DATE: 8/1/07

TO: Sandra Bastinelli

FROM: LT Camille Soondar

SUBJECT: CMS Response to Comments Received for PRA Package CMS-10116 as related to the Federal Register (FR) Notice titled: Medicare Program: Conditions for Payment of Power Mobility Devices (PMDs), including Power Wheelchairs and Power-Operated Vehicles (Published 4/27/07; Vol. 72, No. 81; p. 21024-21025)

The Division of Medical Review (DMR) is providing responses to the Paperwork Reduction Act (PRA) comments on CMS-10116 received from the industry as it relates to the Federal Register Notice published on April 27, 2007. Due to the number of comments received, DMR and CAG have collectively combined our responses into this document. Comments from various industry organizations that are repetitive in nature have been combined into single responses. Industry comments related to CMS-3017-F, the Mobility Assistive Equipment NCD or PMD LCD was responded to by Karen Rinker and concurred by Louis Jacques in CAG.

A. Industry Comment:

CMS issued a Federal Register notice which provided no data demonstrating that the agency did in fact "monitor" the paperwork burden required of providers and suppliers. CMS did not identify any study conducted, any data collected, nor did the agency address possible alternative collections of information that could reduce unnecessary burden and/or improve the utility of the information. OMB should not grant this extension, and should require monitoring of the paperwork burden, posting the test results, and allowing the supplier and physician communities the opportunity to comment.

A. CMS Response: CMS disagrees. CMS believes that we have interpreted OMB's terms of clearance appropriately and have provided sufficient data related to monitoring the Power Mobility Device (PMD) paperwork burden requirements**.** The supporting documentation related to this paperwork collection detailed the efforts CMS and its contractors embarked on during this initiative.

B. Industry Comment:

Suppliers and providers are concerned that the PMD Final rule provides a flawed estimate of the overall administrative and significantly increased paperwork burdens on physicians and fails to provide a specified record keeping requirement for both physician and PMD suppliers.

B. CMS Response: CMS disagrees. The only additional burden to physicians is the collection and submission of the supporting documentation from the beneficiary's medical record. CMS addressed this additional physician burden in the rule by establishing the add-on G code, which has been well accepted by the physician community.

C. Industry Comment:

The overall burdens and subjectivity associated with the final rule has resulted in a restriction in access to Medicare PMDs.

C. CMS Response: CMS disagrees. CMS believes this collection places no significant burden on Medicare's beneficiaries and their access to PMDs.

D. Industry Comment:

Suppliers project that only 156,000 Medicare beneficiaries will receive a PMD in 2007.

D. CMS Response: CMS disagrees. Based on current CMS' historical data sources, we have identified that approximately 243,000 PMD prescriptions are submitted yearly. This information was provided in the supporting documentation.

E. Industry Comment:

CMS should re-evaluate the data collection contained in the final rule and 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 on May 5, 2005.

E. CMS Response: CMS believes the physician or treating practitioner is in the best position to evaluate and document the beneficiary's clinical condition and PMD medical needs, and good medical practice requires that this evaluation be adequately documented. Thus, to minimize the documentation requirements for providers while assuring that documentation is adequate, physician and treating practitioners now submit a written prescription and copies of the relevant existing documentation from the beneficiary's medical record, rather than having to transcribe medical record information onto a separate form. The NCD is beyond the scope of this collection and therefore will not be addressed here.

F. Industry Comments:

CMS should: a) provide a degree of objectivity regarding the information necessary to supports the health care practitioner's prescription for the most appropriate PMD; b) incorporate the algorithmic process established in the LCD to demonstrate PMD coverage criteria; c) ensure that the health care practitioner conducts a face to face examination; d) ensure that the health care practitioner chooses the most appropriate mobility device for the beneficiary; e) certify, under penalty for perjury, that the health

care practitioner conducted the examination and that the beneficiary meets the medical necessity for PMD as stated in the rule.

F. CMS Response: CMS appreciates the recommended suggestions, however the NCD is beyond the scope of this collection and therefore will not be addressed here.

G. Industry Comment:

CMS should recommend a form to ensure that the following recommendations are met: a) provide a degree of objectivity regarding the information necessary to supports the health care practitioner's prescription for the most appropriate PMD; b) incorporate the algorithmic process established in the LCD to demonstrate PMD coverage criteria; c) ensure that the health care practitioner conducts a face to face examination; d) ensure that the health care practitioner chooses the most appropriate mobility device for the beneficiary; e) certify, under penalty for perjury, that the health care practitioner conducted the examination and that the beneficiary meets the medical necessity for PMD as stated in the rule.

G. CMS Response: CMS believes the physician or treating practitioner is in the best position to evaluate and document the beneficiary's clinical condition and PMD medical needs, and good medical practice requires that this evaluation be adequately documented. Thus, to minimize the documentation requirements for providers while assuring that documentation is adequate, physician and treating practitioners now submit a written prescription and copies of the relevant existing documentation from the beneficiary's medical record, rather than having to transcribe medical record information onto a separate form. The NCD is beyond the scope of this collection and therefore, will not be addressed here.

H. Industry Comment:

Supplier comments submitted on May 22, 2006 remain correct today and the supplier burden estimates provided are accurate.

H. CMS Response: CMS believes comments submitted in 2006 are separate and distinct to the collection requested in 2006 and therefore, this 2007 collection does not take into account comments submitted for a previous collection and will not be addressed here.

I. Industry Comment:

CMS has demanded that physicians, without specific guidelines or content standards from CMS, craft a long narrative prescription and select relevant medical records to support PMD prescriptions.

I. CMS Response: CMS disagrees. CMS has provided a variety of educational methods for physicians including Open Door Forums,

MedLearn Matters materials, informational one-pages and scripts for the Medicare call centers.

J. Industry Comment:

CMS has provided insufficient or non-existent training to physicians on how to meet the documentation standards.

J. CMS Response: CMS disagrees. CMS and the DME PSCs have provided suppliers and the medical community with extensive educational outreach pertaining to the documentation requirements for PMDs.

K. Industry Comment:

CMS did not review or approve the detailed product description listing the specific PMD bases and all options and accessories that will be billed separately.

K. CMS Response: The detailed product description is a requirement of the Local Coverage Determination and not this collection and will not be addressed here.