

November 25, 2005

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS Interim Final Rule on Conditions for Payment of Mobility Devices, CMS-3017-IFC

Dear Dr. McClellan:

On behalf of the Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized wheelchairs and power operated vehicles (POVs), we are submitting comments regarding the interim final rule (IFR) on conditions for payment of mobility devices (CMS-3017-IFC). On August 25th, the Centers for Medicare and Medicaid Services (CMS) issued the IFR that makes comprehensive changes to the Medicare PMD benefit. 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. CMS Lacks the Authority to Eliminate the Certificate of Medical Necessity (CMN) and Replace It with A More Burdensome Recordkeeping Requirement

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.

Furthermore, the Federal court system has upheld the CMN as the Medicare document of record that determines eligibility for a PMD. In *Maximum Comfort, Inc. v. Thompson*, 323 F. Supp. 2d 1060 (E.D. Cal. 2004) the Court wrote:

the plain language of [42 U.S.C.] § 1395m(j)(A)(2)(i) supports the plaintiff’s position that it may only use a CMN to provide the necessary information for the determination of medical necessity and reasonableness. The Secretary cannot require that DME suppliers, such as plaintiff, obtain Medicare beneficiaries’ medical records and make a judgment as to whether the equipment is medically

necessary and reasonable. It is clear from the plain text of the Medicare Act that, while Congress granted the Secretary broad discretion over medical necessity and billing criteria and procedures, it did not do the same regarding medical necessity documentation. Instead, Congress addressed that issue itself and established that any and all information required from suppliers to make a medical necessity determination must be contained in a CMN.

Id. at 1074-75.

In the interim rule, CMS acknowledges that the CMN was previously established to allow efficient adjudication of claims by automating the submission of certain information needed to make medical necessity determinations.” 70 Fed. Reg. 50944. Yet, CMS determined that an OIG analysis of the CMN “found in some cases a 45 percent rate of non-compliance of CMNs. This finding underscored the belief that the CMNs do not accurately reflect the contents of the physician’s medical record.”

Medical record content has **NEVER** been the standard by which Medicare coverage is determined. As an example, CMS proposed to amend 42 C.F.R. § 410.38 to require that physicians document in their medical records the need for the prosthetic, orthotic, durable medical equipment, and/or supplies (“DMEPOS”) being ordered.¹ CMS acknowledged in their proposed rule that the physician documentation of medical need for DMEPOS constitutes a “collection of information” and is subject to approval from OMB per the PRA. Although CMS and OMB sought comments from Medicare stakeholders, including physicians and clinicians, CMS **NEVER** finalized this proposal and OMB **NEVER** approved this proposed collection of information. It is unrealistic to suggest physicians will somehow document in their medical records according to a standard that has not existed previously.

Lastly, CMS Administrator McClellan has testified that the CMN reflects the physician’s determination of medical necessity and upheld the role of the CMN in the PMD claims process. As Dr. McClellan told the Senate Finance Committee:

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 the 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. However, this does not abdicate the responsibility to have appropriate documentation as to the medical necessity of the claim. As a condition of coverage, CMS does require that the beneficiary’s need for a wheelchair or power wheelchair is supportable. In fact, all claims for power wheelchairs must include a Certificate of Medical Necessity (CMN) which ‘certifies the need for the device and that it is reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body part.’”

2. Clarity and Consistency is Necessary as it Applies to the Physician Documentation Requirements Set Out in the Interim Final Rule

Burdens 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 recordkeeping requirement on physicians by requiring that each physician document medical need (according to ill defined Medicare guidelines) in their medical records. All of these new collections of information, including the new recordkeeping requirement, must be subject to PRA protections.

The PMC fully supports the requirement that a beneficiary have a “face-to-face” exam prior to a physician prescribing a PMD. This process enables beneficiaries, their physicians and caregivers to express an interest in the beneficiary’s need for the PMD, the physician to perform the examination, and the physician to write a detailed written order and evaluation for the PMD. By eliminating the CMN and basing PMD eligibility on unspecified documentation, the interim final rule 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. This is not consistent with the intent of Congress to emphasize the role of the treating physician in making medical necessity determinations.

The following are questions that remain unanswered due to the lack of clarity created by CMS’ interim final rule and the proposed new collection of information:

First, when the physician provides the prescription and the face-to-face examination report, both extensive documents addressing medical necessity, who decides whether additional documentation is needed?

Second, the new process requires that a doctor or treating practitioner:

- evaluate the beneficiary in the last 30 days to analyze mobility needs;
- document that the patient was evaluated for that purpose;
- conduct and document a face-to-face evaluation;
- write a seven-element prescription; and
- acknowledge consideration of the mobility algorithm.

Can a supplier reasonably rely on the physician’s documentation developed during the face to face visit?

Third, the supplier must obtain a seven-element prescription, as well as a documented face-to-face examination report. If the supplier agrees with the treating practitioner that the documentation provided is adequate, and subsequently a DMERC reviewer decides differently, will the supplier be held liable for the claim? Under what circumstance is a supplier protected by the waiver of liability provision established by Congress in Section 1879 of the Social Security Act.

The arbitrary and subjective nature of the collections of additional documentation contained in this interim final rule threaten the ability of our members to provide prescribed equipment to beneficiaries who rely on this equipment to perform their activities of daily living. The interim final rule would force the supplier to guess as to the veracity of the medical records and provide CMS and its DMERCs with carte blanche authority to overrule the prescription of the treating physician.

3. Estimation of the New Paperwork Burden on Physicians and Suppliers Contained in the Interim Final Rule is Unrealistic

CMS, in its interim final rule, estimates that the time for a physician to prepare, collect and submit medical records combined with the time it will take a supplier to collect, review and maintain such records will total 10 minutes contrasted with 12 minutes for filling out a CMN. It is wholly unrealistic to assume that a physician will prepare, maintain, collect and submit medical records to a supplier and such supplier will then maintain and review these records in 10 minutes. CMS has not provided any supporting documentation to support their burden estimate but we would request that the agency do so and allow the public to comment on the specific calculations prior to the rule being finalized.

a. Physician Requirements:

Prescription – Physicians are required, under this new regulation, to create a prescription with several specific components, all of which are currently included in the Certificate of Medical Necessity form. Without a form or format, the new prescription will create a larger burden on physicians as they attempt to document free-hand all of the components contained in this rule.

Chart Notes and Evaluations - Physicians are required, under this new regulation, to prepare, maintain and provide a record of the face to face examination of the beneficiary for the power mobility device. According to the preamble of the interim final rule, “the parts of the medical record selected [by the physicians] should be sufficient to delineate the history of events that led to the request for the PMD; identify the mobility deficits to be corrected by the PMD; and document that other treatments do not obviate the need for the PMD, that the beneficiary lives in an environment that supports the use of the PMD and that the beneficiary or caregiver is capable of operating the PMD...”² Physicians do not currently nor have they in the past charted according to these standards and thus the new burden placed on them will be substantial. Further, there is no established mechanism to determine if the physician’s medical records comply with these requirements. CMS must consider these requirements in their burden estimate.

Additional Medical Records – Physicians are also required, under this new regulation, to collect, copy, redact, and send any other pertinent medical records or test results, which will substantiate the previous prescription and face to face examination documentation.

All requirements are applicable to 100% of all PMD prescriptions, which is not current practice and will thus place new and substantial burdens on our nation’s physicians. This burden must be calculated by CMS and not summarily dismissed as current medical practice. Current medical practice is for physicians to consider their patient’s condition and complete a Certificate of Medical Necessity to prescribe, document, and establish the need for PMDs.

b. Supplier Requirements:

The supplier must collect both the prescription and additional information from the patient's medical record on 100% of its claims. Not only has CMS underestimated the burden associated with this requirement, CMS has also overlooked the cost required to maintain these massive amounts of records for 7 years. Further, suppliers will now be placed in the role of evaluating medical information contained in the physician's written charts to determine if the prescription should be filled -- a role never contemplated by the Medicare program.

The most common request for "additional documentation" is for copies of chart notes. To underscore the burden associated with the collection of this information, one of our members collected "additional documentation" in 1999 primarily consisting of chart notes for 283 claims. The total project required 1334 man-hours, or 4.71 hours per claim.

4. 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 63 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.

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.

6. 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 Administrative Procedures Act (APA). While CMS did issue a proposed rule for the face-to-face examination requirement in August 2004, that proposal was never implemented. This interim final rule differs significantly from the proposed rule, 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. The PMC sought a preliminary injunction in Federal court concerning the violations of due process associated with the development of the IFR. We attach our filing to demonstrate our legal concerns with such rule.

7. RECOMMENDATION: CMS Should Revise the CMN to Reflect the Functional Ambulation Standard in the New National Coverage Determination

The PMC recommends that any documentation requirement be incorporated into a revised CMN that includes the eligibility criteria and algorithmic process established in the NCD for PMDs issued May 5, 2005. The CMN was defined by Congress, developed by CMS, and approved by the OMB to establish medical need and thus to determine eligibility for the power mobility benefit. The treating physician completes the CMN and is in the best position to assess patient need and certify that the beneficiary meets the functional ambulation standard. Suppliers who submit the physician signed and completed revised CMN to the Medicare program should have a clear and unequivocal expectation that, if not fraudulent, such documentation establishes medical necessity.

At a minimum, suppliers should be able to rely on the documentation developed by the treating physician during the congressionally mandated face to face visit.

The PMC thanks you for the opportunity to submit comments and looks forward to working with OMB, CMS, and all stakeholders on these important issues.

Sincerely,

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