The Honorable Pete Stark
June 12, 2008

**INTRODUCTION OF LEGISLATION TO DELAY MEDICARE'S DME COMPETITIVE BIDDING DEMONSTRATION PROGRAM**

Madam Speaker, I rise today to introduce the "Medicare DMEPOS Competitive Acquisition Reform Act of 2008." I am pleased to be introducing this bill with my Ranking Member on the Ways and Means Health Subcommittee, Rep. Dave Camp (R-MI); Ways and Means Committee Chairman Charles B. Rangel (D-NY); House Minority Leader John Boehner (R-OH); Energy and Commerce Chairman John D. Dingell (D-MI); and Energy and Commerce Committee Health Subcommittee Chairman Frank Pallone (D-NJ). In particular, I would like to thank Mr. Camp for helping to craft this bipartisan legislation.

The Medicare Modernization Act mandated a competitive bidding program for durable medical equipment in Medicare and allowed the program to be nationally implemented after a several year phase-in. Unfortunately, the Administration developed the program with blinders on to the needs of patients and the small companies who make up the durable medical equipment industry.

Our subcommittee held a hearing on implementation of the bidding program on May 6, 2008. We heard testimony from numerous stakeholders about the difficulties they encountered during the bidding process. For example, nearly two-thirds of applicants were disqualified because of improper documentation – when they had initially been promised that such documentation errors would be pointed out to them and they'd have an opportunity to correct any errors. We also heard from beneficiary organizations concerned about a number of issues, including maintaining access to benefits during what is likely to be a very tumultuous transition period.

Without Congressional intervention, the flawed program begins on July 1, 2008. The bill we're introducing today delays implementation of the competitive bidding program for 18 months to provide the Centers on Medicare and Medicaid Services (CMS) with the time to create an improved program based on standards laid out in this legislation. Importantly, this bill comes at no cost to the federal government. The cost of delaying the program is fully paid for by the DME industry.

Let me clear from the outset in saying that I do not think this legislation goes far enough. If it were entirely up to me, I would be introducing legislation to repeal the current competitive bidding program and take far simpler approach to adjusting Medicare's DME payment rates.

The program has already proved useful. It has shown that companies are willing to take Medicare's business for far lower prices than the current fee schedule rates. Overall, the estimate is that Medicare would save 26% over the current fee schedule in these communities. That's a significant savings that we can't afford

to ignore. However, instead of repeating the bidding process again and again in each and every community, I think Medicare might better be served – and significant administrative costs saved – by taking what we learned in this first round to change the fee schedule rates by which we pay for DME now. Those improvements could be done once and would immediately be in effect nationwide. That seems far simpler and far less disruptive to both suppliers and beneficiaries than the program that CMS is now phasing in.

One aspect of the competitive bidding program that I fully embrace is the requirement that DME suppliers meet quality standards through an accreditation process. Unfortunately, as the Government Accountability Office and Office of Inspector General have told us in numerous reports, the DME industry has a ripe history of waste, fraud and abuse.

The program's accreditation provisions are a good start in tackling these problems, and our bill strengthens those requirements. Specifically, the bill sets a hard deadline of October 2009 for DME all suppliers to be accredited. It also addresses a loophole that currently allows subcontractors to remain unaccredited. It closes that loophole by requiring that every company that supplies DME items to Medicare beneficiaries, whether they are the primary supplier or have a subcontract to supply DME, must be accredited as meeting quality standards. Just recently, additional concerns have been raised about the quality of some of the accreditation organizations. While we did not address that in this bill, I believe the Administration has both the authority and the obligation to ensure that accreditation is meaningful.

This bill was developed with strong bipartisan support and with input from patient advocates and industry representatives – many of whom have endorsed the legislation. It is the true definition of a compromise. It doesn't eliminate the program as some of us would have liked, but it lays out the standards for a much more fair and appropriate competitive bidding program for the future.

Again, as the program has shown, Medicare is overpaying for durable medical equipment. Enactment of this legislation reduces such overpayments and simultaneously paves the way for a better competitive bidding program for patients and suppliers. I am proud that we were able to develop this compromise and require the industry themselves to come to the table to help pay for the delay. This bill is in the best interest of our senior citizens and people with disabilities who depend on this equipment to maintain independent lives. I urge my colleagues to join us in acting swiftly to enact this much needed legislation.

Organizations endorsing the bill include:

American Academy of Physical Medicine and Rehabilitation
American Association for Homecare
American Podiatric Medical Association
American Society of Transplantation
Consortium for Citizens with Disabilities Health Task Force

Health Industry Distributors of America
Invacare
ITEM Coalition
National Coalition for Assistive and Rehab Technology
National Community Pharmacists Association
Orthotic and Prosthetic Alliance
Pedorthic Footwear Association
Rite Aid
The Endocrine Society
Vision Council of America
Wound Ostomy Continence Nurses Society
3M Corporation

A more detailed summary of the bill follows:

**Medicare DMEPOS Competitive Acquisition Reform Act of 2008**
***Introduced by Reps. Stark, Camp, Rangel, Boehner, Dingell, Pallone and others***

**Summary**
The Medicare DMEPOS Competitive Acquisition Reform Act of 2008 delays implementation of the Medicare durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive bidding program. It would also make improvements to the bidding process, establish quality measures for DME suppliers in Medicare, and make additional changes to the program. The cost of the delay would be offset by a reduction in current DMEPOS payment rates.

**Background**

Durable Medical Equipment (DME) has historically been paid using a fee schedule. The Balanced Budget Act of 1997 established a demonstration program to test competitive bidding as a new way to set payment for DMEPOS. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 went further, requiring CMS to implement competitive bidding nationally for the following selected categories of items and services: oxygen supplies and equipment; standard power wheelchairs and scooters; complex rehabilitative wheelchairs; mail-order diabetic supplies; enteral nutrients and equipment; continuous positive airway pressure (CPAP) devices and Respiratory Assist Devices (RADs); hospital beds; negative pressure wound therapy devices; walkers; and support surfaces, including mattresses. Under the program, suppliers bid to provide items for one or more of the categories in a geographic area. Those whose bids are awarded are then permitted to supply the selected items to beneficiaries; organizations that are not awarded bids are precluded from providing Medicare beneficiaries with DMEPOS items targeted for bidding in the bidding area. Unless this or other legislation is enacted to delay the program, Round I, which affects 10 metropolitan statistical areas is slated to start on July 1. The agency is required to begin implementation of Round 2, which will affect 70 communities, in 2009, although CMS has not released the exact schedule. After

Round 2 is completed, competitive bidding may be expanded across the country and prices may be adjusted in non-bid areas using information from the bidding program.

**Legislation**

**Temporary Delay Rounds 1 & 2**

- Terminate contracts awarded under Round 1 and restart the contracting process in those areas in 2009.
- Round 2 contracting process would begin in 2011.
- Payment adjustments for DMEPOS in non-competitive bid areas may not take effect until Round 2 is completed.

**Offset**

- In January 2009, eliminate the annual inflationary adjustment for all items covered by Round 1 of the competitive bidding program and reduce payment rates for those items by 9.5 percent nationwide. This policy does not affect diabetic supplies furnished by retail suppliers because they were not covered by the bidding program.
- Items that had been subject to the reduction would receive a 2 percent payment increase in 2014, except in any area where a competitive bidding contract is in effect or CMS has otherwise adjusted payment rates.

**Bidding Process Improvements**

- Require CMS to notify bidders about paperwork discrepancies and give suppliers the opportunity to correct within a reasonable time frame.
- Provide CMS the authority to subdivide MSAs with more than 8 million people.
- Exempt rural areas and MSAs with a population of less than 250,000 from competitive bidding for at least five years.
- Require that suppliers who bid on diabetic testing supplies offer brands that cover at least 50% of the market by volume (does not apply to Round 1).
- Before using its authority to adjust prices in non-bid areas, CMS must issue a regulation and consider how prices set through competitive bidding compare to costs for such items in non-bid areas.
- Require HHS's Office of Inspector General to verify calculations used to determine the pivotal bid amount and winning bid amounts.

**Quality Measures**

- Require all suppliers to be accredited by October 1, 2009. Ensure that all suppliers, whether they are billing Medicare directly or are a subcontractor to another supplier, be subject to accreditation.
- Require contracting suppliers to disclose all subcontracting relationships to CMS.
- Exclude physicians and other practitioners from DMEPOS accreditation requirements until CMS develops provider-specific standards. Allow CMS to waive physician accreditation if the agency determines they are subject other mandatory quality requirements.

- Establish a separate ombudsman within CMS to handle supplier and beneficiary issues related to the competitive bidding program.

**Other Changes**

- Exclude complex rehabilitation wheelchairs, and related accessories when furnished with such wheelchairs, from competitive bidding.
- Exclude negative pressure wound therapy from Round 1 and require CMS to evaluate how these items are coded and paid.
- Exclude Puerto Rico from Round 1 re-bidding (did not receive enough valid bids in original Round 1 for CMS to award any contracts).
- Allow physicians and other treating practitioners to supply "off-the-shelf orthotics" to their patients without being awarded competitive bidding contract.
- Allow hospitals in bidding areas to supply the same DMEPOS items that physicians and other practitioners will be able to supply (those that are considered an integral part of professional services) without being awarded contracts for those items.
- Ensure that podiatrists and other similar practitioners can prescribe DMEPOS items by using broader definition of physician in Social Security Act. (This relates to a drafting error in MMA that pointed to the wrong definition of physician in the Social Security Act when requiring face-to-face examination in order to prescribe DMEPOS items.)
- Delay mandated GAO report to coincide with delay to Round 1 and expand scope of report.
- Provides CMS implementation funding of $120 million.