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

A. Background

CMS is renewing our request for 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 terms of clearance identified in the Notice of Action dated October 16, 2006 of which the Office of Management and Budget (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. On June 12, 2008, OMB renewed the Paperwork Reduction Act (PRA) request with a Term of Clearance stipulating that CMS provide industry guidance related to the provisions associated with the information collection.

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.

In 2006, 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. Details of the educational and outreach campaign are provided in the PRA package sent to OMB in June 2008.

In response to the June 2008 Terms of Clearance stipulated by OMB, CMS issued industry guidance related to the provisions associated with the collection of information. On October 2008, CMS issued a "Dear Physician" letter titled, "Power Wheelchair and Power Operated Vehicles-Documentation Requirements" outlining requirements related to the prescription order and medical documentation in support of Medicare coverage for power mobility devices. This letter was sent to providers to comply with the OMB Terms of Clearance.

Previous to the implementation of the regulation, many suppliers alleged that the documentation requirement would be additional and thus burdensome. However, as a normal course of business, all Medicare providers and suppliers are expected to provide medical record documentation upon request to support a request for payment of an item, device, service or supply. Medical Review (MR) and Benefit Integrity (BI) departments of Medicare contractors regularly make these requests when reviewing specific claims. A separate add-on payment to the treating physician 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. 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. CMS believes that this reflects a reasonable paperwork requirement for physicians.

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. Additional guidance is provided in CMS DME contractors' articles attached to their Local Coverage Determinations (LCDs) outlining documentation guidance.

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. Regulation CMS-3017-F, published April 5, 2006 in the Federal Register, implements section 1834(a)(1)(E)(iv) of the Act.

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. 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, summaries 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; document that other treatments do not obviate the need for the PMD; communicate that the beneficiary lives in an environment that supports the use of the PMD and convey 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 makes 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
Any personally identifiable health information is subject to HIPPA requirements. All healthcare providers are required to comply with all Federal and State privacy laws.

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 consideration of this information collection request is expect to be published on **XXXX 2009-Bill Parham stated he will complete section 8.**

9. Payments/Gifts to Respondents
Physicians and treating practitioners 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. A HCPCS code was created to represent this additional service. The HCPCS code G0372 was assigned and has associated payment rate of $14.47 for 2008.

10. Confidentiality
The information collected is kept confidential 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 89,411 physicians wrote prescriptions for PMDs in 2008.

The annual burden is based on the annual number of prescriptions for PMDs, the average time needed to write the prescription and the reimbursement rate associated with G0372, the HCPCS code used to bill Medicare for the burden associated with this documentation requirement. To calculate the burden, we used actual claims data reported through November 2008. To forecast the number of claims for PMDs for future years, we relied on Medicare enrollment data that appear in the 2008 Medicare Trustee's Report. For 2009, we project that 240,325 PMD claims will be submitted. CMS estimates that it will take approximately 2 minutes for the physician or treating practitioner to prepare and submit the prescription. This translates into an annual burden of 8,011 hours (240,325 x 2 ÷ 60). CMS believes that the typical amount of additional physician services and resources involved is equivalent to the physician fee schedule relative values established for a level 1 office visit for an established patient (Current Procedural Terminology (CPT) code 99211). CPT code 99211 is defined as 5 minutes of time for services rendered by a healthcare provider. By using the allotted time and payment rate associated with G0372, we derived an annual cost estimate of $1,391,030 for the documentation requirement associated with the prescription.

§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. As previously mentioned, CMS estimated that 89,411 physicians wrote prescriptions for PMDs in 2008.

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. CMS estimates that the burden will be no more than 10 minutes.

The annual burden is based on the annual number of prescriptions for PMDs, the average time needed to supply the supporting medical documentation, and the reimbursement rate associated with G0372, the HCPCS code used to bill Medicare for the burden associated with this documentation requirement. To calculate the burden, we used actual claims data reported through November 2008. To forecast the number of claims for PMDs for future years, we relied on Medicare enrollment data that appear in the 2008 Trustee's Report. For 2009, we project 240,325, PMDs claims will be submitted. CMS estimates that it will take approximately 10 minutes for the physician or treating practitioner to prepare and submit the supporting document This translates into an annual burden of 40,054 hours (240,325 x 10 ÷ 60). CMS believes that the typical amount of additional physician services and resources involved is equivalent to the physician fee schedule relative values established for a level 1 office visit for an established patient (Current Procedural Terminology (CPT) code 99211). CPT code 99211 is defined as 5 minutes of time for services rendered by a healthcare provider. By using the allotted time and payment rate associated with G0372, we derive an annual cost estimate of $6,954,977 for the documentation requirement associated with submitting supporting medical records.

CMS believes that the associated burdens associated with the documentation requirement related to regulation CMS-3017-F, Conditions for Payment for Power Mobility Devices are balanced with the agency's need to safeguard against fraud and abuse. The total burden associated with the documentation requirements translates into 48,065 hours, 8,346,007 dollars and impacts 89,411 providers.

13. Capital Costs

There are no capital cost 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

Since the implementation of regulation CMS-3017-F, there have been no new requirements that have necessitated changes to any burden. The change in total burden is attributable to an estimate of claims for PMD that were higher than the estimate of claims calculated for this PRA package.. For example, last time CMS calculated burden estimates associated with this regulation to be 243,000 claims. For this package, CMS estimates that 240,325 claims will be submitted for payment in 2009. This translates into 48,065 hours instead of 48,600 hours, resulting in a difference of 535 hours less burden than originally estimated.

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 consists of two parts: the physician's prescription and related medical documentation used to support Medicare coverage for mobility devices. 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.

.