Supporting Statement For Paperwork Reduction Act Submissions Medicare Program; Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles (CMS-10116)

A. Background

CMS is seeking approval for the collection requirements associated with the final rule, CMS-3017-F (71 FR 17021), which was published on April 5, 2006 and became effective on June 5, 2006. 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.

CMS-3017-F finalized provisions set forth in the interim final regulation (70 FR 50940) published on August 26, 2005. This final rule conforms our regulations to section 302(a)(2)(E)(iv) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This rule defines the term power mobility devices (PMDs) as power wheelchairs and power operated vehicles (POVs or scooters). It sets forth revised conditions for Medicare payment of PMDs and defines who may prescribe PMDs. This rule also requires a face-to-face examination of the beneficiary by the physician or treating practitioner, a written prescription, and receipt of pertinent parts of the medical record by the supplier within 45 days after the face-to-face examination that the durable medical equipment (DME) suppliers maintain in their records and make available to CMS and its agents upon request. Finally, this rule discusses CMS' policy on documentation that may be requested by CMS and its agents to support a Medicare claim for payment, as well as the elimination of the Certificate of Medical Necessity (CMN) for PMDs.

CMS and its contractors embarked on a comprehensive educational and outreach initiative aimed at educating DME providers, suppliers, and manufacturers (herein referred to as the "DME Industry") on the process used to determine the appropriate PMD to ensure that beneficiaries receive the right PMDs for their medical conditions. CMS' targeted its efforts to improve Medicare's PMD coverage and payment policies. CMS issued new billing codes which incorporated industry standards of performance and durability, designed to support accurate payment and coverage decisions. CMS modified and strengthened the standards suppliers must meet in order to bill Medicare for PMDs, and developed a new accreditation program for suppliers to ensure that they will not only provide beneficiaries with high quality services but that they will comply with all Medicare requirements for providing this equipment and billing appropriately.

In 2006 CMS' Office of External Affairs (OEA) released two Press Releases as well as three Fact Sheets. CMS held six regular Home Health, Hospice and DME Open Door Forums (ODFs) of which two listed PMD pricing and coding as an agenda item as well as held one special ODF on Competitive Acquisition for DMEPOS. In addition, CMS issued six MedLearn Matter Articles and Customer Service Job Aids related to PMD contractor change requests (MM 3952; MM4372; MM5128; MM4121; MM5255; MM5417).

During this time, the DME Program Safeguard Contractors (PSCs) and DME Medicare Administrative Contractors (MACs) provided the "DME Industry" with extensive educational efforts targeted at the three PMD documentation requirements mandated by the Final Rule:

- Documentation of the face-to-face examination by the physician or treating practitioner,
- Completion of a prescription (order) for the power mobility device, and
- Submission of the report of the face-to-face exam, the order, and other pertinent parts of the patient's medical record by the physician to the supplier.

The DME PSCs held numerous discussions with the "DME Industry" about the PMD policy. They provided clarification about the required documentation requirements and the additional reimbursement and incentive to physicians for the work of gathering and sending the pertinent parts of the medical record to the DME supplier. Several of the comments received by the DME PSCs included questions about:

- What type of information should be included on the face-to-face examination;
- How to document and report the findings during the face-to-face examination;
- Use of a supplier-generated form as the primary source of documentation of the face-to-face examination;
- How to complete the prescription (order) for the PMD; and
- Difficultly receiving the report of the face-to-face examination, prescription, and other pertinent information from the patient's medical records from physicians.

Although the "DME Industry" had initially reported difficulty in receiving the report of the face-to-face examination, prescription, and obtaining the pertinent documentation from the patient's medical record within 45 days after the face-to-face examination, this outreach from the DME PSCs has helped to decrease the "DME Industry" objections.

The DME MACs collectively reported receiving approximately 3,553 telephone calls, including onsite visits by the "DME Industry" about PMDs. Overall, the DME MACs received inquiries related to the documentation requirements and general questions about the new policy. Initially, the "DME Industry" did express their burden associated with the requirements, however, after extensive educational outreach about the PMD coverage, payment, and coding requirements, the "DME Industry" reportedly applauded CMS' willingness and commitment to work with the "Industry". In fact, one of the DME MAC Jurisdictions reported a significant reduction in their call volume and expressed burden from Fiscal Year (FY) 2006, Quarter 3 to FY 2007, Quarter 2.

Overall, the Provider Outreach Education (POE) department at each of the DME contractors collectively conducted approximately 158 educational efforts related to PMDs in the form of quarterly bulletin articles, ListServe messages, Web postings, presentations at external events to include conferences, seminars, open houses and state associations meetings, as well as presentations at contractor council meetings.

The DME contractors utilize the information in the report of the face-to-face examination when they review documentation that is submitted either as part of an Advance Determination of Medicare Coverage (ADMC) (prior authorization) request or when they request documentation as part of a medical review or benefit integrity audit. Prior to the requirement for a dedicated face-to-face examination, the documentation that was received to support the medical necessity for PMD claims was often very incomplete. Physicians typically provided records from office visits which were focused on the patient's other medical problems and did not include information about their mobility limitations. Using all the information that is submitted from the face-to-face examination and from other records provided by the physician and the supplier, the nurse reviewer at the DME contractors can now more often get a better picture of the patient's abilities and limitations which allows the contractors to use their clinical judgment to determine if the PMD coverage criteria have been met.

For audit/investigation purposes, the requestor seeks information from the beneficiary's medical record corroborating the need for the item(s) being reviewed. Many suppliers have complained about the burdensome documentation that is needed to respond to an audit request and is required to be gathered at the time of claim submission. However, the Medical Review (MR) and Benefit Integrity (BI) departments review these issues with suppliers as part of the communication that occurs normally during these activities. The Final Rule also explains how this documentation does not need to be submitted with every claim, but must be made available to CMS and it agents upon request.

B. Justification

1 . Need and Legal Basis

Sections 1832(a)(1) and 1861(s)(6) of the Social Security Act (the Act) established that the provision of durable medical equipment (DME) is a covered benefit under Part B of the Medicare program. Section 1834(a)(1)(A) of the Act provides that Medicare will pay for covered items defined in section 1834(a)(13) which, in turn, defines the term "covered item" to include DME defined in section 1861(n) of the Act. Section 1861(n) provides that DME includes wheelchairs, including power-operated vehicles that may appropriately be used as wheelchairs, that are necessary based on the beneficiary's medical and physical condition, meet safety requirements prescribed by the Secretary, and are used in the beneficiary's home, including an institution used as the beneficiary's home other than a hospital described in section 1861(e)(1) or a skilled nursing facility described in section 1819(a)(1) of the Act. Section 414.202 of our regulations further

defines DME as equipment that can withstand repeated use, is primarily and customarily used to serve a medical purpose, generally is not useful to a person in the absence of an illness or injury, and is appropriate for use in the home. We have interpreted the term wheelchair to include both power wheelchairs and power-operated vehicles (POVs or scooters), and we collectively refer to power wheelchairs and power-operated vehicles as power mobility devices (PMDs). Section 1833(e) of the Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. section 1395(l). As indicated in the Final Rule, it is expected that the patient's medical records will reflect the need for care provided. Pertinent parts from the documentation of the beneficiary's PMD evaluation may include the history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans, and prescription or other parts of the medical record that the physician deems necessary to demonstrate the patient's need for the particular item. This documentation must be available upon request. In addition, CMS' Program Integrity Manual (PIM), Chapter 5, provides guidance for all Durable Medical Equipment, Prosthetic, and Orthotic Supplies (DMEPOS) items.

2. Information Users

Section 302(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173 (MMA), added section 1834(a)(1)(E)(iv) to the Act, which provides that payment may not be made for a covered item consisting of a motorized or power wheelchair unless a physician (as defined in section 1861(r)(1) of the Act), or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act) has conducted a face-to-face examination of the beneficiary and written a prescription for the item. CMS-3017-F implements section 1834(a)(1)(E)(iv) of the Act

The physician or treating practitioner must conduct a face-to-face examination of the beneficiary and write a PMD prescription. The PMD prescription must be in writing and signed and dated by the physician or treating practitioner who performed the face-to-face examination and received by the supplier within 45 days after the face-to-face examination. This was changed from the original 30 days due to a large number of persuasive public comments on the interim final rule. We believe this represents a good balance between the agency's desire to have a timely process that lessens the opportunity of fraud and abuse, the beneficiary's need for ready access to needed medical equipment, and the prescriber and supplier community's need for a timeframe that realistically reflects their workflow capabilities The face-to-face examination requirement does not apply when only accessories for PMDs are being ordered.

In addition to the prescription for the PMD, the physician or treating practitioner must provide to the supplier supporting documentation which will include pertinent parts of the medical record that clearly supports the medical necessity for the PMD in the beneficiary's home. Pertinent parts from the documentation of the beneficiary's PMD evaluation may include the history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans, and prescription

or other parts of the medical record that the physician deems necessary to demonstrate the patient's need for the particular item. The pertinent parts of the medical record must comply with all Federal laws and regulations, including the privacy rules.

The physician or treating practitioner should select only those parts of the medical record that clearly demonstrate medical necessity for the PMD. The parts of the medical record selected 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. In addition, the PMD must meet any safety requirements specified by CMS.

The supplier must obtain the prescription and supporting documentation prior to dispensing the PMD. Upon request, suppliers must submit to CMS and its agents the PMD prescription and supporting documentation that they received from the physician or treating practitioner. Upon request, suppliers must submit additional documentation if the PMD prescription and supporting documentation are not sufficient to determine that the PMD is reasonable and necessary. Additional documentation may include physician office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals, and test reports. This documentation does not need to be submitted with every claim, but must be made available to CMS and its agent upon request.

3. Use of Information Technology

This collection requires physicians or treating practitioners to provide a written prescription and supporting documentation, including pertinent parts of the beneficiary's medical record to suppliers. Generally, physicians do not maintain electronic medical records. This collection also requires the supplier to maintain the prescription and the supporting documentation provided by the physician or treating practitioners and make them available to CMS and its agents upon request. Since there is no industry standard for electronic medical records, and any electronic medical record submission would apply to all suppliers, the DME Medicare Administrative Contractors (MACs) cannot accept electronic medical records.

There is no explicit signature requirement for this collection.

Full implementation of the HIPAA standard transaction formats will allow this information to be submitted electronically. There is no current timeframe to implementation of the full HIPAA transaction standard.

4. Duplication of Efforts

This collection requests documentation from the treating physician or practitioner's files.

Those individuals are the primary source of the needed information. This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This collection does not impact small businesses or other small entities beyond the normal course of business (obtaining and storing business files.)

6. Less Frequent Collection

The information collected is needed to determine coverage for services provided. Collecting this information at the time of physician encounter is the most efficient and least burdensome time to collect this information.

7. Special Circumstances

Response within 45 days
The PMD prescription must be in writing and signed and dated by the physician or treating practitioner who performed the face-to-face examination and received by the supplier within 45 days after the face-to-face examination.

More than Original and One Copy
Respondents are not asked to submit more than the original or one copy of the PMD prescription and the pertinent parts of the medical record and any other supporting documentation as defined in this regulation.

Retain Records for More than Three Years
All of the records requested in this information collection are part of the medical record. Respondents retain medical records as part of their standard business practices.

Conjunction with a Statistical Survey
The data acquired in this information collection is not and will not be used in conjunction with a statistical survey.

Use of Statistical Data Classification
This information collection does not employ the use of a statistical data classification that has not been reviewed and approved by OMB.

Pledge of Confidentiality
There is no pledge of confidentiality.

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Confidential Information
The data gathered by this information collection does not require the submission of proprietary trade secrets.

8. Federal Register/Outside Consultation

The 60-day FR notice for the resubmission of this information collection request was published on **04/27/2007**.

The regulation CMS-3017-F (71 FR 17021) published in the Federal Register on April 5, 2006.

The regulation CMS-3017- IFC (70 FR 50940) published in the Federal Register on August 26, 2005.

9. Payments/Gifts to Respondents

Physicians and treating practitioners will be allowed to bill for the history and physical examination made through the appropriate evaluation and management code. A separate add-on payment to the office visit was established by the rule to recognize the additional physician and treating practitioner work and resources required for submitting pertinent parts of the medical record.

10. Confidentiality

The information collected will be kept confident in accordance with HIPAA and Privacy Act standards as applicable.

11. Sensitive Questions

This information collection does not contain any sensitive questions.

12. Burden Estimates (Hours & Wages)

§410.38(c)(2)(ii) states that Medicare Part B will pay for a power mobility device if the physician or treating practitioner writes a prescription, which is received by the supplier within 45 days after the date of the face-to-face examination of the beneficiary. The burden associated with writing the prescription is the time and effort necessary for the physician or treating practitioner to draft a prescription that contains the information required by this regulation. CMS estimates that it will take approximately 2 minutes for the physician or treating practitioner to prepare and submit the prescription. CMS estimates that approximately 243, 000 PMD prescriptions are submitted yearly, for an approximate total annual

burden of 8,100 hours (243,000 x 2 ÷ 60). This estimate includes PMDs submitted for purchased mobility products and an estimate of PMDs submitted with initial claims for rental products.

§410.38(c)(2)(iii) requires physicians and treating practitioners to collect and submit to suppliers supporting documentation from the beneficiary's medical records which demonstrates that the item being provided is medically necessary. This is in addition to writing and submitting the prescription to the supplier. §410.38(c)(5)(i) requires a supplier to maintain a copy of the PMD prescription and supporting documentation to support its claim for payment for the prescribed PMD and to make this information available to CMS and its agents upon request.

The burden includes physicians identifying parts of the medical record, having them copied, and providing the medical record and prescription to the supplier and/or beneficiary. In some instances, the physician might need to submit additional information at the request of the supplier. On the supplier side, the burden includes receiving the documentation, examining the documentation to ensure it is complete, and storing the documentation. In some instances, the supplier may determine that the medical record documentation may not be sufficient to meet CMS documentation requirements and may request that the physician submit more information such as additional chart notes which document medical history.

Overall, as discussed above, we believe that there will be a shift in the burden of information collection from the supplier to the physician. CMS believes that this overall physician and supplier burden is similar to the burden we previously estimated for a CMN. CMS estimates that this combined burden will be no more than 10 minutes. We have estimated that approximately 243,000 PMD prescriptions for these devices will be written yearly. This will result in an estimated burden of 40,500 hours (243,000 prescriptions x 10 minutes ÷ 60).

The total annual burden associated with the aforementioned information collection requirements is 48,600 burden hours (8,100 + 40,500).

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

This collection does not result in any additional cost to the Government.

15. Changes to Burden

In analyzing the documentation requirements burden, CMS does not believe that the documentation requirements impose any additional unnecessary burden on the DME Industry. CMS believes that most physicians are already conducting a face-to-face examination before prescribing a wheelchair. Given that physicians and treating practitioners can now prescribe POVs, thereby removing the requirement that a specialist can order a POV, CMS believes that the increased burden of 48,600 hours for physicians and treating practitioners is based on the Congressional decision to allow a broader range of physicians and treating practitioners to prescribe POVs. This increased burden is offset by the new payments implemented in connection with the Final Rule, which is demonstrated by the shift in prescriptions from one class of equipment, power wheelchairs, to another class of equipment, POVs. In addition, CMS believes that with the recent coverage decision on Mobility Assistive Equipment, the implementing details in the Final Rule (e.g. improved documentation for suppliers; physician and treating practitioner payments; improved classification of mobility equipment; the elimination of the CMN), and the provider outreach and education provided by CMS, the DME PSCs and DME MACs, the needs of mobility-impaired beneficiaries and the needs of suppliers have been better met.

Previously we estimated 187,000 PMD prescriptions (a difference of 23%) based on an examination of historical claims data that was currently available during the last submission when this information collection was prepared for PMDs, resulting in a previous burden of 37,400 (a difference of 23%). Currently, based on the historical claims data that is now available, CMS has estimated a 10% increase in total PMD prescriptions, as was previously stated in the Regulatory Impact Statement of the Final Rule. Over the past three years, the percentage of power wheelchairs prescribed have shifted, with an estimated decrease from 91% to 86%, while the percentage of POVs have shifted, with an estimated increase from 8% to 14%.

Upon review of the tools CMS, the DME PSCs and DME MACs have used to conduct a comprehensive educational outreach, CMS and the DME PSCs have considered the input received from suppliers and clinicians concerning the documentation requirements and have had many discussions about this. CMS believes that most physicians are already conducting a face-to-face examination before prescribing a wheelchair. Physicians are trained on how to document the evaluation of patients. The written guidance provided by the DME PSCs could be used by the supplier to help educate the physician on what should be included. The PSCs have also indicated in their articles, other educational contacts, and policy that if the physician did not feel capable of performing and documenting a mobility evaluation, that the examination could be conducted by an independent physical therapist or occupational therapist. These medical professionals are well versed in documenting mobility evaluations.

The Final Rule clearly outlines the elements that must be present in the prescription and has been reinforced in multiple educational contacts with suppliers. The elements are very simple, should be easy for the physician to complete, and pose no additional burden. The DME PSCs have heard very few complaints about the physician's ability to complete this prescription. The submission of the report of the face-to-face exam, the order, and other pertinent information from the patient's medical records is not significantly different than the difficulty that suppliers have in obtaining documentation for other DMEPOS items. In addition, CMS has provided additional reimbursement to physicians, through a G HCPCS code, for the work of gathering and sending these records to the supplier. This provides an added incentive for the physician to provide this information.

Please note that an administrative error was identified on the previous submission. CMS incorrectly reported the total annual responses as 37,400. This figure represents the estimated total annual hours requested. The number of total annual responses should be corrected to reflect 238,000 responses. This error does not result in any additional changes to the previous information collection package approved by OMB.

It should also be noted that on section 13 b. of the current 83-I form, the total annual responses was incorrectly reported as "342,000" and should be corrected to "243,000" to be consistent with the supporting documentation.

16. Publication/Tabulation Dates

There are no plans to publish or tabulate the data associated with this information collection request.

17. Expiration Date

The instrument in this collection is the physician's prescription. Doctors are required to sign and date prescriptions as part of their standard operating procedures. In addition, this collection does not utilize a standard prescription form. We request specific information that must be included in the prescription. However, while we recommend that physicians follow the format outlined in the Mobility Assistive Equipment (MAE) National Coverage Determination (NCD), we do not specify a required format for the prescription. This collection does not lend itself to the displaying of an expiration date

18. Certification Statement

There are no exceptions to the certification statement as identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of the OMB 83-I Form.

C. Collections of Information Employing Statistical Methods

This information collection does not utilize any statistical methods.