

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 reinstating 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.

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 its agents upon request. CMS believes that this reflects a reasonable paperwork requirement for physicians. This package does not contain a collection instrument.

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.

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. The impact on small businesses is minimized because the information is already collected by providers and suppliers for the purpose of medical necessity and completing the medical record, CMS is requiring minimal information to be submitted to suppliers and the requirements do not go beyond what would already need to be included in the medical record. An important effect of this rule on suppliers, be they large or small, is that they have increased ability to assure that prescriptions are valid in terms of medical necessity before they supply equipment to beneficiaries, and that they will therefore be reimbursed for the provided equipment. This is of special significance to small businesses whose profit margins may be less than that of larger supply houses.

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 July 26, 2024 (89 FR 60641). There was one public comment received but it was outside the scope of the information collection.

The 30-day Federal Register notice published on October 8, 2024 (89 FR 81530).

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 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 (see Table 1). To forecast the future burden, we used actual claims data reported in CY2021 – 2023. For CY2024, we project 46,990 PMDs claims will be submitted. 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 9,398 hours ($[46,990 \times 12] \div 60$) in CY2024. This breaks down into 1,566 hours for preparing prescriptions and 7,832 hours for preparing supporting documentation (assuming 2 and 10 minutes to complete each requirement, respectively). For these services, CMS reimburses physicians the rate associated with HCPCS code G0372 (\$11.02). Therefore, the total reimbursement for fulfilling all estimated PMD documentation requirements in CY2024 is estimated to be \$517,830 ($46,990 \times \11.02). 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 burden of \$28,752 per year assuming it requires 2 minutes to store a single record $((46,990 \times 2)/60 = 1,566$ hours; $1,566$ hours \times $\$18.36/\text{hour} = \$28,752$). 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 10,964 ($9,398 + 1,566$).

Table 1. Annual Burden Estimates

Annual number of prescriptions for PMDs	46,990
Average time needed to prepare prescriptions and the supporting medical documentation	9,398 hours
Reimbursement rate associated with G0372	\$11.02
Total reimbursement for fulfilling all estimated PMD documentation requirements in CY2024	\$517,830
Wages	\$28,752
Total burden hours	10,964

13. Capital Costs

There are no capital cost associated with this collection.

14. Cost to Federal Government

We anticipate that a Grade 13 Step 1 Federal employee will spend 2 hours a year on this PRA package. The locality adjusted wages for a CMS employee at that Grade and Step is \$117,962 annually or \$56.62 hourly as of 2024. Thus, the annual cost to the Federal government of this PRA package is \$113 (2 hours \times $\$56.62$).

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 55,700 submitted claims in 2020. For this package, CMS estimates that 46,990 claims will be submitted for payment in CY2024, which translates into a reduction of 2,033 hours from the prior estimates (the burden hours have decreased from 12,997 to 10,964).

Several factors may account for the reduction in the total number of hours burden. In particular, for 2020, we predicted that 55,700 PMD claims would be submitted. However, this number takes into consideration only the combination of beneficiary, supplier and HCPCS codes that were generated during that time period. This combination of information may lead to an overestimation of burden because if a beneficiary rents a power mobility device, the rental period can be up to 13

months. When this is true, the same beneficiary will be counted as receiving a power mobility device in two different years, though only one prescription was written.

Therefore for this PRA package we have been advised that the best approximation of number of prescriptions written is the count of claims that gathers beneficiary, supplier, and HCPCS code combinations for claims having the modifiers NU (purchase of new equipment), UE (purchase of used equipment), or KH (initial claim, first month rental). This method will help decrease the duplication noted above.

Given this methodology and the actual dated reviewed for 2021 – 2023, we predict approximately 46,990 PMD claims will be submitted in 2024.

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.