

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Part 410
[CMS-3017-IFC]
RIN 0938-AM74
Medicare Program; Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles
AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule conforms our regulations to section 302(a)(2)(E)(iv) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173). 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 and a PMD prescription and pertinent parts of the medical record that the durable medical equipment supplier maintains in records and makes available to CMS or its agents upon request. Finally, this rule discusses CMS' policy on documentation that may be requested by CMS or its agents to support a Medicare claim for payment, as well as the elimination of the Certificate of Medical Necessity for PMDs.

DATES: Effective date: These regulations are effective on October 25, 2005.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 25, 2005.

ADDRESSES: In commenting, please refer to file code CMS-3017-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/regulations/ecomments> (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3017-IFC, P.O. Box 8013, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3017-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed).

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Karen Daily, (410) 786-0189.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing

policies. You can assist us by referencing the file code CMS-3017-IFC and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all electronic comments received before the close of the comment period on our public web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

[If you choose to comment on issues in this section, please include the caption "BACKGROUND" at the beginning of your comments.]

Sections 1832(a)(1) and 1861(s)(6) of the Act establish that the provision of durable medical equipment is a covered benefit under Part B of the Medicare program. Section 1834(a)(1)(A) provides that Medicare will pay for covered items defined in section 1834(a)(13) which, in turn, defines the term "covered item" to include durable medical equipment (DME) defined in section 1861(n). 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). 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).

When POVs were first introduced, we were concerned about their stability and the danger they could pose to a Medicare beneficiary. Therefore, we issued a regulation (57 FR 57688) allowing only specialists in physical medicine, orthopedic surgery, neurology, and rheumatology to prescribe POVs. At that time, we believed that these specialists were the most qualified to perform the required evaluation to determine whether a POV was medically necessary and whether the beneficiary had the capacity to operate the POV safely and effectively. At the same time, beneficiaries were able to get a prescription for a power wheelchair without seeing a specialist. We did not issue a similar regulation for power wheelchairs because we did not harbor the same concerns about their safety.

Our requirement that only certain specialists could prescribe a POV may have created a disincentive for qualified beneficiaries to obtain POVs. Many beneficiaries may not have realized that under an exception to this requirement set forth in § 410.38(c)(4), they could obtain a prescription from their physician if a specialist was not reasonably accessible. For example, if travel to the specialist would be more than one day's round trip from the beneficiary's home or if the beneficiary's medical condition precluded travel to the nearest available specialist, we stated that these circumstances would satisfy the "not reasonably accessible" requirement. We allowed this exception under the current regulation because it addressed the needs of beneficiaries who lived in rural or other areas with limited access, or who were physically unable to see a specialist.

However, since POVs were first introduced the technology has improved. For example, the POV now has an improved turning radius that gives it greater stability and makes it easier to use. Given that these technological advancements have made many POVs safer to use, a specialist assessment of the beneficiary's capacity to operate a POV, while recommended, is no longer required.

In addition, CMS and the Office of the Inspector General (OIG) have identified inflated and falsified billings as a serious problem among certain DME suppliers. Medicare payments for power wheelchairs have increased approximately 350 percent from 1999 to 2003 (from \$259 million in 1999 to approximately \$1.2 billion for 2003),

while overall Medicare program outlays have risen approximately 28 percent.

In an effort to address fraud and abuse, Medicare contractors have always had the authority to review claims and additional documentation to determine if services provided were reasonable and necessary in accordance with section 1862(A)(1)(a).

Section 302(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 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. This regulation is intended to implement section 1834(a)(1)(E)(iv) of the Act.

Payment for the history and physical examination will be made through the appropriate evaluation and management (E&M) code corresponding to the history and physical examination of the patient. Due to the MMA requirement that the physician or treating practitioner create a written prescription and this regulation's requirement that the physician or treating practitioner prepare pertinent parts of the medical record for submission to the DME supplier, we will establish an add-on G Code (used in addition to an E&M code for the examination) to recognize the additional physician work and resources required to establish and document the need for the PMD. We believe that the typical amount of additional physician work and resources involved is equivalent to the physician fee schedule relative values established for a level 1 office visit for an established patient (CPT 99211). The payment amount for such a visit is \$21.60; therefore, the payment amount for this new G code for 2005 will be \$21.60, adjusted by the geographic area where the service is provided, and based on the physician fee schedule relative values for a level 1 established office visit (CPT 99211). This change to the physician fee schedule will be effective with this rule.

II. Provisions of the Interim Final Rule

[If you choose to comment on issues in this section, please include the caption "Provisions of the Interim Final Rule" at the beginning of your comments.]

We are revising § 410.38(c) of our regulations to specify the following:

- The definition of a "power mobility device (PMD)". We are defining PMDs as a subclass of wheelchairs that includes both power wheelchairs and power-operated vehicles that a beneficiary uses in the home.

- The definition of a "physician" and a "treating practitioner". As directed by section 1834(a)(1)(E)(iv), we are defining the term "physician" in accordance with section 1861(r)(1) of the Act. We are defining the term "treating practitioner" to mean a physician assistant, nurse practitioner, and clinical nurse specialist, as those terms are defined by section 1861(aa)(5) of the Act. We are using the term "treating" to further explain that the practitioner must be the one who has conducted the face-to-face examination of the beneficiary. We believe that the removal of restrictions regarding who can prescribe POVs will increase a beneficiary's access to the PMD that is most appropriate for the beneficiary's condition. Currently, physicians (other than the specialists currently described in section 410.38) and other treating practitioners cannot prescribe POVs and are limited to prescribing power wheelchairs.

- The definition of "supplier." We are defining the term supplier for the purposes of this rule as a durable medical equipment (DME) supplier.

- 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 30 days after the face-to-face examination. We are defining the term "prescription" as a written order that must include the beneficiary's name, the date of the face-to-face examination, the diagnoses and conditions that the PMD is expected to modify, a description of the item (for example, a narrative description of the specific type of PMD), the length of need, the physician or treating practitioner's signature and the date the prescription is written.

- A beneficiary discharged from a hospital does not need to have a separate face-to-face examination if the physician or treating practitioner who performed the face-to-face examination during his or her hospital stay issues the written prescription and supporting documentation for the PMD and they are received by the supplier within 30 days after the date of discharge.

• 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 support 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, and treatment plans. 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 most cases, the information recorded at the face-to-face examination will be sufficient. However, there may be some cases where the physician or treating practitioner has treated a patient for an extended period of time and the information recorded at the face-to-face examination refers to previous notes in the medical record. In this instance, those previous notes would also be needed.

An example (not all inclusive) of the pertinent parts of the medical record would be beneficiary X recently sustained traumatic amputation of his right leg below the knee and his right arm below the elbow as a result of an automobile accident. He also sustained significant lacerations to his left foot, which is extensively scarred. Prior to the trauma, beneficiary X had been an active retiree. Lacking sufficient ambulation to move about his home, patient X has used a bedside commode and is dependent on others to bring food to his bedroom. He is eager to regain independent mobility, and requests a PMD during a follow-up examination with his treating physician. Based on his knowledge of the beneficiary's prior medical history and his assessment of the beneficiary's current condition, using his clinical judgment the physician decides to prescribe a power wheelchair. The physician's knowledge of the provisions of the Mobility Assistive Equipment (MAE) National Coverage Decision (NCD) (available at

http://www.cms.hhs.gov/manuals/pm_trans/R37NCD.pdf) informs his discussion of available options with the beneficiary. The physician believes that the beneficiary would not be able to safely operate a POV. The physician writes a prescription with the required information including the description of the device (*i.e.*, a power wheelchair). The Subjective section of the physician's progress note for the face-to-face examination summarizes the history of the automobile accident, subsequent hospitalization and surgical revision and closure of the amputation stumps. The patient's request of the device is also mentioned. In the Objective findings, the physician notes the beneficiary's general appearance and the absence of the amputated arm and leg. The function of the remaining extremities is noted, including movement and strength in the remaining left arm and left leg. The Assessment includes the physician's determination that the beneficiary cannot ambulate sufficiently to get beyond his bedroom, and that mobility devices other than a power wheelchair are not sufficient to correct the deficit, and the Plan indicates the prescription of a power wheelchair, with a notation that the beneficiary's home environment does not prevent the appropriate use of the device. Believing the progress notes sufficiently present the rationale for prescription of the device, the physician instructs the office staff to send a copy of the progress notes along with the prescription to the supplier.

Another example (not all inclusive) of the pertinent parts of the medical record would be beneficiary Y lives in a small rural town. He developed heart failure after a myocardial infarction earlier in the year, for which he had been transported by air to the state's university medical center 75 miles away. His medical history also includes hypertension, mild osteoarthritis, and gastroesophageal reflux. He is treated medically for his cardiac condition by his cardiologist at the university medical center. He sees his primary care physician in town for his other medical conditions. The cardiologist maintains good contact with the primary care physician, routinely sharing copies of his test results and chart notes. Over the past few months, beneficiary Y has complained progressively of difficulty walking due to fatigue. The cardiologist is aware of this and has adjusted his medications accordingly and added home oxygen to his regimen. The beneficiary phones his primary care physician, who he last saw two months ago, with a request for a POV.

Beneficiary Y's primary physician schedules a home visit to examine him after office hours. He notes that the home is a one story rambler and that the halls and doorways are wide enough to allow the use of a POV. The beneficiary's physical examination findings at rest are consistent with his heart failure diagnosis, but do not seem severe enough to prevent the beneficiary from walking short distances in his home. The physician knows from experience that the severity of the symptoms and signs of heart failure can vary over the course of the day and with exertion. The physician asks the beneficiary to stand and walk from the bedroom to the dining room, a distance of 20 feet. The beneficiary stops after a few steps, saying he needs to catch his breath. Patient Y continues to walk slowly, but manages to get to the dining room after about a minute. Based on his knowledge of the beneficiary's prior medical history and his assessment of the beneficiary's current condition, the physician decides that the beneficiary needs a PMD and that other mobility devices are not sufficient to correct his mobility deficits to perform mobility related activities of daily living in his home. The physician's knowledge of the provisions of the Mobility Assistive Equipment (MAE) NCD informs his discussion of available options with the beneficiary. The physician believes that the patient has adequate strength and stability to safely operate a POV.

The Subjective section of the physician's progress note for the home visit briefly notes the history of cardiac disease, and refers to the cardiologist's notes for more details. The beneficiary's request for the device is also mentioned. In the Objective findings, the physician notes the beneficiary's general appearance and the physical examination findings including the patient's attempt to walk to the dining room. Basic information about the beneficiary's home setting is also included. The Assessment includes the physician's determination that the patient cannot ambulate adequately, and that his cardiac symptoms are worsened by the exertion of ambulation. The Plan indicates the prescription of a POV with a notation that the beneficiary's home environment does not prevent the appropriate use of the device. Believing that the progress note alone does not sufficiently present the rationale for the prescription of the device, the physician instructs the office staff to send the prescription and additional records to the supplier, including copies of the cardiologist's notes, echocardiogram

and cardiac stress test results, and arterial blood gas results.

- Physicians, treating practitioners, and suppliers must comply with all applicable Federal laws and regulations, including the HIPAA Privacy Rule. Any physician, treating practitioner or supplier that is a HIPAA covered entity must meet the relevant HIPAA Privacy Rule requirements, including the minimum necessary standard, when disclosing the supporting documentation and requested additional information. The physician, treating practitioner or supplier that is a HIPAA covered entity should make sure to redact any materials that may be contained within the medical record that are not necessary to support the prescription. For example, a gynecologic report would not be needed in the records submitted for a beneficiary whose clinical need for a PMD is based solely on disability secondary to a stroke.

- The supplier must obtain the prescription and supporting documentation prior to dispensing the PMD.

- Upon request, suppliers must submit to CMS or 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 or its agent upon request.

- The PMD must meet any safety requirements specified by CMS.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal**

Register and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority, under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, or contrary to the public interest, and if the agency incorporates a statement of this finding and supporting reasons in the rule issued.

Since this change conforms our regulations to section 1834(a)(1)(E)(iv) of the Act, we believe it would be contrary to the public interest to delay implementing this beneficiary relief pending notice-and-comment procedure. The Congress has prohibited Medicare from paying for covered items consisting of motorized or power wheelchairs unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) conducts a face-to-face examination of the beneficiary and writes a prescription for the item. We believe that the face-to-face examination and prescription requirements are mandated by section 302(a)(2)(E)(iv) of the MMA and involve little exercise of agency discretion. Therefore, we believe that notice and comment procedure are unnecessary with respect to these provisions. In addition, this rule removes a current regulatory restriction that limits POV prescribing to certain specialists. We believe that this limitation is inconsistent with the MMA, which expressly allows a physician, physician assistant, nurse practitioner or a clinical nurse specialist to prescribe a PMD, and we believe that removing this limitation will increase beneficiary access to the appropriate PMD for his or her medical condition. Moreover, because CMS and the OIG have concluded that fraudulent billing practices for PMDs have been a substantial problem, evidenced by an approximate 350 percent increase in billings for these devices in 1999 to 2003, we believe that it would be contrary to the public interest to delay a regulation intended to stem the abusive billing practices of certain DME suppliers. We believe that requiring the physician or treating practitioner to submit to the DME supplier the prescription along with the pertinent parts of the medical record that demonstrate the medical necessity for the PMD, and the requirement that the supplier must obtain the prescription

and supporting documentation prior to dispensing the PMD will address some of these abusive billing practices by restraining the billing for PMDs outside of bona fide patient care activity. The additional payment to the physician or treating practitioner is consistent with these changes.

On May 5, 2005, CMS issued a new National Coverage Decision (NCD) for Mobility Assistive Equipment, which includes power mobility devices. In addition, in September 2005, the Certificate of Medical Necessity (CMN) for power wheelchairs and POVs will expire. These changes, plus the changes made by MMA and through this regulation will provide greater certainty in this area and assist suppliers of PMDs in complying with not only the mandates of MMA but also the new NCD. Specifically, new requirements for specific content of the written prescription, the submission of pertinent portions of the medical record, and the submission of additional supporting information, together with elimination of the CMN, and the additional payment, operationalize the NCD requirements and statutory changes in ways that will not only bring more certainty to all participants, but also greatly reduce the risk that a supplier will be denied payment through no fault of its own. Delaying any element of these interrelated changes will jeopardize the smooth implementation of these reforms.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this as an interim final rule. We are providing a 90-day public comment period.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide a 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the

affected public, including automated collection techniques.

To be able to address public comments on these information collection requirements prior to the effective date of this rule, written comments and recommendations will be considered from the public if received by the individuals designated below by September 26, 2005.

We are soliciting public comment on each of these issues for the following section of this document that contains information collection requirements:

Section 410.38 Durable medical equipment: Scope and conditions.

Certificate of Medical Necessity (CMN) Discussion

The Certificate of Medical Necessity (CMN) was previously established to allow efficient adjudication of claims by automating the submission of certain information needed to make medical necessity determinations. CMS implemented a CMN requirement for certain items of DME under section 1834(j)(2) of the Act and applied that requirement to payment claims for manual wheelchairs, motorized wheelchairs and power-operated vehicles (scooters) since the items were potentially subject to abuse by unscrupulous DME suppliers. The historical coverage criteria for these items were subjective and interpreted differently by clinicians; services that were not medically necessary were described in a manner that made those services appear to be medically necessary. The CMN was created to eliminate some of the subjectivity associated with this decision making process.

Recently, a CMS contractor completed an analysis of the utility of each CMN and found in some cases a 45 percent rate of non-compliance of CMNs. This finding underscored the belief that the CMNs do not accurately reflect the contents of the physician's medical record. Some portion of this non-compliance is attributed to failure to fully understand coverage criteria.

With the publication of the national coverage determination on Mobility Assistive Equipment in May 2005, CMS provided guidance on how contractors are to determine whether PMDs have been appropriately prescribed. As a result, physicians, treating practitioners and suppliers better know how to properly evaluate and document a beneficiary's medical condition and appropriately prescribe PMDs. Therefore, we have determined that the practical utility of a CMN, given the function-based approach to coverage, is

questionable and for these reasons, the continued use of a CMN for power wheelchairs or power-operated vehicles is no longer required.

CMS previously estimated that the burden associated with the completion and collection of the CMNs for power mobility devices as 38,192 hours or approximately 12 minutes per CMN. This burden estimate included the time required for physicians to extract data from the medical record, record that on the CMN, and forward the CMN to the supplier. It did not include the burden of the physician writing the prescription itself. It included the time required for the supplier to determine, when a beneficiary was seen for a PMD, whether a CMN had been submitted and, if so, whether it contained the necessary physician information; to notify the physician if additional information was needed; to collect and enter the supplier information on the CMN; and to store the CMN. Eliminating the CMN results in the elimination of this burden for both physicians and suppliers.

Section 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 30 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, and that 187,000 PMD prescriptions will be submitted each year, for a total annual burden of $187,000 \times 2 \div 60 = 6,233$ hours.

Section 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. *Section 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 believes that this overall physician and supplier burden is similar to the burden we previously estimated for a CMN.

The burden includes physicians identifying parts of the medical record, having them copied, and giving them to the beneficiary with the prescription. 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, reviewing 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 estimates that this combined burden will be no more than 10 minutes. We have previously estimated that 187,000 prescriptions for these devices will be written yearly. This will result in an estimated burden of 31,167 hours ($187,000 \text{ prescriptions} \times 10 \text{ minutes} \div 60$).

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn.: William N. Parham, III, CMS-3017-IFC, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer, CMS-3017-IFC, Christopher.Martin@omb.eop.gov. Fax (202) 395-6974.

VI. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Congressional Review Act, the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential

economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year). The Congressional Review Act imposes a similar requirement, and provides for the Congress to review major rules.

In analyzing the effects of this regulation, we believe that most physicians are already conducting a face-to-face examination before prescribing a wheelchair. Also, though treating practitioners are now allowed to prescribe PMDs, we do not believe that these changes will significantly alter the number of prescriptions for PMDs. This rule also removes the requirement that a specialist order a POV. Given that physicians and treating practitioners can now prescribe POVs, we believe as a result of this regulation that more PMD prescriptions will be for POVs, rather than the more expensive power wheelchairs. In addition, in conjunction with this rule, an additional payment will be made to physicians and treating practitioners for the submission of the written prescription and pertinent parts of the medical record to the DME supplier. Taken together, we believe that the impact of these changes as a result of this regulation will have minimal net impact on the Medicare program.

While we believe that the net impact on Medicare reimbursements for PMDs of this rule and the recently published NCD will be minimal, the provisions of this rule will likely cause a shift in the composition of the PMDs reimbursed by Medicare. We expect that this rule will result in a shift in PMD prescriptions from power wheelchairs to POVs. We have no empirical basis for projecting shifts in market share. Nor do we have a basis for discriminating between the shift that is the result of the NCD and the shift that is a result of this rule. However, we believe that the Congressional decision to allow a broader range of physicians and treating practitioners to prescribe POVs will lead to an increased number of POV prescriptions. This shift could well be 10 percent or greater. If 10 percent or more of the estimated 175,000 power wheelchair prescriptions in FY 2004 shifted from power wheelchairs to POVs (with the total unchanged at 187,000 prescriptions for both categories of PMDs), this would imply reduced sales for the former of \$84 million (assuming an average cost of \$4,800) and increased sales of the latter of \$35M (assuming an average cost of \$2,000). Accordingly, we are classifying this as an economically

significant rule under EO 12866, and as a major rule under the Congressional Review Act.

Under the Executive Order, we analyze the benefits, costs, and alternatives of major rules. While difficult to quantify, we believe that Medicare beneficiaries will benefit from the increased ability to obtain POVs. Beneficiaries would gain both from the increased utility of the less cumbersome devices, and from reduced cost-sharing (on average, \$560 in decreased coinsurance if average costs of the devices were \$2,000 and \$4,800, respectively). We expect the shift in the composition of prescriptions to result in a net minimal impact on the value of Medicare reimbursements for PMDs. Since manufacturers typically produce both types of PMDs (other than specialty "high end" manufacturers unaffected by this rule), we expect the net effect on PMD manufacturer revenue from Medicare reimbursement of PMDs should be negligible.

There are other costs and benefits. Taxpayers, suppliers, and patients will all gain from increased accuracy in prescribing and increased certainty of proper payment. The increased burden on physicians and treating practitioners from the new analytic and documentation requirements will be offset by the new add-on payment we are implementing with this rule. As discussed in the preceding PRA analysis, suppliers will face decreases in record-keeping requirements. None of these other effects are economically substantial (for example, increased payments to physicians and treating practitioners are likely to be on the order of \$5 million annually). As a result, we believe that the predominant effects of this rule are both positive and substantial, and that the benefits of this rule outweigh its costs.

We do not believe that any reasonable alternatives exist that would alter these conclusions or lead to even larger economic benefits. The primary causes of these effects were the Congressional decisions to allow a substantial increase in the number and types of providers allowed to prescribe POVs, and to require a face-to-face examination. We are required to implement those statutory changes. Coupled with our recent national coverage decision, other implementing details in this rule (especially improved documentation for suppliers), and other planned reforms (physician and treating practitioner payments, improved classification of mobility assistive equipment, elimination of the CMN), we expect the needs of mobility-impaired beneficiaries to be better met, and the needs of

suppliers to be better met, than under any alternative set of reforms.

We welcome additional information on the likely effects of this rule, and suggestions for changes that would improve the rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We have determined that this rule will not have a significant economic impact on a substantial number of small entities. Furthermore, the RFA does not require such analysis for rules that, like this one, do not require a proposed rule.

However, we appreciate that there are three classes of small entities that will face impacts and we address their potential concerns. Furthermore, HHS policy is to voluntarily analyze impacts on small entities if there is even a possibility of significant impact. The analysis that follows, together with the preceding impact analysis and other information in this preamble, constitutes an Initial Regulatory Flexibility Analysis.

First, equipment manufacturers may be affected if substantial changes in the market for PMDs arise from this rule. As indicated previously, we expect the principal economic effect of this rule to be to shift prescriptions from one class of equipment, power wheelchairs, to another class of equipment, POVs. That effect will arise largely among those Medicare beneficiaries who can operate a POV and do not, therefore, require a power wheelchair. The manufacturing of these two types of equipment is dominated by a handful of firms. Most of these firms produce both types of vehicles and can presumably shift production from one line to another without incurring major cost. As indicated previously, volume increases likely to occur independently of this rule may obviate the need for any such shifts. Accordingly, we do not believe that the impact on these entities will be significant, nor that a substantial number of "small" entities will be affected. We note that there are a number of small firms that specialize in "high end" equipment for patients with very severe mobility impairments who need highly specialized equipment or accessories. We believe these firms will be unaffected by this rule, as the

segment of the market they serve would not be candidates for POVs.

Second, physicians and treating practitioners gained a great deal of important new guidance through our recent national coverage decision. The newly added classes of treating practitioners will benefit in their ability to serve their patients by prescribing the equipment most suitable to their needs. Nonetheless, there is some inconvenience associated with more complex decision algorithms and the documentation requirements added by this rule. These costs do not rise to the level of "significant" within the standards of the RFA, but we nonetheless plan to ameliorate them through additional payment when PMDs are prescribed.

Third, suppliers of durable medical equipment include thousands of firms, both large and "small" within the RFA definitions. The principal effect of this rule on these suppliers will be to increase their 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 equipment they supply. This is a positive effect rather than a negative effect (the RFA requires consideration of alternatives that minimize adverse impacts). As previously indicated, we believe that there are few if any alternatives to this rule that would provide higher benefits.

We welcome additional information on the problems faced by small entities, comments on these conclusions, and suggestions for changes that would provide even greater benefits.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined and the Secretary certifies that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose requirements mandate the expenditure in any 1 year by State, local, or tribal governments, in the

aggregate, or by the private sector, of \$100 million in 1995 dollars, adjusted for subsequent inflation (that threshold is now approximately \$120 million). This rule contains no mandates other than that for documentation of prescriptions, and hence does not remotely approach that cost threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This regulation does not impose any costs or burden on State or local governments.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV, as set forth below:

PART 410 SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 is revised to read as follows:

Authority: Secs. 1102, 1834, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395m, and 1395hh).

Subpart B—Medical and Other Health Services

■ 2. Section 410.38 is amended by revising paragraph (c) to read as follows:

§ 410.38 Durable medical equipment: Scope and conditions.

* * * * *

(c) *Power mobility devices (PMDs)*. (1) *Definitions*. For the purposes of this paragraph (c), the following definitions apply:

Physician has the same meaning as in section 1861(r)(1) of the Act.

Power mobility device means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is

operated by a tiller) that a beneficiary uses in the home.

Prescription means a written order completed by the physician or treating practitioner who performed the face-to-face examination and that includes, the beneficiary's name, the date of the face-to-face examination, the diagnoses and conditions that the PMD is expected to modify, a description of the item (for example, a narrative description of the specific type of PMD), the length of need, and the physician or treating practitioner's signature and the date the prescription was written.

Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5) of the Act, who has conducted a face-to-face examination of the beneficiary.

Supplier means a durable medical equipment (DME) supplier.

(2) *Conditions of payment*. Medicare Part B pays for a power mobility device if the physician or treating practitioner, as defined in paragraph (c)(1) of this section:

(i) Conducts a face-to-face examination of the beneficiary for the purpose of evaluating and treating the beneficiary for his or her medical condition and determining the medical necessity for the PMD as part of an appropriate overall treatment plan;

(ii) Writes a prescription, as defined in paragraph (c)(1) of this section, which is provided to the beneficiary or supplier, and is received by the supplier within 30 days of the face-to-face examination.

(iii) Provides supporting documentation, including pertinent parts of the beneficiary's medical record (e.g., history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans and/or other information as may be appropriate) that supports the medical necessity for the power mobility device, which is received by the supplier within 30 days after the face-to-face examination.

(3) *Exceptions*. (i) Beneficiaries discharged from a hospital do not need to receive a separate face-to-face examination as long as the physician or treating practitioner who performed the face-to-face examination of the beneficiary in the hospital issues a PMD prescription and supporting documentation that is received by the supplier within 30 days after the date of discharge.

(ii) Accessories for PMDs may be ordered by the physician or treating practitioner without conducting a face-to-face examination of the beneficiary.

(4) *Dispensing a power mobility device*. Suppliers may not dispense a

PMD to a beneficiary until the PMD prescription and the supporting documentation have been received from the physician or treating practitioner who performed the face-to-face examination of the beneficiary. Such documents must be received within 30 days after the date of the face-to-face examination.

(5) *Documentation.* (i) A supplier must maintain the prescription and the supporting documentation provided by the physician or treating practitioner

and make them available to CMS and its agents upon request.

(ii) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the power mobility device.

(6) *Safety requirements.* The PMD must meet any safety requirements specified by CMS.

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(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)
Dated: July 28, 2005.

Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Dated: August 3, 2005.

Michael O. Leavitt,
Secretary.

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