Supporting Statement Part A

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. CMS nor its contractors have issued any written updates since 2008.

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

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. Suppliers use this information to provide the PMD to the beneficiary appropriately.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. These pertinent parts of the medical record must comply with reasonable and necessary criteria as well as with all Federal laws and regulations, including the privacy rules. These medical records must be maintained and stored by the supplier in the case of an audit.

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. 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. 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.

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 impacts both small and large businesses because of the need to provide a written prescription and supporting documentation that adds to their normal course of business.

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 Federal Register notice published on December 9, 2016 (81 FR 89104). There was one comment received and it has been addressed.

The 30-day Federal Register notice published on February 17, 2017 (82 FR 11037). There were no public comments received.

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.

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.

§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.

CMS estimated that 46,566 physicians wrote at least one prescription for PMDs in CY2015. . CMS does not anticipate additional growth in the provision of power mobility devices.

The documentation burden includes (1)physicians or treating practitioners writing a prescription for a PMD, as well as identifying pertinent parts of the medical record; and (2) having office staff prepare and transmit these documents 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 for preparation of the prescription is no more than 2 minutes; the burden for preparation of the medical records (including copying, faxing, electronic transmission and mailing activities performed by office staff) is estimated to be no more than 10 minutes.

The annual burden is based on the annual number of prescriptions for PMDs, the average time needed to prepare prescriptions and 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 forecast the future burden, we used actual claims data reported in CY2015. For CY2016, we project 72,500 PMDs claims will be submitted from approximately 46,000 providers. Supplier documentation regarding each of these claims is maintained in accordance with §1833(e) of the Social Security Act.

For both PMD documentation requirements combined, CMS estimates a total burden of 14,500 hours (72,500 x 12 ÷ 60) in CY2015. This breaks down into 2,417 hours for preparing prescriptions and 12,083 hours for preparing supporting documentation (assuming 2 and 10 minutes to complete each requirment, respectively). For these services, CMS reimburses physicians the rate associated with HCPCS code G0372 ($10.19). Therefore, the total reimbursement for fulfilling all estimated PMD documentation requirements in CY2016 is estimated to be $738,775 (72,500 x $10.19) which includes a reimbursement of $123,129 for prescription writing and $615,645 for preparation of supporting documentation. CMS believes that the 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 supplier must maintain a record for each Medicare beneficiary who requires a PMD. This translates in to a buden of $43,264.30 per year assuming it requires 2 minutes to store a single record. [(72,5000 x 2)/60 = 2417 hours; 2,417 hours x $17.90/hour = $43,264.30]. Again, CMS believes that the conditions for Payment for Power Mobility Devices are balanced with the agency's need to safeguard against fraud and abuse.

The total burden hours are 16,917 (14,500 + 2,417).

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

Estimates of burden associated with regulation CMS-3017-F presented in this PRA package differ from those of previous PRA packages due to differences in the estimated total number claims

submitted for payment as well as changes in reimbursement rates. For example, the previous CMS calculation estimated 173,810 submitted claims in 2012. For this package, CMS estimates that 72,500 claims will be submitted for payment in 2016, which translates into a reduction of 20,262 hours from the prior estimates.

Several factors may account for the reduction in the total number of hours burden. In particular, CMS initiatives, designed to both reduce Agency costs and control fraud and abuse, have been enacted that may account for the observed reduction in the number of submitted claims in CY2015. For example, a new Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) was established under the Medicare Modernization Act (MMA) of 2003. Round One of DMEPOS Competitive Bidding, authorized under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), was launched on January 1, 2011 in nine different areas of the country for nine product categories, including PMDs. Furthermore, the lump sum payment option was eliminated on January 1, 2011, in most areas of the country for PMDs furnished on or after January 1, 2011, requiring Medicare to pay for PMDs on a rental basis for up to 13 months, prior to the beneficiary being allowed to own the device. Also, CMS announced the Prior Authorization of Power Mobility Devices Demonstration on November 15, 2011. On July 29, 2014 CMS expanded the demonstration. This expanded demonstration began on October 1, 2014. We believe the decrease in spending is due in part to national Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers adjusting their billing practices nationwide (not just in the demonstration states) and reflects suppliers complying with CMS policies based on their experiences with prior authorization in the demonstration states

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number.

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.

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