HOUSE SMALL BUSINESS

SUBCOMMITTEE ON

RURAL AND URBAN ENTREPRENEURSHIP

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STATEMENT BY

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ON BEHALF OF

THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)

Mr. Chairman and distinguished members of the Subcommittee, on behalf of the Advanced Medical Technology Association, AdvaMed, I thank you for holding this hearing on the Medicare Part B competitive acquisition program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

As you may know, AdvaMed represents over 1,600 of the world's leading medical technology innovators who manufacture over 90 percent of the life-enhancing medical devices, diagnostic products, and medical information systems purchased annually in the United States and nearly 50 percent of the medical technology products purchased globally. Many of the technologies developed by AdvaMed companies have significantly improved the quality of care provided in outpatient settings under Part B and, by doing so, have reduced the need for and cost of more expensive institutional care. Advanced medical technologies today are not only making life better for patients through faster recovery and better outcomes; in many cases, advanced technologies are also saving money for taxpayers. It is also important to note that over 70 percent of our members are relatively small companies with sales of less than $30 million per year. The company I work for, KCI, although a medium size company today, started as a small, family-owned business thirty years ago. We understand how small business drive progress.

Medical technology research and innovation conducted by both large and small companies help drive improvements in the effectiveness and efficiency of our health care system. That is why, as the leading trade association representing manufacturers of innovative medical devices and device-based therapeutic systems, we appreciate the opportunity to share our concerns about the impact of the upcoming durable medical equipment competitive bidding program on outpatient device manufacturers and the patients they serve.

DMEPOS Is Valuable to Beneficiaries and Medicare

For a Medicare beneficiary, access to quality DMEPOS and related services can often mean the difference between remaining at home and admission for institutional care. Twenty-five years ago, DMEPOS was comprised primarily of simple products used to improve the

functional status of patients or to treat relatively uncomplicated conditions. Today, however, sophisticated medical devices used to treat complex conditions in highly compromised patients have migrated safely and effectively from institutional settings into home care. Additionally, advanced diagnostic equipment provides clinical data previously only available through professional laboratories. This evolution of DMEPOS from simple to complex products has improved both clinical and economic outcomes for patients and payers alike.

Competitive Bidding Does Not Appropriately Address Complex Technologies

Unfortunately, the current DMEPOS competitive bidding program has failed to address the fact that there are fundamental differences between simple functional products on the one hand, and diagnostic or therapeutic devices, on the other. Let's take walkers and hospital bed frames as an example. The intended use of these products is to provide support to beneficiaries with mobility limitations. There is little, if any, clinical efficacy research required for these products; and minimal patient and caregiver education necessary to ensure their safe and effective use.

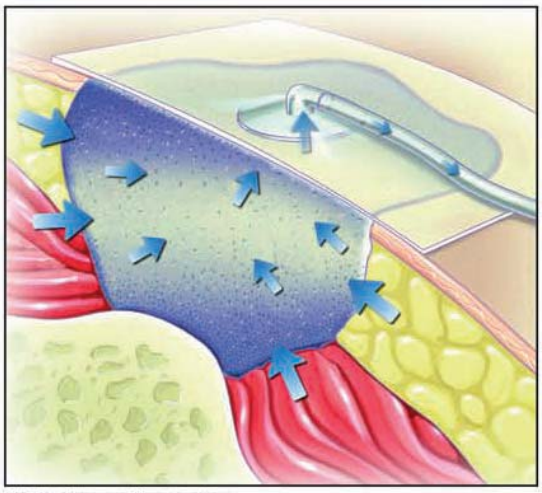
Conversely, therapeutic products like Negative Pressure Wound Therapy (NPWT) systems, which are prescribed for treatment of complicated wounds, frequently occurring in highly compromised patients, require extensive clinical efficacy research and intense levels of support for both patients and their clinical caregivers. Misuse or failure of these therapeutic products could result in serious, potentially life-threatening complications. Because the intended use, clinical evidence requirements, and service needed for therapeutic products are very different from those of simple functional equipment, the DMEPOS competitive bidding program should have, but did not, reflect those differences in four important areas: selection of products for bidding; clinical support and patient education; supplier capacity and capability; and impacts on patients and total Medicare spending.

1. Selection of product categories and codes for bidding:

Therapeutic products deliver clinical outcomes and, therefore, codes selected for bidding should include products of comparable clinical effectiveness. However, some of the codes CMS

selected for bidding include products with wide ranges of quality, functionality, and clinical application. Categories such as Group 2 support surfaces, enteral nutrition pumps, and negative pressure wound therapy systems include such a wide range of products that bidding cannot be the "apples to apples" comparison that was intended by Congress when this program was authorized. Since price is the primary determining factor in selection of winning bidders, the less expensive products at the bottom of the price range are likely to replace the products in the top of the price range, which are the ones prescribed most frequently today. It would be like including four wheel trucks and eighteen wheel trucks in the same bid process using price as the basis for determining winning bidders. In that case, it's unlikely that eighteen wheel trucks would continue to be available and you would no longer have the ability to transport large, heavy loads. In the case of DMEPOS competitive bidding, a similar shift in product availability could mean that the products necessary for the most compromised patients would no longer be available, leading to poor health outcome and increased treatment costs.

As an example, I'll use KCI's V.A.C. Therapy system. V.A.C. Therapy creates an environment that promotes wound healing using three components that work together: a negative pressure pump, an environmentally safe collection canister and a unique foam dressing which is packed into the wound and covered with transparent film. When the pump applies controlled negative pressure to the wound site, the foam dressing compresses in a way that looks a lot like "shrink wrapping" of food. (See Attachment A.)



V.A.C.® Therapy illustration

This compression of the foam dressing under controlled negative pressure provides three important benefits for wound healing:

First, unhealthy fluids and bacteria are pulled out of the wound and into the collection canister. With the excess fluid removed, blood flow to the cells is improved. With the bacterial counts reduced, infections can be prevented or treated more effectively. In other words, V.A.C. Therapy helps remove all of the substances which impede wound healing.

Second, V.A.C. Therapy creates a uniform pressure that pulls the wound edges to the geometric center of the wound — we call this "macrostrain" — which helps to reduce the overall size of the wound and encourages new tissue to grow back in the shape of the original tissue.

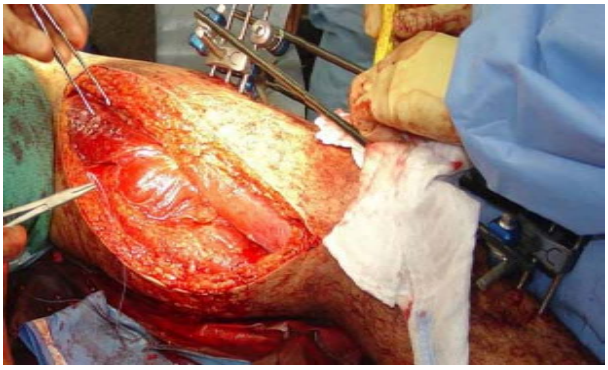
The third benefit, which is truly unique to V.A.C. Therapy because of the unique properties of the foam dressing, is the ability to provide a controlled stretch of individual cells lining the wound, triggering a series of biochemical reactions which cause the cells to divide and replicate more quickly – we call this "microstrain." This cellular stimulation occurs only with V.A.C. Therapy's special foam dressings and the patented pressure sensing technology allows the pump to monitor the amount of pressure at the wound site. There is no evidence that other products currently assigned to the NPWT HCPCS are capable of providing this cellular stimulation or the same rapid wound healing documented with V.A.C. Therapy.

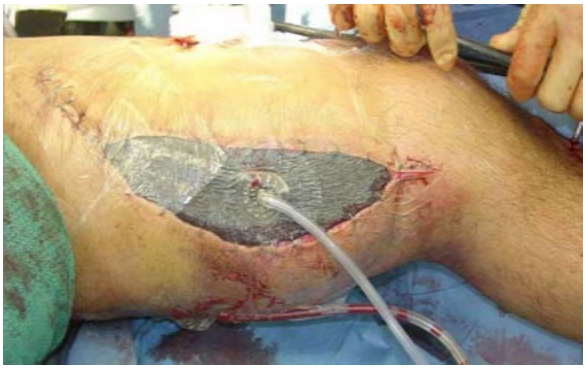
It is also important to note that although V.A.C. Therapy was cleared by the FDA in 1995, CMS, then HCFA, did not cover it until 2000, stating that the level of evidence for the 510(k) clearance did not meet their requirements for establishing either clinical efficacy or safety in the home. However, CMS recently assigned other products to the NPWT HCPCS codes using only the FDA clearances without requiring any evidence of clinical effectiveness or safety in the home.

Since the FDA first cleared V.A.C. Therapy in 1995, nearly two million patients have been treated with the device in U.S. hospitals, long-term care facilities and homes, including

more than three hundred thousand Medicare Part B patients. V.A.C. Therapy has the largest body of clinical evidence of virtually any wound care product with 15 randomized controlled clinical trials, more than 400 peer-reviewed journal articles, six clinical practice guidelines, and 62 textbook citations. V.A.C. Therapy is used to treat a wide variety of acute and chronic wounds and is the only product cleared by the FDA specifically for use in the home.

Outside of Medicare, V.A.C. Therapy is used extensively to treatment war wounds caused by improvised explosive devices. Data published by military physicians from the hospital in Balad, Iraq in 2006 showed that the rate of infections in these types of wounds was decreased from 80% to 0%, and treatment time was reduced from 83 days to 4 days, significantly increasing the limb salvage rate. (See Attachment B.) For this reason, KCI was asked to flight certify V.A.C. Therapy to assist in transfer of these patients from the combat theater to medical facilities in Europe and the United States.

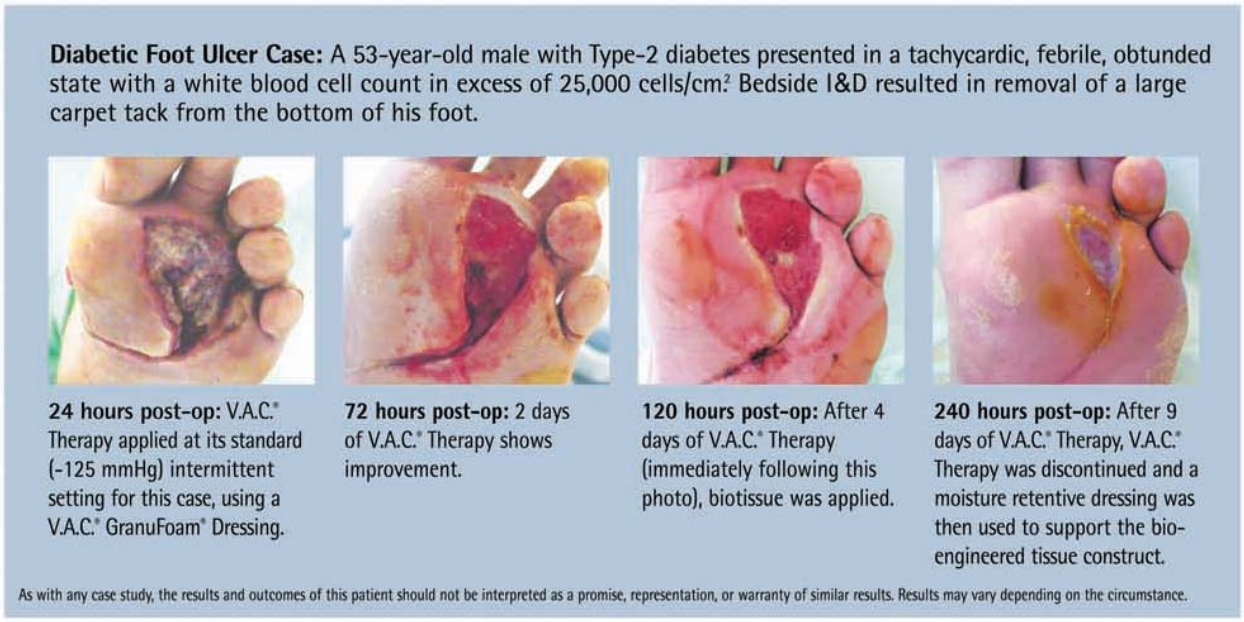




Before and After: V.A.C. Therapy placed on leg trauma wound (IED injury);
Air Force Theater Hospital, Balad Air Force Base, Iraq.

For Medicare Part B beneficiaries, V.A.C Therapy is more often used to treat complex chronic wounds occurring in compromised patients. Because V.A.C. Therapy is the only device proven effective in growing tissue over bone and tendon, it is used frequently to salvage limbs of diabetic patients. V.A.C. Therapy is also effective at healing the most serious types of pressure ulcers in immobile, bedridden patients. A retrospective comparison of V.A.C. Therapy patients managed under the Medicare home health benefit showed that compared with patients

experiencing similar wounds, V.A.C. Therapy patients had lower rates of hospitalization and need for emergent care, as well as improved pain and increased rates of ambulation when compared to patients who were not treated with V.A.C. Additionally, Patients treated with V.A.C. in the home care setting had average cost savings from $3,600 to $12,000 per patient. The average inpatient cost savings ranged from $950 to $31,000 per patient.



Genecov, D. G., et al. A controlled sub-atmospheric pressure dressing increases the rate of skin graft donor site reepithelialization. *Annals of Plastic Surgery,* 1998; 40(3): 219-25.

Case study: Diabetic foot ulcer healed in 9 days, using V.A.C. Therapy

Today, physicians prescribe V.A.C. Therapy to improve clinical outcomes, salvage limbs, reduce the need for institutional care and allow ambulatory patients to be treated while maintaining a normal lifestyle. As a result of the new competitive bidding program, beginning July 1st of this year, V.A.C. Therapy will no longer be available for Medicare Part B beneficiaries in any of the 10 Competitive Bidding Areas for a period of three years because of the methodology CMS used to bid this category.

Individual clinicians and medical societies, including the two largest wound care professional groups in the US, told CMS that other products assigned to the Negative Pressure Wound Therapy codes were not clinically equivalent and, for that reason, this category should not be competitively bid. (See Attachment C.) They also described the serious, potentially life-

threatening consequences of restricting patient access to effective NPWT products, such as a reduced risk of secondary amputation (4% with V.A.C. compared to 10% in the control group). Had CMS used an outside clinical panel to solicit feedback about the product categories and codes they intended to bid, feedback would have supported the removal of NPWT from bidding until clinical comparability of products in the NPWT codes could be validated.

Members of Congress have also challenged the appropriateness of the decision to include NPWT in the current round of competitive bidding, but to date CMS has not answered the questions raised about the lack of clinical comparability in this category.

Our recommendation: with outside clinical panels relevant to the products being reviewed through an outside clinical expert panel. We believe this problem could have been avoided if stakeholders had been given the opportunity to comment on product categories and codes in advance. We urge Congress to direct CMS to allow for such public comment on the categories and codes proposed for all future phases of the DMEPOS competitive acquisition program. We believe that CMS should also convene a meeting of the Program Advisory and Oversight Committee (PAOC) to discuss the categories and codes as well as accept written comments from clinical experts and stakeholders. All of the input received should be taken into account in making final determinations about product categories and their component codes. CMS should also be required to provide a written rationale for final determinations and to respond to all comments received.

2. Clinical support and patient education:

Patients using diagnostic and therapeutic equipment must be educated to ensure that the products are used safely and effectively. It is also important that patients and caregivers have access to appropriate levels of clinical and technical support 24/7 to assist if product problems or clinical complications arise. Without good clinical and technical support, the health and well-being of patients using these products could be jeopardized. For these reasons, CMS should have, but did not, develop product-specific supplier quality standards, specific to each therapeutic product category, except for three categories: respiratory products, complex rehabilitative wheelchairs, and orthotics (which latter item is not included in competitive bidding). NPWT is one of the most complex DME products used in the home setting, and it is

used to treat some of the most compromised patients. Yet there are no quality standards specific to suppliers of NPWT.

Our recommendation: Outside expert opinion and public meetings should be used to identify the need for and develop supplier quality standards specific to individual therapeutic product categories when appropriate.

3. Validating supplier capacity and capability:

For complex product categories, selection of contract suppliers should be based not only on their ability to acquire these products, but also on their ability to provide the support services necessary to ensure safe and effective use. CMS should have, but did not, confirm that all winning suppliers of therapeutic products had both necessary product capacity and support capability. For example, over the past few weeks, KCI has received calls from winning NPWT suppliers who have no previous experience with this product category. Here are a few examples:

- One call came from a winning bidder who does not currently have any NPWT therapy products, and is now trying to determine how he will provide the therapy. He is also trying to figure out how to set up a wound care program from scratch to support what he now believes are challenging clinical and customer service responsibilities that come with these products and patients.
- We learned of one national medical equipment company to whom CMS awarded a contract to supply NPWT in all of the first 10 competitive bidding areas, even though they have never provided these products anywhere. They knew so little about the requirements of the category that they asked us whether a physician's prescription is required for NPWT – it is.
- Another call came from a supplier who had no prior experience but was awarded contracts in the two Florida competitive bidding areas. He offered to sell us his company – along with the contracts.
- Finally, one supplier told us his NPWT therapy bid was a "shot in the dark," because he has very minimal experience with the products.

Clearly, CMS failed to ensure adequate supplier product and support capability in the NPWT category before it awarded contracts. While CMS' approach may be appropriate with simple functional equipment like walkers or wheelchairs, it raises serious questions about whether

patients will have access to both effective NPWT products and appropriate levels of service and support when the program goes into effect.

Our recommendation: For therapeutic product categories, CMS should validate winning suppliers' capacity to acquire the products and capability to support patients and caregivers using those products by developing supplier quality and accreditation standards for those categories.

4. Impact on patients and total Medicare expenditures:

Changes in therapeutic product availability occurring as a result of competitive bidding could impact clinical outcomes and total Medicare treatment costs. For that reason, assessment of the impact of competitive bidding on therapeutic product categories must include comparison of clinical outcomes and assessment of the effect on other Medicare costs. When asked about their plans for monitoring these important metrics, CMS officials have repeatedly said that they do not plan to look at either clinical outcomes or the impact on total Medicare treatment costs. If effective therapeutic products are not available and clinical outcomes are compromised, Medicare Part B savings could be offset by increases in other Medicare costs related to unnecessary or extended hospitalizations (reduced by 26 percent with V.A.C. used in dehisced sternal wounds), increases in emergent care, and prolonged treatment times.

Our recommendation: Congress should direct CMS to evaluate the impact of competitive bidding of therapeutic products based on clinical outcomes and total Medicare costs.

5. Required Bidding Process for Expansion.

We have strong concerns about CMS's ability to use bid amounts determined in setting payments in an MSA (that is a CBA) to set rates in another (non-CBA) MSA. Patient needs and costs for providing care and technologies are not the same in every MSA. If this program continues, CMS should be required to conduct a separate bidding process in each and every MSA in order to ensure that the payment amounts used by Medicare reflect local market conditions.

Our recommendation: We would, therefore, recommend repeal of the existing statutory authority granted to CMS to forego such separate competitive bidding processes.

In summary, we believe medical devices play an important role in improving both the effectiveness and efficiency of outpatient care covered under Medicare Part B. If programs like DMEPOS competitive bidding fail to appropriately address the quality of products, services, and outcomes of these therapeutic products, the research and development investment required for technology innovation may be unsustainable for many small businesses, who contribute so much to the health care system today. We thank you for your interest in hearing our concerns and look forward to working with you in the future to ensure that technology innovation continues to bring value and positive clinical outcomes to patients, providers, and to the Medicare program.