

**PREPARED STATEMENT OF THE PMC TO BE PRESENTED AT CMS' SPECIAL OPEN
DOOR FORUM ON THE INTERIM FINAL RULE ON PMDs
September 13, 2005**

The Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized wheelchairs and power operated vehicles, supports efforts to provide meaningful reform to the Medicare power mobility benefit. Such reform should entail specified documentation requirements, effective anti-fraud provisions, ensuring access to needy beneficiaries to appropriate power mobility devices (PMDs), and placing the physician in the best position to evaluate the beneficiaries for need. While the PMC is supportive of various aspects of the new interim final rule, including the face-to-face requirement and elimination of the specialist requirement in order to qualify for a power operated vehicle (POV), the interim final rule fails to meet many crucial reform criteria in several respects. Some of the PMC concerns with the interim final rule are as follows:

1. The Interim Final Rule Fails to Provide the Necessary Level of Specificity As to What Physician Records Are Needed to File a Claim

The interim rule requires that physicians prepare and provide relevant medical records to suppliers together with a prescription, and that these records must "clearly support" the medical necessity of the PMD. However, it is not clear from the interim final rule how suppliers can be reasonably required to determine whether these records "clearly support" the provision of PMDs. The Medicare program does not contemplate that a supplier would be required to review and interpret physician medical records and make an independent medical judgment that may conflict with that of the beneficiary's treating physician. Suppliers and beneficiaries must be able to rely on the treating physicians' independent medical judgment. As stated by CMS Administrator Dr. McClellan in a March 8, 2004 statement to the United States Senate:

The clinical criteria for deciding when a manual or power wheelchair is medically necessary and appropriate for a beneficiary has been and will continue to be a matter of clinical judgment by a physician. It's also my understanding that CMS does not want to list specific condition-based criteria since **the decision to determine the appropriateness of providing a manual or power wheelchair is best left to the physician's judgment (emphasis added).**

Moreover, the PMC is concerned that reliance on subjective medical records such as progress notes, will preserve the adhoc discretionary authority of Medicare contractors to inappropriately deny claims since physicians don't always record notes clearly and rarely note in their records with the level of specificity expected from Medicare contractors. There is no uniform standard associated with such medical notes and the medical judgment of the treating physician is often overruled by a Medicare contractor who has never examined or even talked with the patient. Progress notes can be interpreted in several different ways and even clinicians can derive different conclusions as to the meaning and scope of such notes. Yet review of a physician's progress notes by Medicare contractors will often overrule all physician's certifications and written statements identifying the health and status of his/her patient.

Contrary to the Congressional intent of the face-to-face requirement, the interim final rule further erodes the doctor's role as gatekeeper and puts suppliers and bureaucrats in the position of routinely overruling their medical judgment, creating even more uncertainty for both beneficiaries and suppliers.

2. The Paperwork Reduction Act (PRA) Still Applies to the Physician Documentation Requirements Set Out in the Interim Final Rule

Contrary to assertions made by CMS, the burden placed on suppliers and physicians will greatly increase under the interim final rule. Suppliers, for the first time, will be required to obtain and maintain an ill defined set of medical records and physicians will be required to prepare, maintain, and provide such medical records to suppliers on 100% of all PMD claims.

In addition to collecting and submitting medical records to suppliers, the interim final rule places a whole new record keeping requirement on physicians by requiring that each physician document medical need (according to ill defined Medicare guidelines) in their medical records. This new record keeping requirement must be subject to PRA protections, including approval by OMB.

3. The Interim Final Rule Will Increase the Administrative and Educational Burdens on Physicians

It is unrealistic to think that CMS will be able to conduct sufficient outreach to adequately educate physicians about the confusing new algorithmic functional ambulation standard, not to mention the 48 new product codes that physicians are expected to know and differentiate so that they can adequately place an eligible beneficiary in the proper PMD. Failure of physicians to sufficiently understand the new coverage policy and product codes will most likely have led to physicians writing fewer prescriptions for PMDs, thereby ignoring real need, or failing to properly document need, leading to inappropriate denials.

4. The 30-Day Timeframe Is Too Short and Could Lead to Access Issues

The interim final rule requires that the prescription and supporting documentation for the PMD claim be submitted within 30 days of the face-to-face examination. Such a short timeframe would make it difficult for many beneficiaries, with appropriate needs, to access PMDs. Under current law, suppliers have 90 days from the submission of a CMN to deliver a motorized wheelchair. This 90-day time frame allows for the opportunity for suppliers to verify and correct information and to obtain additional information. Further, in some instances, especially with higher end rehab equipment, physicians have to wait until the beneficiary sees an occupational or physical therapist before knowing what type of power mobility to prescribe. It would be difficult for a beneficiary to be able to schedule a physician visit and a subsequent visit with a rehabilitation specialist all within a 30-day time frame.

To better promote efficiency and ensure that beneficiaries have the requisite time for all necessary examinations, the PMC recommends that timeframe be extended to at least 90-days that is the current requirement for delivery of DME under the CMN.

5. Contractors and Suppliers Need More Time to Implement Changes to the Medicare PMD Benefit

Medicare contractors have indicated that they need until April 1, 2006 to update their systems to accept the new information required under this rule. Without a delay or until such time as the claims process systems are updated, suppliers will have to collect the documentation required by the new regulations as well as the CMN in order for their claims to be processed. Furthermore, other significant changes are being developed. Contractors are expected to release new draft Local Coverage Determinations with comment period to further explain the medical conditions that will trigger Medicare coverage for mobility equipment, and CMS will implement 49 new codes for these products along with a new fee schedule; these changes are planned to go in effect January 1, 2006. All of these significant changes modify the eligibility assessment and claims process for PMDs. These changes must be coordinated seamlessly, and more time is needed for modification of the interim final rule and smooth transition to take place. The PMC urges CMS to, at a minimum, delay implementation date for the new rule until April 1, 2006 at the earliest.

6. The Centers for Medicare and Medicaid Services (CMS) Lacks the Authority to Eliminate the Certificate of Medical Necessity (CMN)

Contrary to the plain language of the Social Security Act (SSA), the interim final rule would eliminate the CMN and the authority provided to suppliers by Congress to distribute such CMN to physicians and beneficiaries. The PMC questions whether CMS has such authority absent Congressional approval.

As part of the SSA, Congress defined the CMN as a “form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member.” The PMC asserts that the Congressionally mandated, Office of Management and Budget (OMB) approved CMN was established for the exact purpose described in the interim final rule - to document the medical need of the patient based on the treating physician’s evaluation of such patient.

The CMN provides clarity and consistency in the Medicare program and is already understood by physicians, suppliers and beneficiaries. Rather than abandoning the CMN, the PMC would support revising the document to reflect the new functional ambulation standard.

7. Issuance of an Interim Final Rule Violates the Administrative Procedures Act (APA)

CMS has issued the changes to the Medicare PMD benefit in the form of an interim final rule, in effect, allowing the rule to go into effect without proper notice and comment periods as required by the APA. While CMS did issue a proposed rule for the face-to-face examination requirement, this interim final rule differs significantly from the proposed rules, adding new documentation requirements on both suppliers and physicians, and eliminating the CMN; all new aspects to the face-to-face requirement that never appeared in the original proposed rule. As a result of these significant changes, the PMC contends that the interim final rule on the face-to-face examination requirement was issued by CMS in absence of proper notice and comment and, therefore, violates the APA.

8. The Role of the Clinician is Marginalized Under the Interim Final Rule

Under the interim final rule, there is no specific role mentioned for clinicians. When prescribing higher level PMDs, clinicians can serve a role in conducting assessments which aid the physician and helps save the Medicare program resources. Clinician assessments, therefore, should be reimbursed by Medicare and made part of the pertinent medical record. If such assessments, however, are paid for by the supplier, they should still be given full consideration and not just routinely dismissed by Medicare contractors simply because the supplier paid for the clinical review.

9. The Interim Final Rule Fails to Eliminate the “In the Home” Restriction

The “in-home” restriction severely impedes on the health and independence of people with disabilities, as it essentially confines people to the four walls of their homes and does not take into account the need for beneficiaries to access their physician’s office, pharmacy, grocery store, bank or place of worship, which are all activities of daily living. Any new guidelines must reflect the functional assessment of a beneficiary’s needs both inside AND outside of the home. By failing to remove this restriction from the Medicare power mobility benefit, needy beneficiaries will continue to be denied access to necessary mobility products and services. As a result, the PMC strongly urges CMS to adopt coverage guidelines that focus on a functional based clinical evaluation devoid of any “in-home” restriction.

The PMC looks forward to working with CMS, beneficiary groups and physician organizations to help alleviate these concerns with the interim final rule, as well as finding solutions that will provide consistency and fairness to the PMD claims process. At a minimum, the PMC recommends that implementation of the interim final rule for PMD be delayed until such time as these important concerns can be addressed.