# Please Persuade Your Legislators to Sign On to the Johnson-Allen Letter

The Johnson-Allen Letter is being circulated for signatures, and it is imperative that we make immediate attempts to get our legislators to sign on. Even those who are not in the currently affected MSAs should contact their legislators, because this may affect them at a later time.

The text of the letter along with the Capitol phone number is provided below.

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 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 TOM ALLEN Members of Congress

Representative Contact Information

The switchboard at the Capitol in Washington, D.C. is 202-224-3121.

For additional contact information, go to DC Link