

November 23, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

VIA ELECTRONIC MAIL: DMEPOS_Quality_Standards_Public_Comments@cms.hhs.gov

Re: Comments on Draft Quality Standards for DMEPOS Suppliers

Dear Dr. McClellan:

On behalf of the Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized scooters and power wheelchairs, we submit these comments in response to the draft quality standards for Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services, which includes suppliers of power mobility devices (PMDs), recently issued by the Centers for Medicare and Medicaid Services (CMS). The draft quality standards promulgated as a part of the Medicare Modernization Act (P.L. 108-173) require suppliers to comply with quality standards established by the Secretary in order to furnish any item or service for which payment is made under Medicare Part B, and to receive and retain a supplier billing number used to submit claims for reimbursement for any such item or service.

The PMC has long advocated for quality standards and for raising the barrier of entry into the Medicare program to only those suppliers who can demonstrate knowledge of Medicare rules and regulations, as well as business ethics and acumen. To this end, the draft quality standards mark an impressive first step in ensuring the high quality DME and associated services are supplied by scrupulous and above-the-board business people.

The PMC would like to take this opportunity, however, to make the following recommendations to the draft quality standards:

General Recommendations:

- **All DME Suppliers Should Be Subject to Quality Standards and Accreditation Requirements and such Requirements Should Not Be Phased-In**

The PMC urges that any new quality standards, including accreditation, be subjected to all DME suppliers once finalized. PMC members are united in calling for the end of “fly by night” operators and others who fail to adhere to the rules of the Medicare program. Moreover, the PMC believes that there should be meaningful barriers of entry to the Medicare program so that fraudulent operators never get the opportunity to put the Medicare program or its beneficiaries at risk. All quality standards and accreditation requirements should be instituted as soon as practicable on all DME suppliers.

- **Accreditation Status for DME Suppliers should be “Grandfathered”**

The Medicare Modernization Act (MMA) requires all DME suppliers be accredited by a national recognized accreditation body. The PMC strongly supports such a provision. In fact, many PMC members have already subjected themselves to the accreditation process despite no government requirement to do so. Since the accreditation process is both expensive and time-consuming, the PMC strongly urges that CMS accept existing accreditation as satisfaction of the accreditation requirement. Requiring suppliers to get re-accredited will be unnecessary and duplicative. Moreover, representatives of accreditation organizations like the Joint Commission on Accreditation of Healthcare Organizations (JAHCO) have publicly stated that accrediting bodies will have a hard time meeting the anticipated new demand, let alone having to re-certify those suppliers who have already been accredited.

- **Special Consideration Should be Provided to Small Suppliers to Ensure that Small Suppliers Can Meet Competitive Bidding Requirements**

To be considered as part of the competitive bidding pool, DME suppliers will now be required to be accredited and adhere to new quality standards. Yet, such requirements constitute an unfunded mandate to suppliers to pay for administrative functions and services that supplement the duties performed by CMS contractors like the National Supplier Clearinghouse (NSC). While some larger suppliers can afford to pay for such services, many smaller suppliers are “mom and pop” operations that lack the resources to be able to pay the large fees charged by accreditation bodies or to make capital improvements to their business in order to get accredited.

Failure to help small suppliers with the costs associated with accreditation and quality standards will adversely limit participation in any national acquisition bidding program. Moreover, many small suppliers serve rural and underserved urban communities where larger suppliers may not operate. If CMS fails to provide some special consideration to these smaller players, like providing access to low-interest Small Business Administration loans, Medicare beneficiaries in these more difficult to reach areas, are at risk for not being served.

- **CMS Should Eliminate Current Supplier Standards**

Once the quality standards and accreditation requirements are implemented, there will be no need for the 21 supplier standards that are currently required. Enforcing both the supplier standards and the new quality standards would be redundant and a waste of Medicare resources. Moreover, elimination of the current supplier standards would free the National Supplier Clearinghouse (NSC) from enforcing the standards, allowing them to operate more efficiently in processing supplier applications and working with accreditation organizations to ensure that the quality standards are workable and enforced.

Specific Recommendations:

Administration

- **Administrative Standards Should be Flexible and Reflect the Size and Scope of the DME Supplier**

Administrative standards should not be a “one size fits all” proposition. Some flexibility should be provided to suppliers who have few (if any) employees and those who serve rural and/or underserved areas. In some cases, these suppliers may find it prohibitive to conform to some of these administrative standards including:

1. Toll-free telephone number – while many suppliers maintain toll free numbers, it is an expensive proposition for some. Moreover, the internet and cell phone services that do not charge for long distance calls are alternatives available to many beneficiaries if the supplier chooses not to maintain a toll-free number. Such a requirement, therefore, should not be part of the quality standards.
2. Business Hours – many smaller suppliers have part-time hours or do business by appointment and, therefore, may not maintain a strict 40-hour work week. Further, many power mobility suppliers maintain warehouses to stock inventory; these warehouses should not be subject to the 40 hour work week requirement.

Financial Management

- **Suppliers Should Not Be Required to Adhere to GAAP Accounting Principles**

Many small suppliers of power mobility devices operate on a cash basis and, therefore use the cash method of accounting rather than General Acceptable Accounting Practices (GAAP) which recognizes revenue when it is realized and expenses when they are incurred. Suppliers should not be forced into a more complex and documentation intensive system just because the standards dictate. Such a requirement is overly prescriptive and reeks of micromanagement. It

would be both a financial and documentation burden on small suppliers who would be required to abandon the more straight-forward cash method of accounting in favor of the GAAP method just for accreditation purposes.

- **Suppliers Should Not Be Required to Notify CMS and Accreditation Agencies When They “First Become Aware” of Potentially Adverse Financial Conditions**

Suppliers, both large and small, may experience issues with cash flow from time to time. Many times, CMS contractors deny appropriate claims, levying large overpayments notices to suppliers, impacting the supplier’s ability to secure financing. Yet, historically a majority of these denied claims are overturned at the ALJ level. So while there may be a short-term cash flow crunch, the underlying financial viability of the supplier remains sound. As a result, suppliers should not be required to notify CMS and accreditation agencies when they “first become aware” of an adverse financial condition since the supplier (nor CMS or the accreditation agency) cannot possibly know if such an adverse condition, like a short term cash flow issue, will ultimately lead to an adverse financial condition like bankruptcy.

Human Resources Management

- **Standards Should Conform to State Licensure Guidelines**

The standards call for suppliers to maintain documentation of annual verification of licenses, yet some states have professional licenses that require two year (or longer) renewals. Further, the standards require documentation of good standing, but some states licensing agencies only have telephonic verification. For these reasons, the standards must recognize the variation in state licensing authority and guidelines.

Performance Management

- **Performance Management Standards are Too Prescriptive and Overbroad**

While the PMC is supportive of suppliers tracking effectiveness and efficiency, the draft standards go too far in prescribing the methods and criteria for measuring such outcomes. For a supplier to be successful in the market place there must be constant evaluation of service performance, staff performance and the meeting of organizational goals. Each supplier, however, may have their own methods or business models as to how evaluate criteria. Moreover, the trends analysis required by the draft standards may require small suppliers to invest in costly software to identify and analyze trends that may only be marginally beneficial.

Appendix A - Supplier Product Specific Service Requirements

- **Power Mobility Suppliers Should Not Be Required to Develop a “Service Plan” for the Beneficiary**

While power mobility suppliers work with physicians and beneficiaries in determining and meeting the need for a power mobility device, deliver the chair and instructing the beneficiary on its use, there are usually no planned or follow-up visits post-delivery. While suppliers respond to beneficiaries calls for service, maintenance or repair, these visits are not part of a “service plan,” not made on a regular basis, nor can they be predicted. For the purpose of suppliers of power mobility, therefore, this quality standard should not apply.

- **Power Mobility Suppliers Should Not Be Required to Provide a Written Estimate for Repairs**

If the repair or service of the chair is not covered by Medicare, suppliers must furnish beneficiaries with an Advanced Beneficiary Notice (ABN). If the repair or service is covered under Medicare, suppliers do not usually provide a written estimate. Requiring power mobility suppliers to provide written estimates in such situations will create significant delays in repairs. In essence, suppliers would be required to go to the beneficiary’s home, assess the repair or service need, return to the office to mail the written estimate, and then make the requisite repair. Since such a situation will cause needless delay for beneficiaries and increased cost for suppliers, the PMC recommends that this provision not be extended to power mobility dealers.

- **Power Mobility Suppliers Should Not Be Required to Notify Physicians of Minor Repairs or of Service Plan Follow-Ups**

Power mobility suppliers who make minor repairs or adjustment to equipment should not be required to notify the physician of such visits. Notifications of these types are burdensome on suppliers and an annoyance to physicians. Communication should only be required in cases where the information sharing will impact a physician’s plan of care for the beneficiary. Similarly, since the PMC believes that power mobility suppliers should not be required to develop a service plan for beneficiaries, there should be no standard requiring follow-up of such plan.

Appendix F – Power Wheelchairs

- **Physician Prescriptions Should Not Be Required to Have the Exact Specifications and Components of the Wheelchair**

Physicians do not possess the intimate knowledge of power mobility products to be able to properly exact make and model type for beneficiaries on prescriptions. Physicians are expected to work with suppliers, clinicians, and others to determine the exact type of chair that properly fits the beneficiary. In some instances, the supplier may have to provide several different models

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of chairs for the beneficiary to “test drive” before they find the proper make and model to suit beneficiary needs. So while PMC supports the prescription requirement, it is unlikely that the prescription will have the degree of specificity required as to make and model of the chair, nor would such a requirement be realistic given the limitation of physician training in this area and the burden on physician’s time to provide such training.

- **Suppliers Should be Not be Responsible for CMS’ “Downcoding” of Equipment**

Under the “Service Plan” section of Appendix F, the standards require suppliers to access the “size and known durability of the wheelchair appear to be appropriate relative to the beneficiary’s approximate weight and height...and access the beneficiary’s planned use for the wheelchair relative to durability and style of wheelchair.” Yet, CMS has indicated that they plan to revise power mobility product codes and will “downcode” product to the least costly equipment that will meet the patient’s need in the home. If CMS is allowed to “downcode” product, suppliers should not be held responsible for “appropriateness” or “durability” of the chair, since they, in essence, did not make those determinations.

We appreciate your time and consideration of these issues and look forward to working with CMS and the power mobility community to address these concerns.

Sincerely,

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PMC Director

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PMC Counsel