

September 14, 2007

Office of Management and Budget
Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building
Room 10235
Washington, DC 20503

Dear Ms. Lovett:

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 concerning the data collection and paperwork burdens associated with the rule entitled, *Conditions of Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles* (CMS-3017-IFC).

Per the August 16, 2007 Federal Register notice (72 Fed. Reg. 46,086-87), the Centers for Medicare and Medicaid Services (CMS) is seeking reapproval from the Office of Management and Budget (OMB) concerning the collection of information requirements associated with the final rule, CMS-3017-F (71 Fed. Reg. 17,021), which was published on April 5, 2006, and became effective on June 5, 2006. The agency also set forth the following:

Specifically, we are seeking OMB approval for the following terms of clearance identified in the Notice of Action dated October 16, 2006, of which OMB has requested CMS to monitor the paperwork burden required of providers and suppliers to determine if the paperwork requirements impose any unnecessary burden on the industry and/or need to be revised in order to improve the utility of the information.

72 Fed. Reg. 46,087.

Contrary to the terms of clearance and sound public policy, the Federal Register notice issued by CMS provides no data demonstrating that the agency did in fact “monitor” the paperwork burden required of providers and suppliers. The agency does not identify any study conducted, any data collected, nor does the agency address possible alternative collections of information that could reduce unnecessary burden and/or improve the utility of the information. Instead, CMS states in the Federal Register notice that it “does not believe” that the documentation requirement imposes any additional unnecessary burden on the durable medical equipment industry. 72 Fed. Reg. 46,087. The failure of the agency to engage in a meaningful analysis of the collection of information burden and utility is a disservice to all Medicare stakeholders, including the beneficiaries throughout the country who support the Medicare program.

The PMC is also concerned that the final PMD rule provides a flawed estimate of the overall paperwork burdens and record keeping requirement imposed on physicians and power mobility device (PMD) suppliers. The overall burdens and subjectivity associated with the final rule has resulted in a restriction in access to Medicare PMDs. In the August 2005 *Federal Register*, CMS set appropriate access levels at 187,000 Medicare beneficiaries qualifying for a PMD. For 2007, if one extrapolates CMS’ projected utilization levels; Medicare would pay for approximately 214,000 PMDs. Yet, current projections estimate that only 156,000 Medicare beneficiaries will receive a PMD in 2007, leaving over 64,000 medically qualified beneficiaries without access.

Not only did CMS fail to accurately gauge the paperwork burden under the rule, they failed to appreciate the scope of the rule, focusing their burden analysis on the elimination of the CMN and failing to consider the new burdens established under the rule, including the development of a detailed product description (DPD). To more accurately measure the paperwork burden on PMD suppliers under the rule, the PMC surveyed its supplier members as to the actual time it takes to obtain, review and retain all the documentation required to file a PMD claim. In addition, suppliers surveyed included the time required for completion of the DPD which, while not even included in the original clearance of the final rule, is yet another component of the supplier’s administrative burden.

The survey results demonstrate that suppliers take considerably longer in obtaining, reviewing and submitting PMD documentation than the ten minutes estimated by CMS in the final rule. One Western-based regional PMC supplier breaks down their paperwork burden as follows:

- I. Initial Interview – **75 minutes to 2 hours**
 - a. Call to beneficiary to collect necessary information – 30 minutes to 1 hour
 - b. Scheduling Face-to-Face examination - 5 minutes
 - c. Calling IVR ensure beneficiary eligibility – 5 to 10 minutes
 - d. Calling Medicare to check “same or similar” – 10 to 15 minutes
 - e. Calling secondary insurance to verify coverage – 10 to 20 minutes
 - f. Compiling client folder – 5 minutes
 - g. Scheduling with beneficiary for in-home assessment – 10 minutes
- II. Initial Doctor’s Package – **10 minutes**
 - a. Compiling documentation and faxing to Physician’s office – 5 to 10 minutes
- III. Follow-Up after Face-to-Face Examination – **5 minutes**
 - a. Most physician’s offices require multiple follow-ups – 5 minutes (per follow-up)
- IV. Review Doctor’s Package – **18 to 23 minutes**
 - a. Review the prescription including checking the ICD-9 code, cross-checking the date of the FTF on the prescription with the date on the chart notes; ensuring the ICD-9 code will support a PMD claim – 3 minutes
 - b. Review chart notes to ensure medical necessity for PMDs has been established – 5 to 15 minutes
 - c. Ensuring the detailed product description has been dated and signed by the physician – 5 minutes (assuming no follow-up is needed)
- V. Requests for Missing Information or Corrections – **30 to 40 minutes depending on number of follow-ups required**
 - a. Most beneficiaries require a minimum of three to four follow-up faxes or requests for information – 5 to 10 minutes/follow-

up

- b. As a result of the 45-day rule some beneficiaries must have another face-to-face examination since all documentation could not be compiled in the 45 day timeframe

VI. Delivery of PMD – **1.5 to 2 hours (not including travel time)**

- a. Re-verify insurance – 10 to 20 minutes
- b. Compile delivery package – 10 to 20 minutes
- c. Scheduling delivery – 10 minutes
- d. Delivery, including in-home assessment, measurements, equipment demonstration – 30 minutes to an hour
- e. Preparing home assessment paperwork – 15 minutes

The PMC hopes CMS will re-evaluate the data collection contained in the final PMD rule and seriously consider adopting a clear documentation requirement and objective standard that includes the eligibility criteria and algorithmic process established in the National Coverage Determination (NCD) for PMDs issued May 5, 2005. At a minimum, the PMC would recommend that CMS adopt documentation and objective standards that fulfill the following criteria:

- provide a degree of objectivity regarding the information necessary to supports the health care practitioner’s prescription for the most appropriate PMD;
- incorporate the algorithmic process established in the local coverage determination (LCD) to demonstrate PMD coverage criteria;
- ensure that the health care practitioner conducts a face-to-face examination;
- ensure that the health care practitioner chooses the most appropriate mobility device for the beneficiary;
- certify, under penalty of perjury, that the health care practitioner conducted the examination and that the beneficiary meets the medical necessity for PMD as stated in the rule.

It is the PMC’s belief that a template that encompasses the above-referenced criteria would provide the documentation needed to satisfy to CMS that a health care practitioner examined the

patient, evaluated the need consistent with national coverage criteria, while providing PMD beneficiaries and suppliers a reasonable assurance that their claim will not be denied. Such a template, moreover, will decrease the administrative burdens on both suppliers and physicians and ensure that beneficiaries have access to Medicare PMDs in a timely manner.

The PMC has learned that state physician groups are developing solutions to help guide health care practitioners in evaluating Medicare beneficiaries for PMD coverage. By helping guide physicians through the elements of Medicare PMD eligibility, these forms detail Medicare criteria and aid in assessing need for the most appropriate PMD devices (if any). Some states, including Colorado, Texas and New York, are advocating use of these tools and others are considering their adoption.

As you are aware, this is not the first comment period regarding data collection under the PMD rule. CMS has previously received many comments challenging their burden assumption, including a letter from Rep. Candace Miller (R-MI), then chair of the House Government Reform Subcommittee on Regulatory Affairs. In her letter, Chairman Miller stated that the Subcommittee is “greatly concerned” that CMS failed to “seriously evaluate the additional burden that the final rule imposes on suppliers of PMDs,” and that CMS did, in fact, increase administrative and documentation collection burdens on suppliers. By way of example, Chairman Miller included with her letter sample forms that would generate all the information required by the final rule, recognizing that these forms could, “relieve some of the new burden placed on suppliers of PMD” and urged CMS to consider “alternative collection methods” in addition to reconsidering the rule’s paperwork burden on PMD suppliers. We have attached the Chairman’s letter to our comments.

The PMC urges adoption of alternative collection methods in addition to your reconsideration of the paperwork burden imposed on PMD suppliers and physicians. As a result, the PMC proposes that OMB grant a provisional 3-month approval of the documentation collection, with a full three year approval contingent on CMS conducting a proper burden analysis for PMD suppliers and developing a standardize template as an alternative to the current documentation collection under the rule.

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

Sincerely,

Stephen M. Azia
PMC Counsel

Eric W. Sokol
PMC Director

Enclosure