



STATEMENT OF

Carol Gilligan, President

**Health Aid of Ohio, Inc.,
Cleveland, Ohio**

Before the

House Committee on Small Business

**Subcommittee on Investigations and
Oversight**

**“Competitive Bidding for Durable
Medical Equipment: Will Small
Suppliers Be Able to Compete?”**

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Good morning Mr. Chairman and Members of the Subcommittee. Thank you for the opportunity to talk with you today about the Medicare Program and its implementation of the competitive acquisition program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), and its impact on my small business and the consumers I serve.

Introduction

My name is Carol Gilligan, and I am president of a health care company called Health Aid of Ohio, in Cleveland Ohio. I started my small business in 1984 to serve seniors and people with disabilities. My company primarily provides what we call “complex rehab” equipment and services to people with specialized needs. We provide sophisticated and customized complex wheelchairs and accessories to people who have very severe and individualized needs. In addition, we provide home oxygen therapy and other respiratory services, and we offer an array of home medical equipment such as beds, walkers and other items that consumers with acute or chronic conditions use to enable them to live in their homes, rather than in more costly institutional settings.

I started my small business over 20 years ago after meeting a girl in my neighborhood who has a rare form of muscular dystrophy. My business was inspired by my desire to be able to really help people who have special needs and mobility limitations. We serve about 5400 consumers out of our location. Approximately 25 percent of my business is from Medicare beneficiaries, and the remaining 75 percent is from Medicaid recipients or private pay consumers. This year, I was honored to be awarded the “Best Rehab Provider in the United States” by HME News, an industry trade publication.

Serving High End Rehab Consumers

I'd like to explain the types of services my company provides to consumers and how the bidding program will impact my business and consumers.

Provision of complex rehab technology is not a commodity. Complex Rehab and Assistive Technology consists of highly individualized products and services that are prescribed by a physician and provided to individuals by specially trained and credentialed members of the rehab technology profession. It is different from traditional durable medical equipment products in that the rehab products are evaluated, fitted, configured, adjusted or programmed to accommodate each individual's specific and unique medical needs; taking into consideration the individual's medical history, diagnosis and disease progression, functional needs, anatomical requirements and anomalies as well as typical environments that the individual incurs throughout the course of their daily activities..

Imposing a competitive bidding process on complex rehabilitative services will substantially undercut the quality of life for thousands of persons with disabilities. Each new consumer our company serves requires a different evaluation and assessment, measuring, fitting, simulations and demonstrations, mixing and matching of products, refitting and then additional modifications. The service component inherent in each specialized piece of equipment is very high, and simply is not amenable to the bidding structure being implemented by the Centers for Medicare and Medicaid Services.

I am accompanied today by my friend, David T. Williams of Amherst Ohio. David is an excellent example of what all goes into the process of providing complex rehab.

To understand why his wheelchair is so complex you need to understand David's clinical picture. In 1975 David was diagnosed with Multiple Sclerosis. Recent advances in diagnostic methodologies and technology have refined that diagnosis to be Chronic Progressive Multiple Sclerosis. This form of Multiple Sclerosis is characterized by acute exacerbations of the disease resulting in the formation of scar tissue in various locations in the brain and spinal cord. This in turn causes a wide variety of symptoms.

In David's case the location of multiple lesions in his spinal cord have resulted in the following symptoms/disabilities:

- quadriplegia (paralysis and/or paraparesis of all four extremities);
- severe chronic neuropathic pain;
- partial paralysis of the diaphragm resulting in periodic hypoxia;
- partial paralysis of the vocal folds interfering with speech and causing difficulty with swallowing;
- loss of peripheral vision and depth perception;
- central sleep apnea;
- neurogenic bladder and bowel resulting in urostomy;
- a history of pressure sores/decubitus ulcers;
- chronic fatigue syndrome; and,
- a history of several episodes of deep vein thrombosis and pulmonary embolisms.

The process starts with a thorough review of his medical record and a complete and detailed evaluation by the multidisciplinary "wheelchair seating clinic" at the Mellen Center for Multiple Sclerosis Treatment and Research of the Cleveland Clinic Foundation. Based on this evaluation David's neurologist prescribed a motorized/power wheelchair that would provide him with pressure management, respiratory relief when necessary, postural stability, adductor spasticity control and the ability to periodically reposition and elevate his legs.

The Certified Rehab Technology Specialists conducted an environmental assessment and, based on the doctor's prescription and the recommendations of the various health professionals in the seating clinic, ordered the following components to provide David with an appropriate wheelchair:

- motorized/power wheelchair base;
- transportation securement system;
- joystick style driver control with tremor dampening and "mushroom cap" style control knob;
- power elevating leg rests; and,
- powered seating system with the following functions:
 - tilt and recline with zero sheer functionality;
 - elevate seat height;
 - trough-style armrests;
 - trunk lateral supports;

- adductor positioning device;
- pelvic stabilizing/positioning seatbelt;
- tall contoured back; and,
- headrest.

In order to meet David's unique needs, physiology, height, weight, abilities and disabilities the wheelchair that you see David driving today is built from components procured from seven different manufacturers. The component parts were assembled by a rehab technology company who had to fabricate some of the hardware needed to blend the different components into one system. The “wheelchair” was then delivered to David and several field adjustments were made during multiple visits to David's home.

Between the time David notified the staff of the seating clinic which rehab technology company he wished to have provide his new system and today, the health care team has spent more than 45 hours over three months doing the environmental assessment, working with David to see the kinds of things he must do every day to maintain the best possible quality of life (and perform all the “mobility related activities of daily living”), ordering the components, supervising the assembly, fitting and adjusting the product and in training David in proper use of the system.

David's case is not unique. It represents the kind of challenge rehab technology companies see on a regular basis.

CMS' Implementation of the DMEPOS Bid Program

In CMS' bid program, if the bid price ends up being unreasonably low, consumers will suffer. For example, these consumers typically need sophisticated seating systems to prevent pressure sores. Seat and back cushions are customized to the individual's specific body to minimize the possibility of decubitus ulcers. If the bid price is unreasonably low, based upon low-ball bidders, consumers will likely not have access to the more expensive customized cushions that prevent pressure sores, and will likely end up being hospitalized as result. Healing decubitus ulcers in the hospital can cost up to seventy thousand dollars. This is truly penny wise and pound foolish policy.

In order to provide the most medically appropriate items to consumers, we must employ specially trained personnel. My employees and the therapists we work with are specially trained to assess and evaluate consumers with severe needs. For example, we have on staff three Assistive Technology Suppliers, with an additional three in training. These are individuals who have been trained and tested to ensure they have the requisite knowledge, experience and expertise to provide the most clinically appropriate items. I have brought here today a custom seat and back mold so you can see the type of detail and customization required for one component of a consumer's mobility system.

Because of the large service component necessary for fitting and modifying complex rehab technology, these items are simply not appropriate for a competitive bid process that is designed to attract low-ball bids on commodity items. Most importantly, if services are reduced or if the provider is unskilled or inexperienced, consumers' conditions will be exacerbated, requiring more extensive medical intervention.

In the bidding program, CMS requires that suppliers bid on the entire complex rehab category. While suppliers have to bid on every code in a product category, they are not required to make available all technology that falls under a particular code. Many of the codes include a wide range of items with varying costs. As a result, this bidding system that encourages low-ball bids will ensure that more complex items that are highly configurable will be very difficult if not impossible for consumers to obtain.

With this bidding program, the government is creating a “one size fits all” category for products, which will likely have the effect of coercing patients into using improper devices. The consumers are the ones who will lose because an ill-fitting device further decreases patients’ mobility and quality of life.

My Experience Submitting Bids

In early April this year, the Centers for Medicare and Medicaid Services, or CMS, announced that my service area, Cleveland, would be one of the initial ten metropolitan areas for this bidding program. CMS also announced that most of the items and services I provide would be included in the bid program. Specifically, high end rehab wheelchairs, consumer mobility, oxygen therapy, hospital beds and other items that my company provides would be included in the bid program. What this means for my company is that my company would need to be a winning bidder for each of the product categories in order to be able to serve Medicare beneficiaries once the program goes live, scheduled for July 1 2008.

I therefore had no choice but to submit a bid, unless I wanted to close my business. I submitted bids on seven of the nine product categories for the Cleveland area: complex rehab power wheelchairs, standard power wheelchairs, oxygen, continuous positive air pressure devices (called CPAPs) and respiratory assist devices (or RADs), hospital beds, walkers, and negative pressure wound therapy pumps.

I’d like to explain how the bid submission process worked for one product category, the “Complex Rehabilitative Power Wheelchairs and Related Accessories” category. In this category, there are approximately 150 separate HCPCS codes. The codes in this product category include complex wheelchairs, positioning accessories, special needs cushions (for example to prevent decubitus ulcers), electronic controllers to allow differently abled people to control their wheelchair according to their individual capabilities, and other items. For each of the 150 codes, my company submitted one price, even though often multiple items with different price points are in each code. For each code, we needed to state a “capacity,” that is, how many of these items we could provide to beneficiaries during the three year contract period.

Each price we submitted for each code could not, according to CMS rules, exceed the current Medicare fee schedule amount. Therefore, if market pricing is above the fee schedule amount, the bid process prevents bids from reflecting real market prices. This does not make sense. If this program is based upon the belief that the market will set the prices, then there should be no artificial ceiling of what price we could submit in my bid.

In order to submit a bid based upon a complete understanding of my total delivered costs, I hired a consultant to help me conduct an “activity-based costing” analysis. While this was a worthwhile undertaking for us to understand better our “total delivered costs” for each product line we provide, the prices we submitted in our bids were not entirely based upon this rational analysis. Instead, my company’s bid prices were based more upon an assessment of what we thought the competition would submit, rather than a realistic assessment of my business financials. This is because, as a small business, we just don’t have access to the volume-based pricing that large national companies do, and in order to have a chance to be a winning bidder, we felt we had to lower our bid prices just to have a chance at surviving.

The other scenario we faced in the bid process was the emerging “low-bidding opportunist mentality” that emerged. This “bidder” looked upon the Cleveland market as a place to expand their market share. This new competitor did not have any market share or did not incur the expense of having an existing business and patient care base. Instead, the entity submitted a very low and if they ended up being a contract supplier, they would set up a business without all of the services we currently provide. They would then conduct a quick sell to a national company should there be any value; otherwise, they would just dabble in that product category. The fact that this scenario could occur was caused by CMS’ lack of public criteria regarding how CMS would evaluate a prospective business’ plan to operate a viable business in the area.

Another deficiency of the bid evaluation process is that CMS will set the bid price based upon the median of potential winners. That is, once CMS has established a cut of suppliers (the “pivotal bid” supplier), CMS will set the bid price at the median submitted bid of potential contract suppliers. If all of those suppliers decide to be contract suppliers, then half of the suppliers will be forced to accept a bid price less than what they submitted as their best price. In contrast, in the demonstrations CMS conducted in Florida and Texas, the bid price was set at the pivotal bid, so each potential contract supplier would receive a bid price that was at or above their submitted bid. This also contrasts to the private sector where your submitted bid is what you get paid. CMS’s decision to make the bid price at the median of potential contract suppliers in and of itself makes it increasingly difficult for any supplier whose submitted bid was above the median of potential winners to maintain a financially viable business.

Another significant difficulty in submitting bids is that there is no guarantee of any particular volume if we actually win the bid. This is in direct contrast to how the private market works. For example, if I know that my company will serve 500 home oxygen patients, we can put together a price that is rationally based upon a known volume. In this case, however, if we win, we will still be competing against other winners, and there is no guarantee of any set number of people that we will serve. Therefore, CMS’s system does not allow bidders to submit rational bid amounts based upon prospective volume.

In CMS’ final rule, it estimated that on average, it will cost a supplier \$2303.16 to submit its bids. This estimate is far from my experience as a small business. We began preparing to submit bids as soon as CMS announced in early April that Cleveland would be a bid area, and worked through the final deadline of September 25. We spent considerable time and resources, both internally and externally to prepare the bids. In total, we spent over thirteen thousand dollars to submit the bids for seven product categories. That figure includes \$3000 for an

activity based costing consultant and \$4000 for an outside accountant, plus over 300 hours of staff time.

If My Company Loses the Bid

If my company loses the bid, the impacts will be far greater than just losing Medicare business. I will likely lose most of my other business for those product categories because referral sources prefer to refer to providers who can take all business, not just patients who have a particular payor. In addition, state Medicaid programs and private payors will likely adopt the new lower Medicare bid fees, further negatively impacting any remaining business. Therefore, the majority of my business would be lost, forcing me to close my doors.

In its final rule, CMS discussed ways in which it was attempting to address the problems that small businesses would specifically encounter in this program. In reality, none of CMS' attempts will actually do anything to alleviate the issues that small business encounters with this program.

First, CMS changed its definition of "small business" from \$6 million in annual revenues to \$3.5 million. This is inconsistent with the Small Business Administration's definition for our industry, and my understanding of our industry, based upon over 20 years experience. CMS should have maintained the SBA definition at \$6 million.

Second, CMS set a target, not a requirement, that 30 percent of the winning suppliers be small business. Therefore, if none of the initial winning suppliers them are small business, CMS will ask small businesses whose bids were too high if they want to participate at the bid rate. Because price is the primary determinant of being a winning bidder; if all small business bidders bid prices are above the winning bid amount, then to accept the bid amount will mean taking a financial loss on a product category. No small provider can afford that.

Third, CMS has set a target, not a requirement, that there be at least five winning suppliers in each product category. I am not sure how that addresses small business concerns because for each product category there are significantly more than five competitors in my market. In fact, there are five very large providers in each of the product categories in the Cleveland area, none of which are small business.

Fourth, CMS established a network scenario that is theoretically geared to help small business. The logistics and legal issues associated with small business forming networks are substantial. For that reason, I doubt that any networks were formed in any of the initial ten bid areas.

Overall, while CMS made some noise about addressing small business issues, I don't believe that CMS has taken any meaningful steps to address the special needs of small business and our ability to participate in this program. I am very concerned about my company's ability to win one or more of the bids, and even if CMS asks us as a small business to participate to meet its 30% small business target, I sincerely doubt that the bid prices will represent a rational business decision for my company. In the end, whether I win or lose the bids, my company will be severely impacted, and may not be able to survive.

Conclusion

As a small business, I believe we are disproportionately negatively impacted by this bidding program. Mr. Chairman and Members of the Subcommittee, there are two bills that have been introduced, H.R. 1845 and H.R. 2231 that would make reasonable changes to how CMS implements this bidding program, and that would begin to address some of the problems faced by small business. I strongly urge this Committee to actively support these measures.

Thank you for the opportunity to appear here today. I would be happy to answer any questions.