

Congress of the United States
Washington, DC 20515

July 13, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C5-11-24
Baltimore, Maryland 21244-1850

Dear Ms. Norwalk:

We are writing to express our concerns regarding patient access to critical medical technologies and supplies under the new competitive bidding program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) which is required to be implemented by the Centers for Medicare and Medicaid Services (CMS) under section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

Access to quality DME and related services can often mean the difference between a patient being able to remain in their own home or being forced into a nursing home or hospital. DME enables providers to give essential care to many of the frailest and sickest Medicare patients, including oxygen therapy for patients with abnormal blood oxygen levels, respiratory-assist devices for patients who are at risk of acute respiratory distress, and enteral nutrition for nutritionally compromised patients.

Although Congress instructed CMS to begin implementing the competitive bidding program in 2007, we strongly believe that due to its direct impact on daily patient care, it must be carefully implemented with significant attention to details, especially the impact on patients. Transitioning to competitive bidding is a major and highly complex undertaking. A large number of issues must be addressed to assure that access and quality of care will not be jeopardized. We strongly urge CMS to take the following steps to address these issues before the bidding process closes and implementation is finalized:

1. **Product Categories and Codes**. Product codes used by CMS are too broad and inconsistent to adequately describe products with diverse and broad ranges of quality, functionality, technology, and clinical utility. Beneficiaries may not have access to a full range of products if the accepted bidding amount does not reflect the varying

1. costs of the range of products. Some categories or codes that comprise those categories, such as support services, complex rehabilitation services, enteral nutrition, and negative pressure wound therapy, are so broad or undifferentiated as to raise important quality issues. There is also confusion over how new technologies and products will be categorized once prices are established. We are concerned that patient access to new products may be compromised using these broad and inconsistent codes. **We recommend that CMS accept and give serious consideration to stakeholder input on refinement of proposed product category subdivisions prior to bidding.**
2. **Compressed Implementation Timeline and Small Suppliers.** The Final Rule came out April 10, 2007 and the bidding process closes on July 13, 2007. Winning suppliers will be announced in December 2007 with payments going into effect in the initial 10 competitive bidding areas (CBAs) in April 2008. The Final Rule is highly complex; interested suppliers need a portion of the bidding period to analyze it and gather information to submit informed bids. The 60-day bidding process does not provide sufficient time for suppliers to learn about the important details and obtain answers to key questions relevant to the preparation of their bids, or allow small suppliers to form the provider networks that are needed for them to participate in the program. Currently, CMS is providing more details regarding the program, but this occurring while the clock is ticking on the 60-day window to bid.

Small suppliers that wish to participate in bidding networks must develop new business organizations to maintain Medicare participation, implement untried computer systems, and address a large number of unresolved policy issues. Participating small suppliers would also face steep expenses from the necessary market assessment and compliance procedures that they would have to bear to ensure that their participation does not subject them to antitrust action and other legal risks. Guidance is needed from CMS or the Department of Justice on how suppliers can avoid violating antitrust laws while disclosing information necessary to determine how to form supplier networks. The formation of these networks would require disclosure and agreement between small suppliers on prices and on which competitive opportunities to pursue.

We recommend that CMS realign the bidding timeline to begin the process after all bidder conferences have occurred. We also urge that sufficient time be provided for as many suppliers as possible to begin and conclude the accreditation process.

3. **Distinction Between Long-Term Care Facilities, Home Health Agencies, and DME Companies.** Different skills are required for long-term care facilities, home health agencies, and DME companies. While long-term care facilities provide medical personnel to administer the enteral products, the Part B provider is required to review medical charts of the beneficiaries to determine actual usage for claims submitted. DME companies are not equipped to service the needs of skilled nursing facilities, which may serve 10-20 enteral patients. Suppliers not currently serving the

home care market will have to make significant changes in the way they operate and serve their customers, including carrying products they are currently unfamiliar with and do not have existing relationships with manufacturers or suppliers. Patient care may be at risk as suppliers learn and adapt to new markets.

4. **Median Price Methodology**. Under the median price methodology, half of the "winning" bidders will be paid for DMEPOS at a rate below what they bid. The Final Rule leaves unanswered the question of whether DMEPOS suppliers would be able to withdraw from offering to supply an item if it is below their submitted bid price. We are concerned that 'winning' suppliers may choose not to participate or would be unable to supply quality products and services if they are forced to provide products at a price below their submitted bid price.

5. **Impact on Patients and Medicare Expenditures**. CMS has not yet presented plans to evaluate the impact of competitive bidding on clinical outcomes, beneficiaries, or Medicare expenditures in other care settings. This is concerning because the program will be implemented in a condensed time frame. **We recommend that specific steps be delineated by CMS on how it intends to provide ongoing assessment of the program. This would include clinical outcomes for patients, including those receiving negative pressure wound therapy, support surfaces and blood glucose self-monitoring for patients with diabetes.**

Thank you for your attention to these important issues. We look forward to working with you to address these outstanding concerns before implementation begins.

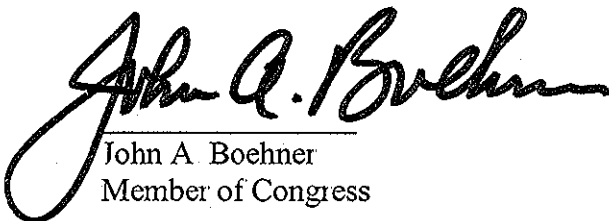
Sincerely,



Sam Johnson
Member of Congress



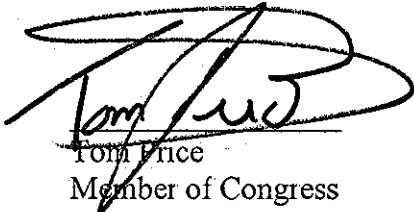
Tom Allen
Member of Congress



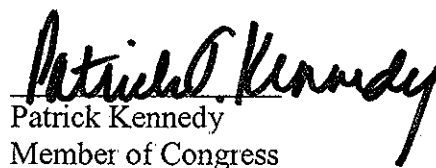
John A. Boehner
Member of Congress



Chet Edwards
Member of Congress



Tom Price
Member of Congress



Patrick Kennedy
Member of Congress



Timothy H. Bishop
Member of Congress



Marsha Blackburn
Member of Congress



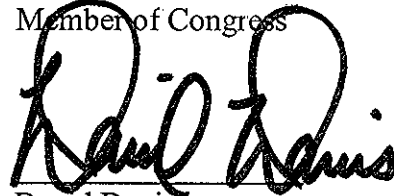
Ginny Brown-Waite
Member of Congress



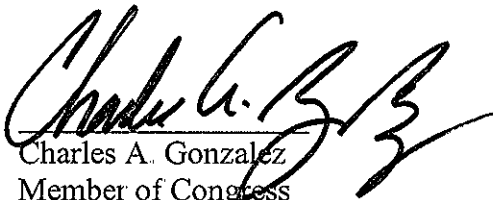
John R. Carter
Member of Congress



Steve Chabot
Member of Congress



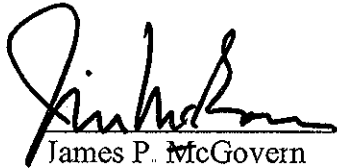
David Davis
Member of Congress



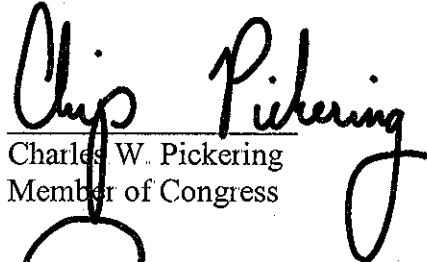
Charles A. Gonzalez
Member of Congress



Brian Higgins
Member of Congress



James P. McGovern
Member of Congress



Charles W. Pickering
Member of Congress




Jean Schmidt
Member of Congress

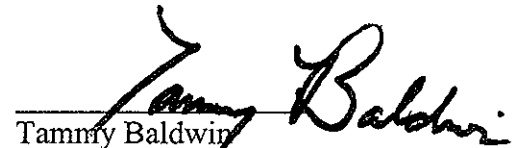


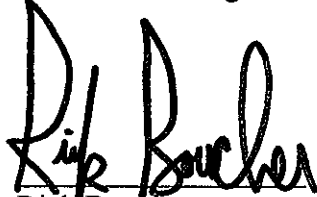
Patrick J. Tiberi
Member of Congress





Charles A. Wilson
Member of Congress



Gary L. Ackerman
Member of Congress



Tammy Baldwin
Member of Congress



Rick Boucher
Member of Congress

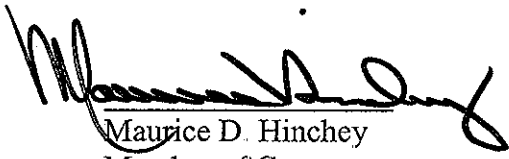

Danny K. Davis
Member of Congress



William D. Delahunt
Member of Congress

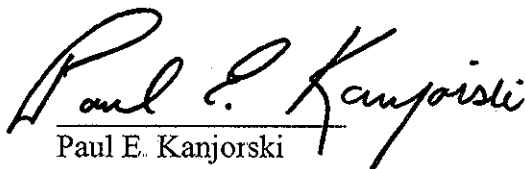

Jo Ann Emerson
Member of Congress

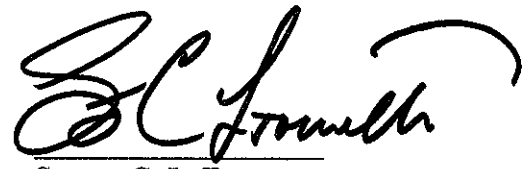

Barney Frank
Member of Congress

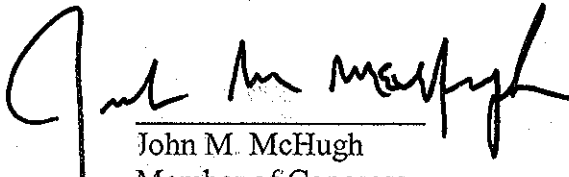

Ralph M. Hall
Member of Congress

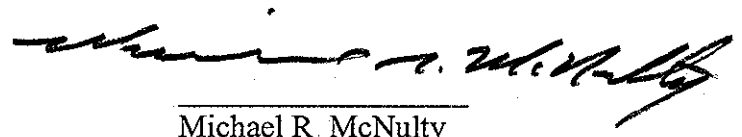

Maurice D. Hinchey
Member of Congress


David L. Hobson
Member of Congress


Paul E. Kanjorski
Member of Congress


Steven C. LaTourette
Member of Congress


John M. McHugh
Member of Congress


Michael R. McNulty
Member of Congress

Jason Altmire

Jason Altmire
Member of Congress

Sam Farr

Sam Farr
Member of Congress

Paul E. Gillmor

Paul E. Gillmor
Member of Congress

Steve Kagen

Steve Kagen
Member of Congress

Michael H. Michaud

Michael H. Michaud
Member of Congress

John W. Olver

John W. Olver
Member of Congress

Tim Ryan

Tim Ryan
Member of Congress

Pete Sessions

Pete Sessions
Member of Congress

Chris Shays

Christopher Shays
Member of Congress

Carol Shea-Porter

Carol Shea-Porter
Member of Congress

Betty Sutton

Betty Sutton
Member of Congress

Peter Welch

Peter Welch
Member of Congress



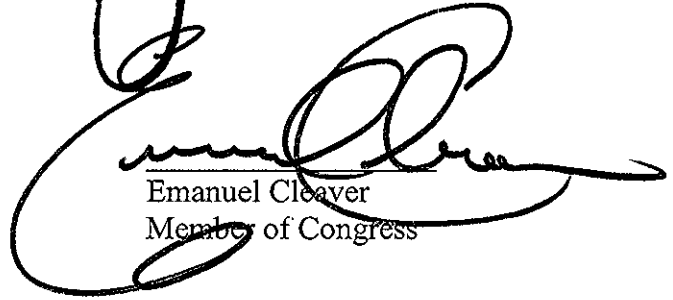
Dennis J. Kucinich
Member of Congress



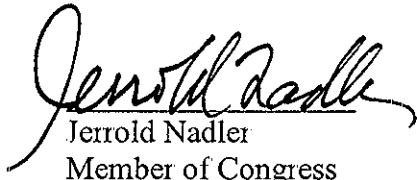
Janice D. Schakowsky
Member of Congress




Ciro D. Rodriguez
Member of Congress

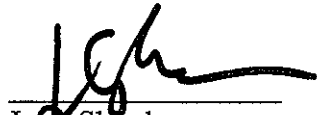


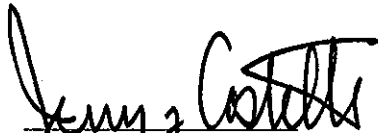
Emanuel Cleaver
Member of Congress

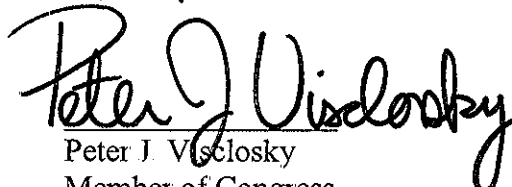


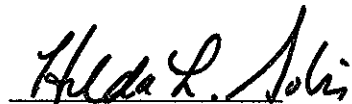
Jerrold Nadler
Member of Congress

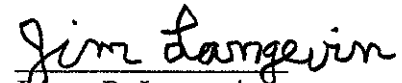

Michael E. Capuano
Member of Congress



John Shimkus
Member of Congress


Jerry Costello
Member of Congress



Peter J. Visclosky
Member of Congress

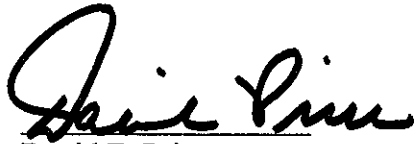

Hilda L. Solis
Member of Congress


James R. Langevin
Member of Congress


Mike Ross
Member of Congress


Michael F. Doyle
Member of Congress

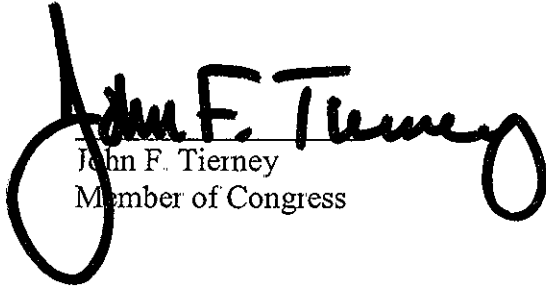

Jerry Lewis
Member of Congress



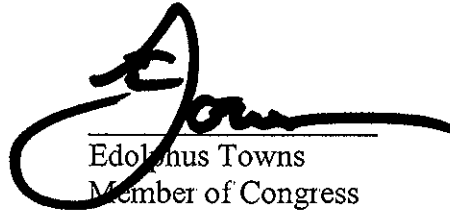
David E. Price
Member of Congress



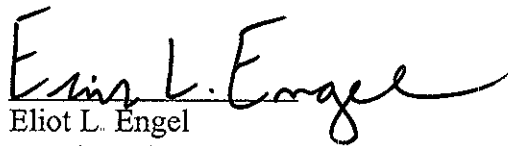
Collin C. Peterson
Member of Congress



John F. Tierney
Member of Congress



Edolphus Towns
Member of Congress



Eliot L. Engel
Member of Congress

A handwritten signature in black ink, reading "Geoff Davis". The signature is written in a cursive style with a horizontal line underneath it.

Geoff Davis
Member of Congress