certification examinations, are fully accredited by the National Commission on Certifying Agencies, the accrediting arm of the National Organization for Competency Assurance. Many of AMT's member-certificants work in relatively small independent and hospital-based laboratories.

AMT is a charter member of the Clinical Laboratory Coalition (CLC), a coalition of numerous organizations and companies representing all sectors of the clinical laboratory services delivery system. AMT shares the CLC's position in staunch opposition to the implementation of competitive bidding for Medicare clinical laboratory services.

While there are numerous reasons why competitive bidding is inappropriate for clinical laboratory testing services, one of the chief reasons is the potential for disproportionate impacts on small businesses, and the resultant loss of access to lab services by the most vulnerable segments of the Medicare population. Small independent laboratories frequently are the only labs that are willing to serve certain Medicare populations, especially nursing home residents. But even the smallest labs typically exceed the threshold of $100,000 in annual Medicare revenues that the Centers for Medicare and Medicaid Services (CMS) has established as the point beyond which a lab is required to participate in the competitive bidding demonstration.

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If forced to bid against large national lab chains, with price being the determinative factor, these smaller labs will simply be unable to compete. And if small labs are excluded from participation in Medicare, they likely will have to close their doors, thus creating access problems for many Medicare beneficiaries.

CMS and its demonstration contractor have done little to alleviate the concerns among small independent and hospital laboratories that predatory pricing by large national labs will squeeze the smaller players out of the program. There is a very real risk that any short-term savings realized from low-ball pricing will be offset by a loss of competition over the long term, as competitors drop out of the market. CMS has promised to evaluate the demonstration's impacts on competition, and to police gaming behavior on the part of bidders, but has not disclosed how it intends to do so and has provided no assurance that any policing activity will occur in time to preserve competition in the acquisition area.

Although most small labs will be required to bid because they receive over $100,000 of revenues annually from Medicare Part B services, many such labs provide only a small portion of the test menu covered by the competitive bidding demonstration. Yet any lab that submits a bid is required to bid on all of the tests covered by the demo. This means that labs performing only a subset of the covered tests must sub-contract with other labs serving the demonstration area to provide the remaining tests. The subcontractor labs will also necessarily be submitting their own bids to CMS as prime contractors, however, placing them in direct competition with the labs with which they have agreed to subcontract.

Another obstacle faced by relatively small laboratories is the extensive paperwork burden and associated direct and indirect costs involved in preparing a bid package. CMS has estimated that each bidding lab will spend approximately 100 hours preparing the bid application form, at a labor cost of $4,113.46 per bidder. AMT believes that CMS's estimate significantly understates the time and resources required to complete the bid package. Even if CMS's estimate is roughly accurate, the cost of preparing and submitting a bid – in terms of both direct monetary costs and diverted manpower resources – will obviously impact small laboratories disproportionately.

In closing, AMT thanks the Committee for holding this hearing and urges Members of the Committee to sponsor legislation to repeal section 302(b) of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 (P.L. 108-173). Competitive bidding will not work for Medicare clinical laboratory services, which are not fungible commodities, but instead are complex medical services that can vary depending upon the setting, patient acuity, required turnaround time, and a host of other factors. Besides the above described impacts on small business, the demonstration will also harm beneficiaries by limiting their choices of labs, and in many cases requiring seniors to travel to new, unfamiliar and inconvenient patient service centers to have their blood drawn. The demonstration therefore should be repealed.

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Statement
of
The American Society for Clinical Pathology

House Committee on Small Business
July 25, 2007

Hearing on

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

Chairwoman Velázquez and distinguished members of the Committee, the American Society for Clinical Pathology (ASCP) commends the House Committee on Small Business for this opportunity to comment on the proposed implementation of the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project by the Centers for Medicare and Medicaid Services (CMS).

For reasons of patient safety and public health, ASCP is opposed to the implementation of competitive bidding for clinical diagnostic laboratory services. ASCP understands the congressional mandate on CMS to implement the demonstration project and recognizes the Herculean task of developing a sound competitive bidding demonstration project. Clearly the multiple complexities of implementing this project without harm to patients and the nation's laboratory infrastructure remain.

ASCP joins with our colleagues in the Clinical Laboratory Coalition in requesting that the Secretary for Health and Human Services stop the demonstration project. We also join with our colleagues in asking Congress to repeal the project.

The specific details of the proposed demonstration project that have been outlined to date by CMS are inadequate. There has been both a lack of clarity in the details as well as lack of focus on patient safety and public health issues. Additionally, the agency has not reported on the potential impact of the proposed demonstration project on local laboratory infrastructure. ASCP firmly believes that, should this project launch, it threatens to rip apart the fragile health care infrastructure in a Metropolitan Statistical Area (MSA). It is clear that to date, the United States Department of

Health and Human Services (HHS) has failed to assure the public and Congress that this demonstration project will "do no harm."

Now that CMS has reached a critical stage in the development of the project it should, at a minimum, take additional steps to ensure that the nation's health is protected. In fact, at last week's Open Door Forum, ASCP asked the agency to provide the laboratory community and the public with additional information and opportunities for input before they proceed with the demonstration project. Here are the steps that ASCP asked the agency to implement before they proceed:

- The confirmation of a new CMS Administrator. Kerry Weems, deputy chief of staff at the (HHS) has been nominated and if confirmed by the Senate, stakeholders and experts should have an opportunity to brief the new CMS leader on the parameters and complexities of the project.

- A "Quality of Care" impact statement should be issued by an independent body for any potential competitive bidding site. This report should focus on both the short and long-term impact of the demonstration project to public health, patient safety and laboratory infrastructure.

- Prior to a "Bidders Conference" the agency should conduct field hearings in proposed sites that involve all stakeholders including Medicare beneficiaries, laboratory personnel and other affected entities.

In closing, ASCP does not believe that CMS will be able to maintain public health and patient safety standards if it implements this project. Allowing this demonstration project to proceed without providing full assurance to the public that there will be no major disruptions to the delivery of quality health care is irresponsible public policy. Therefore, ASCP respectfully requests Congress to repeal the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project

ASCP is a nonprofit medical specialty society representing 140,000 members, including board certified pathologists, other physicians, clinical scientists, medical technologists and technicians. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive education programs, publications and self-assessment materials

If you have any questions or comments, please contact Jeff Jacobs, Vice President, Public Policy in the ASCP Washington Office by phone at (202) 347-4450, or fax at (202) 347-4453.

Advancing Excellence

"Competitive Bidding for Clinical Lab Service: Where's it Heading and What Small Business Can Expect"

Statement to House Committee on Small Business

By

College of American Pathologists

July 25, 2007

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The College of American Pathologists is pleased to have this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) implementation of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 provisions related to a demonstration project for clinical laboratory services, under Section 302(e), Competitive Acquisition of Certain Items and Services.

The College of American Pathologists (CAP) is a national medical specialty society representing over 16,000 pathologists who practice anatomic pathology and laboratory medicine in the United States and Canada. The College's Commission on Laboratory Accreditation is responsible for the accreditation of over 6,000 laboratories worldwide. Many of our members provide medical director services for clinical laboratory testing in multiple settings including hospitals, independent labs and related health care settings.

The College has long advocated that competitive bidding, as a payment method for clinical laboratory services is fraught with adverse consequences. A 2000 Institute of Medicine (IOM) report on Medicare laboratory payment, mandated by Congress, did not recommend competitive bidding as a basis for payment of clinical laboratory services and reached the conclusion that the disadvantages of competitive bidding outweigh the advantages. It further stated that the impact of competitive bidding could disproportionately disadvantage certain essential segments of the laboratory industry.

CAP is particularly concerned with the potential of competitive bidding to negatively impact small regional health centers and small independent laboratories. The demonstration is currently set up so that "winning" bidders have exclusive rights to the entire Medicare market within a competitive bidding area (CBA) and "non-winning" bidders will not be allowed to bill for clinical laboratory services provided to Medicare beneficiaries within the CBA. This use of an "exclusive" model, runs counter to the competitive nature of U.S. markets today and can lead to predatory pricing whereby large laboratories use "low-bids" as a mechanism to reduce their competition, most notably smaller regional health centers and independent laboratories who do not have the same scale efficiencies to compete effectively.

CMS states in their "bidder's package" that they are exempting small laboratories. However, the College does not believe these provisions are adequate and are inconsistent with the definition of small business standards that is set by the Small Business Administration. Specifically, CMS is defining "small" labs as those with less than $100,000 in annual Medicare payments from clinical laboratory services within a CBA. The Small Business Administration, on the other hand, defines "small" medical labs as those with $11.5 million or less in total revenues. Even if one were to assume that nearly half of a laboratory's revenue came from Medicare, that would reduce the small business definition to about $5.5 million, which is considerably above the $100,000 revenue threshold that CMS has set.

CMS has stated in public forums that a Technical Expert Panel (TEP) has evaluated and provided input into the structure of the competitive bidding demonstration. While the names of the TEP are available on the CMS website, there are no minutes or summary of the discussions or issues discussed by the TEP. Further, it is our understanding that the TEP only met twice and one of those meetings was by conference call. The College is deeply concerned that the demonstration project is moving forward without adequately addressing issues regarding beneficiary access and quality of care that have been raised by both the Institute of Medicine and the clinical laboratory community.

Most notably, there has been no analysis provided on the potential adverse impact that competitive bidding would have on access to care for Medicare beneficiaries, including nursing home residents. Small community based hospital laboratories and small regional independent laboratories are often a key component for ensuring Medicare beneficiaries access to high-quality clinical laboratory services. Physicians often refer to clinical laboratories in their communities because they are readily available for consultations about testing results and other matters related to collecting patient specimens and quick turnaround time. Yet, these small labs are the ones that are most likely to lose under the current bidding structure.

CMS has stated that they will continue to monitor access to care, once the demonstration project is underway. What happens if CMS discovers midway through the demonstration project that the one or two winning laboratories are not sufficient to provide adequate access to Medicare beneficiaries? Even worse, what if CMS discovers that one of the bidding laboratories falls out of compliance with CLIA because they under-estimated their ability to continue to provide high-quality services at such a low price. CMS has stated that they would have to exclude that laboratory from the CBA immediately. The real problem becomes that the "non-winning" laboratories would have already exited the market at this point, and thus would not be available to restore access to high-quality care. This is a situation that could potentially occur and needs to be considered and adequately addressed earlier, rather than later in the process.

In closing, the College strongly believes that given the concerns outlined above, Congress should repeal the current demonstration project until a full evaluation of these issues is undertaken in a transparent and open manner. This process must clearly document how all of these issues will be adequately addressed so as to ensure that Medicare beneficiaries continue to receive high-quality access to clinical laboratory services.

Statement of Laboratory Corporation of America Holdings ("LabCorp") for the U.S. House Committee on Small Business Hearing on the Medicare Competitive Bidding Demonstration for Clinical Laboratory Services

July 25, 2007

Laboratory Corporation of America Holdings ("LabCorp") congratulates Chairwoman Velazquez and the Committee on Small Business for conducting this hearing on the Medicare Competitive Bidding Demonstration for Clinical Laboratory Services. While it is one of the world's largest clinical laboratories, testing more than 370,000 specimens daily for over 220,000 clients nationwide, LabCorp stands together with small laboratories in opposition to the Medicare Competitive Bidding Demonstration for Clinical Laboratory Services.

Unlike durable medical equipment (DME), clinical laboratory services are not fungible commodities, but complex medical services requiring significant training, expertise and supervision to perform and analyze. The Medicare Clinical Laboratory Fee Schedule contains approximately 1,100 CPT codes for clinical laboratory tests; not all laboratories provide all of those services, and some services are unique to one laboratory. The Centers for Medicare and Medicaid Services (CMS) is proposing to limit the demonstration to approximately 358 CPT codes that represent 99% of Medicare laboratory testing volume and payment; but this proposal would leave out the remaining two-thirds of the CPT codes in the Medicare Clinical Laboratory Fee Schedule, meaning that any issues associated with the majority of the CPT codes in the Medicare Clinical Laboratory Fee Schedule would not be accounted for in the demonstration. Previous attempts to test competitive bidding for clinical laboratory services have collapsed due to the complexity of the market and the difficulty of developing a workable bidding model. No competitive bidding design can alleviate these problems, because the basic premise of competitive bidding does not work for clinical laboratory services.

By its very nature, competitive bidding places emphasis on obtaining the best price over quality and access, and its implementation could result in a reduction in the widespread and ready access to quality laboratory services that Medicare beneficiaries currently enjoy. Slower testing times, lost specimens, and inconclusive results could become necessary byproducts of competitive bidding for laboratory services. Laboratories are less likely to invest in new testing technologies or improve existing ones for better patient care if competitive bidding reduces reimbursement for testing. Patients in rural areas could routinely have to travel significant distances to have specimens collected in laboratories that are no longer able to justify the cost of serving those patients with local patient service centers. Some laboratories may have to cease offering certain vital services to Medicare beneficiaries if the provision of those services is no longer financially feasible, and in some circumstances they may have to cease offering services altogether.

Laboratories that would have expected to provide at least $100,000 in demonstration tests to Medicare beneficiaries residing in the Competitive Bidding Area during the demonstration that are not selected among the winning bidders will be unable to provide services within the Competitive Bidding Area for three years - which could put some laboratories out of business. Given that laboratory services account for only a tiny fraction of total health care costs but impact an estimated 70% of medical decisions, such an outcome would be penny wise and pound foolish.

Large, national labs like LabCorp often rely upon smaller labs to perform subcontracted services for clients located in geographical areas where we do not have a local lab, as well as for particular kinds of tests we may not perform ourselves. Thus, the threat posed to smaller labs by competitive bidding represents a threat to larger labs as well. As a member of the Clinical Laboratory Coalition, LabCorp has worked with representatives of smaller labs to ask CMS numerous questions about the competitive bidding demonstration. While CMS has answered a few of those questions, most remain unanswered.

Since the health of Medicare beneficiaries is dependent upon ready access to quality clinical laboratory services, and is therefore dependent upon the health of the clinical laboratory industry, it is critical that any attempt to demonstrate competitive bidding for laboratory services recognize and accommodate the operational realities of the clinical laboratory industry, represent a fair and meaningful test of competitive bidding, and minimize adverse impacts to our healthcare system. Unfortunately, the draft bidders' package that CMS recently issued in preparation for the demonstration project fails to meet those goals, despite years of effort on this project by CMS and its contractor, RTI International.

Again, we applaud Chairwoman Velazquez and the Committee for conducting this hearing, and look forward to working with the Committee on issues of common concern to both small and large businesses, such as the Medicare Competitive Bidding Demonstration for Clinical Laboratory Services.

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