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.

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.

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.

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

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.

American Health Care Association

1201 L Street, NW, Washington, DC 20005-4046
Main Telephone: 202-842-4444
Main Fax: 202-842-3860 2nd Main Fax: 202-289-4253
Writer's Telephone: 202-898-2858
Writer's E-Mail: byarwood@ahca.org
www.ahca.org

Leslie Norwalk
Acting Administrator
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

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.

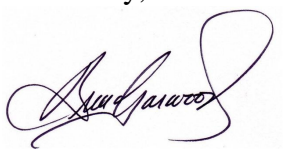
As with DMEPOS, competitive bidding for laboratories deprives the SNFs of their ability to choose high quality laboratories dedicated to SNF resident laboratory services. Again, federal requirements mandate that SNFs assume responsibilities that "each resident must receive and the facility must provide 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.