rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 29, 2006.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.582 is amended by:

■ a. Removing in the introductory text of paragraph (a)(1) the phrase ''carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester and its desmethoxy metabolite methyl 2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl carbamate'' and adding in its place ''(carbamic acid, [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenylcarbamate).''

■

■ b. Revising the commodities ''almond, hulls; pea and bean, dried shelled, except soybean, subgroup; and strawberry'' and adding alphabetically the remaining commodities listed below to the table in paragraph (a)(1). The amended table reads as set forth below.

■ c. Removing paragraph (a)(3).

§ 180.582 Pyraclostrobin; tolerances for residues.

(a) * * *

(1) * * *

Commodity	Parts per million
Almond, hulls	7.0
* * * * *	
Bean, succulent shelled	0.5
* * * * *	
Mango[1]	0.1
* * * * *	
Papaya[1]	0.1
* * * * *	
Pea and bean, dried shelled, except soybean, subgroup 6C	0.5
* * * * *	
Strawberry	1.2
* * * * *	
Vegetables, foliage of legume, group 7	25
* * * * *	

[1] There are no U.S. registrations on mango or papaya as of April 5, 2006.

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[FR Doc. 06–3262 Filed 4–4–06; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 410

[CMS–3017–F]

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: Final rule.

SUMMARY: 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 suppliers maintain in their records and make 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 (CMN) for PMDs.

DATES: *Effective Date:* These regulations are effective on June 5, 2006.

FOR FURTHER INFORMATION CONTACT: Karen Rinker, (410) 786–0189. Camille Soondar, (410) 786–9370 for CMN issues.

SUPPLEMENTARY INFORMATION:

I. Background

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule finalizes provisions set forth in August 26, 2005 (70 FR 50940) interim final regulation.

In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with Congress's intent to ensure timely publication of final regulations.

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). 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).

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 previous 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) of the Act.

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. 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 established an add-on G Code G0372 (used in addition to an E&M code for the examination) to recognize the additional work and resources required to document the need for the PMD. Prescribing physicians or treating practitioners who submit the required supporting documentation may submit a claim for payment for the add-on G code. The payment amount is based on the physician fee schedule relative values for a level 1 established office visit (CPT 99211), which we believe is equivalent to the typical amount of additional physician work and resources. We published the implementing instructions for the 2005 G Code in Change Request (CR) 4121 which became effective on October 25, 2005.

II. Provisions of the Interim Final Rule

The interim final rule with comment period (IFC) revised § 410.38(c) of our regulations (August 26, 2005). A summary of those revisions follows:

- The definition of a ''power mobility device'' (PMD). We defined 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) of the Act, we defined the term ''physician'' in accordance with section 1861(r)(1) of the Act. We defined 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 used the term ''treating'' to further explain that the practitioner must be the one who has conducted the face-to-face examination of the beneficiary.
- The definition of ''supplier.'' We defined the term supplier as a durable medical equipment 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, 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 defined 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, 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.

We explained that 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. Prior to the effective date of the interim final rule, section 410.38(c) of the regulation limited some physicians and all treating practitioners from prescribing POVs.

- 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. Analysis of and Responses to Public Comments

We received approximately 65 timely comments. In general, the commenters appear to be pleased with the provisions in the interim final rule, specifically the add-on payment for additional documentation submission, the removal of the sub-specialty requirement for prescribing POVs, and the elimination of the Certificate of Medical Necessity.

In addition, the industry response has been very positive. As a result of the educational outreach to physicians and treating practitioners, suppliers have noted a significant improvement in the timeliness, completeness, and substantive content of medical record documentation submitted in support of PMD prescriptions.

Comment: Several commenters stated that in practice, it is difficult to obtain all of the needed documentation from the prescribing practitioner within 30 days of the face-to-face examination, especially if the beneficiary has a complex condition requiring additional evaluation for the fitting of the device and appropriate accessories.

Response: We agree. We have extended the allowable time frame from 30 days to 45 days. CMS believes the additional 15 days is a reasonable compromise to accommodate the workflow between the supplier and physician or treating practitioner without seriously compromising the beneficiary's need for the expedient and efficient obtainment of necessary durable medical equipment, and CMS's need to ensure timely administration of the DME benefit while minimizing fraud and abuse.

Comment: Several commenters, along with some physician groups, applauded the establishment of the add-on G code and payment for the submission of medical record documentation by the physician or treating practitioner to the PMD supplier.

Response: We appreciate these comments. To further assist with implementing the add-on G code and payment for the submission of medical record documentation, we have issued implementing instructions to local contractors.

Comment: Some commenters suggested that the additional payment to physicians and treating practitioners would be insufficient if the supporting documentation comes from an external source since this would increase the burden.

Response: We believe that the additional payment is sufficient for the increased burden, including if the documentation comes from an outside source. This outside source material, such as consultant reports and test results, is generally already contained in the beneficiary's medical record, even though the physician or treating practitioner did not create it. In the absence of this outside source material supporting the need for the device, the prescribing physician or treating practitioner would likely have created equivalent documentation internally. Thus, the payment is sufficient for the burden of submitting this documentation whether it was created internally or externally.

Comment: Several commenters said that the Mobility Assistive Equipment (MAE) National Coverage Decision (NCD) is too complex for physicians to accomplish. The MAE NCD, which includes PMDs can be accessed at *http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=280.3&ncd_version=2&basket=ncd%3A280%2E3%3A2%3AMobility+Assistive+Equipment+%28MAE%29.*

Response: CMS believes this comment is outside the scope of this rule, and we will not address it here.

Comment: Some commenters said that it would take physicians and treating practitioners longer than 10 minutes to identify and submit supplemental documentation to the DME supplier.

Response: It is important to bear in mind that this estimate does not include the time needed to evaluate the patient or generate the original documentation by the physician or treating practitioner. The resources needed for creation of the medical record documentation are included in the calculation of the payment for the service that is being documented, in this case the Evaluation and Management (E&M) code for the face-to-face examination. The combined payment based on the E&M code and the add-on code is to recognize the additional physician/treating practitioner work and resources required to document the need for the PMD. If a physician or treating practitioner believes that a home visit is necessary, a claim for that service would be submitted. Similarly, the time for consulting a non-prescriber such as a PT/OT to evaluate the beneficiary and produce a consultation report for the referring physician or treating practitioner is accounted for in the appropriate consultation code.

The 10 minute figure is an estimate, based on experience and extensive review of historical claims data, of the average time consumed specifically to flag existing portions of the medical record, tell an office staff person to make a copy of those portions of the record, and for that person to copy and put them in an addressed envelope or give them directly to the patient, and for the supplier to receive this documentation. We expect that the actual time will vary based on individual practices and the complexity of the individual beneficiary's condition.

Further, the determination of what parts of a record are extraneous will depend on the clinical condition of the patient and the basis of the mobility impairment. For example, we would expect that gynecologic information would be redacted if the beneficiary's need for a PMD is based on a stroke. However, if the beneficiary's mobility deficit arose from complications of a gynecologic malignancy, such information may be relevant. We believe that the physician or treating practitioner can make this distinction readily. In general, visits to a physician, and the resulting documentation, are problem-focused. This serves to simplify the task of redaction.

Comment: Several commenters said that CMS should increase the amount of education activity directed at physicians and treating practitioners. One commenter recommended a web-based guide based on the MAE NCD. Another asked how CMS plans to train physicians on completing the prescription with the required detail.

Response: The NCD is not part of this rule so we will not address that aspect of these comments here. We agree that physician and treating practitioner education about the appropriate prescription of PMDs is a priority. To that end, we have used a variety of methods including an Open Door Forum, MedLearn Matters materials, DMERC articles, informational one-pagers, and scripts for Medicare call centers. We have hosted a Physician Partners meeting on this topic and have communicated with physician professional societies. Further, some physician groups are working with DME suppliers to resolve documentation issues at the local level and have stated that they would be educating their members nationally once the DMERCs finalize a Local Coverage Determination (LCD) on PMDs. LCDs allow Medicare contractors to determine whether or not to cover an item or service in accordance with 1862(a)(1)(A) of the Social Security Act.

Comment: One professional organization representing over 94,000 physicians and medical students expressed support for the removal of the requirement for subspecialty prescription of POVs and for the elimination of the CMN.

Response: We have retained these provisions in the final regulation.

Comment: Several commenters said that we should keep the CMN.

Response: CMS' experience has been that the CMN does not reliably accomplish its original purpose with regard to PMDs. The CMN did not serve to help physicians better document their patients' clinical needs for a PMD, it did not serve to ensure that beneficiaries always received appropriate equipment, and it did not serve as an effective deterrent to fraud and abuse. We believe the beneficiary's physician or treating practitioner is in the best position to evaluate and document the beneficiary's clinical condition and PMD medical needs, and good medical practice requires that this evaluation be adequately documented. Thus, to minimize the documentation requirements for providers while assuring that documentation is adequate, physicians and treating practitioners will now prepare written prescriptions (as required by MMA sec. 302 and this regulation) and submit copies of relevant existing documentation from the beneficiary's medical record, rather than having to transcribe medical record information onto a separate form such as a CMN.

Comment: Several commenters asked that CMS create more specific guidelines that would outline all the documents needed from the patient's medical record or create a template (for example, a standard set of questions) to capture the information that CMS determines is medically necessary to justify the prescription.

Response: CMS believes the current documentation requirements provide suppliers with a comprehensive picture of a patient's history, physical examination and functional assessment describing the patient's mobility limitation and his/her physical and mental ability to operate a PMD. CMS and the DMERCs have implemented extensive educational outreach to both suppliers and the medical community pertaining to the documentation requirements for PMDs. Examples of formal communication include CMS program instructions, MedLearn Matter articles, and several DMERC supplier articles explaining the new responsibilities of suppliers and a draft PMD Local Coverage Determination (LCD) formalizing all of these changes. In addition, medical review activities vary depending on the situation under review. CMS cannot develop an all inclusive list of documents or information that Medicare contractors may request during audits. When requesting additional documentation, Medicare contractors write to suppliers and ask for the specific documentation or information they need for the review.

CMS has defined the circumstances under which contractors request additional information in the Program Integrity Manual (PIM). Local Coverage Determinations are issued by our contractors to describe in more detail the conditions under which Medicare payment is made. This additional documentation is only collected during the course of medical review audits and does not need to be collected for all claims.

Comment: A commenter asked that CMS specify the quantity and type of documents that the supplier should collect.

Response: We disagree. As noted in previous responses, there is no set volume of documentation (for example, number of pages or number of sections from a record) that, taken alone without regard to substantive content, will guarantee that the beneficiary's clinical condition meets the conditions for payment. Similarly, there is no type of document that, taken alone without regard to substantive content, will guarantee that the beneficiary's clinical condition meets the conditions for payment. It would be misleading to suggest otherwise.

Comment: Some commenters expressed an apparent desire for a benchmark of completeness of medical record documentation.

Response: This comment appears to reflect difficulty distinguishing the adequacy of the substantive clinical information described in various pieces of the medical record from the pieces of the medical record themselves. It is important to remember that the submission of any particular piece or combination of medical record documentation does not guarantee that the substantive clinical information contained therein establishes the medical need for the device. If the beneficiary's clinical condition does not meet the conditions for payment, the accurate medical record, regardless of completeness, volume and detail, would not support coverage by Medicare. Conversely, if the beneficiary's clinical condition is such that the conditions for payment are met, that might be adequately documented in a variety of ways from the available portions of the medical record.

Comment: A commenter asked that we clarify the terms ''prescription in writing''. Does that mean hand-written or that the physician must list all the equipment and accessories on the prescription?

Response: Section 302(a)(2)(E)(iv) of the MMA states, in part, that the physician or treating practitioner must write a prescription for the item. This rule provides that the prescription must be dated, signed and include the details of what should be provided by the supplier, but does not include accessories.

Comment: A commenter asked if the provisions of the regulation apply to manual wheelchairs.

Response: No, this regulation applies to POVs and power wheelchairs, both of which are types of PMDs.

Comment: Several commenters said that we should allow physical therapists and occupational therapists (PT/OTs) to have a greater role, either as prescribers of PMDs or as an integral part of the evaluation.

Response: Section 1834(a)(1)(E)(iv) of the Social Security Act limits the types of practitioners who can prescribe PMDs to physicians (as defined in section 1861(r)(1)), and to physician assistants, nurse practitioners, and clinical nurse specialists (as those terms are defined in section 1861(aa)(5)) and does not include PTs or OTs. We acknowledge that PT and OT expertise can be an important contribution in some contexts. In addition, the DMERCs have published an article describing a way to integrate PT/OT services into the evaluation process. A PT/OT can file a claim for payment for their evaluation services, provided that all other applicable payment conditions are met.

Comment: A commenter asked that we use a different statutory definition of physician, which would allow podiatrists to prescribe PMDs.

Response: Section 1834(a)(1)(E)(iv) of the Social Security Act (the Act) specifically provides that only physicians as defined under section 1861(r)(1) of the Act may prescribe PMDs. CMS does not have the authority to alter or use a different definition of the term ''physician.''

Comment: A commenter asked why a PT/OT would not be paid like the prescribing practitioner for the submission of supporting documentation to the DME supplier.

Response: The responsibility for the submission of supporting documentation lies with the physician or treating practitioner. If the physician or treating practitioner believes that a professional consultation with a PT/OT is appropriate, the physician or treating practitioner can obtain the consultation. As with other clinical contexts, it is customary for the consultant to send a written report of the findings and recommendations back to the originating physician or treating practitioner for incorporation in the patient's medical record. The physician or treating practitioner would submit the consultation report as part of the supporting documentation.

Comment: Several commenters discussed specific issues with PMD suppliers, such as market limitations based on geographic distribution or failure to dispense a prescribed device.

Response: We view these comments as being outside the scope of this regulation and will not respond to them here.

Comment: Several commenters asked that we eliminate the ''in the home'' restriction for PMD coverage.

Response: The ''in the home'' restriction is statutory and thus these comments are outside the scope of this regulation.

Comment: Some commenters noted that the mobility impairment can make it difficult to accomplish a face-to-face examination, especially if the physician or treating practitioner does not make home visits.

Response: Per section 1834(a)(1)(E)(iv) of the Social Security Act, CMS does not have the discretion to eliminate the requirement for the face-to-face examination.

Comment: A few commenters mentioned that the examples we provided in the preamble to the interim final rule were unrealistic; especially in that physicians no longer make house calls. The commenters suggested that CMS clarify who is accountable for visiting the beneficiary's home to determine equipment needs.

Response: We believe that the supporting documentation must show that the beneficiary lives in an environment that supports the use of the PMD, but CMS does not require a home visit for purposes of meeting this requirement. For the examples provided in the interim final rule, CMS believes that overall they are realistic and provide more clarity on the pertinent parts of the medical record.

Comment: Several commenters objected to the ATP certification requirement that was proposed in the DMERCs' LCD.

Response: We view these comments as being outside the scope of this regulation since the ATP certification requirement is not a requirement of this regulation. Accordingly, we will not respond to these comments here.

Comment: A commenter asked what proof needs to be provided to CMS to show that the supplier received the prescription from the physician or treating practitioner within 30 days after the face-to-face examination.

Response: We note that in response to comments, we have changed the 30 day requirement to 45 days. We believe that a supplier should use established methods for documenting the receipt of the prescription (date/time stamps, delivery receipts, etc.).

Comment: A commenter asked how long the prescription is good for (for example, how long does the supplier have to fill it).

Response: We have not specified the duration of the prescription's validity in this rule. We understand that depending upon the complexity of the PMD and its accessories, it may take several months to fabricate and adjust the PMD before final delivery is made to the beneficiary, that is, the prescription is filled. We do not believe that this extreme length of time will be needed for less complex PMD prescriptions.

Comment: If the prescription that the supplier receives is missing information (such as the diagnosis codes), can the supplier ask the physician for the missing information and annotate the prescription, or does the prescription need to be sent back to the physician or treating practitioner for the change to be made?

Response: If a supplier believes the prescription is inadequate, it should send it back to the physician or treating practitioner or call the physician or treating practitioner and request that the physician or treating practitioner send a new prescription. CMS believes that permitting a supplier to annotate a prescription would not provide adequate assurance that the physician or treating practitioner has in fact agreed to the annotations. Since the 45-day period begins with the date of the face-to-face examination, any revision of the prescription by the prescriber would not reset this 45-day period unless the prescriber also conducted a new face-to-face examination with the revision of the prescription.

Comment: Several commenters suggested eliminating the language, ''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* * *.'' (70 FR 50946). The commenters do not believe that suppliers should be responsible for reviewing a physician's clinical assessment especially since they are not clinicians themselves. A commenter

questioned whether or not the supplier would be held liable if the supplier agrees with the physician's additional documentation but the DMERC reviewer decides differently. Or would the supplier be protected by the limitation of liability provision in 42 U.S.C. 1395pp(a)?

Response: We believe that it is the supplier's responsibility to provide a legible copy of the written prescription and any other required information as defined in this rule. CMS believes that a party engaged in healthcare-related businesses should ensure that its staff has adequate expertise to carry out its responsibilities, and should obtain the training necessary to achieve and maintain that level of expertise. The supplier should obtain as much documentation from the patient's medical record as it determines that it needs to assure itself that the coverage criteria for payment have been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, then for assigned claims the supplier is liable for the dollar amount involved unless a properly executed advance beneficiary notice (ABN) of possible denial has been obtained. A supplier must maintain the prescription and supporting documentation provided by the physician or treating practitioner and make them available to CMS and its agents upon request.

Comment: A commenter suggested that CMS create and require a certification of expertise in the assessment of seating and mobility of the disabled population. This would allow any healthcare professional to assess PMDs.

Response: We believe this comment is beyond the scope of this rule, therefore we defer a response.

Comment: A commenter suggested that providers of rehabilitation seating and wheeled mobility products be listed on the National Registry of Rehabilitation Technology Suppliers (NRRTS) registry or submit documentation to meet those standards.

Response: This is beyond the scope of the regulation. Therefore, we will not respond to this comment in this final rule.

Comment: Several commenters suggested that some provisions of the interim final rule are inconsistent with other guidance CMS has issued on the topic. Commenters say, for example, that the LCD implies the receipt of supporting documentation is discretionary where the rule does not; the DMERC letter contradicts the rule by stating that a physician must distinguish between the patient's in-home and out-of-home mobility needs and that the patient must pay the difference for out-of-home features; the rule states physicians or treating practitioners must provide the supplier with supporting documentation where the LCD states the report of the face-to-face examination should provide information relating to the following questions and the report should provide pertinent information, and the DMERC letter states that a physician may choose to refer patients to other qualified medical professionals and the rule does not.

Response: This final rule trumps any sub-regulatory guidance and should be followed. To the extent that any commenters believe that the LCDs addressing PMDs do not reflect the provisions of this rule, we suggest that the commenters make these comments to the draft LCDs. In addition, CMS would not use a regulation to ask the DMERCs to clarify their letters.

Comment: One commenter mentioned that the wheelchair codes are not easily accessible on the CMS Web site and suggested that CMS put a query program on the Web site to allow a search for codes by description.

Response: The codes are a separate CMS initiative and since they are outside the scope of this rule, we defer a response.

Comment: A few commenters suggested that CMS delay the implementation of the regulation until April 2006 (the same timeframe as the coding initiative and elimination of the CMN) and believes that CMS violated the APA by publishing an IFC.

Response: We disagree with commenters' suggestion that we violated the Administrative Procedure Act (APA) by publishing this rule as an interim final rule. The APA provides that the procedure of publishing a notice of proposed rulemaking can be waived if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest, and if the agency incorporates a statement of this finding and supporting reasons in the rule issued.

As we stated in the interim final rule, we believe that we had good cause to waive the notice of proposed rulemaking because the rule conformed our regulations to section 1834(a)(1)(E)(iv) of the Act, removed a regulatory restriction on who could prescribe a POV, addressed fraudulent and abusive billing practices for PMDs, and implemented reforms that would bring more certainty to all participants in the PMD industry. The full text of our statement in support of waiving the notice of proposed rulemaking can be found at 70 FR 50943.

In addition, CMS believes that parties affected by the IFC have taken significant steps towards implementing the IFC's provisions and that delaying the rule's effective date would only cause significant confusion among physicians and treating practitioners, beneficiaries and the supplier community.

Comment: A few commenters disagreed with the statement in the IFC that a greater percentage of POVs are necessarily appropriate because these commenters believe that POVs are actually less maneuverable, less stable and usually do not fit into a beneficiary's home.

Response: CMS does not agree. As we mentioned in the interim final rule, the technology for these devices has improved. CMS also believes that Congress intended that more POVs be prescribed when it did not limit who could write PMD prescriptions to physician sub-specialties in section 1834(a)(1)(E)(iv) of the Act.

Comment: One commenter suggested that when referring to the ''description of the item'' as part of the prescription that we include ''(for example, power wheelchairs)''.

Response: The ''description of the item'' on the prescription can be general (for example, power wheelchair or power mobility device) or may be more specific.

Comment: A few commenters suggested that CMS does not have the authority to eliminate the CMN, especially after the Federal Court upheld the CMN in the Maximum Comfort vs. Thompson case.

Response: CMS does have the authority to eliminate the CMN. The use of specific CMNs is not a statutory requirement. Further, the decision issued in *Maximum Comfort, Inc.* v. *Thompson*, 323 F.Supp.2d 1060 (E.D. Cal. 2004), appeal docketed, No. 05–15382 (9th Cir. May 5, 2005), being the decision of a single district court, has no precedential effect. The United States has appealed the decision to the U.S. Court of Appeals for the Ninth Circuit. For this reason, CMS has no current plans to change its longstanding national policy regarding medical necessity documentation. The CMN was established to allow efficient adjudication of claims by automating the submission of certain information needed to make medical necessity determinations. However, a recent analysis by a CMS contractor on the utility of each CMN found in some cases a rate of CMN non-compliance as high as 45 percent. This finding underscored

our belief that the CMNs do not accurately reflect the contents of the patient's medical record. Some portion of this non-compliance is attributed to failure to fully understand coverage criteria.

As we stated in the interim final rule, we believe that recently published new coverage criteria for mobility assistive devices, including PMDs, provides guidance on what Medicare will consider when determining coverage, and that physicians, treating practitioners and suppliers will better know how to properly evaluate and document a beneficiary's clinical condition. Therefore, we determined that the practical utility of a CMN, given the function-based approach to coverage, was questionable, and that the continued use of a CMN for power wheelchairs or power-operated vehicles would no longer be required.

Comment: A few commenters suggested that CMS implement a prior authorization process for rehabilitation equipment which would shift the burden from the supplier to Medicare and compliment the standard practice of most third-party payers.

Response: We believe this comment is beyond the scope of this rule, therefore we will not address this comment.

Comment: A commenter noted that some medical records are illegible.

Response: We do not require a supplier to dispense a PMD if the supplier believes that the supporting documentation is inadequate. In general, CMS views illegible supporting documentation to be inadequate since the supplier cannot possibly know what to dispense or if the PMD is medically necessary if it can not read the records.

Comment: Some commenters recommended that physicians and treating practitioners follow a template tied to the MAE NCD algorithm.

Response: As mentioned previously, CMS believes the NCD is beyond the scope of this rule and defers a response.

Comment: A commenter asked if the face-to-face examination during a hospital stay could be performed on any day of that stay.

Response: We have not specified any particular day within the hospitalization. Most hospital inpatients have one or more face-to-face examinations every day during the hospitalization. For administrative simplicity for this rule, we are using the date of discharge as the date of the face-to-face examination. The date of discharge is discrete and readily verifiable.

Comment: A commenter stated that the hospital discharge summary would need to be sent with the order for beneficiaries whose face-to-face examination took place during the hospitalization, so that the supplier could confirm that the time requirement had been met.

Response: Though this is one way of documenting the date of discharge, we recognize that the transcript and release of hospital records can be, in some cases, a long process. The physician or treating practitioner may choose to document the date of discharge in some other manner.

Comment: Several commenters addressed the quality of prescribers' medical record documentation and burden on suppliers to handle submitted documentation. Commenters noted that DME suppliers already collect supporting information from prescribers. Based on past experience from a survey month, the commenters found that suppliers requested additional documentation 75 percent of the time and consumed over 3 hours of supplier staff time in these instances. They also noted that in some cases the volume of submitted documentation is over 10 pages.

Response: We believe, based on comments from some suppliers and a review of our claims review data, that physician and treating practitioner behavior in this regard has changed, likely as a result of the significant education outreach efforts by CMS, the DMERCs and the power mobility community. Thus, we expect that suppliers are now more likely to receive adequate supporting information in the first instance, and that the need to request additional information will be significantly reduced, with a corresponding reduction in supplier staff resource needs.

Comment: A commenter claimed that the requirement that a supplier submit documentation to CMS or its agents to substantiate medical necessity imposed a new burden.

Response: We disagree. The medical review process under which CMS reviews claims for accuracy already includes this requirement. We also believe that it is clearly in the public interest for CMS to pay claims accurately.

Comment: A commenter asked how CMS arrived at the figure of 187,000 as the number of PMD prescriptions written on a yearly basis.

Response: CMS examined historical claims data for POVs and power wheelchairs. CMS has projected an estimation of 187,000 prescriptions that would be written on a yearly basis for PMDs based on historical claims data for PMDs. This figure does not include manual wheelchairs, wheelchair accessories or other wheelchair-related services aside from actual PMDs.

Comment: A commenter said that a 2003 CMS Paperwork Reduction Act (PRA) collection for the CMNs stated that it could take as long as 5 hours for a non-medical office clerk to review documentation.

Response: The use of the term ''as long as'' clearly denotes an extreme instance rather than an average or representative figure. The length of time needed to review documentation will depend on the complexity of the individual case and the skill and experience of the reviewer.

III. Provisions of the Final Rule

We are revising § 410.38(c) of our regulations to specify the same provisions outlined in the interim final rule except for the following changes:

- The PMD prescription and supporting documentation must be received by the supplier within 45 days after the face-to-face examination.
- 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 45 days after the date of discharge.
- We clarified the definition of ''supplier'' to mean an entity with a valid Medicare supplier number, including an entity that furnishes items through the mail. Since DME suppliers are required to have a valid Medicare supplier number this is not a substantive change.
- We substituted the word ''after'' for the word ''of'' in § 410.38(c)(2)(ii) so that the phrase ''within 45 days after the face-to-face examination'' is consistent with the phrases in § 410.38(c)(2)(iii) and (c)(3)(i) and so that there is no confusion regarding the length of the time between the date of the face-to-face examination and the date by which the supplier must receive all pertinent PMD documentation from the physician or treating practitioner.
- We revised the authority section to part 410 to include section 1893 of the Act. Section 1893 of the Act charges the Secretary with creating a program to protect the integrity of Medicare and authorizes the Secretary to enter into contracts for the purpose of performing utilization and fraud reviews.

In addition, we listed two narrative examples of what would constitute the pertinent parts of a medical record in the interim final rule. For clarification, in those examples we used the

commonly accepted SOAP convention. SOAP, a term of art, refers to the four major parts of the medical record documentation of an outpatient visit. S, for Subjective, refers to the information provided by the patient in his or her own words, generally the reason for the visit, the description of his or her symptoms and relevant historical data. O, for Objective, refers to data that the physician or treating practitioner discovers using physical examination techniques and basic instrumentation. A, for Assessment, refers to the physician or treating practitioner's application of professional knowledge to the interpretation of the accumulated data to generate possible diagnoses and conclusions. P, for Plan, refers to the physician or treating practitioner's strategy to resolve any issues generated in the assessment. This strategy commonly may include prescribing a drug or device, ordering further diagnostic testing, and/or scheduling a return visit for the patient. We are not requiring that the SOAP format be used or that the descriptions be of a certain length for documentation in the beneficiary's medical record, as treating practitioners use a variety of methods depending on their professional training and the context of the clinical encounter. Whatever the length or format or accumulated volume of the documentation materials, its substance must clearly establish that the device dispensed was fully consistent with Medicare's coverage criteria. Medicare's national coverage determination on Mobility Assistive Equipment, which includes power mobility devices, can be accessed at: *http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=280.3&ncd_version=2&basket=ncd%3A280%2E3%3A2%3AMobility+Assistive+Equipment+%28MAE%29.* Local Coverage Determinations can be obtained from Medicare's Durable Medical Equipment Regional Contractors (DMERCs).

V. Collection of Information Requirements

The collection of information requirements associated with this regulation were first introduced in CMS–3017–IFC (70 FR 50940). Subsequently, the information collection requirements were submitted to the Office of Management and Budget (OMB) for review and approval, and were approved under OMB No. 0938–0971. The information collection requirements have a current expiration date of May 31, 2006.

The 60-day **Federal Register** notice for the re-approval of the information collection requirements approved under OMB No. 0938–0971, titled ''Conditions of Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles (CMS–3017–IFC)'' was published on March 24, 2006 (71 FR 14898).

If you comment on any of these information collection and recordkeeping requirements, please mail copies directly to the following: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

To be assured consideration, comments and recommendations pertaining to the information collection must be received at the address above, no later than 5 p.m. on May 23, 2006.

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 19, 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 change alone 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, 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 PMD), 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 $35 million (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). As previously noted, we expect the increase in PMD prescriptions and 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 PMD (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 payments we implemented in connection with this rule. As discussed in the preceding PRA analysis, suppliers will face slight increases 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 in 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. Even if we had discretion, we judge them to be desirable changes. Coupled with our recent 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 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.

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 arose 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 potentially benefit from either class of equipment, but who do not need the additional functionality (at the cost of inconvenience) provided by power wheelchairs. 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 with relative ease. As indicated previously, volume increases likely to occur independently of this rule will likely obviate the need for any such shifts. Accordingly, we do not believe that the impact on these entities will be significant, or 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 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. 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.

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, X-rays.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV. In addition, the interim regulations published on August 26,

2005 (70 FR 50940) are confirmed as final and revised 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, 1871, and 1893 of the Social Security Act (42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd).

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, 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 an entity with a valid Medicare supplier number, including an entity that furnishes items through the mail.

(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 meets the following conditions:

(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 that is provided to the beneficiary or supplier, and is received by the supplier within 45 days after the face-to-face examination.

(iii) Provides supporting documentation, including pertinent parts of the beneficiary's medical record (for example, 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 45 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 45 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. These documents must be received within 45 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.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: March 10, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: March 30, 2006.

Michael O. Leavitt,

Secretary.

[FR Doc. 06–3271 Filed 3–31–06; 4:02 pm]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 06–609; MB Docket No. 05–279; RM–11276]

Radio Broadcasting Services; Black River and Old Forge, New York

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of Radioactive, LLC., reallots Channel 223A from Old Forge, New York to Black River, New York, and modifies the construction permit authorization, accordingly. The coordinates for Channel 223A at Black River are 44–04–01 North Latitude and 75–38–53 West Longitude, with a site restriction of 13.3 kilometers (8.3 miles) northeast of the community. Canadian concurrence has been obtained.

DATES: Effective May 1, 2006.

FOR FURTHER INFORMATION CONTACT: Helen McLean, Media Bureau, (202) 418–2738.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 05–279, adopted March 15, 2006, and released March 17, 2006. The full text of this Commission decision is available for inspection and copying during regular business hours at the FCC's Reference Information Center, Portals II, 445 Twelfth Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *www.BCPIWEB.com.* The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.