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On Behalf of the American Association for Homecare

Before the Subcommittee on Healthcare and Technology

House Committee on Small Business

On

Medicare’s Durable Medical Equipment Competitive Bidding Program:

How Are Small Suppliers Faring?

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Chairman Ellmers, Ranking Member Richmond, and members and staff of the House Small Business Subcommittee on Healthcare and Technology, my name is Tammy Zelenko. I am president and CEO of Advacare Home Services, a small business in Bridgeville, Pennsylvania. Advacare is a provider of home oxygen therapy, obstructive sleep apnea therapy, nebulizers, suction therapy, continuous passive motion therapy, hospital beds, wheelchairs and bathroom safety items. My company furnishes virtually all medically necessary physician-prescribed home and respiratory medical equipment and related services to Medicare beneficiaries. Through four locations in the Pittsburgh area, we provide high quality care to approximately 2,000 patients annually and employ 49 full-time associates.

I would like to thank the Subcommittee for holding this important hearing to examine the impact the Medicare competitive bidding program for durable medical equipment is having on small health care practices across the country. I am pleased to share my personal experience with the initial round of the Medicare bidding program and make constructive recommendations on how Congress can help support small health care providers and the patients they serve.

I am a member of the American Association for Homecare (AAHomecare) and I am testifying on their behalf. I also serve on the executive committee of the Pennsylvania Association of Medical Suppliers (PAMS), my state organization representing home medical equipment and service providers (HME), where I am the past president.
AAHomecare is the national trade association for home medical equipment service providers, manufacturers and other stakeholders in the homecare community. Nearly 80 percent of AAHomecare members are considered to be small businesses. AAHomecare members serve the medical needs of Americans who require home oxygen therapy, mobility assistive technologies (standard and complex wheelchairs), hospital beds, diabetic testing and medical supplies, inhalation drug therapy, home infusion and other home medical products, services and supplies.

We believe that home medical equipment is a vital component of the continuum of care and is a fundamental component to controlling health care costs by keeping beneficiaries in the most cost-effective and patient-preferred setting—their homes—rather than providing acute care in emergency departments and extended care institutional settings.

My goal before this Subcommittee today is to tell you about the negative impact the Medicare bidding scheme is having on small health care providers who are also small businesses. My aim is not to argue against competition. In fact, both the Association and I support healthy and fair competition.

HME providers compete every day to provide quality health care items and services to Medicare beneficiaries and embrace the opportunity to continue to compete to serve our patients. Competition breeds medical innovation, improved care and creates well-paying jobs in communities across the country. However, the competitive bidding program designed by the Centers for Medicare and Medicaid Services (CMS) is anti-small business, it is a job killer, and it will negatively impact the quality of care that our nation’s most frail and elderly depend on to remain independent in their homes.

My testimony will highlight the flaws of the current competitive bidding program and recommend a sound, sustainable and budget-neutral alternative—the Market Pricing Program (MPP) for home medical equipment—that can be implemented on the same timeline as the current bidding program.

Advacare’s Story

When I started Advacare Home Services, my goal was to grow a company that would provide only the highest quality of care to people in my community. I could compete with any provider because I offered better service. We provide trained and competency-tested service technicians and registered respiratory therapists in the home to instruct, educate, and train our patients and their caregivers on the use of home medical equipment so that patients with acute care or chronic needs could remain in their homes. We provide a comprehensive education, assessment and coaching program that empowers our patients to better understand their
disease, make proactive changes in their self-management techniques and help them remain independent.

We are often the eyes and ears of the elderly and the conduit between the patient, caregiver, physician, and community. We communicate critical information to the physician. We support patients in their home environment with self-assessment tools. We create a customized care plan based on physician orders and patient-specific goals. There are costs to providing this type of care, and I have spent the last 24 years investing my time, energy, resources, technology and money into building a reputation on quality and outstanding care in my profession.

I always felt that if I worked smart, not just hard, that I, too, could have the “American Dream.” I come from a family of seven children. My father parked cars for a living, and I was the only child to go to college and receive a Master’s degree. I put myself through college while working full-time at a home medical equipment company.

In 1986, I started out at my first home medical equipment company in the billing department, and worked my way through each of the departments and into management. In 1997, I was hired as the Director of Operations by seven local hospitals to start up their HME company.

As a small business owner, I was able to compete against the local, regional, and national providers within my market. Each year I gained market share, grew my practice, and received recognition due to the outstanding service that my company provided. However, all of that changed overnight when the bidding program went into effect. The bidding program, for me and thousands of providers like me, has created the biggest barrier for my company to survive.

I firmly believe that the government deserves to pay fairly for the items and services that HME providers furnish. Serving Medicare beneficiaries is a privilege, not a right. However, I am equally as passionate that the government should not be able to pick “winners” and “losers” and bar otherwise qualified providers from serving Medicare beneficiaries.

But even more troubling is the longer-term effect of this bidding program. Its design is neither sustainable nor based on sound economic principles. I am not aware of any auction or bidding program that is designed in the same manner as CMS’ program.

In my role as a member of my state association, I get to speak with HME providers who share similar stories and no longer want to participate in the bidding program because it perverts the marketplace. It arbitrarily selects winners and losers, it arbitrarily sets reimbursement rates that are not sustainable, and it arbitrarily forces providers to trim the services they provide to frail and elderly patients to meet unrealistic reimbursement rates.
Competitive bidding has been in the design phase for a number of years. During this time, I recognized that change was coming and I would have to prepare and become more efficient. I just could not have anticipated that Medicare officials would design a program that is so anti-business that it has been panned by every professional auction expert and economist who has looked at it. I began investing in technologies years ago to promote better efficiencies in preparation for competitive bidding. I invested in electronic medical record technologies. I purchased GPS devices for service technicians and state-of-the-art medical equipment and technology and invested in a new billing system and software. I believed these changes would prepare us for the bidding program. I was wrong.

This is the first year that I did not grow my company, the first time that I had to pass all of the healthcare premiums increases on to my employees, the first time that I could not offer reimbursement for continuing education.

**Negative Impact on Small Businesses**

The serious design flaws of the bidding program have had a substantial negative impact on my operations, to the detriment of: the patients Advacare services; my business; my staff; and, my local community. While larger regional or national HME providers have been able to subsidize some of the loss in revenue from the arbitrarily low bid prices through locations that are not yet subject to bidding, small businesses like mine cannot. Cost shifting should not be a survival technique and it cannot go on indefinitely as this program expands nationwide.

The following are some of the direct effects that the bidding program is having on small provider practices:

- **Revenue, Staffing and Benefit Changes**
  - Drastic decrease in Medicare revenue since the bidding program began;
  - Shifting health care cost increases to employees;
  - Eliminating employer coverage of continuing education credits for respiratory therapists;
  - Limiting allowances for educational seminars and travel;
  - Allowing staffing positions to go unfilled when employees left Advacare; and,
  - Subcontracted to a contracted oxygen provider in order to stay in the Medicare market.

- **No Longer Able to Support Local Community**

  Advacare has been providing outstanding clinical care to Medicare beneficiaries for 15 years. We have supported our local communities and hospitals in a range of ways such as donating supplies to aid in disaster relief, participating on local foundation boards,
and contributing to local health care organizations and hospitals. The decreased revenue due to the low bid rates and not being awarded contracts means that I am unable to support the local community. Providers located outside of the area who won contracts are not contributing to the community, so my local organizations are suffering from the poorly designed bidding program as well.

- **Sales and Marketing Impacted**

  Competitive bidding has created enormous barriers to gain new Medicare customers, making it very difficult to compete with the winning contractors.

**Negative Impact on Patients**

- **Quality and Services Are Reduced**

  Before bidding, we competed on the level of service we provided. We furnished our patients with customized care plans to ensure proper levels of education, assessment, service and follow up to allow beneficiaries to receive care in their homes rather than more costly institutional settings. Because the competitive bidding rates are too low, we can no longer provide that level of service. Our respiratory therapists can no longer provide the clinical follow up on our oxygen patients that we have managed for years. The continuity of care that we had with the patient, caregiver, physician, and community resources no longer exists, and patient-centered care is compromised.

- **Patients Are Forced to Switch Providers**

  We experience challenges every day working with Medicare beneficiaries who can no longer stay on Advacare’s services, and we can no longer bill for their supplies. Advacare is forced to try to find a contracted supplier to take our patients who have been on our service for years even though patients do not want to switch providers.

- **Patients Must Receive Services from Multiple Providers**

  Often, our customer service department receives orders for multiple items all of which we could supply before the bidding program. Now, we can only provide the items that are not part of bidding, and we then help the referral source find other companies for items that Advacare can no longer provide. This means that beneficiaries must now receive HME items from multiple companies, which creates confusion and disrupts the continuum of care upon which they previously could rely.
Flaws in the Competitive Bidding Program

Experts in the design and operation of auctions have explained in great detail why the CMS bidding program will fail. CMS is the only group predicting that the program is sustainable over the longer term and operating flawlessly. They are basing this on a short-lived, small sample in nine markets—a program that even CMS officials call a “pilot.” Yet, Round 2, with 91 markets, is more than 10 times as complex as Round 1. AAHomecare and small businesses like mine are on the front lines and can see fundamental flaws that need to be addressed immediately. And 244 experts from across the world have weighed in identifying similar problems and have told CMS, Congress and the Administration that the program will fail.

These are our main concerns:

1. Providers’ Bids Are Not Binding Commitments

In Medicare’s bidding program, bidders are not bound by the prices they bid. Any HME provider can decline to accept an offered contract from CMS after the prices, called Single Payment Amounts, are announced by the government. And because of CMS’ decision about pricing, 50 percent of all bidders’ prices will be lower than their best submitted bid. Medicare’s rule undermines the credibility and integrity of bids, and, without binding commitments, encourages low-ball bids from providers.

To add insult to injury, if HME providers turn down contracts, their bid prices are still included in Medicare’s calculation of bid amounts, and other bidders invited to participate are forced to choose between accepting the low price that they did not influence or losing their business altogether by not participating.

CMS states that 92 percent of contract awardees accepted their contract offer. But to decline a contract would immediately imperil a provider’s practice because Medicare typically represents 40-60 percent of an HME provider’s revenue. Now that we are in the second year of the Round 1 program, we are seeing both contracted and non-contracted providers exit the market, change their business model, close down or sell. What has propped this program up is its limited scope—it is being run in only 9 areas across the country. HME providers have been able to subsidize their competitive bidding markets with revenue from non-competitive bid areas. Yet, this cross-subsidization will evaporate as: 1) bidding is expanded to 91 additional areas in 2013, 2) private payors adopt competitive bid rates, and 3) CMS applies bid pricing to non-bid areas, including all rural areas in the U.S., as early as 2015.
2. The Pricing Calculation Is Flawed

Rather than paying contracted providers the clearing price (the last-accepted bid) which is the standard in bidding and reverse auction programs, Medicare’s bidding program establishes prices at the unweighted median among the winning bids, resulting in 50 percent of the winning bidders being offered a contract price less than their bids. We know of no other auction or bidding program that has such a perverse rule where bidders are offered contracts at less than the amount they submitted during the bidding process.

3. Composite Bids Are Distorted

A composite bid is an average of a bidder’s bids across many products weighted by the government’s estimated demand. The composite bid methodology as designed by CMS provides strong incentives to distort bids away from market prices. Only heavily weighted (based on utilization) products within a category will impact the composite bid. Providers can “game” the system by bidding very little off the current Medicare allowable for certain products with little weight while bidding more aggressively on other items with a higher weight. This creates a program where individual products are not closely related to costs and providers participating in the program can “game” the system in order to manipulate the single payment amount. In addition, Medicare set a maximum for all items bid—again distorting the bidding process by not permitting bidders to fairly bid based on their true, fully-loaded costs.

4. Lack of Transparency Is Overwhelming

CMS has shared virtually no data with the public on the selection of contracted providers, calculation of historical demand (capacity), calculation of the single payment amount for products and services covered by bidding and outcomes-related findings to evaluate the program. Instead, CMS has made generalized statements that point to the so-called success of the program. Even the Agency’s first year update after the implementation of the program is based on generalizations with little data to back up its findings.

Moreover, the savings numbers recently quoted by CMS appear to “double-count” savings resulting from anti-fraud and abuse initiatives that were implemented concomitantly with this program. For example, new provider screening tools, real-time claims monitoring and an avalanche of incremental pre- and post-payment audit activity have been implemented since the program began in 2011. It is surprising and shocking to us that Medicare has elected to audit contract winners in Round One markets so heavily when, in fact, CMS has stated that the program should, on a stand-alone basis, root out fraud and abuse.
Under the current program, pricing can be easily manipulated through subjective adjustments to the capacity that a provider lists on its bid forms. During the announcement of the Round One Rebid pricing, a CMS official stated the following about contract winners’ financial stability. During a press call on July 2, 2010, the CMS official stated –

"We do screen bids that are on the low side (to) determine whether or not the provider can actually provide the service or the item at that price. That includes looking at invoices...and the provider's financials, including their liquidity and credit, and their ability to expand into a market area. Where we do not feel comfortable, we may not count their capacity at all, or to the degree that they wish us to, in determining the number of winning providers. In fact, we did that 30% of the time. So we have been very careful in selecting providers and in scrutinizing these bids, in terms of prices and sustainability. I think we're comfortable, when we look at the prices that we see."

This fact calls into question the validity of the payment rates established by the program and the supposed objective process that CMS established for the program and published in its Final Rule. The above public comment confirms that CMS may adjust a provider’s stated capacity if it questions the provider’s bid because it was considered low. By adjusting capacity, CMS manipulated the single payment amount and subjectively decided how many winners were needed. The bidding program then just becomes another way to apply administered pricing rather than letting the market set reimbursement rates. This subjectivity is playing with the very viability of numerous small businesses across the country.

5. The Bidding Program Is Designed to Be “Gamed”

Due to the methodology concerning how payment rates are calculated, the impact of non-binding bids and the ability to manipulate the capacity that a provider self-reports, the program is built to be “gamed.” CMS even appears to acknowledge this fact in its first annual report on the bidding program when they state that, “we are strengthening our bona fide bid review process...to check that very low bids are sustainable by checking more of those bids.” Questioning the sustainability of very low bids implicitly brings into question a program where the single payment amount offered by CMS is, by definition, lower than 50 percent of the accepted bids presented. If the bid amounts represent the lowest pricing while maintaining quality service, how can a program that reduces the pricing additionally be sustainable over the long term?

Under a “win at any cost” program, providers would do well to submit an unreasonably low bid—“a suicide bid”— in order to win a contract. These providers then would be assured of
a contract but they must hope that other providers bid more rationally so that the single payment amount would be higher than their submitted bid. From here, providers facing low reimbursement rates could agree to furnish competitively bid items but subsidize their revenue from non-Medicare or non-competitive bidding patients. CMS has never shared with the public how many of the 356 original contract providers have sold their businesses, gone out of business or simply did not bill Medicare for competitively bid items. This is a critical question for Congress to consider, because there were 6,922 unique HME providers submitting claims/providing services in 2010 in the nine bidding areas.

6. CMS Monitoring Is Weak and Non-Transparent

When the bidding program was first implemented, CMS required HME providers to provide the exact brand and model of equipment they were providing to Medicare beneficiaries. CMS also stated that it would begin to measure the patient satisfaction of beneficiaries who received HME services. This equipment report was intended to allow the Agency to determine if contracted providers began to substitute lower quality equipment under the program than was previously furnished to beneficiaries. However, CMS modified this requirement one quarter of the way into the pilot, so there is no way to monitor the quality of equipment Medicare beneficiaries are receiving. And to date, we have seen no beneficiary satisfaction data whatsoever, despite the program’s 16-month implementation.

7. There Is No Due Process

Currently, there are no due process protections or appeals processes in place for providers to appeal CMS’ methodology for establishing payment rates, making contract awards, designating bidding areas, deciding on the phased-in implementation approach, selecting items and services or the bidding structure and number of contractors. Numerous companies were initially qualified due to a technical error on CMS’ fault, and yet it took over 120 days to resolve the issue—a date past the implementation date of 1/1/11.

8. Bidding Areas Are Too Large

CMS has created bidding areas that make it difficult, if not impossible for small providers to service. The Pittsburgh Metropolitan Statistical Area (MSA) covers more than 5,000 square miles and includes the city of Pittsburgh, seven surrounding counties and pieces of seven other counties. The Philadelphia MSA, which is part of the second round of competitive bidding, covers more than 9,000 square miles.
THE BIGGER PICTURE

The CMS program distorts the marketplace and, by ignoring the pricing methodology used in the original demonstration projects in Florida and Texas where the “clearing price” was used (i.e. setting the reimbursement rate using the highest contract supplier’s bid), the program goes against the original intent of Congress when it voted to implement the program in 2003. It radically reduces the number of providers (competitors), thereby creating oligopolies in the marketplace at a time when our senior population is growing rapidly.

According to a recent Bloomberg Government report, “the bidding process employed by CMS will likely reduce the number of market participants and spur a wave of consolidation within the highly fragmented home medical equipment industry...As a result of the new program, the government awarded Medicare contracts to just 365 providers for 2011 in those same nine markets [of Round 1 of competitive bidding], an 85 percent reduction.”

Moreover, it not only allows bidders to “game” the system’s pricing rules but it actually encourages such manipulation during the bidding process. And it forces providers to reduce supportive services in order to meet drastically lower reimbursement rates that were obtained through a fundamentally flawed process.

These deficiencies, which I experienced first-hand, have been highlighted numerous times before the Congress. Meanwhile, CMS staff touts high cost savings and low negative beneficiary impact. However, the program is only running in nine markets, or six percent of the country. The competitive bidding program is particularly devastating to small businesses from day one. While larger regional or national providers, in the first year of a three-year fixed pricing contract, have been able to offset excessive and arbitrary price reductions in the bid areas with revenue from non-bid areas, this is not the case for small companies like mine.

AAHomecare does not stand alone in raising concerns with the current program. In fact, well over 200 economists, computer scientists, statisticians and auction experts from around the world have advised CMS that significant modifications need to be made to the bidding program to make it sustainable over time. Moreover, more than 30 consumer and beneficiary groups believe that the bidding program is flawed and needs to be changed.

AAHomecare has worked with auction experts to create an alternative to the current model that would give CMS a sustainable market-based pricing program for home medical equipment. This alternative preserves the concept of competition and ensures future beneficiary access.
Cost Effectiveness of Homecare

HME offers an efficient and cost-effective way to allow patients to receive care they need at home. The need for HME and HME providers will continue to grow to serve the ever-increasing number of older Americans. Homecare represents a small but cost-effective portion of the more than $2.3 trillion national health expenditures (NHE) in the United States, and approximately 15.5 million Medicare beneficiaries require some type of home medical equipment annually, from rather simple bedside commodes for people who have hip replacements to high-tech ventilators for quadriplegics.

Yet, not all products are created equal: some require licensed or credentialed clinicians to be on staff or cost $15,000 just to procure. And while Congress and the Office of Inspector General have shed light on products they believe to be overpaid, many others are unprofitable for us to provide even before the bidding program. The high cost of fuel, labor, rent and utilities and regulatory compliance associated with billing and collections, audits, HIPAA privacy, identity theft, IT security, Sarbanes-Oxley, waste disposal, beneficiary and employee safety, OSHA, DOT and FDA regulations continues to escalate year after year. Anyone who has ever required HME or had a relative who needed it can attest that our service includes much more than just the equipment.

The more that people receive quality equipment and services at home, the less that is spent on hospital stays, emergency room visits, and nursing home admissions. Home medical equipment is an important part of the solution to the nation’s healthcare funding crisis. The facts bear this statement out as private health care plans have contracted for our services for decades and reaped the cost savings along the way. Even the current Administration is trying to develop programs to manage chronically ill Medicare patients in the home through new demonstration projects and the Innovation Center.

Fixing the Bidding Program

Congress’s objective in requiring Medicare to use a competitive bidding model to establish payment amounts for HME was to reduce Medicare expenditures and ensure that beneficiaries have access to quality items and service. This objective cannot be met because CMS has designed a program that does not hold bidders accountable, does not ensure that bidders are qualified or capable to provide the products in the bid markets, and, due to the arbitrary nature of the capacity analysis, has produced bid rates that are financially unsustainable.

As I mentioned previously, auction experts and economists have warned that the Medicare bidding program is unsustainable in its current form. It will create significant barriers to access and will destroy the HME infrastructure that seniors and people with disabilities depend on as the program expands and providers cannot offset bid pricing with non-bid revenue.
Unfortunately, the recommendations of auction experts, beneficiary and consumer groups, the Medicare Program Advisory and Oversight Committee (PAOC)—the panel created by Congress to advise CMS on the design and implementation of the program—and AAHomecare and other interested groups have not been acted upon. We now look to Congress to fix systemic problems so that Congressional intent is followed.

To fix the fundamental flaws in the bidding program, an alternative market-based pricing program for HME has been developed, which has been specifically tailored to the HME marketplace. The proposal, known as the Market Pricing Program (MPP), would require changes to ensure a financially sustainable program. MPP uses an electronic state-of-the-art reverse auction to establish market-based reimbursement rates for HME around the country. These changes are consistent with Congress’ original intent: to create a program that is based on competition while maintaining beneficiary access to quality items and services. The MPP would be implemented on the same timetable and apply to the same DME product categories as the current program, and will reduce government spending for DME items nationwide. It is intended to be budget-neutral.

The following are key components of the Market Pricing Program:

1. MPP would require that providers stand by their bids if offered a contract. This feature is known as a “binding” bid.
2. MPP would establish reimbursement rates at the “clearing price” (the last bid accepted) rather than the “median price,” which CMS currently uses. Under the CMS methodology, half of all contract providers are paid less than they actually bid.
3. MPP would bid areas that are much smaller so that any provider could service an entire area subject to the auction.
4. MPP would bid the same product categories as the current competitive bidding program, but all products would not be bid in each area. MPP would bid 2 product categories for exclusive contracts in certain areas and apply the reimbursement rate to economically similar areas. This feature encourages competition, eliminates the incentive to submit unrealistic (suicide) bids, and allows providers to remain in practice until the next auction cycle commences.

Other important elements of MPP include:

**Timeline**

MPP would be effective on July 1, 2013. The design of the program would be developed through a collaborative, transparent process, involving all stakeholders (HME providers, CMS, beneficiaries), with the guidance of an auction expert and the oversight of the market monitor, to establish market rules, to set market-based and sustainable reimbursement
rates, and protect beneficiary access to, and choice of, quality HME products, services, and supplies. The use of an auction expert to help the Secretary of the Department of Health and Human Services design the auction program and a market monitor to help the Secretary ensure that the program is operating effectively and efficiently are common among public auctions.

**Auction Operation**

MPP would auction a representative 20 percent of the market (counties eligible for bidding) with two-year contracts. The remaining market areas eligible for the program would be served by any eligible providers furnishing HME at the reimbursement rates determined by the auction. The reimbursement rate established through the auction would apply to similar geographic areas (i.e., urban to urban, suburban to suburban) and be adjusted for regional characteristics.

Each year thereafter, MPP would auction a representative 10 percent of the market (counties eligible for bidding) with two-year contracts starting on July 1 of the year of auction.

An additional 10 percent of eligible market areas would be subject to auction each subsequent year until market pricing programs are occurring in 100 percent of eligible market areas throughout the United States. The process would continue and the Secretary, in consultation with the auction expert, would continue to select additional eligible market areas on an ongoing and rotating basis. This design would create the most accurate competitive market payment methodology in the Medicare program.

**Rural Exemption**

The same areas that are exempted under the competitive bidding program would be exempted under MPP.

**Transparent Process Required**

In establishing MPP, the Secretary would utilize an open and transparent process that includes all relevant stakeholders in the market. Provider and beneficiary education would be required in consultation with the auction expert and market monitor.

**How MPP Benefits Small Businesses**

For small businesses like mine, MPP has a number of key improvements over the current bidding program that will help my chances of survival. The smaller market areas mean that I will still be able to provide to patients that are nearby but not in the contracted area. The
Pittsburgh MSA includes seven counties. If CMS bid just one county under MPP, and pricing was applied to the other six, even if I did not win a contract, I would still have the opportunity to service patients in the other six counties at the market-based rate. Additionally, reducing the products bid in each contracted area to two items will allow me to continue servicing patients for all of the other categories, easing the burden of not being awarded contracts since I will no longer fear being completely excluded from the marketplace for every product category. Further, utilizing the “clearing price” methodology to set the market price means that I will not be paid less than my bid. Making bids binding will ensure that providers cannot game the system and then reject their contract award if the price is too low. Finally, the state-of-the-art auction system utilized in MPP will allow me to more easily understand my own business costs, and it will provide transparency throughout the bidding process for me and my competitors.

Conclusion

Small businesses are the backbone of the American economy. In these difficult economic times, Congress should take action to protect small providers and the patients and communities they serve. To do this, Congress must stop the current bidding program and replace it with MPP, which will allow small businesses to compete and ensure patients have access to the medically necessary HME items and services that they need.