

**TESTIMONY OF ROBERT H. HARALSON, M.D., M.B.A.**

**ON BEHALF OF**

**THE AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS**

**ON**

**Competitive Bidding for Durable Medical Equipment: Bad Medicine for  
Small Suppliers**

**BEFORE THE HOUSE SMALL BUSINESS COMMITTEE**

**SUBCOMMITTEE ON RURAL AND URBAN ENTREPRENEURSHIP**

**May 21, 2008**

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Good afternoon Mr. Chairman, Mr. Fortenberry, and members of the Subcommittee. I am Dr. Bob Haralson, and I serve as the executive director of medical affairs for the American Association of Orthopaedic Surgeons and am here on behalf of the AAOS which represents more than 17,000 board-certified orthopaedic surgeons.

I would like to thank you for the opportunity to present our concerns with the many changes being implemented by law and regulation concerning durable medical equipment, prosthetics, orthotics and supplies- collectively referred to as DMEPOS. We share Congress' aims of increasing the quality of patient care, eliminating fraud and abuse in federal health care programs, and reducing the costs of delivering care to beneficiaries, and it is our pleasure to appear before you today to continue our work toward those goals.

With that said, I would like to highlight, what we believe to be the unintended consequences of applying rules meant for retail DMEPOS suppliers to physicians in small practices across the country who provide certain DMEPOS as part of providing

high quality care to their patients. It is important to note that we are talking about physicians who supply DMEPOS *only to their patients*, not to the general public. And because many of our physicians who provide DMEPOS to their patients are essentially small businesses and many provide those items to their patients because they are the only “supplier” in rural areas, we are especially appreciative of your willingness to discuss this issue today.

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In the field of orthopaedic surgery, we have several sub-specialties that are especially reliant on the provision of DMEPOS to meet basic patient care needs such as foot and ankle surgeons and sports medicine. As you well know, the provision of DMEPOS is not the main facet of the care we provide to patients, but it is a critical part of ensuring that many patients are able to ambulate out of our offices as safely as possible.

When analyzing the impact of the new rules and regulations around DMEPOS, including competitive bidding, it’s important to remember that, from the physician perspective, there are different rules that apply to the different categories of DMEPOS.

- (1) Durable Medical Equipment- As you are probably aware, physicians are not allowed to supply most DME to patients because of the Stark self-referral regulations. However, because some DME is so important to a patient’s ability to safely leave the physician’s office- and so important for preventing

further injury an exception from the Stark prohibition was created for several items. In the area of orthopaedic surgery, this exception includes crutches, canes, walkers, and folding manual wheelchairs. Physicians are able to provide these items to their patients if the arrangement fits within the Stark in-office ancillary exception.

(2) Orthotics- The provision of orthotics to patients in the course of care is also incredibly important. According to the U.S. Code, the definition of orthotics includes “leg, arm, back, and neck braces and artificial legs, arms, and eyes.” Orthotics are treated differently under regulation than DME in that there is not an outright prohibition on physician provision of orthotics. In order to provide patients with orthotics and submit a claim to Medicare, physicians are required to ensure that they fit the arrangement into the Stark in-office ancillary exception.

(3) Prosthetics- The final major category is prosthetics, defined in the U.S. Code as items that “replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care).” While the provision of items meeting this definition is important to other specialties, the current rules have not substantially impacted the care that orthopaedic surgeons provide to their patients. In addition, Congress did not authorize CMS to include prosthetics as part of the competitive bidding program.

With that groundwork laid, I'd like to take you through some of the concerns that we have regarding new and revised rules pertaining to the provision of DMEPOS to our patients. While I know that our focus here today is the competitive bidding program, I'd like to give you the full picture of how the provision of DMEPOS to our patients is becoming increasingly difficult- including the potential impact of the competitive bidding program. Specifically, I'd like to address:

- (1) The Application of DMEPOS *Quality Standards* to Physician-Suppliers;
- (2) The Quality Standard *Accreditation* Process for Physician-Suppliers;
- (3) The Impact of the DMEPOS *Competitive Bidding* Program on Physician-Suppliers

Collectively, these changes threaten to interfere with the continuity of patient care and the primacy of the patient-physician relationship and significantly increase the administrative burden of many physicians participating in the Medicare program.

## **DMEPOS QUALITY STANDARDS & PHYSICIAN-SUPPLIERS**

In order for a physician to be able to provide allowed DMEPOS to their patients and bill Medicare for those products, the physician must not only be enrolled to participate in Medicare as a physician- but must also enroll as a DMEPOS "supplier." The rules make no differentiation between large retail DMEPOS suppliers and physicians who are also serving as DMEPOS suppliers solely during the course of caring for their patient.

As directed by Congress, CMS has been going through the process of issuing new “Quality Standards” for suppliers of DMEPOS. I’d like to personally thank CMS staff for their willingness to work with us on how these Quality Standards are applied to physicians who enroll as DMEPOS suppliers. These are Quality Standards that must be met in order to submit DMEPOS claims to Medicare; and these same Quality Standards must be met in order to submit a bid under the competitive bidding program.

Our major concerns regarding the Quality Standards are two-fold:

First, we are concerned about the roll-out and opportunity for input regarding these DMEPOS Quality Standards. The impact of these standards is wide-reaching - and because of that is something that requires broad input. As I mentioned, we have been appreciative of CMS’ willingness to work with us on the standards. But with something as important as the quality of the care and access to the supplies that our patients need, we believe the Quality Standards should have been published through the formal rulemaking process. Such a process would have ensured that all stakeholders were aware of the potential impact of these standards, and it would have ensured that CMS shared the analysis behind what was included, what was excluded, and why they applied the same standard to physicians that they applied to other suppliers.

Second, the AAOS believes that a “one-size fits all” approach to the Quality Standards is not in the best interest of patients and will have an adverse impact on the patient’s ability

to access DMEPOS from their physician. We have made CMS aware of these concerns, and while staff have acknowledged the difficulties of applying Quality Standards to physician-suppliers, the AAOS is concerned that CMS believes it lacks the authority from Congress to provide flexibility for physician-suppliers in setting the Quality Standards. This is certainly an area where we request the Committee's assistance.

### **THE QUALITY STANDARD ACCREDITATION PROCESS**

The second major topic I'd like to bring to your attention is the burden of the Quality Standard Accreditation process. We acknowledge and share Congressional and CMS interest in ensuring Medicare beneficiaries receive high quality care, supplies, and service. We are equally committed to ensuring that patients have access to the care and supplies that they need in a safe, efficient, and timely manner. Unfortunately, our members are finding it increasingly difficult to participate as DMEPOS suppliers.

As I mentioned, the provision of these items is limited by law and the type of medicine that orthopaedic surgeons practice. Therefore, in most cases orthopaedic surgeons are submitting claims for a very small number of DMEPOS items. However, in order to go through the accreditation process, physician practices will be charged approximately \$3,000 *per location* to be accredited as having met the Quality Standards. This only makes it increasingly difficult for physicians to participate, especially in the context of impending cuts in payments for physician services and rising costs of providing care. We

have spoken to some small practices that provide so little in terms of DMEPOS that total Medicare claims for the year are only \$1,500- yet for those patients who need these items, it is a critical service. I suspect for some practices, that number is even lower. Ultimately, this process will result in a net loss for many physician practices, many in rural areas, across the country.

We believe that this requirement is duplicative of other training that health care professionals, particularly orthopaedic surgeons, receive and that these new requirements are financially and administratively burdensome. This will undoubtedly result in many physicians no longer providing these services to their patients which would adversely impact patient care.

### **THE IMPACT OF COMPETITIVE BIDDING ON PHYSICIAN-SUPPLIERS**

This leads me to the specifics surrounding the competitive bidding program. While *all* physicians who also function as DMEPOS suppliers are subject to the Quality Standards and the accreditation process- for some products, physicians will also be required to submit bids against much larger organizations whose primary reason for existence is the provision of DMEPOS.

Using the public comment period, we expressed our concerns to CMS that the costs and burden associated with competitively bidding for certain products that are so small to the

overall practice of orthopaedic surgery- yet so integral to patient care when utilized - were making physician participation as DMEPOS suppliers untenable.

We would like to applaud CMS for their decision to exempt physicians from having to competitively bid DME that we are allowed under Stark to provide- including crutches, canes, walkers, and folding manual wheelchairs. These items are so integral to a patient's ability to safely leave the site of care that the ability to provide these items should not be impeded by requiring physicians having to submit a bid against much larger organizations that provide these items en masse.

We are, however, extremely dismayed regarding one other category of products subject to the competitive bidding program- and that is "off-the-shelf orthotics." I previously mentioned that orthotics are typically referred to as leg, wrist, back, and neck braces. Congress went on to further define "off the shelf" as orthotics "which require minimal self adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual."

In the final rule where CMS published the physician exception for crutches, canes, walkers, and folding manual wheelchairs, they went on to create a separate exception from the competitive bidding process for off-the-shelf orthotics- but only extended the exception to occupational and physical therapists. In creating the exception, CMS

acknowledged that these items are integral to care, thus necessitating the exception- but in what we believe to be a glaring omission did not include *physicians* in the exception.

In this area, it is not a question of CMS authority. We believe that in the DMEPOS market, orthopaedic surgeons will almost universally be considered small suppliers. And the statute mandating the competitive bidding program *requires* that the “Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program.”

Many patients require immediate access to these items for immobilization, injury support, facilitation of safe mobility, or post-surgical recovery. It is unsafe and clinically inappropriate to delay a patient’s access to items such as orthotics or to send a patient out of a physician’s office without the necessary DMEPOS. We are hard pressed to understand why CMS would believe it necessary to create the exception for therapists, but not physicians.

## **Recommendations**

Finally, I’d like to leave you with a few recommendations regarding physician provision of DMEPOS in the Medicare program which will ensure patient access to necessary items while maintaining the integrity of the program, which I know is a goal shared by all of the stakeholders you’ve heard from today.

First, regarding the Quality Standards and accreditation, we'd seek your support in recognizing that physicians are already trained to provide and administer DMEPOS to patients. AAOS continues to work with CMS to assure quality in the Medicare program. We firmly believe that, given the complexity of today's health care environment, steps must be taken to ensure that there are not unnecessary or duplicative efforts required of program participants that would discourage patient access to care. In terms of providing public confidence that the providers and suppliers of orthotics are trained and qualified, we believe that professional society credentialing and training processes and state regulation of practitioners already provide many of the necessary safeguards in this area. While we understand the need for a process of this nature, **we ask *not* that physicians and health care professionals be exempted from having to be accredited, but rather that they be deemed as having met the requirements of accreditation once they are licensed or credentialed to practice medicine under state law.**

In the event that this is not a possibility, **we ask for a delay in the accreditation deadlines for new and existing suppliers**, so that a more coherent set of Quality Standards can be applied to physicians and health care professionals, recognizing fundamental differences between physicians and health care professionals that supply patients DMEPOS during the course of care and retail DMEPOS suppliers.

Finally, with regard to the DMEPOS competitive bidding program- our recommendation is simple: that **physicians be added to the already existing exception for off-the-shelf**

**orthotics.** Failure to exempt physicians from having to competitively bid to furnish off-the-shelf orthotics to their patients could cause significant access and patient safety issues. Because no off-the-shelf orthotics were included in the list of products to be competitively bid in the first two rounds of the program, there is still an opportunity to remedy this omission before physicians are unable to provide the products to the patients who need them in a safe, efficient, and convenient environment.

## **SUMMARY**

The quality and accreditation requirements applicable to physicians and health professionals should balance the costs of compliance against the affected physician-suppliers' potential for covering these costs. If physicians cannot cover the costs of DMEPOS participation, we run the risk of discouraging participation by small physician practices and reducing patient access to items essential to quality medical care. The ability of a physician to address a patient's condition *during* the physician-patient visit and to ensure that the patient has received the appropriate DMEPOS with proper instruction on its use and application is integral to the quality and efficiency of patient care. However, to require a patient to go elsewhere to receive products that could otherwise have been delivered in their physician's office may lead to disjointed care without the input or expertise of the treating physician.

I would like to thank you, Chairman Shuler, ranking member Fortenberry, and members of the Subcommittee for the opportunity to speak to you this afternoon.