SEP - 7 2005

116 Lexington Ave.
Elmira, New York 14905-1907
September 1, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3017-1FC
P.O.Box 8013
Baltimore, Maryland 21244-1850

RE: CMS-3017-1FC

Dear Sirs:

Thank you for the opportunity to comment on the above referenced document.

I. Background

Durable medical equipment, which for purposes of this letter, we may define as power wheel-chairs and scooters, has been in the news over the last several years. Sadly there has been much fraud regarding these devices. In one case an elderly couple was surprised when a company showed up to deliver two unordered and unneeded power chairs.

If one watches television they see many power mobility devices advertised "at little or no cost to you. We will work with Medicare." Clearly there must be steps to reduce fraud.

We are concerned that this proposed regulation does not include educational, work, religious, social and other settings as well as homes and hospitals. These devices can help people get out in the community.

Provisions of the Interim Final Rule we do not feel the definitions should include "in the home".

In discussing "supporting documentation remove "in the home".

Thank you.

Sincerely,

David Eichenauer

DE/se

SAGINAW MEDICAL
SERVICE, INC.
PHYSICIAN SUPPLIES & EQUIPMENT
(989) 793-4444
HOME CARE SUPPLIES & EQUIPMENT
(989) 793-6000

September 20, 2005

Centers for Medicare & Medicaid Services
Dept. of Health & Human Services
Attn: CMS-3017-IFC
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-3017-IFC

It seems to me that there is a strong reticence to deal with the offending parties in fraudulent providing of equipment. The solution is always greater regulations and more paperwork.

The biggest problem which I see with the new rule is the onerous documentation. We have little hope of ever getting useable documentation unless we work with the physician's office. It is not a question of attempting to qualify individuals who do not. It is a question of securing adequate data upon which to base supplying equipment to qualified individuals.

On paper it sounds like an easy thing to obtain. In practicality we have an extremely difficult time obtaining proper documentation. In fact, we have a very difficult time getting a simple, **original prescription.** Paying physicians to supply documentation may help. Only they know if the proposed amount would cover their cost or not. Unless payment causes a higher level of useable data, we see it as a slow, laborious process.

The number of codes for power chairs seems to us to be over-kill. We do not see how that is necessary or helpful. We cannot fathom why 49 codes are necessary.

Sincerely,

Wayne McDonald

WM/ea

AMERICAN PODIATRIC MEDICAL ASSOCIATION, INC.

October 19, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3017-IFC
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-3017-IFC
Comments on Medicare Program; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles; Interim Final Rule (70 Fed. Reg. 50940, August 26, 2005)

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 podiatric physicians, is pleased to provide comments on the interim final rule that defines power mobility devices (PMDs) as power wheelchairs and power operated vehicles (POVs). The rule also sets forth revised conditions for Medicare payment of PMDs and defines who may prescribe PMDs; requires a face-to-face examination of the beneficiary by the physician or treating practitioner and a PMD prescription; and eliminates the Certificate of Medical Necessity for PMDs.

The APMA supports the efforts of the Centers for Medicare & Medicaid Services (CMS) to overhaul its policies affecting PMDs so as to ensure that beneficiaries who need assistance with mobility have access to appropriate technologies, and that Medicare pays appropriately for the devices. We agree that new procedures should exist for prescribing, supplying and billing for PMD but we believe that a revision to the new regulations is warranted.

We do not support the decision to not recognize doctors of podiatric medicine as being among the types of physicians who may order PMDs. We understand that in developing the regulations, CMS implemented provisions in the Medicare Modernization Act (MMA). We believe that a minor technical oversight occurred in the law that unintentionally narrowed the class of practitioners who can prescribe PMDs. Rather than use the definition of physician in Section 1861(r) of the Social Security Act, Congress referred to Section 1861(r)(1). The consistent and medically preferable approach would be to use the entire Section 1861(r) definition in the Act, with its inherent limitation by the scope of practice of the practitioners. Within their scope of practice, podiatric physicians are eminently qualified to determine the medical necessity of PMDs and we believe that the new regulations would do more harm than good if they prohibited

podiatric physicians from providing medically necessary and appropriate decisions within their scopes of practice and expertise.

We do not expect that podiatric physicians would routinely order PMDs. However, there may be occasions when a patient being treated by a podiatric physician legitimately requires a PMD. Consider a patient who has sustained trauma to both lower extremities and has limited mobility to the extent that a PMD is warranted. Since podiatric physicians are not recognized as health care professionals who may order these items, the patient would either not have access to a medically necessary item or would have to be referred to another physician or a treating practitioner, such as a physician's assistant, nurse practitioner, or clinical nurse specialist. This would be an unnecessary burden on the patient.

Podiatric physicians complete four years of podiatric medical school after college followed by a minimum of two years of post-graduate residency training. Medicare recognizes podiatrists as physicians within their scope of their practice. We do not understand why other physicians and practitioners are allowed to prescribe PMDs as medically necessary items, yet podiatric physicians are not allowed to do so within their scope of practice.

We urge CMS to immediately revise its regulations and recognize podiatric physicians among the types of physicians and practitioners who may prescribe PMDs.

The APMA appreciates the opportunity to offer these comments. If you require additional information, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,

Harold B. Glickman DPM

Harold B. Glickman, DPM
President

Clinician Task Force Co-coordinators

Barbara Crane, PhD, PT, ATP
Assistant Professor
University of Hartford
180 Middletown Avenue
Wethersfield, CT 06109
Barb.crane@cox.net
(860) 529-4936

Laura Cohen, PhD, PT, ATP
Clinical Research Scientist
Shepherd Center
2020 Peachtree Rd NW
Atlanta, GA, 30309
Lauracohen2004@yahoo.com
(404) 350-3082

November 20, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8013
Baltimore, MD 21244-1850

ATTN: CMS-3017-IFC

To whom it may concern,

The Clinician Task force submits the following comments in response to the August 26, 2005 released ***File Code CMS-3017-IFC.***

The enclosed comments are respectfully submitted by the Clinician Task Force. The Clinician Task Force is comprised of approximately 30 members, primarily seating and wheelchair practitioners, whose work involves providing wheelchair seating and mobility services to individuals with disabilities. All of our members care deeply about individuals with disabilities who require wheeled mobility. Most members of the task force have over 10 years of experience practicing in assistive technology, primarily in wheelchair and seating evaluation and recommendation.

Comments submitted electronically to: **www.cms.gov/regulations/ecomments**

Interim Final Rule
COMMENTS on file code CMS-3017-IFC

General Comments:
By developing policies that focus on waste, fraud and abuse, CMS has subjugated standards of medical care.

CMS has disregarded the American Medical Association, Primary Care for Persons with Disabilities: Access to Assistive Technology, Guidelines for the Use of Assistive Technology: Evaluation Referral Prescription, that:

1. states "General practitioners are the most commonly reported source of information on disability services but have been shown to have minimal knowledge of assistive technology."
2. defines "An 'appropriate prescription' is one that takes into consideration the comprehensive assessment process..." and that "The physician usually performs a brief screening test in the above areas (functional) and refers the patient to the appropriate member of the heath care team for in-depth evaluation, as indicated."

CTF Recommendations:
CMS must amend these Conditions for Payment of Power Mobility Devices as per the above guidelines to:

1. accept that it is the role of the physician, not a supplier, to assess the need for additional information and "consult with/refer to specific members of multidisciplinary teams for evaluation"
2. recognize that a patient assessment that focuses on function is time intensive- best accomplished in extended sessions or multiple sessions and
3. acknowledge that while "not every professional is needed for every patient or device" and "The physician may directly contact a DME vendor, but in most situations a therapy evaluation should be completed first."

I. Background:

"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."

Clinician Task Force Comments:
According to the president of the American Medical Association, CMS is scheduled to cut payments to physicians by 26%, which will cause many physicians to restrict the number of Medicare beneficiaries they will be able to treat. (see attached article "Medicare's Ohio Squeeze"). This is just one illustration of the inadequacy of Medicare reimbursement for this new requirement for physicians. The additional $21.60 is not adequate additional reimbursement for generating, compiling, and providing the supplier with the necessary additional documentation.

Physicians do not routinely perform functional mobility assessments, therapists do. There is no provision in these regulations for coverage of therapy services for function and mobility assessments and these payment structures are also inadequate under the current CPT code reimbursement system. A comprehensive assessment of individuals requiring powered mobility devices typically requires more than 1 hour of therapy assessment, in addition to the physician assessment. Many assessments require 2- 3 hours of examination and equipment trial time, and this does not include the time needed to complete a home assessment (also required by the new MAE NCD). If the fee schedule is not properly adjusted to recognize and reimburse for appropriate services, the result will be limited access of beneficiaries based on the unavailability of service providers willing to supply the necessary services and documentation.

Neither therapists nor suppliers are reimbursed for home assessments. Home assessments are not within the scope of practice for equipment suppliers and although they are within the scope of practice for therapists, they are not adequately reimbursed. Consequently, therapists involved in patient examinations do not have the ability to routinely provide home assessments.

There are multiple geographic differences in the various regions of the United States. Several examples of time required to provide examination, documentation of services, and the amount of reimbursement available under the CPT coding system for therapists are provided in the chart below. These are based on experiences of several members of the Clinician Task Force in their current course of practice. If an assessment is performed in a patient's home, allowing simultaneous home assessment, there is additional non-reimbursable travel time that makes the performance of these assessments financially unfeasible for most out patient facilities. While home care billing structures do provide additional reimbursement for home-based services, many Medicare beneficiaries served do not meet the home-bound requirement for eligibility of these services and most home-care service providers have limited experience with seating and mobility assessment and therefore, have limited ability to complete the necessary evaluation and documentation.

CITY:	MANHATTAN, NY	HARTFORD, CT	ASHEVILLE, NC	ATLANTA, GA	LOS ANGELES, CA
DOOR TO DOOR TRAVEL TIME	30 minutes to 2 hours (to cover same distance depending on traffic).	Average of 1 hour each way	20 mins to 2 hours one way	1 hour avg each way (varies with traffic)	30mins to 2 hours
TRAVEL EXPENSES	Parking - $15.00/hr. Parking ticket $150.00	$100/hr	48.5 cents/mile + therapists salary	100/hr travel and 48.5 cents/mile	$85/ hour
TRAVEL TIME	Non-billable for outpatient facility – May be billable for Home Care Therapist				

	(though often not skilled in wheeled mobility assessments)				
SEATING AND MOBILITY EVALUATION TIME	2 hours: • ¾ hour for interview and postural assessment • ½ hour to 1 hour for initial trial of seating and wheeled mobility equipment (indoor and outdoors) • ¼ hour to determine next steps. (Assumes the demonstration product available for trial) – more time is needed to arrange for trial demo equipment, plus subsequent visits are often required to continue trial and assessment, complete recommendations and order forms				
SEATING AND MOBILITY DOCUMENTATION TIME	20 minutes – 1 ½ hours - depends on presented needs, complexity of the patient's diagnosis and medical history and equipment required for maximizing function: (also dependent on facility based documentation requirements and systems used) • Mobility Only • Postural Support and Mobility • Postural Support, Tissue Integrity and Mobility.				
SEATING AND MOBILITY REIMBURSEMENT (CPT)	Manhattan	Hartford	Asheville	Atlanta	LA
97001 (PT Eval)	$89.55	$82.24	$72.98	$78.20	$82.11
97003 (OT Eval)	$96.64	$88.31	$77.78	$83.86	$88.13
97112/unit (Treatment)	$35.10	$32.15	$28.41	$30.54	$32.09
97535/unit (Safety and adaptive equipment)	$35.53	$32.69	$28.86	$30.99	$32.60
97542/unit (wheelchair mgmt/propulsion training)	$33.02	$30.49	$27.11	$28.95	$30.42
HOME EVALUTION TIME	30-60 minutes	1 hour	Avg 1 hour	1-2 hours	45 mins to 1 ½ hours
HOME EVALUATION DOCUMENTATION TIME	20 minutes	30 minutes	20 minutes	30-60 mins	30 mins
HOME EVALUATION REIMBURSEMENT (CPT)	Not separately billed	Not separately billed (PT)	May be initial or subsequent visit: CPT Codes billed as above +	97003 OT eval- 62.00/15 minutes 97535 OT safety and	

			97535 allowable $28.86/unit.	adaptive equipment 62.00/15 min.	

Without adequate reimbursement of professional services, it will be impossible for beneficiaries to obtain the examination and documentation services mandated within this Interim Final Rule. This will result in restricted access to appropriate PMD and continued problems with waste and abuse within the system. The goals Congress established within the MMA will not be met by any of the following provisions.

CTF Recommendations:
CMS must recognize the role of physical and occupational therapists in functional mobility and safety assessment and documentation. Additionally, there must be recognition of the need for these services and a system of reimbursement that recognizes this process. It is also important for CMS to recognize that not all therapists will be skilled in the assessment and documentation process and may need to refer a patient to a knowledgeable therapist for this assessment. Proper education and training must be provided to therapists so that they will understand both the need for this assessment and the skills required to perform the assessment.

CMS must conduct a through review of CPT codes/descriptors and reimbursement to ensure adequate access to physical evaluations for the purpose of assessing for power mobility needs, technology assessments for beneficiaries with complex mobility and seating needs, and home assessments.

CMS must also ensure that any conditions for payment of these codes, (i.e. regulations that prohibit billing for multiple services on the same day) be eliminated. The process a beneficiary must go through in order to qualify for power mobility has already been substantially protracted. CMS must take steps to ensure that any unnecessary delays or redundancy is eliminated from the process.

Section II: Provisions of the Interim Final Rule

"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."

"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."

"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."

Clinician Task Force Comment:
While collection of this type of information is common therapy practice, it is not routine medical practice. As discussed in Lisa Iezzoni's book "When Walking Fails" (2003), physicians are trained in medical school to diagnose and treat acute illnesses and physicians receive little or no training in assessing or describing mobility impairments and receive no training in technology. The result of this requirement will be restriction of access to PMD by Medicare beneficiaries because there will not be adequate access to physicians capable of meeting these requirements. It is the experience of the clinicians working on this task force, that the examples presented in this Interim Final Rule are not illustrative of current routine medical practice. Most physicians rely on subjective patient reports regarding their functional limitations, not physical assessment, and these reports are not often accurate (Iezzoni, 2003).

A recent example is offered of typical examination findings and associated documentation by a physician referring a Medicare beneficiary with a significant mobility impairment for an assessment for a mobility device:

> Reason for referral, according to the patient, is the 'need for a new manual wheelchair'. The patient is a Medicare beneficiary and Medicare paid for a power wheelchair in 1996. The patient's diagnosis is spastic quadriplegia due to Closed Head Injury sustained in 1994. The physician signed a referral for a physical therapy evaluation for a manual or power wheelchair and sent the latest progress notes from 11-2002 to 8-2005. The physician's notes make no mention of the patient's use of a wheelchair, even though the patient has used one since 1994. The only patient needs addressed in the progress notes are the patient's seizure medication needs and suicidal tendencies and medications prescribed for depression. Documentation of the physician's physical assessment of the patient includes the following information: 'He is somewhat verbal, but a little bit hard to understand, smiling. Neck is supple, no nodes. Heart with regular rate and rhythm, no murmur. Lungs are clear to auscultation bilaterally. Extremities: no cyanosis, clubbing or edema.'

While this is only one example, it is extremely typical of physician's examination findings and associated documentation for patients with significant mobility impairments. Members of the clinician task force have found the above documentation to be commonplace and believe it is implausible to expect that physicians will ever provide the

examination and documentation outlined within this interim final rule. The determination of an appropriate power mobility device according to Medicare guidelines is quite simply not their area of expertise.

CTF Recommendation:
While the CTF recognizes the role of the primary care physician in providing leadership in the management of the overall health and well-being of patients, we feel that physician's notes do not and will not typically provide required documentation of mobility impairments and resolution of these functional needs through use of technology. The CTF recommends physician review and approval of a comprehensive therapy assessment that includes all required elements should be adequate in justifying medical need for the recommended equipment. The required elements must be clearly defined for therapists and physicians to allow full inclusion as part of the assessment and documentation process.

Our comments pertain to the IFR and not the numerous other documents that have been subsequently released to clarify the IFR (Medlearn Matters, Physician letters, DMERC clarifications and change requests). These clarifications, in particular, the October 2005, Dear Physician letter from Dr Norris, Interim Medical Director DMERC Region D, clearly and concisely summarizes the IFR documentation and face to face evaluation requirements. It is reasonable to expect that CMS compile and incorporate all of the clarification documents released subsequent to the IFR and publish these documents as part of the Final Rule.

"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."

Physicians are not only required to provide any medical records that support prescription of PMD (which is a major problem in itself) but also must remove any materials that are not appropriate to provision of the PMD – all for the same $21.60. This is also improbable and inconsistent with practical experience despite HIPAA requirements.

"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."

It is important to note that a major component of the past "waste, fraud and abuse" cases has been physician prescription. This is not necessarily intentional on the part of the physician. It may in many cases be due to a lack of awareness of mobility and seating product options and the nuances of the Medicare prescription process. Once again, the knowledge base required for a power mobility device recommendation is simply not a physician's area of expertise.

Although this text appears to recognize the contribution of therapy assessment services and reports, there is no information provided regarding how suppliers are supposed to obtain this additional information, particularly if these additional examinations are performed by therapists or other professionals. The IFR mandates provision of prescription and examination notes, but does not address how this additional documentation will be provided to the supplier. The providers of these additional services and documents do not appear to receive any additional reimbursement for providing this documentation to suppliers. This section of the interim final rule should specify appropriate evaluations – by therapists – and should have provisions for reimbursement of these services that are appropriate to meet the stated goals of this regulation. The burden of determining if sufficient documentation is available to support a PMD request resides with the supplier. Due to the ambiguous documentation requirements and the history of physician documentation regarding mobility devices, this will result in many suppliers minimizing their risk for lack of reimbursement. For individuals with more involved needs and consequently, more expensive equipment, this will result in restricted access.

CTF Recommendation:
The Clinician Task Force strongly supports a prior authorization process for rehab equipment - particularly PMD to shift the burden of determining coverage to the payer-Medicare, versus the supplier. This recommended practice is the standard for all other third party payers including Medicaid, private insurers, HMOs and the VA. It is only reasonable to have the payer make the determination of payment prior to provision of equipment.

Section IV: Waiver of Proposed Rulemaking
"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."

"...but also greatly reduce the risk that a supplier will be denied payment through no fault of its own."

Clinician Task Force Comments:
There is nothing presented in this rule that does either of these things. Replacement of the CMN with this "prescription" and "supporting documentation" provides suppliers with less certainty of meeting the regulation, not more. This also increases risks to suppliers of denial of payment. The CMN, in spite of all of its limitations, at least provided discrete, defined information requirements that a supplier could clearly uphold to determine a beneficiary's qualification. The provision of unspecified and unclear "supporting documentation" is far more difficult for suppliers to assess. Clearly the burden of determining sufficient medical documentation is on file falls to the supplier. The supplier is the one at financial risk and there are no consequences to the physician for providing insufficient documentation. Therefore the supplier is faced with determining if the risk of providing the equipment to the beneficiary is warranted. As mentioned before,

the Clinician Task Force supports expended use of Prior Authorization of rehab equipment – particularly powered mobility devices.

"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."

CTF Recommendation:
This interim final rule does not provide adequate evidence to justify omission of the notice of proposed rulemaking. The CTF recommends that an appropriate process that allows full consideration of constituents' comments and provides adequate education for all involved in this process be implemented.

Section V: Collection of Information Requirements

Comments regarding the need for the information collection and its usefulness in carrying out the proper functions of our agency:

While the Clinician Task Force (CTF) would agree that documentation of medical need is appropriate for adjudicating a claim for a powered mobility device, previous and current physician documentation patterns dictate that adequate documentation will never exist in the physicians' notes. The collection of copious physicians notes will never achieve the goals of the agency as these notes will remain inconsistent from physician to physician and will in most cases not adequately document the mobility needs of beneficiaries, even when those needs are present.

CTF Recommendation:
The CTF proposes that documentation commonly provided by therapists (physical or occupational or both) as a result of a complete physical and functional assessment would allow the agency to accomplish its goals of determination of need for PMD. CMS must provide adequate guidance for physicians and therapists to allow inclusion of necessary information in the assessment and documentation process. As stated previously subsequent clarifications released by the Agency and DMERCs outline this information and need to be synthesized, compiled and incorporated in the published Final Rule.

Comments regarding Accuracy of CMS Estimate:
The CTF believes that the CMS estimate of the information collection burden is far from accurate, as described below:

Burden estimated by CMS is 12 minutes for each CMN – including time needed to extract appropriate data from the medical record, record the data and forward the CMN to the supplier – we believe this estimate is much higher than the time actually spent by physicians, particularly when an independent therapist completed the CMN (which was allowed by CMS) and forwarded the CMN to the physician – which is very common, current practice. The physician simply needed to review and sign the document and return it to the supplier. The CTF believes this task would require less than 5 minutes of physician time.

Burden estimate associated with new requirements:

CMS is estimating it will take only 2 minutes for physicians to prepare and submit the new prescription. This does not include any of the time necessary to document all necessary information in the medical record – which is far more than 2 minutes. Clinicians who currently generate this type of extensive documentation (currently primarily performed by therapists) require a minimum of 30 minutes of documentation time per evaluation. In addition, the prescription will need to be completed for a total of 32 minutes per beneficiary (not 2). Using the CMS estimate of 187,000 PMD prescribed per year totaling 99,733 hours of time, not the CMS estimated 6,233 hours.

Physicians will also carry the burden of identifying parts of the medical record that are appropriate to support the use of PMD, having them copied, and giving them to the beneficiary with the prescription. **Omitted from this list of requirements is the HIPAA requirement to redact all non-pertinent information – which will also be necessary**. The burden estimate for this process is 10 minutes of physician time. Again we believe this will take the physician longer than 10 minutes, particularly to redact all non-essential information. We believe a reasonable estimate for total physician burden will approach 45 minutes per claim, not the estimated 10 minutes. This would increase the burden estimated per annum to 140,250 hours. This burden will be acceptable for very few physicians, preventing access of beneficiaries to the services required to obtain necessary PMD.

Although CMS asserts that this new rule involves a "shift in the burden of information collection from the supplier to the physician" the CTF believes that the burden on the supplier will be **increased** not decreased. The supplier is responsible for determining if adequate documentation has been provided to support a claim – not the physician. It is always the supplier's burden to make this determination and to request further documentation as needed because the supplier will be subject to post payment audits and revocation of payment if the claim is determined to be unfounded. The physician has no such responsibility and pays no penalty for not supplying adequate documentation. With the CMN necessity, the supplier could be reasonably assured that a beneficiary met the basic requirements for coverage, relying on physicians chart notes makes this far less certain. In spite of CMS's assertion that the ultimate result of the new NCD on MAE was that "...physicians, treating practitioners and suppliers better know how to properly evaluate and document a beneficiary's medical condition and appropriately describe PMDs," there have been only minimal web-based informational postings concerning these extensive policy changes with no implementation and transition plan. It is the Clinician Task Forces group experience that referring physicians and OT/PT colleagues are largely unaware of the new NCD, LCD, face to face requirement and documentation requirements. CMS provider education is severely lacking. Widespread confusion persists regarding the new guidelines. Physicians have very little knowledge of how and when to appropriately prescribe PMDs and the new NCD did not remedy this, if anything it made it more ambiguous. To risk redundancy, the CTF strongly recommends that the clarification documents released subsequent to the IFR be incorporated into the published Final Rule. In particular the language included in Dr Norris's physician letter October, 2005, will surely help to clarify and outline the contents of appropriate documentation.

Comments regarding the quality, utility, and clarity of the information to be collected.

The near-total reliance of CMS on the physicians' chart notes will detrimentally affect the quality, utility and clarity of the information to be collected. Physicians are notorious for illegible documentation. They have received very little guidance on how to document mobility limitations discovered in the face-to-face examination process. In addition, physicians do not routinely document mobility related issues and do not routinely examine or evaluate mobility, mobility device use, or mobility related activities of daily living. Most physicians rely on physical and occupational therapists to perform these assessments and to properly document impairments, goals, and assistive devices that may be required. Physicians' notes generated during a routine examination have not and will never adequately document mobility related issues. This is unlikely to undergo widespread change in the near future.

In addition, there has been an inadequate and delayed attempt to educate physicians via a 4 page MedLearn Matters information sheet released September 14, 2005. Additional substantial efforts to properly and effectively educate physicians regarding the changes in the NCD are still needed. The vast majority of physicians we have contact with have no awareness of these changes. They have not changed their practice patterns to include thorough examinations of mobility and mobility related activities of daily living, nor are they documenting these issues thoroughly within their progress notes. More time is needed prior to transition to plan for these vast changes. We recommend a transition period with implementation on October 25' 2005 and enforcement beginning in April 2006. This transition time will allow for adequate education and training to facilitate a smooth shift to the new requirements. We recommend education and training that consists of multiple methodologies. Relying on website postings to educate the provider community is unrealistic and ineffective. Alternate strategies including web conferences, online and in person courses provided through professional organizations with continuing medical education (CME) and continuing education units (CEUs), publications in professional journals and trade magazines is needed.

CTF Recommendations:
Our primary recommendation is that there be a prior authorization process for rehab equipment particularly PMD. CMS contractors should review all documentation prior to delivery of the equipment to determine if documentation is adequate and if medical necessity requirements are met. This process is the only way to assure suppliers that they have adequate documentation of medical need and more confidence in their ability to be reimbursed for the equipment they will provide. This will also alleviate the need for post payment audit as all equipment recommendations will be reviewed prior to supplying them.

There have been several forms and formats commonly used by therapists to report the findings of a physical and functional assessment, the most common of which is the letter of medical necessity. This information is commonly reviewed by funding sources to allow the funding source to determine medical need for a recommended device. These forms do contain several common elements and are in widespread use by therapists, but are not commonly used by physicians. Example formats that suggest specific collection of necessary information would be far more appropriate, accurate, legible, and complete

than any unstructured physicians notes would ever be. In spite of the fact that additional information is provided regarding the new decision algorithm established in the new NCD, physician's notes will be chronically inadequate without a specific format to follow. We also recommend that the most appropriate source for this documentation is via an independent therapist evaluation (i.e. a therapist with no financial ties to the supplier), not the physicians face to face examination. Documentation must include information in the following areas: the individual's medical history; physical abilities and needs; functional abilities and needs; seating and positioning abilities and needs; home accessibility; currently used assistive devices; and environmental considerations. Again, these elements are typically assessed in a comprehensive occupational or physical therapy mobility device evaluation. Often these therapists work in conjunction with an equipment supplier and the specifics of the evaluation will be documented in the therapy notes, not in the physicians' notes.

Section VI. Regulatory Impact Statement

"In analyzing the effects of this regulation, we believe that most physicians are already conducting a face-to-face examination before prescribing a wheelchair."

Clinician Task Force Comments:

In our experience, current practice involves the following sequence of events:

1. a beneficiary may contact his or her physician to initiate a wheelchair prescription.
2. The physician will then refer a beneficiary to a supplier or perhaps a therapist.
3. The therapist and/or supplier) will meet with the beneficiary, perform a thorough evaluation and submit documentation of need to the physician to review and sign.

For physician determination of the need for a mobility device, it is not uncommon for many transactions with the physician to be performed via phone, email, or regular mail and not via a face-to-face examination.

"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."

We believe the extra $21.60 will not properly offset the costs associated with the additional documentation, compiling of information, and transmission of all the necessary paperwork to the supplier. In addition, as we stated in several points above, physicians are not willing or able to perform these tasks. Therefore, the net result will be a significant decline in access of beneficiaries to appropriate PMD. Beneficiaries will be harmed by these changes. Patients will be required to attend at least one additional face-to-face examination with their physicians (and in many cases more than one will be necessary) and will face significant limitations in access to powered mobility devices. The net result will be:

1. inappropriate provision of manual mobility devices for beneficiaries who require powered mobility to meet their needs
2. inappropriate provision of appropriate manual wheelchair, and

3. inappropriate provision of wheelchair seating system products

All of which may result in increased deformity, pressure sores, pain, injury, and numerous other secondary complications. This will ultimately result in continued mobility impairment and increased costs due to inappropriate medical care.

"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 statement is totally unfounded and is in direct contrast to our experience over the past twenty something years. The main effect on suppliers is that they will be unable to obtain sufficient documentation and unable to supply appropriate equipment to beneficiaries.

"We expect that this rule will result in a shift in PMD prescriptions from power wheelchairs to POVs."

With the requirement for use "in the home", clarified in the definitions of PMD, this is unlikely to happen. A primary reason for need of power wheelchairs is for adequate maneuverability for use in a beneficiary's home. While POV technology has changed, these devices still require large available maneuvering space, particularly for turns, and in many cases, are not appropriate for use "in the home". The more restrictive requirements for use" in the home" will actually restrict beneficiary access to POVs.

Additional comments and recommendations:

It is the experience of this group of expert clinicians that physicians are not aware of the new MAE process or these new documentation requirements. Many of the clinicians on this task force routinely interact with physicians and have inquired of physicians what their awareness and knowledge of these changes is. It has been universally reported to this task force that physicians are unaware of these new requirements and are not routinely applying the clinical decision making algorithm outlined in the new NCD on MAE. In addition, it is also very clear that physicians are not aware of the provisions in this interim final rule. At the risk of sounding redundant, we reiterate that physicians have many specialty areas however, this is simply not their practice area.

Furthermore, the Clinician Task Force strongly recommends a prior authorization process for use in determining Medicare coverage of rehab equipment particularly PMD. This prior authorization process should be used for all equipment currently covered by the ADMC rules and would replace the ADMC in these cases. Prior authorization of PMD is the only way to accomplish the goal of controlling waste and abuse and reducing the financial risk and burdens on equipment suppliers. Increased administrative costs of prior authorization will be offset by cost savings from prevention of fraud, waste and abuse, and current costs of post-payment audits.

CTF Member List:

Co- Coordinators

Laura Cohen PhD, PT, ATP
Clinical Research Scientist
Crawford Research Institute
Shepherd Center
Atlanta, Georgia
Lauracohen2004@yahoo.com
RESNA Member, APTA Member

Barbara Crane, PhD, PT, ATP
Assistant Professor, Physical Therapy
University of Hartford
Hartford, CT
barb.crane@cox.net
RESNA Member, APTA Member

Task Force Members

Michael Babinec, OTR/L, ABDA, ATP
The Invacare Corp.
Elyria, Ohio
mbabinec@invacare.com
RESNA Member, AOTA Member

Adrienne F Bergen PT, ATP/S
Consultant
Delray Beach, FL
adriennebergen@aol.com
RESNA Member, Friend of NRRTS

Kendra Betz, PT
APTA Member

Susan Christie, PT, ATP
Supervisor, Assistive Technology Center
Bryn Mawr Rehab Hospital
Malvern, PA
christies@MLHS.org

Elizabeth Cole, MSPT
Director of Education, Sunrise Medical
Longmont, CO
Elizabeth.cole@sunmed.com
RESNA, Friend of NRRTS

Kimberly A. Davis, MSPT, ATP
Clinical Research Scientist
Crawford Research Institute
Shepherd Center
Atlanta, Georgia
RESNA Member

Gerry Dickerson, ATS, CRTS
Director of Rehabilitation Technology
MedStar, Inc.
College Point, NY
gdcrts@aol.com
RESNA Member, NRRTS Member, NCART

Carmen DiGiovine, PhD
Assistive Technology Unit, UIC
Chicago, IL
cpdigiov@uic.edu

Linda-Jeanne Elsaesser PT, ATP
Consultant
Elsaesser Consulting, Inc.
Saylorsburg, PA 18353
elsaesser@enter.net
RESNA Member

Jan Furumasu PT ATP
Physical Therapy Instructor
Rancho Los Amigos National Rehabilitation Center
Downey CA
jfurumasu@ladhs.org
RESNA Member

David Kreutz, PT, ATP
Shepherd Center
Atlanta, GA
David_Kreutz@shepherd.org
APTA Member, RESNA Member

Ziggi Landsman
Director of Assistive Technology
United Spinal Association
New York, NY
zlandsman@unitedspinal.org

Barbara Levy, PT, ATP
Supervisor Seating and Mobility Clinic
CarePartners/Thoms Rehabilitation Hospital
Asheville, NC
BLevy@CarePartners.org
APTA Member, APTA Liaison, RESNA Member, Friend of NRRTS

Dan Lipka, M. Ed., OTR/L, ATS
President, NRRTS
Miller's Assistive Technologies
Akron, OH
ddl@millers.com
RESNA Member, NRRTS Member, AOTA Member, NCART Member

Eva K. Ma OTR, ATP, ABDA
Consultant
Portland, OR
EvaMa@aol.com
AOTA member, NDTA, RESNA member, Friend of NRRTS

Simon Margolis, CO, ATS, ATP
VP for Clinical and Professional Development
National Seating and Mobility, Inc
Plymouth, MN
smargolis@nsm-seating.com
RESNA Member, NRRTS Member, NCART Member

Chris Maurer, PT, ATP
Shepherd Center
Atlanta, GA
Chris_Maurer@shepherd.org
APTA Member

Jean Minkel, PT
Minkel Consulting
New York
jminkel@aol.com
APTA Member, RESNA Liaison

Jill Monger PT, MHS, ATP
Assistant Professor, MUSC Seating Clinic Director
Medical University of South Carolina
Mt. Pleasant, SC
carterjm@musc.edu
APTA Member, RESNA Member

Jessica Pedersen MBA, OTR/L, ATP
Administrative Director Specialized Therapy Services
Rehabilitation Institute of Chicago
Chicago, IL
jpedersen@ric.org
AOTA Member, RESNA Member

Tina Roesler MSPT
Director of Training and Education
The ROHO Group
Belleville, IL
Tinar@therohogroup.com
RESNA Member, APTA Member

Mark R. Schmeler, PhD, OTR/L, ATP
Director, Center for Assistive Technology
University of Pittsburgh Medical Center
Pittsburgh, PA
schmelermr@upmc.edu
AOTA Member, RESNA Member

Mary Shea, MA, OTR/L, ATP
Clinical Manager, Wheelchair Clinic
Kessler Institute for Rehabilitation
West Orange, NJ
mshea@kessler-rehab.com
RESNA Member, AOTA Member, NYSOTA Member

Jill Sparacio, OTR/L, ATP, ABDA
Sparacio Consulting Services and Misericordia Homes
Downers Grove, IL
Otspar@aol.com
AOTA Member

Pam Stockman, OTR/L
University of Washington Medical Center
stockman@u.washington.edu

David Wysocki, MS, OTR/L, ATP
AOTA Member, RESNA Member

5

Braxton, Shawn L. (CMS/OSORA)

From: James Bond [james.bond@alicks.com]
Sent: Wednesday, November 23, 2005 7:45 PM
To: Braxton, Shawn L. (CMS/OSORA)
Subject: New rules

My name is James Bond and I am a Rehab Technology Specialist for Alick's Home Medical Equipment.
I would ask that you would re think the new rules and regulations on power wheelchairs and scooters.
The 30 day time frame is too short, the new codes are too many. The fact that we as a supplier are put at risk of $5000 or more is not fair. We would ask that a review be done for a fee and let us know yes or no so that no body is at risk.
I am a proud member of NRRTS and would ask to have them work closely with us that we as a high end provider of Rehab products don't get over looked. Our web site is http://www.nrrts.org/ and I would like to thank you ahead of time for your help.
James C Bond RTS

The Power Mobility Coalition
WORKING TOGETHER FOR FREEDOM AND INDEPENDENCE

November 25, 2005

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS Interim Final Rule on Conditions for Payment of Mobility Devices, CMS-3017-IFC

Dear Dr. McClellan:

On behalf of the Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized wheelchairs and power operated vehicles (POVs), we are submitting comments regarding the interim final rule (IFR) on conditions for payment of mobility devices (CMS-3017-IFC). On August 25th, the Centers for Medicare and Medicaid Services (CMS) issued the IFR that makes comprehensive changes to the Medicare PMD benefit. While the PMC is supportive of various aspects of the new interim final rule, including the face-to-face requirement and elimination of the specialist requirement in order to qualify for a power operated vehicle (POV), the interim final rule fails to meet many crucial reform criteria in several respects. Some of the PMC concerns with the interim final rule are as follows:

1. CMS Lacks the Authority to Eliminate the Certificate of Medical Necessity (CMN) and Replace It with A More Burdensome Recordkeeping Requirement

Contrary to the plain language of the Social Security Act (SSA), the interim final rule would eliminate the CMN and the authority provided to suppliers by Congress to distribute such CMN to physicians and beneficiaries. The PMC questions whether CMS has such authority absent Congressional approval.

As part of the SSA, Congress defined the CMN as a "form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member." The PMC asserts that the Congressionally mandated, Office of Management and Budget (OMB) approved CMN was established for the exact purpose described in the interim final rule - to document the medical need of the patient based on the treating physician's evaluation of such patient.

Furthermore, the Federal court system has upheld the CMN as the Medicare document of record that determines eligibility for a PMD. In *Maximum Comfort, Inc. v. Thompson*, 323 F. Supp. 2d 1060 (E.D. Cal. 2004) the Court wrote:

> the plain language of [42 U.S.C.] § 1395m(j)(A)(2)(i) supports the plaintiff's position that it may only use a CMN to provide the necessary information for the determination of medical necessity and reasonableness. The Secretary cannot require that DME suppliers, such as plaintiff, obtain Medicare beneficiaries' medical records and make a judgment as to whether the equipment is medically

> necessary and reasonable. It is clear from the plain text of the Medicare Act that, while Congress granted the Secretary broad discretion over medical necessity and billing criteria and procedures, it did not do the same regarding medical necessity documentation. Instead, Congress addressed that issue itself and established that any and all information required from suppliers to make a medical necessity determination must be contained in a CMN.

Id. at 1074-75.

In the interim rule, CMS acknowledges that the CMN was previously established to allow efficient adjudication of claims by automating the submission of certain information needed to make medical necessity determinations." 70 Fed. Reg. 50944. Yet, CMS determined that an OIG analysis of the CMN "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."

Medical record content has ***NEVER*** been the standard by which Medicare coverage is determined. As an example, CMS proposed to amend 42 C.F.R. § 410.38 to require that physicians document in their medical records the need for the prosthetic, orthotic, durable medical equipment, and/or supplies ("DMEPOS") being ordered.[1] CMS acknowledged in their proposed rule that the physician documentation of medical need for DMEPOS constitutes a "collection of information" and is subject to approval from OMB per the PRA. Although CMS and OMB sought comments from Medicare stakeholders, including physicians and clinicians, CMS ***NEVER*** finalized this proposal and OMB ***NEVER*** approved this proposed collection of information. It is unrealistic to suggest physicians will somehow document in their medical records according to a standard that has not existed previously.

Lastly, CMS Administrator McClellan has testified that the CMN reflects the physician's determination of medical necessity and upheld the role of the CMN in the PMD claims process. As Dr. McClellan told the Senate Finance Committee:

> The clinical criteria for deciding when a manual or power wheelchair is medically necessary and appropriate for a beneficiary has been and will continue to be a matter of clinical judgment by the physician. It's also my understanding that CMS does not want to list specific condition-based criteria since the decision to determine the appropriateness of providing a manual or power wheelchair is best left to the physician's judgment. However, this does not abdicate the responsibility to have appropriate documentation as to the medical necessity of the claim. As a condition of coverage, CMS does require that the beneficiary's need for a wheelchair or power wheelchair is supportable. In fact, all claims for power wheelchairs must include a Certificate of Medical Necessity (CMN) which 'certifies the need for the device and that it is reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body part.'"

[1] 68 Fed. Reg. 17125, 17130

2. Clarity and Consistency is Necessary as it Applies to the Physician Documentation Requirements Set Out in the Interim Final Rule

Burdens placed on suppliers and physicians will greatly increase under the interim final rule. Suppliers, for the first time, will be required to obtain and maintain an ill defined set of medical records and physicians will be required to prepare, maintain, and provide such medical records to suppliers on 100% of all PMD claims. In addition to collecting and submitting medical records to suppliers, the interim final rule places a whole new recordkeeping requirement on physicians by requiring that each physician document medical need (according to ill defined Medicare guidelines) in their medical records. All of these new collections of information, including the new recordkeeping requirement, must be subject to PRA protections.

The PMC fully supports the requirement that a beneficiary have a "face-to-face" exam prior to a physician prescribing a PMD. This process enables beneficiaries, their physicians and caregivers to express an interest in the beneficiary's need for the PMD, the physician to perform the examination, and the physician to write a detailed written order and evaluation for the PMD. By eliminating the CMN and basing PMD eligibility on unspecified documentation, the interim final rule erodes the doctor's role as gatekeeper and puts suppliers and bureaucrats in the position of routinely overruling their medical judgment, creating even more uncertainty for both beneficiaries and suppliers. This is not consistent with the intent of Congress to emphasize the role of the treating physician in making medical necessity determinations.

The following are questions that remain unanswered due to the lack of clarity created by CMS' interim final rule and the proposed new collection of information:

First, when the physician provides the prescription and the face-to-face examination report, both extensive documents addressing medical necessity, who decides whether additional documentation is needed?

Second, the new process requires that a doctor or treating practitioner:

- evaluate the beneficiary in the last 30 days to analyze mobility needs;
- document that the patient was evaluated for that purpose;
- conduct and document a face-to-face evaluation;
- write a seven-element prescription; and
- acknowledge consideration of the mobility algorithm.

Can a supplier reasonably rely on the physician's documentation developed during the face to face visit?

Third, the supplier must obtain a seven-element prescription, as well as a documented face-to-face examination report. If the supplier agrees with the treating practitioner that the documentation provided is adequate, and subsequently a DMERC reviewer decides differently, will the supplier be held liable for the claim? Under what circumstance is a supplier protected by the waiver of liability provision established by Congress in Section 1879 of the Social Security Act.

The arbitrary and subjective nature of the collections of additional documentation contained in this interim final rule threaten the ability of our members to provide prescribed equipment to beneficiaries who rely on this equipment to perform their activities of daily living. The interim final rule would force the supplier to guess as to the veracity of the medical records and provide CMS and its DMERCs with carte blanche authority to overrule the prescription of the treating physician.

3. Estimation of the New Paperwork Burden on Physicians and Suppliers Contained in the Interim Final Rule is Unrealistic

CMS, in its interim final rule, estimates that the time for a physician to prepare, collect and submit medical records combined with the time it will take a supplier to collect, review and maintain such records will total 10 minutes contrasted with 12 minutes for filling out a CMN. It is wholly unrealistic to assume that a physician will prepare, maintain, collect and submit medical records to a supplier and such supplier will then maintain and review these records in 10 minutes. CMS has not provided any supporting documentation to support their burden estimate but we would request that the agency do so and allow the public to comment on the specific calculations prior to the rule being finalized.

a. Physician Requirements:

Prescription – Physicians are required, under this new regulation, to create a prescription with several specific components, all of which are currently included in the Certificate of Medical Necessity form. Without a form or format, the new prescription will create a larger burden on physicians as they attempt to document free-hand all of the components contained in this rule.

Chart Notes and Evaluations - Physicians are required, under this new regulation, to prepare, maintain and provide a record of the face to face examination of the beneficiary for the power mobility device. According to the preamble of the interim final rule, "the parts of the medical record selected [by the physicians] 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...."[2] Physicians do not currently nor have they in the past charted according to these standards and thus the new burden placed on them will be substantial. Further, there is no established mechanism to determine if the physician's medical records comply with these requirements. CMS must consider these requirements in their burden estimate.

Additional Medical Records – Physicians are also required, under this new regulation, to collect, copy, redact, and send any other pertinent medical records or test results, which will substantiate the previous prescription and face to face examination documentation.

All requirements are applicable to 100% of all PMD prescriptions, which is not current practice and will thus place new and substantial burdens on our nation's physicians. This burden must be calculated by CMS and not summarily dismissed as current medical practice. Current medical practice is for physicians to consider their patient's condition and complete a Certificate of Medical Necessity to prescribe, document, and establish the need for PMDs.

---

[2] 70 Fed. Reg. 70042

b. Supplier Requirements:

The supplier must collect both the prescription and additional information from the patient's medical record on 100% of its claims. Not only has CMS underestimated the burden associated with this requirement, CMS has also overlooked the cost required to maintain these massive amounts of records for 7 years. Further, suppliers will be now be placed in the role of evaluating medical information contained in the physician's written charts to determine if the prescription should be filled -- a role never contemplated by the Medicare program.

The most common request for "additional documentation" is for copies of chart notes. To underscore the burden associated with the collection of this information, one of our members collected "additional documentation" in 1999 primarily consisting of chart notes for 283 claims. The total project required 1334 man-hours, or 4.71 hours per claim.

4. The Interim Final Rule Will Increase the Administrative and Educational Burdens on Physicians

It is unrealistic to think that CMS will be able to conduct sufficient outreach to adequate educate physicians about the confusing new algorithmic functional ambulation standard, not to mention the 63 new product codes that physicians are expected to knowing differentiate so that they can adequately place an eligible beneficiary in the proper PMD. Failure of physicians to sufficiently understand the new coverage policy and product codes will most likely have lead to physicians writing fewer prescriptions for PMDs, thereby ignoring real need, or failing to properly document need, leading to inappropriate denials.

5. Contractors and Suppliers Need More Time to Implement Changes to the Medicare PMD Benefit

Medicare contractors have indicated that they need until April 1, 2006 to update their systems to accept the new information required under this rule. Without a delay or until such time as the claims process systems are updated, suppliers will have to collect the documentation required by the new regulations as well as the CMN in order for their claims to be processed.

6. Issuance of an Interim Final Rule Violates the Administrative Procedures Act (APA)

CMS has issued the changes to the Medicare PMD benefit in the form of an interim final rule, in effect, allowing the rule to go into effect without proper notice and comment periods as required by the Administrative Procedures Act (APA). While CMS did issue a proposed rule for the face-to-face examination requirement in August 2004, that proposal was never implemented. This interim final rule differs significantly from the proposed rule, adding new documentation requirements on both suppliers and physicians, and eliminating the CMN --- all new aspects to the face-to-face requirement that never appeared in the original proposed rule. As a result of these significant changes, the PMC contends that the interim final rule on the face-to-face examination requirement was issued by CMS in absence of proper notice and comment and, therefore, violates the APA. The PMC sought a preliminary injunction in Federal court concerning the violations of due process associated with the development of the IFR. We attach our filing to demonstrate our legal concerns with such rule.

7. RECOMMENDATION: CMS Should Revise the CMN to Reflect the Functional Ambulation Standard in the New National Coverage Determination

The PMC recommends that any documentation requirement be incorporated into a revised CMN that includes the eligibility criteria and algorithmic process established in the NCD for PMDs issued May 5, 2005. The CMN was defined by Congress, developed by CMS, and approved by the O MB t o e stablish m edical ne ed a nd t hus t o de termine e ligibility f or t he p ower m obility benefit. The treating physician completes the CMN and is in the best position to assess patient need and certify that the beneficiary meets the functional ambulation standard. Suppliers who submit the physician signed and completed revised CMN to the Medicare program should have a clear and unequivocal expectation that, if not fraudulent, such documentation establishes medical necessity.

At a minimum, suppliers should be able to rely on the documentation developed by the treating physician during the congressionally mandated face to face visit.

The PMC thanks you for the opportunity to submit comments and looks forward to working with OMB, CMS, and all stakeholders on these important issues.

Sincerely,

Stephen M. Azia
PMC Counsel

Eric W. Sokol
PMC Director

ABP
ministration

P.O. Box 82060, Rochester, MI 48308, 1-800-831-0999

November 9, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3017-IFC
P.O. Box 8013
Baltimore, MD 21244-1850

To Whom It May Concern:

ABP Administration (ABP) is contracted to perform third party administration for DME/P&O across the nation for over 2 million members. The programs administered by ABP include Medicare Advantage Plans or Insurance Plans that utilize CMS medical policy.

ABP supports the recent amendment to the HHS spending bill introduced by Senator Arlen Specter which calls for a delay in implementation of the new Interim Final Rule for Power Mobility Devices. As Specter, his junior colleague from Pennsylvania Senator Rick Santorum and Senate Finance Chairman Charles Grassley wrote to CMS Administrator Marc McClellan, "The absence of a reasonable period for advance preparation to the change in rules may overwhelm PMD providers and manufacturers striving to comply and remain commercially viable."

The following is a list of concerns that ABP has regarding the new PMD's codes and coverage criteria:

- ABP requests CMS reconsider the elimination of the CMN. Rather, we would suggest that CMS develop a clear and specific CMN that if completed correctly by a physician would justify the need for the prescribed PMD. This CMN should require that the physician attest to the accuracy of the information provided and the need for the equipment prescribed. Thus, the PMD provider would not have to make a subjective determination of the patient's qualification under CMS guidelines or what additional information from the physician may be required for the PMD prescribed.

- Without a clear definition of CMS policy, some PMD provider's will not accept assignment of the claim which will result in placing the burden of payment on the beneficiary who may or may not get reimbursed.

- If CMS does decide that it will not revise the CMN, then CMS and the regional DMERC's need to agree on very specific and regionally consistent documentation that must be supplied and attested to by the prescribing physician. An example of this would be a detailed functional mobility evaluation that covers all items noted in the MAE Coverage Algorithm recently sent to PMD providers. Again, it should be the responsibility of CMS to determine what documentation is required rather than leaving it to the subjective determination of various PMD providers.

- One of the coverage requirements for power wheelchairs with Specific Use, High Activity Specific Use, Specialized Use or High Activity Specialized Use (e.g. power base with power tilt) that a face to face comprehensive evaluation must be conducted by a RESNA certified ATP. Currently in southeast Michigan there are only two ATP's that are not affiliated with a PMD provider. Therefore, this would result in significant delays in providing such equipment to those that need it.

- While the massive proposed changes in coding have been delayed. It is our sincere hope that when these are implemented that full and complete information regarding required documentation and allowable amounts will be provided at least 90 days prior to the implementation date. This will give ABP and PMD providers the opportunity to make procedural and system changes necessary to comply with the new codes and requirements.

It is very important that the documentation requirements qualifying a patient for a PMD come at the direction of CMS rather than leaving it up to ABP who is not in a position to make subjective determination on claim payment in our attempt to follow CMS guidelines.

Sincerely,

Debbie Pincura

Debbie Pincura
Director of Network Administration

Cc: A.J. Filippis, President

Edward B. Healton, MD, MPH
Senior Vice President, Medical Affairs

National
Rehabilitation
Hospital

NRH

Adding life to years®

The NRH Medical
Rehabilitation Network

November 2, 2005

Mark B. McClellan, MD, PhD,
Administrator, Centers for Medicare
& Medicaid Services, Department of Health
And Human Services,
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-3017-IFC

Dear McClellan, MD, PhD:

I am writing to comment on the Interim Final Rule on the Conditions for Payment of Power Mobility Devices.

As a physician actively practicing in rehabilitation medicine, I always rely on the skills of physical therapists and occupational therapists in assessing patients for power mobility devices. Physical therapists and occupational therapists are the key specialists in the assessment of patients' mobility related activities of daily living. Physical and occupational therapists understand patient diagnoses, impairments, and functional limitations, as well as the technical domain of seating and mobility equipment, including power mobility devices.

Physical and occupational therapists currently practicing in the area of seating and mobility have amassed considerable expertise and are extremely dedicated to making sure that beneficiaries receive the equipment that will meet their needs. I always seek the recommendations of physical therapists and occupational therapists to ensure that patients receive the power mobility device that will be most safe and effective to meet their needs for mobility, activities of daily living, postural support, pressure relief and prevention of skin breakdown. Without the input of physical and occupational therapists, the potential for negative consequences to the patient, as a result of receiving inappropriate equipment, would be greatly increased.

Thank you for your serious consideration of these comments.

Sincerely,

Edward B. Healton, MD MPH

MedStar Health
102 Irving Street, NW, Washington, DC, 20010-2949
phone: 202 877 1140 • *fax*: 202 829 8437 • *tdd*: 202 877 1450 • *internet*: www.nrhrehab.org

AOTA® The American Occupational Therapy Association, Inc.

Occupational Therapy: Skills for the Job of Living

Via overnight mail

October 22, 2005

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3017-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Program; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles; Interim Final Rule with Comment

Dear Doctor McClellan:

The American Occupational Therapy Association (AOTA) represents more than 35,000 occupational therapy professionals, many of whom provide services to Medicare beneficiaries. We appreciate the opportunity to comment on the Center for Medicare and Medicaid Services' (CMS') Interim Final Rule regarding Conditions for Payment of Power Mobility Devices (PMDs), including Power Wheelchairs and Power Operated Vehicles dated August 26, 2005 (referred to hereinafter as the "IFR").

I. The Contribution of Occupational Therapy To Beneficiaries Requiring PMDs

Occupational therapy is a health, wellness, and rehabilitation profession working with people experiencing stroke, spinal cord injuries, brain injury, congenital conditions, developmental delay, joint replacements and surgeries, mental illness, and other conditions. It helps people regain, develop, and build skills that are essential for independent functioning, health, and well-being in the home and community. Occupational therapy professionals have unique expertise in evaluating participation and enabling engagement in meaningful occupations. Specifically, occupational therapy evaluations involve a multifaceted evaluation of the individual's physical seating needs, functional abilities, limitations (visual, sensory, motor function, judgment, etc.) and home and community access needs. Occupational therapists are able to effectively evaluate and identify impairments and limitations that need to be addressed to enable safe transfers, weight shifts for pressure relief and skin protection, wheelchair features required to enable maximum function, and access for transfers to toilet, bath and bed. Additionally, once the equipment is delivered, occupational therapists train the individual in how to use the PMD to be safe in their home and in their community. Current Medicare policy covers an evaluation of a beneficiary to determine the need for mobility assistive equipment, including PMDs, as part of the occupational therapy scope of practice.

II. Occupational Therapy Evaluations May Be Substituted For Part Of The Physician Face-To-Face Evaluation Or May Demonstrate Medical Necessity In Addition To The Face-To-Face Evaluation

The IFR sets forth the requirement that physicians must conduct a face-to-face examination of the patient for a PMD, and that the supplier must receive from the treating physician a written order for a PMD within 30 days after the face-to-face examination. However, the IFR fails to clarify the important role that occupational therapists play in the evaluation and treatment process. Often physicians and suppliers consult with occupational therapists to conduct beneficiary PMD evaluations and assessments in the normal course of treatment. This omission ignores the potential for a more appropriate determination of medical necessity if an occupational therapy evaluation is part of the data reviewed.

AOTA appreciates that the Durable Medical Equipment Carriers (DMERCs) have clarified to physicians that it is permissible for them to refer patients to occupational therapists to perform part of the required face-to-face-evaluation. The DMERC letters state, in part:

> ***Therapist referrals:***
> - **You may choose to refer your patient to another qualified medical professional, such as a physical therapist (PT) or occupational therapist (OT), to perform part of this examination.** If so, it is important that this person have no financial relationship with the supplier. (Exception: If the supplier is owned by a hospital, a PT/OT working in the inpatient or outpatient hospital setting may perform part of the face-to-face examination.)
> - Once you have received and reviewed the PT/OT's written report, you must see the patient (if you did not do so prior to referral) and perform any additional examination that you deem necessary.
> - The report of your visit should state your concurrence or any disagreement with the PT/OT examination. If you saw the patient to begin the face-to-face examination prior to referral to the PT/OT, you should note agreement, sign, and date their report but are not required to see the patient again.
>
> See, for example, http://www.tricenturion.com/content/Doc_View.cfm?type=wn&File=pmd%20physician%20letter%2Edoc

However, it is imperative that CMS' regulations clearly state this policy as well. Policy guidance in the form of Dear Physician letters are not legally binding, rather they are only interpretive guidance from the DMERCs. Also, busy physicians, suppliers and therapists need to have important policy information that applies nationwide in one easy to access location. It is not reasonable to expect that practitioners and suppliers will look beyond the Final Rule for nationwide policy directives, or that they will drill down to the level of a Dear Physician letter.

It is important for CMS to provide physicians and suppliers with explicit direction that the occupational therapy evaluation may substitute for part of the physician's face-to-face evaluation. For those physicians who conduct the entire face-to-face evaluation, it is imperative to inform them that they also might find it important to have an occupational therapy evaluation, and that such evaluation would be

considered documentation supporting medical necessity. Finally, the mechanism for reporting the occupational therapy evaluation of the beneficiary's PMD needs should be clearly stated in the Final Rule. Occupational therapists may properly bill these evaluations through the revised CPT 97542 *wheelchair management (eg, assessment, fitting, training) each 15 minutes.*

CMS should include in the body of the Final Rule the specific role of occupational therapists in the treatment and evaluation process by explicitly recognizing the team approach that may be involved with evaluating beneficiaries for PMDs, and the participation of therapists in that team approach. Including language about the role of occupational therapists in the Final Rule is critical to ensure appropriate, cost-efficient issuance of PMD.

For all these reasons, AOTA strongly urges CMS to explicitly state in the Final Rule that an occupational therapy evaluation of the beneficiary for a PMD is a covered service, reportable separately through CPT code 97542. Further, it is essential that CMS clearly states that the occupational therapy evaluation of the beneficiary's need for a PMD will be considered evidence in the medical record of medical necessity in addition to or as part of the physician's face-to-face evaluation.

III. Prior Occupational Therapy Interventions Support Medical Necessity of PMDs

CMS should consider evidence in the medical record of previous rehabilitation services, including occupational therapy, as contributing to the demonstration of medical necessity for the PMD. Whether a beneficiary previously received such services focused on maximizing function is relevant to whether a PMD is required. Within the PMD user population, there should be few circumstances where attempts for the beneficiary to make gains in their participation and engagement in meaningful occupations (activities of daily living and instrumental activities of daily living) did not include rehabilitation evaluation and treatment by a therapist, including occupational therapy practitioners. *AOTA recommends that CMS consider evidence in the medical record of previous rehabilitation services, including occupational therapy, as contributing to the demonstration of medical necessity for PMDs.*

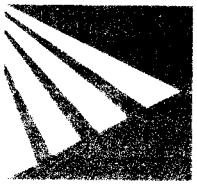
IV. Important of Issuing a Final Rule that Considers Public Comments

The timing of the implementation of the IFR prior to the end of the comment period remains problematic. Although on the surface, it would appear that an IFR setting forth the statutory requirement of a face-to-face evaluation and abolishing the certificate of medical necessity is straightforward, in fact the IFR contains a number of critical details that require policy clarification prior to implementation. If it is not too late, CMS should that it postpone the implementation of the IFR until it can consider all the public comments. In addition, CMS should publish a final rule that considers public comments and makes revisions accordingly. *AOTA urges CMS to make revisions to the IFR that are reflective of public comments, and to publish those policy changes in a Final Rule.*

AOTA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on this Interim Final Rule. We look forward to a continuing dialogue with CMS on these issues as they apply to occupational therapy.

Sincerely,

Leslie Stein Lloyd, Esq.
Director
Reimbursement and Regulatory Policy Department



RAMP

Restore Access to Mobility Partnership

November 22, 2005 – VIA OVERNIGHT DELIVERY

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. McClellan:

Re: CMS Interim Final Rule on Conditions for Payment of Power Mobility Devices, CMS-3017-IFC

Introduction

The Restore Access to Mobility Partnership (RAMP) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Interim Final Rule on Conditions for Payment of Mobility Devices, issued August 26, 2005 ("The Rule"). RAMP, a coalition representing power wheelchair providers and manufacturers, is committed to ensuring that Medicare beneficiaries with medical need have access to appropriate mobility products, including power mobility devices (PMDs).

Summary of Comments

The Rule requires physicians to write a prescription for a power mobility device (PMD), to document in the medical record the results of a "face-to-face examination", and provide those two documents, along with "other supporting medical documentation", to the Medicare Part B supplier within 30 days of the date of the face-to-face exam. CMS defines the seven criteria physicians must include in the written prescription to meet Medicare requirements.[1]

RAMP fully supports the requirement that a beneficiary have a "face-to-face" exam prior to a physician prescribing a PMD. This process enables beneficiaries, their physicians and caregivers to express an interest in the beneficiary's need for the PMD, the physician to perform the examination, and the physician to write a detailed written order and evaluation for the PMD. These documents, along with any other clinician evaluation, will provide the best information for CMS to make a medical need

[1] 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. See Interim Final Rule, 42 CFR 410.38(c).

determination. We question the value and need for any additional document for CMS to ensure medical need is met. We request that CMS respond, in its response to comments, how historical notes and medical records would be more valuable than the written order and documentation of the face-to-face examination. RAMP does not believe that CMS' approach that requires physicians to provide suppliers with documentation of medical need directly from progress notes will address CMS' stated objective of ensuring the existence of adequate documentation to substantiate medical need, nor will it address CMS' objective of addressing fraud and abuse.

While the requirements for the written prescription are specific and defined, the requirements for the supporting medical documentation are wholly undefined in the Rule. CMS summarily explains in the preamble that the "physician or treating practitioner prepare pertinent parts of the medical record for submission to the DME supplier." The regulation states that the prescribing physician is to provide "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..."

There is simply insufficient information in this IFR for physicians to understand the scope of documentation that CMS is expecting physicians to provide. While some clarification of the scope, breadth and detail of the required physician documentation is contained in separate documents issued in piecemeal fashion by CMS and the Durable Medical Equipment Regional Carriers (DMERCs), CMS has not conducted the education campaign that is necessary for prescribing physicians to understand their new documentation responsibilities. To that end, RAMP strongly recommends that CMS provide physicians with a standard set of questions that CMS expects physicians to address, to ensure appropriate documentation of medical need.

1. Prescribing Physicians Need CMS to Provide Detailed Education Regarding Coverage Criteria and Documentation Responsibilities

RAMP does not believe that the documentation format and process CMS has proposed is the most effective way to collect information that will fully substantiate need for a power mobility device. As currently drafted, the rule does not provide sufficient information to the physician community to be able to understand exactly the format and content of the documentation CMS is seeking. Therefore, the documentation requirement will be of little use to CMS and its contractors in the event of an audit, for purposes of determining medical need.

CMS still needs to conduct extensive educational efforts - through newsletters (through state and national professional societies), through the Web, and in-person education programs where physicians and their office managers can have a meaningful opportunity to understand the scope and depth of the information CMS is expecting physicians to document and provide to suppliers. RAMP strongly believes that CMS has not sufficiently educated physicians and their representatives, even at this late date beyond the October 25, 2005, effective date. For this reason, RAMP strongly urges CMS to incorporate public comments, revise the regulation with significantly more detailed information directed at physicians, issue the Rule in final form at a later date and find mechanisms for broad physician exposure.

Based upon the experience of many suppliers represented by RAMP, we have found that physicians simply do not maintain medical records in the format, and to the level of detailed information that CMS expects. This is due to two reasons: First, physicians do not typically

document the way that CMS anticipates. They typically document the presenting or chief complaint with single word notations of observations or patient reports. Therefore, CMS must provide some standard series of questions/issues that CMS expects physicians to address in the medical records. Second, CMS has provided physicians with virtually no education to enable physicians to understand the scope and depth of information that CMS expects.

If CMS does not provide concrete and explicit guidance as to what information physicians must provide, then RAMP believes that it is incumbent upon CMS to demonstrate that it would be common practice for physicians to chart in a way that is likely to lead to the provision of information necessary to establish medical necessity. Phrased differently, if CMS is choosing to implement a documentation instrument that is unlikely to provide determinative information on a routine basis, it should not be allowed to impose this quite burdensome documentation requirement. We note that CMS also makes the unfounded assertion that the documentation requirement is not burdensome, but rather an additional gathering and sending of existing information. At this juncture, RAMP does not believe that CMS has adequate empirical basis to support its current documentation requirements.

Therefore, RAMP recommends that CMS modify the rule, or provide implementing instructions, to resolve these problems by issuing a series of questions or inquiries, in a standard format (not a standard form). This series of questions would significantly help physicians to understand the scope and specific detailed information CMS is expecting physicians to document. These questions would identify what issues that CMS expects physicians to address in the medical records to substantiate medical need. For example, the questions could be listed in the rule or other CMS issuance, as the types of issues that CMS expects physicians to be addressing in the medical record. These questions could be substantially similar to those issued in the DMERC draft LCD issued September 14, 2005 (rendered moot by CMS' subsequent retraction of the PMD HCPCS codes issued September 14), which reads as follows:

"The report of the face-to-face examination that is required for all patients receiving a POV or power wheelchair (PWC) (see related Policy Article) should provide information relating to the following questions."

POV/PWC	What is this patient's mobility limitation and how does it interfere with the performance of activities of daily living?
POV/PWC	Why can't a cane or walker meet this patient's mobility needs in the home?
POV/PWC	Why can't a manual wheelchair meet this patient's mobility needs in the home?
POV	Does this patient have the physical and mental abilities to transfer into a POV and to operate it safely in the home?
PWC	Why can't a POV (scooter) meet this patient's mobility needs in the home?
PWC	Does this patient have the physical and mental abilities to operate a power wheelchair safely in the home?

We also recommend that CMS provide physicians with specific documentation guidance, building upon information the DMERCs issued in those same draft LCDs issued September 14, 2005. For example, in the September 14, 2005 draft LCD for PMDs, the DMERCs identified the following areas the physician may include. To be more helpful, these issues, bulleted below, should be rephrased as specific questions, guiding the physician to provide information related to the medical need for the PMD. For example, the first issue, "Symptoms", could be generated into a question such as "What symptoms does the beneficiary have the related to his/her need for a PMD?" A similar question should be provided for each of the items bulleted below:

- The report should provide pertinent information about the following elements, but may include other details. Each element would not have to be addressed in every evaluation.
    - Symptoms
    - Related diagnoses
    - History
        - How long the condition has been present
        - Clinical progression
        - Interventions that have been tried and the results
        - Past use of walker, manual wheelchair, POV, or power wheelchair[2] and the results
    - Physical exam
        - Weight
        - Impairment of strength, range of motion, sensation, or coordination of arms and legs
        - Presence of abnormal tone or deformity of arms, legs, or trunk
        - Neck, trunk, and pelvic posture and flexibility
        - Sitting and standing balance
    - Functional assessment - any problems with performing the following activities including the need to use a cane, walker, or the assistance of another person
        - Transferring between a bed, chair, and PMD
        - Walking around their home - to bathroom, kitchen, living room, etc. - provide information on distance walked, speed, and balance

---

2. <u>This Rule Will Significantly Increase the Likelihood that Suppliers Will Be Denied Payment Through No Fault of Their Own, Or Beneficiaries will be denied Access</u>

In the IFR, CMS states that "These changes, plus the changes made by MMA [Medicare Modernization Act] 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 [National coverage Determination]." CMS continues, that this rule would "also greatly reduce the risk that a supplier will be denied payment through no fault of its own."

There is nothing presented in this rule that does either of these things. Replacement of the certificate of medical necessity (CMN) with this "prescription" and "supporting documentation" provides suppliers with significantly less certainty of meeting the regulation, not more. This also increases risks to suppliers of denial of payment. The CMN, in spite of all of its limitations, at least provided very apparent evidence to a supplier of physician decision regarding a beneficiary's qualification. The provision of unspecified and unclear "supporting documentation" is far more difficult for suppliers to assess. Making the assessment of the quality of medical necessity for a particular beneficiary is clearly and solely within the purview

---

[2] This series of detailed concerns should reflect a specific response to why non-power mobility is no longer appropriate for the patient where the physician is prescribing a PMD.

of the physician's judgment; it should not be a "decision" a supplier has to make. The result will be that suppliers will have insufficient documentation from physicians, and will have two options. Either (1) the supplier will not be able to provide medically needed PMD to beneficiaries because the physician has not provided sufficient documentation in the supplier's opinion (not the physician's); or (2) the supplier will provide medically necessary PMD, but will have a significantly increased risk of having payment recouped in the event of an audit, even though the physician's intent was clear. Neither of these outcomes is acceptable.

CMS states in its IFR that 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." RAMP strongly believes that this statement is wholly unfounded. As described in the Rule, the "quality" of the documentation and the actual medical necessity may be reviewed on a far more subjective basis by the DMERCs due to the failure of the Rule to specifically describe the documentation requirements. This is likely to lead to a greater number of denials, rather than fewer. The main effect of this rule on suppliers is that suppliers will be unable to obtain sufficient documentation and therefore unable to supply equipment to beneficiaries who have real medical need, or suppliers will make their best guess at determining if they have collected adequate subjective documentation from the physician and risk extrapolations and penalties from CMS through the course of medical review audits.

3. Inconsistencies Between the IFR and DMERC Local Coverage Determinations

The IFR and Local Coverage Determinations (LCDs) for PMDs the DMERCs issued the week of October 17, 2005, and currently in effect, contain inconsistencies related to documentation. The IFR states, "In addition to the prescription for the PMD, the physician or treating practitioner must provide to the supplier supporting documentation..." In contrast, 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 about the following elements..." [emphasis added]. These inconsistencies between the IFR and LCD can, again, lead the DMERCs to subjective and differing interpretations of the patient's medical record and could ultimately give the DMERCs the ability to deny any PMD claim in an audit. We, therefore recommend that the DMERCs revise the LCDs to reflect which physicians' new prescribing responsibilities are mandatory and which are recommended elements of the rule.

4. Extension of 30-day Timeframe Is Necessary

The IFR states that the physician must provide the provider with a written prescription and supporting medical documentation within 30-days of the face-to-face examination. This timeframe may not provide adequate time for the process to be completed. Given provider experience, the thirty-day time frame is generally unrealistic as medical practices strain under their patient loads. Under previous policy, providers would routinely need numerous follow-ups with physicians just to obtain a prescription and completed CMN. Generally, acquiring supporting records required even more follow up and time. In order for sufficient time for the physician to provide the prescription and supporting documentation to the Provider, CMS should extend the timeframe in the IFR to sixty (60) days from the date of the "face-to-face" examination.

5. Lack of Detailed Documentation Guidance May Lead to Increased Fraud and Abuse

The IFR will likely increase the opportunity for unscrupulous entities to engage in fraudulent and abusive practices because suppliers are no longer required to submit a physician-signed

- document with a claim for the PMD. While suppliers are required to obtain a written prescription and supporting documentation prior to delivery, this information is not required to be submitted with the claim. We strongly urge CMS to put an appropriate mechanism in place on the front end of the claims system, which will strengthen program integrity efforts and provide beneficiaries and providers with some level of assurance that when a claim is paid, Medicare has approved the claim. This mechanism can take the shape of a standardized series of questions that physicians respond to that would provide medical necessity information. It should include a physician attestation statement indicating that the physician has completed the necessary information to support the prescription, that the physician has included it in the medical record and has provided this information to the provider. This attestation can be submitted electronically with the PMD claim. We are happy to provide some recommendations on a series of physician questions for CMS to review and respond to.

Conclusion

RAMP strongly encourages CMS to seriously consider our recommendations so that the changes and documentation requirements are much more clearly defined and communicated and the new system provides more safeguards against fraud and abuse, not less. We appreciate the opportunity to comment on this Rule. For further information, or if you have any questions, please contact Cara C. Bachenheimer, Invacare's Vice President, Government Relations, at 440-329-6226, or via electronic mail at cbachenheimer@invacare.com.

Sincerely,

Restore Access to Mobility Partnership

RAMP Members include: The American Association of Homecare; Invacare Corporation; The MED Group; Mobility Products Unlimited, LLC; Pride Mobility Products Corp.; and Sunrise Medical.

12

United Spinal Association

Expanding Opportunities for Veterans
and All Paralyzed Americans

Comments Submitted by the

United Spinal Association

On November 25, 2005

To the
Centers for Medicare and Medicaid Services
(CMS)

Regarding the Interim Final Rule With Comment Period Released on August 26, 2005

"Medicare Program; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power Operated Vehicles"

75-20 Astoria Boulevard
Jackson Heights, NY 11370-1177

Tel 718 803 3782
Fax 718 803 0414
www.unitedspinal.org

INTRODUCTION

The United Spinal Association is a national disability advocacy organization dedicated to enhancing the quality of life for individuals with spinal cord injury and spinal cord disease by assuring quality health care, promoting research, and advocating for civil rights and independence. The following comments focus on many provisions in the August 26th Interim Final Rule (IFR) on power mobility devices (PMD). Overall, United Spinal recognizes the value associated with this the face-to-face examination requirement, and in addition, we appreciate the Centers for Medicare and Medicaid Services (CMS) attempt at decreasing provider and supplier reliance on the Certificate of Medical Necessity. However, we are concerned that several provisions in this regulation may threaten access to PMDs for people with disabilities. Generally, we find that the IFR fails to recognize the complexity of the PMD prescription and acquisition process. United Spinal encourages CMS to take into greater consideration the Medicare beneficiaries impacted by this rule who depend on Mobility Assistance Equipment (MAE) to live healthy and independent lives.

Moreover, United Spinal continues to strongly oppose CMS' current interpretation of the "used in the patient's home" language. Although this IFR attempts to improve the prescription and acquisition processes for PMDs, United Spinal feels that by confining any assessment to beneficiary needs only within the home, CMS is restricting itself from making any true improvements to the power wheelchair and scooter benefit. There continues to be no clinical basis for the "in the home" restriction. In addition, by asking treating practitioners to document medical need only within the home setting, CMS is severely restricting patients from receiving the most appropriate devices to meet their mobility needs.

I. BACKGROUND

Specialist's Assessment for POV Prescription

The August 26th IFR states that a specialist is no longer required by Medicare to assess an individual for a power operated vehicle (POV) as previously required by regulation 57 FR 57688. While United Spinal does not oppose this change for the prescription of POVs, we urge CMS to invest in education and outreach to those physicians who have not historically been prescribing POVs for this change to improve access for beneficiaries. Even for those physicians who have been prescribing POVs for many years, the new requirements and regulations issued over the last several months are, at a minimum, overwhelming. United Spinal is concerned that without proper outreach, providers who are unfamiliar with the process will refrain from prescribing POVs to beneficiaries or will do so improperly.

Development of New G Code

United Spinal agrees with CMS' creation of a new G code that recognizes the additional burden associated with the preparation of a written prescription and pertinent parts of the medical record for submission to the supplier in order to establish medical need for the PMD.

As stated in the IFR, CMS finds that in prescribing a mobility device, there is an increased burden on physicians above and beyond the evaluation and management (E&M) code corresponding to the history and physical examination of the patient.

United Spinal is concerned that the proposed G code value of $21.60 will not provide sufficient incentive for physicians to participate in the prescription of PMDs. Under these new requirements, prescriptions will become more complex and time-consuming than under the old rules. United Spinal believes that the PMD assessment/prescription process is much more complex than laid out in this regulation and commonly includes other professionals such as physical therapists and other clinicians. A G code reimbursement of $21.60 not only fails to take into account the additional burden that physicians will face under the new regulation, but completely ignores the important role of clinicians in the assessment process.

Recommendation - If physicians and clinicians are not provided an incentive to participate in the Medicare process established for the prescription of a PMD, United Spinal fears that Medicare beneficiaries with disabilities may have difficulty finding a physician and clinician willing to assess them for these important devices. Therefore, United Spinal urges CMS to create a payment structure that will provide an incentive not only to physicians but also to clinicians involved in this complex and time consuming process.

II. PROVISIONS OF THE INTERIM FINAL RULE

30-Day Face-to-Face Examination Requirement

United Spinal recognizes that the Medicare Modernization Act of 2003 (MMA) requires CMS to implement a face-to-face examination requirement for the prescription of durable medical equipment (DME). We understand the value of this requirement and believe that for the prescription of most devices, this is already standard practice. However, United Spinal is extremely concerned by this regulation's requirement that 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."

United Spinal recognizes the 30-day requirement for the face-to-face examination as unrealistic, and we find that this specific requirement does not take into account the complex process of prescribing a PMD. Again, we are concerned that CMS is not recognizing the integral role of clinicians in the PMD prescription process given that a PMD is rarely provided to an individual who has not first received an intensive clinical assessment by a therapist or clinician.

To obtain an appointment with a physician, attend a session or a series of sessions with a therapist and have complete and accurate medical records to the supplier within a 30 timeframe would seem a difficult task for the average consumer, especially those in more rural settings. However, the individuals to whom this requirement is applicable have severe mobility impairments, are likely dependent on others for transportation, and generally have low incomes

and few resources. Taking these additional factors into account, the 30-day requirement seems simply impracticable.

Recommendation - By mandating this arbitrary and unrealistic timeframe, we believe that CMS is creating a significant barrier to access to PMDs. Therefore, United Spinal urges CMS to extend this time requirement to reflect the complex process associated with the acquisition of a PMD for a Medicare beneficiary. Additionally, United Spinal requests CMS consider a process of prior authorization and approval to ensure that beneficiaries are not denied needed equipment as a result of arbitrary time requirements.

Documentation Requirements

With the removal of the Certificate of Medical Necessity (CMN), CMS is now requiring an extensive amount of readily available documentation from the physician via the supplier in order to establish medical necessity for a PMD. Although this IFR explains by example the type of documentation to be used in the prescription process (patient history, physical examination, diagnostic tests, summary of findings, diagnoses, and treatment plans), it does not provide the level of specificity or clarity that physicians, clinicians and suppliers need as they transition from the CMN. United Spinal is concerned that an increased level of confusion and a subsequent reluctance to participate on the part of the treating practitioners, including the clinicians, and suppliers will create a barrier to access to PMDs for individuals with disabilities.

Additionally, the removal of the CMN and new documentation requirements laid out in this regulation place a new burden of proof on the suppliers. Suppliers are now required to make the final decision as to whether medical necessity has been established by the physician's and clinician's documentation or whether additional information is needed before a PMD can be granted. In the current environment, this is a daunting responsibility for a supplier and creates a disincentive to participate in the Medicare program.

Recommendation - Without clear guidelines and requirements for establishment of medical necessity, we believe that suppliers, especially smaller suppliers or those with less experience in the Medicare program, will be reluctant to provide PMDs to Medicare recipients, thereby reducing access to PMDs for people with disabilities. Therefore, United Spinal urges CMS to develop clear guidelines for documentation requirements.

Assessment Process

In an attempt to illustrate the type of information that might justify medical need, the IFR provides two examples of what CMS considers appropriate and comprehensive evaluations. United Spinal is extremely concerned that in both examples CMS fails to include a clinical evaluation by a therapist, a standard and integral part of the prescription process. United Spinal feels that this omission again illustrates a disconnect between CMS' view of the prescription process for PMDs and what really occurs in the field.

One of the provided examples includes a home visit by the physician to assess the home environment of the patient. United Spinal finds this scenario unrealistic and far from standard practice. Additionally, both examples repeatedly refer to the physicians' knowledge of the recent National Coverage Determination (NCD) for Mobility Assistance Equipment (MAE). We find it very unlikely that the average physician will be familiar with the coverage standards established by the new NCD, especially without a final Local Coverage Determination (LCD) in existence.

Recommendation - Therefore, United Spinal urges CMS to be clearer in its requirements for establishing medical necessity and create a process in which physicians, clinicians, suppliers and, of course, consumers will be well-served. We believe such a system is essential to ensure access to PMDs for people with disabilities.

III. RESPONSE TO COMMENTS

Implementation/Timing

United Spinal vehemently opposes CMS' decision to waive the Notice of Proposed Rule Making and implement the new requirements established by this regulation prior to the end of the comment period.

Over the last several months, stakeholders have been inundated with new regulations and requirements on the prescription, coding, payment, and coverage of wheelchairs and POVs under Medicare. This series of events began with CMS' interest in reducing waste, fraud and abuse in the system while improving access to the most appropriate devices for people with disabilities. United Spinal believes that the new regulations have only served to complicate further the MAE Medicare benefit and, in fact, stands to hinder access to MAE for beneficiaries.

By implementing these new regulations without first considering the input of all stakeholders, United Spinal believes that CMS is missing an important chance to create a truly appropriate and comprehensive prescription process. We believe that the established processes for public comment are not simply formalities but rather opportunities for CMS to learn from experts in the field and the consumers on which such regulations have real-life implications. The changes outlined in the IFR are significant yet underdeveloped, representing a superficial view of the assessment process for PMDs.

Recommendation – United Spinal regrets that CMS did not find it necessary to consider the public comment before implementation of this important rule, and we encourage CMS to revise this rule in proposed form.

CMS-3017-IFC

13

8580 Farley St Apt 609
Overland Park, KS 66212-4626

Saturday, October 8, 2005

The Honorable Dennis Moore
1727 Longworth House Office Building
Washington, DC 20515-1603

Dear Representative Moore,

As an advocate for people with disabilities, I urge Congress to intervene and insist that Health and Human Services (HHS) Secretary Leavitt stop CMS from implementing a series of new Medicare policies that are inconsistent, poorly drafted, and harmful to beneficiaries by severely restricting access and impeding on the health and independence of people with disabilities.

HHS implementation plan for these separate, but related, policies is undefined. As a result of these policy changes:

- Beneficiaries will not have access to power mobility devices that meet their needs.

- Medicare will only provide a wheelchair that is functional in the patient's home. HHS insists it needs new legislation to provide equipment that affords access to the community.

- HHS will erect artificial barriers by requiring unrealistic and undefined documentation rules, making it more difficult for beneficiaries to receive the appropriate mobility device.

- Instead of developing policies that target fraud and abuse by unscrupulous suppliers, HHS would penalize individuals with real mobility limitations.

- HHS announced a new national coverage policy based on functional criteria, which is a step in the right direction. However, the coding, coverage and documentation policies issued since then will prevent anyone from actually benefiting from the changes.

I am most concerned with HHS' commitment to the "in the home" restriction, which prevents beneficiaries from receiving devices they need to move past their front doors. Earlier this year, as HHS revised its wheelchair coverage policy, the agency missed the opportunity to reconsider this restriction and chose to maintain the "in the home" language. It is now clear that Medicare will not cover the

appropriate and necessary wheelchairs that most beneficiaries need to live healthy and independent lives through restricting access.

Again, I ask you to intervene and insist that HHS Secretary Leavitt stop CMS from implementing these Medicare policies until they can draft medically appropriate policies that ensure beneficiary access to the devices they need. Current and proposed policies severely restrict beneficiary access to power wheelchairs and scooters. If these new polices are implemented as written and within this time frame, Medicare beneficiaries will become prisoners in their own home. People with disabilities want to live in their homes, not become prisoners in them.

Sincerely,

Mr. Arthur Butler
8580 Farley St Apt 609
Overland Park, KS 66212-4626

Mobility SolutionS

November 21, 2005

Mark McClellan, M.D., PhD
Administrator
Center for Medicare and Medicaid Services
Attention: CMS-3017-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on the Draft DMEPOS Quality Standards

Dear Dr. McClellan:

Mobility Solutions, Incorporated, a member of the Custom Rehab Network of California (CRN), is pleased to submit comments on the draft DMEPOS quality standards developed by the Centers for Medicare and Medicaid Services. CRN is a network of Rehab Technology Companies throughout California who provide appropriate assistive technology to accommodate the unique medical and functional needs of individuals with complex disabilities. Rehab Technology Companies provide custom manual and power wheelchairs for the most severely affected patients in our population. We support the development and implementation of quality standards and accreditation for DMEPOS providers, but have a number of significant concerns with respect to the structure and content of the draft standards.

Administration

Procurement and Testing of quality DME and Supplies

Rehab Technology Companies should not be required to monitor manufacturers' compliance with FDA requirements. It is the responsibility of the FDA to monitor manufactures and to pass these duties on to suppliers is inappropriate and overly burdensome.

Delivery of Quality services to beneficiaries

Although most suppliers provide access to staff and premises 40 hours per week, we feel that is inappropriate for CMS to require this standard. By clearly posting your hours of operation and relaying any changes or holiday schedules in an appropriate manner should be sufficient to allow patient access to needed services. In addition, Rehab Technology Companies typically do not provide life sustaining equipment and therefore should not be required to have 24 hour/day, 7 day/week emergency service. After hours emergency service should be required if life sustaining equipment is provided but not if a manual wheelchair is provided. A 60 minute response time is also unrealistic and well outside best practice standards.

7895 Convoy Court, Suite 11 • San Diego, CA 92111 • (858) 278-0591 • Fax (858) 278-0490
1001 East Cooley Drive #104 • Colton, CA 92324 • (909) 824-2185 • Fax (909) 824-0958
www.mobility-solutions.com

Financial Management

Financial Management Plan

An annual operating budget according to generally acceptable accounting principals would be cost prohibitive for all small to medium size providers. It is also too prescriptive a requirement to be included in standards that apply nationally. We feel that basic information such as annual operating budget, income statements and balance sheets should suffice in showing the financial viability of a given provider.

Notification of Potential Adverse Financial Operations

As most payments to Rehab Technology Companies comes from third party payors, manufactures and vendors work in partnership with suppliers to adjust to adverse conditions in this arena. To have it a requirement to report these day to day occurrences for Rehab Technology Companies would be impractical and should be eliminated.

Performance Management

We recognize that this section outlines a reasonable way to manage a business but do not believe that this level of detail should be contained in the Medicare Supplier Standards.

Equipment and Safety

Rehab Technology Companies do not employ staff with expertise to perform environmental safety assessments as described in the draft document. These duties are best performed by trained professional such as Occupational Therapist.

Beneficiary Rights and Ethics

Setting up after hours and emergency service for companies that provide custom manual and power wheelchair should not be required as a day to day business practice. This type of service should be required by companies that provide life sustaining equipment such as oxygen or ventilators.

There should also be no implied expectation that all complaints can be resolved. There should be a concerted effort to resolve complaints but not a requirement to resolve ALL complaints.

Appendix A, Supplier Specific Product Requirements

Inspection and Preparation

It is not the responsibility of the Rehab Technology Company to periodically review the patients' medical condition. That is the sole responsibility of the treating physician. It *is* appropriate for the supplier to contact the treating physician to discuss necessary changes in the existing equipment prescription when they become aware of a change in condition that may render the patients' existing equipment inappropriate.

Delivery and Setup

Rehab Technology Companies provide custom wheelchair solutions to varying types of patients. Due to the very nature of these pieces of equipment, it would be impossible for them to provide loaner equipment in all but a fraction of the cases they encounter on a daily basis. Effectively the requirement of a loaner wheelchair will make repairing these custom wheelchairs cost prohibitive and leave the patients without a company to repair their wheelchairs!

Appendix F: Power Wheelchairs & Appendix G: Manual Wheelchairs

The list of requirements here seem to be exhaustive and too prescriptive.

We feel that there should be a requirement for a quality and safety check but not a long checklist of items that may become obsolete as technology changes.

A home assessment should be provided before the wheelchair process is started to determine the appropriate equipment and not at time of delivery as is suggested in the draft.

Instructing the patient on how to program their power wheelchair is not a good idea! This practice is best left to the Rehab Technology Company as their employees have been trained by factory representatives on the safety and appropriateness of the multiple setting required in the programming of a power wheelchair.

Instructing on the general use of manual and power wheelchair is best left to the professionals who have been trained in these areas, physical and occupational therapists. Rehab Technology Companies should be required to show the features of the wheelchair and how that specific wheelchair functions but not be required to instruct the patient on its specific use.

Mobility Solutions, Incorporated, as part of the Custom Rehab Network, appreciates the opportunity to submit these comments. As we have previously stated, we support CMS' efforts to develop standards for DMEPOS suppliers but recommend that CMS modify the draft standards as we have suggested above. Please feel free to contact us should you need us to shed further light on our suggestions.

Sincerely,

Rick Frelke
Corporate Secretary

Martin Helsing
President and CEO

COPY

Rainer Boehm, MD
Senior Vice President &
North American Region Head

Novartis Pharmaceuticals Corporation
180 Park Avenue
105/3W254
Florham Park, NJ 07932

Tel 862-778-6092
Fax 973-781- 3134

15

NOVARTIS
ONCOLOGY

November 23, 2005

Roger L. Williams, M.D.
Executive Vice President and
Chief Executive Officer
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852

Re: Inclusion of new therapeutic category/class for oral iron chelating agents in revised USP Medicare Model Guidelines

Dear Dr. Williams:

On behalf of Novartis Pharmaceuticals Corporation (Novartis), I appreciate this opportunity to communicate to USP our concern that there is neither a category nor class within the existing Model Guidelines for deferasirox (marketed as Exjade®), an oral iron chelating product. Novartis is part of the Novartis Group of Companies, a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. On November 2, 2005, Novartis was granted FDA-approval for deferasirox, a once-daily, oral chelator for the treatment of chronic iron overload due to blood transfusions in patients two years and older. We understand that USP is currently in the process of revising its Model Guidelines to reflect, among other items, the addition of new covered Part D drugs such as deferasirox. We urge that USP, as part of this current initiative, add a category or class for oral iron chelating agents. Failure to include a category or class in the USP for oral iron chelating agents could result in the denial of access to this important new Part D covered drug to Medicare beneficiaries.

As more fully detailed in the background discussion attached as Exhibit A, iron overload is a condition that has significant impact in the Medicare population leading to morbidity and mortality that could be avoided if iron levels were reduced. After receiving as few as 20 units of packed red blood cells (i.e., 10-20 transfusions), a patient may develop excess iron stores. Until recently, the only agent approved in the U.S. to treat transfusion-related iron overload was deferoxamine (marketed by Novartis under the brand name Desferal®), which requires continuous subcutaneous infusion. The newly approved oral iron chelator deferasirox -- the first such agent approved for marketing in the United States -- holds great promise to increase the ease of treatment of transfusion-related iron overload. Deferasirox offers the potential to improve the quality of life of patients with iron overload and, through increased compliance, reduce the complication rate from iron excess.

The omission in the current USP Model Guidelines of a category or class specific for an oral iron chelator is not surprising, given that when these guidelines were developed, there was no oral iron chelator on the market. However, going forward, this omission could result in Medicare beneficiaries being denied access to this important new therapy. Without a defined category or class for oral iron chelators, Medicare Part D plans that use the Model Guidelines as a basis for their formulary design would not be required to offer access to this agent. While CMS has stated that it carefully reviews each formulary beyond the Model Guidelines structure, the availability of an infusion chelation therapy under Medicare Part B could be an excuse used by Part D plans to deny coverage of this (or future) oral iron chelating agents. This would not be a medically sound determination. Infusion therapy is contraindicated in many elderly patients with Myelodysplastic Syndrome or aplastic anemia because of low platelet counts and thin skin.

In order to assure that Medicare beneficiaries with iron overload due to repeated blood transfusions have access to oral iron chelation, we urge USP and its Model Guidelines Expert Committee to create a defined category or class in the revised Model Guidelines into which deferasirox would fit. This could be in a newly created category for oral iron chelators or as an oral iron chelator class within the broader category of heavy metal chelators.

Novartis requests that USP and its Model Guidelines Expert Committee consider this information as part of its current assessment of newly approved Part D drugs and create a new category or class for this agent. Specifically, we ask that this letter and accompanying material be provided to the Expert Committee so that it can be considered prior to the issuance for public comment of the draft revision of the Model Guidelines.

Thank you for your cooperation in this matter. Should you have any further questions, please do not hesitate to contact me at 1-862-778-6092.

Sincerely,

Rainer Boehm, M.D.
Sr. Vice President and
North American Region Head

Attachment

Cc: Mark McClellan, M.D., Ph.D, Centers for Medicare and Medicaid Services
Jeffrey Kelman, M.D., Centers for Medicare and Medicaid Services
Babette Edgar, Centers for Medicare and Medicaid Services

Exhibit A - Further Background On Deferasirox

Iron overload is a frequent complication occurring in patients with diseases that require repeated blood transfusions. Unfortunately, the body has no effective method for removing excess iron. When total body iron stores rise above normal, the excess becomes deposited into tissues such as the heart, liver and pancreas and can result in cardiac disease, diabetes mellitus, and liver disease including cirrhosis, fibrosis or even cancer.

Each unit of transfused blood contains 200-250 mg of iron and a person receiving chronic transfusions can develop excess total body stores after as few as 20 units of packed red blood cells (i.e., 10-20 transfusions). There are many conditions that are treated with repeated blood transfusions including Myelodysplastic Syndrome (MDS), sickle cell anemia, beta-thalassemia, aplastic anemia, and other rare chronic anemias. While every one of these diseases can affect Medicare beneficiaries, MDS is a condition most commonly seen in the elderly. MDS has a prevalence in the United States of 83,000 with approximately 6,000 to 14,000 of these patients requiring repeated blood transfusions to maintain their effective red blood cell levels.

The clinical burden of iron overload cannot be underestimated. Considering MDS as an example, a recent publication by Malcovati and associates in the Journal of Clinical Oncology concluded that developing secondary iron overload significantly impacted survival in transfusion dependent MDS patients[1]. The article demonstrated that iron overload as measured by serum ferritin was an independent prognostic factor for morbidity and mortality in patients with MDS. Other studies have shown that approximately 75% of MDS who receive repeated blood transfusions have increased cardiac iron levels and approximately 30% of iron-overloaded MDS patients die from cardiac failure and not the primary hematologic disease.

For the past four decades the only treatment available to reduce total body iron levels was the injectable iron chelator deferoxamine (marketed by Novartis under the brand name Desferal®). While very effective in treating iron overload, deferoxamine is delivered using an infusion pump. Treatment times are often upwards of eight to ten hours a day five to six days a week; needless to say, compliance with this regimen has historically been poor leading to unnecessary treatment failures and even death.

The acceptance of iron chelation using deferoxamine is well established in patients with iron overload as the result of repeated blood transfusions. The National Comprehensive Cancer Network (NCCN) states in its treatment guidelines for MDS that "the use of deferoxamine is highly recommended" for patients with iron overload[2]. The National Institutes of Health's National Heart, Lung, and Blood Institute (NHLBI) states in its treatment guidelines for sickle cell disease that "exchange transfusions and chelation therapy are the *only two accepted methods of managing* transfusion-relation iron overload[3]." (Italics added)

Novartis recently received FDA-approval to market the novel oral iron chelator deferasirox (marketed as Exjade®). Deferasirox is the first oral iron chelating agent

---

[1] Malcovati L, Della Porta M, Pascutto C, Invernizzi R, et. al. "Prognostic Factors and Life Expectancy in Myelodysplastic Syndromes Classified According to WHO Criteria: A Basis for Clinical Decision Making" *Journal of Clinical Oncology*. October 20, 2005. 23(30). p. 1-10.

[2] NCCN treatment guidelines for Myleodysplastic Syndrome (p.17) as accessed on November 17,

approved in the US for the treatment of transfusion-related chronic iron overload regardless of the primary diagnosis. Studies have demonstrated that deferasirox is effective in treating transfusion-related iron overload; thus, use of this new oral chelator would fall within the above mentioned guidelines as an accepted treatment method. Indeed, because of the ease of administration of deferasirox, it is expected to replace deferoxamine in the management of many patients.

While deferasirox is the only oral iron chelator approved for marketing in the United States, in Europe deferiprone (manufactured by Apopharma) is an approved oral iron chelator. In addition, Genzyme has an oral iron chelator, deferitin, in Phase II clinical development in the United States.

MOBILITY
PRODUCTS•UNLIMITED, LLC

November 22, 2005 VIA OVERNIGHT MAIL

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. McClellan:

Re: CMS Interim Final Rule on Conditions for Payment of Mobility Devices, CMS-3017-IFC

Introduction

Mobility Products Unlimited, LLC, appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Interim Final Rule on Conditions for Payment of Mobility Devices, issued August 26, 2005 ("The Rule"). Mobility Products is a power wheelchair and power operated vehicle provider. As a company, we are committed to ensuring that Medicare beneficiaries with medical need have access to appropriate mobility products, including power mobility devices (PMDs).

Summary of Comments

The Rule requires physicians to write a prescription for a power mobility device (PMD), to document in the medical record the results of a "face-to-face examination", and provide those two documents, along with "other supporting medical documentation", to the Medicare Part B supplier within 30 days of the date of the face-to-face exam. CMS defines the seven criteria physicians must include in the written prescription to meet Medicare requirements.[1]

[1] 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. See Interim Final Rule, 42 CFR 410.38(c).

Mobility Products supports the requirement that a beneficiary have a "face-to-face" exam prior to a physician prescribing a PMD. This process enables beneficiaries, their physicians and caregivers to express an interest in the beneficiary's need for the PMD, the physician to perform the examination, and the physician to write a detailed written order and evaluation for the PMD. Those documents, along with any other clinician evaluation, will provide the best information for CMS to make a medical need determination. We question the value and need for any additional document for CMS to ensure medical need is met. We request that CMS respond, in its response to comments, as to how historical notes and medical records would be more valuable than the written order and documentation of the face-to-face examination. MPU does not believe that CMS' approach that requires physicians to provide suppliers with documentation of medical need directly from progress notes will address CMS' stated objective of ensuring the existence of adequate documentation to substantiate medical need, nor will it address CMS' objective of addressing fraud and abuse.

While the requirements for the written prescription are specific and defined, the requirements for the supporting medical documentation are wholly undefined in the Rule. CMS summarily explains in the preamble that the "physician or treating practitioner prepare pertinent parts of the medical record for submission to the DME supplier." The regulation states that the prescribing physician is to provide "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..."

While we understand that the algorithm contained in the National Coverage Determination (NCD) issued on May 5, 2005, potentially provides some guidance for the single face-to-face examination, neither it nor the IFR provide sufficient information for physicians to understand the scope of documentation that CMS is expecting physicians to provide. While some clarification of the scope, breadth and detail of the required physician documentation is contained in separate documents issued in piecemeal fashion by CMS and the Durable Medical Equipment Regional Carriers' (DMERCs), CMS has simply not conducted any education campaign that is adequate for prescribing physicians to understand their new documentation responsibilities. To that end, we strongly recommend that CMS provide physicians with a standard set of questions that CMS expects physicians to address, to ensure appropriate documentation of medical need.

1. <u>Prescribing Physicians Need CMS to Provide Detailed Education Regarding Coverage Criteria and Documentation Responsibilities'</u>

We do not believe that the documentation format and process CMS has proposed is the most effective way to collect information that will fully substantiate a beneficiary's need for a power mobility device. As currently drafted, the rule does not provide sufficient guidance to the physician community to be able to understand exactly the format and content of the documentation CMS is seeking. Therefore, the documentation requirement

will be of little use to CMS and its contractors in the event of an audit, for purposes of determining medical need.

CMS still needs to conduct extensive educational efforts - through newsletters (through state and national professional societies), through the Web, and in-person education programs where physicians and their office managers can have a meaningful opportunity to understand the scope and nature of the information CMS is expecting physicians to document and provide to suppliers. We strongly believe that CMS has not sufficiently educated physicians and their representatives, even at this late date beyond the October 25, 2005, effective date. For this reason, MPU strongly urges CMS to incorporate public comments, revise the regulation with significantly more detailed information directed at physicians, issue the Rule in final form at a later date and find mechanisms for broad physician exposure.

Based on our own experience and that of many other suppliers, we have found that physicians simply do not maintain medical records in the format, and to the level of detailed information that CMS expects. This is due to two reasons: First, physicians do not typically document the way that CMS anticipates. They typically document the presenting or chief complaint with single word notations of observations or patient reports. Therefore, CMS must provide some standard series of questions/issues that CMS expects physicians to address in the medical records. Second, CMS has provided physicians with virtually no education to enable physicians to understand the scope and depth of information that CMS expects. Therefore, even if the face-to-face progress note has the "correct" details in it, it is unlikely that the patient's other progress notes or medical history will specifically reference the need for power mobility. It appears to us that the IFR requires such supporting documentation, of some kind.

If CMS does not provide concrete and explicit guidance as to what information physicians must provide, then we believe that it is incumbent upon CMS to demonstrate that it would be common practice for physicians to chart in a way that is likely to lead to the provision of information necessary to establish medical necessity. Phrased differently, if CMS is choosing to implement a documentation instrument that is unlikely to provide determinative information on a routine basis, it should not be allowed to impose this quite burdensome documentation requirement. We note that CMS also makes the unfounded assertion that the documentation requirement is not burdensome, but rather simply the gathering and sending of existing information. At this juncture, we believe that CMS does not have an adequate empirical basis to support its current documentation assumptions and requirements.

Therefore, we recommend that CMS modify the rule, or provide implementing instructions, to resolve these problems by issuing a series of questions or inquiries, in a standard format (not a standard form). This series of questions would significantly help physicians to understand the scope and specific detailed information CMS is expecting physicians to document. These questions would identify what issues that CMS expects physicians to address in the medical records to substantiate medical need. For example, the questions could be listed in the rule as the types of issues that CMS expects

physicians to be addressing in the medical record. These questions could be substantially similar to those issued in the DMERC draft LCD issued September 14, 2005 (rendered moot by CMS' subsequent retraction of the PMD HCPCS codes issued September 14), which reads as follows:

"The report of the face-to-face examination that is required for all patients receiving a POV or power wheelchair (PWC) (see related Policy Article) should provide information relating to the following questions."

POV/PWC	What is this patient's mobility limitation and how does it interfere with the performance of activities of daily living?
POV/PWC	Why can't a cane or walker meet this patient's mobility needs in the home?
POV/PWC	Why can't a manual wheelchair meet this patient's mobility needs in the home?
POV	Does this patient have the physical and mental abilities to transfer into a POV and to operate it safely in the home?
PWC	Why can't a POV (scooter) meet this patient's mobility needs in the home?
PWC	Does this patient have the physical and mental abilities to operate a power wheelchair safely in the home?

The report should provide pertinent information about the following elements, but may include other details. Each element would not have to be addressed in every evaluation.

- Symptoms
- Related diagnoses
- History
    - How long the condition has been present
    - Clinical progression
    - Interventions that have been tried and the results
    - Past use of walker, manual wheelchair, POV, or power wheelchair [2]and the results
- Physical exam
    - Weight
    - Impairment of strength, range of motion, sensation, or coordination of arms and legs
    - Presence of abnormal tone or deformity of arms, legs, or trunk

[2] This series of detailed concerns should reflect a specific response to why non-power mobility is no longer appropriate for the patient where the physician is prescribing a PMD.

- Neck, trunk, and pelvic posture and flexibility
- Sitting and standing balance

- Functional assessment - any problems with performing the following activities including the need to use a cane, walker, or the assistance of another person
  - Transferring between a bed, chair, and PMD
  - Walking around their home - to bathroom, kitchen, living room, etc. - provide information on distance walked, speed, and balance

---

We further recommend that CMS clarify what the "other supporting documentation" should specifically contain in order for a supplier to avoid a recoupment at audit; particularly as we know that physicians will not necessarily document mobility-specific information.

2. <u>This Rule Will Significantly Increase the Likelihood that Suppliers Will Be Denied Payment Through No Fault of Their Own, Or Beneficiaries will be denied Access</u>

In the IFR, CMS states that "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 [National Coverage Determination]." CMS continues that this rule would "also greatly reduce the risk that a supplier will be denied payment through no fault of its own."

There is nothing presented in this rule that does either of these things. Replacement of the certificate of medical necessity (CMN) with this "prescription" and "supporting documentation" provides suppliers with significantly less certainty of meeting the regulation, not more. This also increases the risk to suppliers of denial of payment. The CMN, in spite of all of its limitations, at least provided very apparent evidence to a supplier of the physician's decision regarding a beneficiary's qualification. The provision of unspecified and unclear "supporting documentation" is far more difficult for suppliers to assess. Making the assessment of the quality of medical necessity for a particular beneficiary is clearly and solely within the purview of the physician's judgment; it should not be a "decision" a supplier has to make. The result will be that suppliers will have insufficient documentation from physicians, and will have two options. Either (1) the supplier will not be able to provide medically needed PMD to beneficiaries because the physician has not provided adequate and sufficient documentation in the suppliers opinion (not the physician's); or (2) the supplier will provide medically necessary PMD, but will have a significantly increased risk of having payment recouped in the event of an audit, even though the physician's intent was clear.. Neither of these outcomes is desirable.

CMS states in its IFR that 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." MPU strongly believes that this statement is wholly unfounded. As described in the Rule, the "quality" of the documentation and the actual medical necessity may be reviewed on a far more subjective basis by the DMERCs due to the failure of the Rule to specifically describe the documentation requirements. This is likely to lead to a greater number of denials, rather than fewer. The main effect of this rule on suppliers is that suppliers will be unable to obtain sufficient documentation and therefore unable to supply equipment to beneficiaries who have real medical need, or suppliers will make their best guess at determining if they have collected adequate subjective documentation from the physician and risk extrapolations and penalties from CMS through the course of medical review audits.

3. Inconsistencies Between the IFR and DMERC Local Coverage Determinations

The IFR and Local Coverage Determinations (LCDs) for PMDs the durable medical equipment regional carriers (DMERCs) issued during the week of October 17, 2005, contain inconsistencies related to documentation. The IFR states, "In addition to the prescription for the PMD, the physician or treating practitioner must provide to the supplier supporting documentation..." In contrast, 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 about the following elements..." [emphasis added]. These inconsistencies between the IFR and LCD can, again, lead the DMERCs to subjective and differing interpretations of the patient's medical record and could ultimately give the DMERCs the ability to deny any PMD claim in an audit. We therefore recommend that the DMERCs revise the LCDs to reflect the mandatory nature of physicians' new prescribing responsibilities. We believe that it was CMS' intention to place this *mandatory* burden on the prescribing physician. If the documentation requirements are not mandatory then the supplier is placed in an even more precarious position.

4. Extension of 30-day Timeframe Is Necessary

The IFR states that the physician must ensure that the provider receives from them a written prescription and supporting medical documentation within 30-days of the face-to-face examination. This timeframe may not provide adequate time for the process to be completed. Given our experience, the thirty day time frame is generally unrealistic as medical practices strain under their patient loads. Under previous policy, we would routinely need numerous follow ups with physicians just to obtain a prescription and completed CMN. Generally, acquiring supporting records required even more follow up and time. In order for sufficient time for the physician to provide the prescription and supporting documentation to the provider, CMS should extend the timeframe in the IFR to sixty (60) days from the date of the "face-to-face" examination.

5. Lack of Detailed Documentation Guidance May Lead to Increased Fraud and Abuse

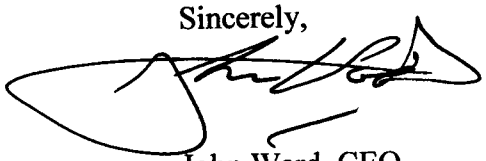
The IFR will likely increase the opportunity for unscrupulous entities to engage in fraudulent and abusive practices because suppliers are no longer required to submit a physician-signed document with a claim for the PMD. While suppliers are required to

obtain a written prescription and supporting documentation prior to delivery, this information is not required to be submitted with the claim. We strongly urge CMS to put an appropriate mechanism in place on the front end of the claims system, which will strengthen program integrity efforts and provide beneficiaries and providers with some level of assurance that when a claim is paid, Medicare has approved the claim. This mechanism can take the shape of a standardized series of questions that physicians respond to that would provide medical necessity information. It should include a physician attestation statement indicating that the physician has completed the necessary information to support the prescription, that the physician has included it in the medical record and has given this information to the provider. This attestation can be submitted electronically with the PMD claim. We are happy to work with CMS on a series of physician questions for CMS review and response.

Conclusion

Mobility Products strongly encourages CMS to seriously consider our recommendations. First, CMS must conduct meaningful physician education. Next, develop a standardized series of questions for physicians to respond to, enabling them to understand the scope and depth of information CMS expects, to acquire it from their patients and to provide it to the supplier. Additionally, expand the time frame for physicians to provide the documentation to suppliers. Finally, explicitly describe what is expected in supporting documentation. We appreciate the opportunity to comment on this Rule. For further information, or if you have any questions, please contact Trienah M. Gorman, Government & Regulatory Affairs, at (386) 271-1335, (386) 527-9419 or tgorman@mpullc.com

Sincerely,



John Ward, CEO

Supporting Quality Health Care Services at Home

Via Hand Delivery and Federal Express

November 23, 2005

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-3017-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS Interim Final Rule on Conditions for Payment of Power Mobility Devices, CMS-3017-IFC[1]

Dear Dr. McClellan:

The American Association for Homecare (AAHomecare) submits these comments on the Centers for Medicare and Medicaid Services' (CMS') interim final rule (IFR) on conditions for payment of power mobility devices (PMDs).[2] AAHomecare is the only national trade association that represents every line of service in the homecare community. Our members include home health agencies and providers and manufacturers of rehab and assistive technologies and services as well as pharmacies providing home infusion and inhalation therapies. These comments are informed by the experience of the AAHomecare Rehab and Assistive Technology Council (RATC), which is composed of providers and manufacturers who serve the needs of Medicare beneficiaries with disabilities or chronic conditions that require them to use PMDs. Consequently, AAHomecare is uniquely qualified to comment on the IFR.

AAHomecare generally supports the requirements of the IFR including the requirement for a face-to-face evaluation of the beneficiary. We remain concerned, however, because a successful transition to the procedures dictated by the IFR depend mostly on the willingness of physicians and other practitioners to properly document the medical needs of the beneficiary in a way that is consistent with CMS' national coverage guidelines for mobility assistive equipment. As a threshold matter, we are concerned that the supporting documentation requirements contained in the IFR are overly broad, making it difficult for a physician to understand the scope of what CMS expects. Further, CMS has done little to educate physicians about their new responsibilities under the IFR. We recommend that CMS engage in an aggressive education campaign targeting the clinical community to

[1] 70 F.R. 50940 (August 25, 2005).
[2] PMDs include both power wheelchairs and power operated vehicles (POVs).

625 Slaters Lane, Suite 200 Alexandria, VA 22314-1171
tel: 703.836.6263 fax: 703.836.6730 www.aahomecare.org

address these concerns. We are also concerned that the 30-day window for documenting the face-to-face evaluation in the written order is too short and should be extended to at least 60 days. We address these and other issues in further detail below.

I. INTRODUCTION

As you know, earlier this year CMS published a national coverage determination (NCD) for mobility assistive equipment. CMS also announced 49 new power wheelchair codes. The NCD contains a complicated algorithm for determining when a Medicare beneficiary who needs mobility assistive equipment may qualify for a PMD. The IFR, in turn, governs the prescription, documentation, and delivery of PMDs. The IFR requires that beneficiaries receive a "face-to-face" evaluation by the physician or treating practitioner; eliminates the certificate of medical necessity (CMN); and imposes extensive new documentation requirements on suppliers and physicians.

In place of the CMN, the rule would require physicians to provide suppliers with a prescription and extensive documentation from the patient's medical record to substantiate medical necessity for the PMD. Medical necessity is determined in reference to the algorithm contained in the NCD. The IFR requires suppliers to maintain this documentation on file in the event of a Medicare audit. If the documentation submitted by the physician does not adequately address the required elements of the algorithm based on the supplier's review, the supplier must request additional documentation from the physician or face an overpayment on audit. The supplier should not have to make a clinical judgement regarding the completeness of the physician's documentation.

On September 14, 2005, following publication of the IFR, the DMERCs published a proposed local coverage determination (LCD) that defines the specific coverage criteria for the power wheelchair codes. The LCD also attempts to further define the documentation requirements in the IFR. The draft LCD announced new codes and included testing requirements for product code verification. After manufacturers raised concerns about the impact of the new codes and testing requirements, CMS announced a delay in the implementation of the codes until CMS has an opportunity to sit down with stakeholders and determine how to proceed. The delay in the codes necessitated a change in the LCD to reflect the current codes. CMS plans to issue a new LCD when the codes are finalized next year.

II. PROVISIONS OF THE IFR

A. CMS Must Engage Physicians in an Aggressive Education Campaign to Ensure Compliance with the IFR

The IFR requires physicians to: write a prescription for a PMD, document in the medical record the results of a "face-to-face" examination of the beneficiary, and provide the prescription and the supporting documentation to the supplier within 30 days of the face-to-face examination. The prescription must contain the following elements: the beneficiary's name; the date of the face-to-face evaluation; the diagnosis and condition

that the PMD is intended to modify; a description of the item, i.e., a narrative description of the PMD; the length of need; the physician or treating practitioner's signature and the date the prescription was written. 42 C. F. R. § 410.38 (c) (1).

While the IFR is highly specific about the requirements for the written prescription, the supporting documentation requirements in the rule are meaninglessly broad. For example, the preamble states only that the physician or treating practitioner prepares pertinent parts of the medical record for submission to the DME supplier. 70 FR at 50942. The rule, in turn, states that the physician is to provide "supporting documentation, including pertinent parts of the beneficiary's medical record (e.g., physical examination, diagnostic test, summaries of findings, diagnoses, treatment plans and/or other information as may be appropriate) that supports the medical necessity for the PMD. . . ." 42 C.F.R. § 410.38 (c) (2) (iii). CMS has not given physicians guidance on what *information* substantiates medical necessity for the PMD.

AAHomecare appreciates the need for CMS to collect information that supports the medical necessity for a PMD. The IFR, however, does not tell physicians what information will support medical necessity. There is no guidance with respect to the content or format of the documentation. Rather, the rule lists various pieces of the patient record that *could* contain relevant information, depending on the circumstances. Our members' experience proves that physicians do not usually chart with the level of descriptiveness that CMS appears to require in the IFR.

We recommend that CMS engage in an aggressive campaign to educate physicians about the requirements of the IFR. Importantly, the education campaign must extend beyond the physician community to include the many medical centers and rehab facilities that serve individuals who require PMDs. All stakeholders must participate in this process so that the outcome for the clinical community is a clear understanding of the practitioner's central role in under the requirements of the IFR. There is precedent for this kind of outreach to physician and DME provider stakeholders. During the approval process for the CMNs in 1995, CMS (then HCFA) engaged physicians and suppliers as stakeholders in addressing their documentation concerns with respect to the CMN.

This type of forum could be held nationally or could be held at the carrier level to ensure the participation of a greater number of physicians. These sessions would give providers and physicians or other practitioners the opportunity to raise specific questions and get timely responses. The education campaign should also produce concise written materials that providers could distribute to physicians. These materials would at least be easier for physicians to digest than the LCD and the NCD, which they must now wade through. CMS' preparation of the materials will ensure their accuracy and credibility in the eyes of physicians and other practitioners.

We also recommend that CMS significantly increase the payment to physicians for preparing the documentation. As we discussed in comments AAHomecare submitted on the paperwork burdens imposed by the IFR, the CMS estimate that it will take physicians and suppliers a combined total of only 10 minutes to prepare and collect the

documentation grossly underestimates the paperwork burden of these new requirements. Physicians are more likely to take their time and provide adequate documentation if they are appropriately reimbursed for the effort.

B. CMS Should Require the DMERCs to Develop Clear Evaluation Criteria that can be Used by Clinicians to Document Medical Necessity

As we noted above, one of AAHomecare's primary concerns is that the documentation physicians provide be adequate to support a medical necessity determination for the PMD. To achieve this goal, it would be useful to have at least a consistent format for the patient assessment. As part of the education campaign we described above, we recommend that CMS work with the DMERCs, PMD providers, and the physician community to develop an evaluation form that physicians and practitioners could use when they assess patients and prescribe PMDs. The discussion pertaining to documentation in the draft LCD provides a good basis for the development of such a form.

The draft LCD suggests questions that the physician or practitioner must address in order to meet the thresholds for medical necessity under the policy. The draft LCD also identifies the types of information that the DMERCs expect to see when reviewing the medical necessity for PMD claims. AAHomecare recommends that CMS work with the other stakeholders to further develop these questions so that physicians and practitioners can use them as a template for the evaluation. This will ensure consistency in the way the clinician documents the decision-making process. Because the forms would reflect the physician's/clinician's work product, they should be accepted as part of the patient's medical record. This approach to education and documentation will serve to underscore for physicians the important role they have in assuring that their patients maintain appropriate access to PMDs.

C. CMS Must Expand the Thirty-Day Window for the Written Prescription

The IFR states that the physician must furnish the provider with a written prescription and supporting medical documentation within 30 days of the face-to-face examination. This timeframe may not provide adequate time for the process to be completed. Under previous policy, providers would routinely need to follow up with physicians on numerous occasions just to obtain a prescription and completed CMN. In order to allow sufficient time for the physician to provide the prescription and supporting documentation to the provider, CMS should extend the timeframe in the IFR to 60 days.

D. CMS Should Harmonize Differences between the LCD and the IFR

There are some inconsistencies between the terms of the DMERC LCD and the IFR. The IFR states the supplier may not dispense the PMD until it has received the PMD prescription and supporting documentation from the physician or treating practitioner. 42 C.F.R. § 410.38 (c) (4). The DMERC LCD at least implies that receipt of the supporting

documentation is discretionary. DMERC instructions should be clear that the supporting documentation is not optional. Further, as we emphasized above, aggressive physician and practitioner education on the required elements of the IFR would serve to minimize problems of inconsistent interpretation on the content or format of the documentation that the clinician submits.

III. CONCLUSION

The American Association for Homecare sincerely appreciates the opportunity to submit these comments. We want to stress our support for the IFR's core requirement of a face-to-face evaluation of the beneficiary by a physician or other qualified practitioner before ordering a PMD. We believe that many of the concerns our members have raised with respect to the new requirements can be addressed through appropriate and aggressive education of the clinical community to provide clear guidance on what specific elements are necessary to substantiate medical necessity. We urge CMS to finalize the IFR in a manner that addresses the concerns we have raised. AAHomecare is committed to working with CMS to address these concerns. Please feel free to contact me if you have any questions.

Sincerely,

Kay Cox

Kay Cox
President and CEO

18

The Power Mobility Coalition

WORKING TOGETHER FOR FREEDOM AND INDEPENDENCE

November 25, 2005

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS Interim Final Rule on Conditions for Payment of Mobility Devices, CMS-3017-IFC

Dear Dr. McClellan:

On behalf of the Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized wheelchairs and power operated vehicles (POVs), we are submitting comments regarding the interim final rule (IFR) on conditions for payment of mobility devices (CMS-3017-IFC). On August 25th, the Centers for Medicare and Medicaid Services (CMS) issued the IFR that makes comprehensive changes to the Medicare PMD benefit. While the PMC is supportive of various aspects of the new interim final rule, including the face-to-face requirement and elimination of the specialist requirement in order to qualify for a power operated vehicle (POV), the interim final rule fails to meet many crucial reform criteria in several respects. Some of the PMC concerns with the interim final rule are as follows:

1. CMS Lacks the Authority to Eliminate the Certificate of Medical Necessity (CMN) and Replace It with A More Burdensome Recordkeeping Requirement

Contrary to the plain language of the Social Security Act (SSA), the interim final rule would eliminate the CMN and the authority provided to suppliers by Congress to distribute such CMN to physicians and beneficiaries. The PMC questions whether CMS has such authority absent Congressional approval.

As part of the SSA, Congress defined the CMN as a "form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury to improve the functioning of a malformed body member." The PMC asserts that the Congressionally mandated, Office of Management and Budget (OMB) approved CMN was established for the exact purpose described in the interim final rule - to document the medical need of the patient based on the treating physician's evaluation of such patient.

Furthermore, the Federal court system has upheld the CMN as the Medicare document of record that determines eligibility for a PMD. In *Maximum Comfort, Inc. v. Thompson*, 323 F. Supp. 2d 1060 (E.D. Cal. 2004) the Court wrote:

> the plain language of [42 U.S.C.] § 1395m(j)(A)(2)(i) supports the plaintiff's position that it may only use a CMN to provide the necessary information for the determination of medical necessity and reasonableness. The Secretary cannot require that DME suppliers, such as plaintiff, obtain Medicare beneficiaries' medical records and make a judgment as to whether the equipment is medically

> necessary and reasonable. It is clear from the plain text of the Medicare Act that, while Congress granted the Secretary broad discretion over medical necessity and billing criteria and procedures, it did not do the same regarding medical necessity documentation. Instead, Congress addressed that issue itself and established that any and all information required from suppliers to make a medical necessity determination must be contained in a CMN.

Id. at 1074-75.

In the interim rule, CMS acknowledges that the CMN was previously established to allow efficient adjudication of claims by automating the submission of certain information needed to make medical necessity determinations." 70 Fed. Reg. 50944. Yet, CMS determined that an OIG analysis of the CMN "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."

Medical record content has ***NEVER*** been the standard by which Medicare coverage is determined. As an example, CMS proposed to amend 42 C.F.R. § 410.38 to require that physicians document in their medical records the need for the prosthetic, orthotic, durable medical equipment, and/or supplies ("DMEPOS") being ordered.[1] CMS acknowledged in their proposed rule that the physician documentation of medical need for DMEPOS constitutes a "collection of information" and is subject to approval from OMB per the PRA. Although CMS and OMB sought comments from Medicare stakeholders, including physicians and clinicians, CMS ***NEVER*** finalized this proposal and OMB ***NEVER*** approved this proposed collection of information. It is unrealistic to suggest physicians will somehow document in their medical records according to a standard that has not existed previously.

Lastly, CMS Administrator McClellan has testified that the CMN reflects the physician's determination of medical necessity and upheld the role of the CMN in the PMD claims process. As Dr. McClellan told the Senate Finance Committee:

> The clinical criteria for deciding when a manual or power wheelchair is medically necessary and appropriate for a beneficiary has been and will continue to be a matter of clinical judgment by the physician. It's also my understanding that CMS does not want to list specific condition-based criteria since the decision to determine the appropriateness of providing a manual or power wheelchair is best left to the physician's judgment. However, this does not abdicate the responsibility to have appropriate documentation as to the medical necessity of the claim. As a condition of coverage, CMS does require that the beneficiary's need for a wheelchair or power wheelchair is supportable. In fact, all claims for power wheelchairs must include a Certificate of Medical Necessity (CMN) which 'certifies the need for the device and that it is reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body part.'"

2. Clarity and Consistency is Necessary as it Applies to the Physician Documentation Requirements Set Out in the Interim Final Rule

Burdens placed on suppliers and physicians will greatly increase under the interim final rule. Suppliers, for the first time, will be required to obtain and maintain an ill defined set of medical records and physicians will be required to prepare, maintain, and provide such medical records to suppliers on 100% of all PMD claims. In addition to collecting and submitting medical records to suppliers, the interim final rule places a whole new recordkeeping requirement on physicians by requiring that each physician document medical need (according to ill defined Medicare guidelines) in their medical records. All of these new collections of information, including the new recordkeeping requirement, must be subject to PRA protections.

The PMC fully supports the requirement that a beneficiary have a "face-to-face" exam prior to a physician prescribing a PMD. This process enables beneficiaries, their physicians and caregivers to express an interest in the beneficiary's need for the PMD, the physician to perform the examination, and the physician to write a detailed written order and evaluation for the PMD. By eliminating the CMN and basing PMD eligibility on unspecified documentation, the interim final rule erodes the doctor's role as gatekeeper and puts suppliers and bureaucrats in the position of routinely overruling their medical judgment, creating even more uncertainty for both beneficiaries and suppliers. This is not consistent with the intent of Congress to emphasize the role of the treating physician in making medical necessity determinations.

The following are questions that remain unanswered due to the lack of clarity created by CMS' interim final rule and the proposed new collection of information:

First, when the physician provides the prescription and the face-to-face examination report, both extensive documents addressing medical necessity, who decides whether additional documentation is needed?

Second, the new process requires that a doctor or treating practitioner:

- evaluate the beneficiary in the last 30 days to analyze mobility needs;
- document that the patient was evaluated for that purpose;
- conduct and document a face-to-face evaluation;
- write a seven-element prescription; and
- acknowledge consideration of the mobility algorithm.

Can a supplier reasonably rely on the physician's documentation developed during the face to face visit?

Third, the supplier must obtain a seven-element prescription, as well as a documented face-to-face examination report. If the supplier agrees with the treating practitioner that the documentation provided is adequate, and subsequently a DMERC reviewer decides differently, will the supplier be held liable for the claim? Under what circumstance is a supplier protected by the waiver of liability provision established by Congress in Section 1879 of the Social Security Act.

The arbitrary and subjective nature of the collections of additional documentation contained in this interim final rule threaten the ability of our members to provide prescribed equipment to beneficiaries who rely on this equipment to perform their activities of daily living. The interim final rule would force the supplier to guess as to the veracity of the medical records and provide CMS and its DMERCs with carte blanche authority to overrule the prescription of the treating physician.

3. Estimation of the New Paperwork Burden on Physicians and Suppliers Contained in the Interim Final Rule is Unrealistic

CMS, in its interim final rule, estimates that the time for a physician to prepare, collect and submit medical records combined with the time it will take a supplier to collect, review and maintain such records will total 10 minutes contrasted with 12 minutes for filling out a CMN. It is wholly unrealistic to assume that a physician will prepare, maintain, collect and submit medical records to a supplier and such supplier will then maintain and review these records in 10 minutes. CMS has not provided any supporting documentation to support their burden estimate but we would request that the agency do so and allow the public to comment on the specific calculations prior to the rule being finalized.

a. Physician Requirements:

Prescription – Physicians are required, under this new regulation, to create a prescription with several specific components, all of which are currently included in the Certificate of Medical Necessity form. Without a form or format, the new prescription will create a larger burden on physicians as they attempt to document free-hand all of the components contained in this rule.

Chart Notes and Evaluations - Physicians are required, under this new regulation, to prepare, maintain and provide a record of the face to face examination of the beneficiary for the power mobility device. According to the preamble of the interim final rule, "the parts of the medical record selected [by the physicians] 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...."[2] Physicians do not currently nor have they in the past charted according to these standards and thus the new burden placed on them will be substantial. Further, there is no established mechanism to determine if the physician's medical records comply with these requirements. CMS must consider these requirements in their burden estimate.

Additional Medical Records – Physicians are also required, under this new regulation, to collect, copy, redact, and send any other pertinent medical records or test results, which will substantiate the previous prescription and face to face examination documentation.

All requirements are applicable to 100% of all PMD prescriptions, which is not current practice and will thus place new and substantial burdens on our nation's physicians. This burden must be calculated by CMS and not summarily dismissed as current medical practice. Current medical practice is for physicians to consider their patient's condition and complete a Certificate of Medical Necessity to prescribe, document, and establish the need for PMDs.

b. Supplier Requirements:

The supplier must collect both the prescription and additional information from the patient's medical record on 100% of its claims. Not only has CMS underestimated the burden associated with this requirement, CMS has also overlooked the cost required to maintain these massive amounts of records for 7 years. Further, suppliers will be now be placed in the role of evaluating medical information contained in the physician's written charts to determine if the prescription should be filled -- a role never contemplated by the Medicare program.

The most common request for "additional documentation" is for copies of chart notes. To underscore the burden associated with the collection of this information, one of our members collected "additional documentation" in 1999 primarily consisting of chart notes for 283 claims. The total project required 1334 man-hours, or 4.71 hours per claim.

4. The Interim Final Rule Will Increase the Administrative and Educational Burdens on Physicians

It is unrealistic to think that CMS will be able to conduct sufficient outreach to adequate educate physicians about the confusing new algorithmic functional ambulation standard, not to mention the 63 new product codes that physicians are expected to knowing differentiate so that they can adequately place an eligible beneficiary in the proper PMD. Failure of physicians to sufficiently understand the new coverage policy and product codes will most likely have lead to physicians writing fewer prescriptions for PMDs, thereby ignoring real need, or failing to properly document need, leading to inappropriate denials.

5. Contractors and Suppliers Need More Time to Implement Changes to the Medicare PMD Benefit

Medicare contractors have indicated that they need until April 1, 2006 to update their systems to accept the new information required under this rule. Without a delay or until such time as the claims process systems are updated, suppliers will have to collect the documentation required by the new regulations as well as the CMN in order for their claims to be processed.

6. Issuance of an Interim Final Rule Violates the Administrative Procedures Act (APA)

CMS has issued the changes to the Medicare PMD benefit in the form of an interim final rule, in effect, allowing the rule to go into effect without proper notice and comment periods as required by the Administrative Procedures Act (APA). While CMS did issue a proposed rule for the face-to-face examination requirement in August 2004, that proposal was never implemented. This interim final rule differs significantly from the proposed rule, adding new documentation requirements on both suppliers and physicians, and eliminating the CMN --- all new aspects to the face-to-face requirement that never appeared in the original proposed rule. As a result of these significant changes, the PMC contends that the interim final rule on the face-to-face examination requirement was issued by CMS in absence of proper notice and comment and, therefore, violates the APA. The PMC sought a preliminary injunction in Federal court concerning the violations of due process associated with the development of the IFR. We attach our filing to demonstrate our legal concerns with such rule.

7. RECOMMENDATION: CMS Should Revise the CMN to Reflect the Functional Ambulation Standard in the New National Coverage Determination

The PMC recommends that any documentation requirement be incorporated into a revised CMN that includes the eligibility criteria and algorithmic process established in the NCD for PMDs issued May 5, 2005. The CMN was defined by Congress, developed by CMS, and approved by the OMB to establish medical need and thus to determine eligibility for the power mobility benefit. The treating physician completes the CMN and is in the best position to assess patient need and certify that the beneficiary meets the functional ambulation standard. Suppliers who submit the physician signed and completed revised CMN to the Medicare program should have a clear and unequivocal expectation that, if not fraudulent, such documentation establishes medical necessity.

At a minimum, suppliers should be able to rely on the documentation developed by the treating physician during the congressionally mandated face to face visit.

The PMC thanks you for the opportunity to submit comments and looks forward to working with OMB, CMS, and all stakeholders on these important issues.

Sincerely,

Stephen M. Azia
PMC Counsel

Eric W. Sokol
PMC Director

IN THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

POWER MOBILITY COALITION, Plaintiff, v. MICHAEL O. LEAVITT, Secretary, United States Department of Health and Human Services, and MARK B. McCLELLAN, Administrator, Centers for Medicare and Medicaid Services, Defendants.	CASE NUMBER 1:05CV02027 JUDGE: Reggie B. Walton DECK TYPE: TRO/Preliminary Injunction DATE STAMP: 10/13/2005

PLAINTIFF'S MOTION FOR
PRELIMINARY INJUNCTIVE RELIEF

Plaintiff, the Power Mobility Coalition ("Coalition"), hereby moves for a preliminary injunction enjoining the enforcement of regulations promulgated by the Department of Health and Human Services ("HHS") on August 26, 2005. *See* Interim Final Rule, *Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles*, 70 Fed. Reg. 50,940 (Aug. 26, 2005) (to be codified at 42 C.F.R. § 410.38(c)) (Exh. 1). Those regulations, which were issued without notice and comment, would radically change the procedures for obtaining reimbursement for motorized wheelchairs and scooters under the Medicare program. The new regulations are scheduled to take effect on October 25, 2005.

Under current Medicare procedures, which reflect specific congressional direction, claimants submit to HHS a standardized from that contains information tailored

to demonstrating whether a Medicare beneficiary's motorized wheelchair or scooter is reimbursable under the program. The new regulations would eliminate that standardized approach and establish a highly discretionary, and much more costly, system in which claimants must collect and review patients' medical records in an effort to determine whether the records will establish eligibility to HHS's satisfaction.

If permitted to take effect pending judicial review, the regulations would cause severe and irreversible economic injury to members of the Coalition and harm Medicare beneficiaries by interrupting their access to necessary medical devices. An injunction, by contrast, would not cause significant harm to the Medicare program. In fact, the administrative processes of the Medicare system will not conform to the challenged regulations until April 2006, even though the regulations will impose severe hardships on equipment suppliers, physicians, and patients beginning on October 25.

This challenge to the new rules has a substantial likelihood of success on the merits. Promulgation of the contested legislative regulations without notice and comment violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 553, and the Medicare Act, 42 U.S.C. § 1395hh(b)(1). In addition, the regulations are arbitrary, capricious, and contrary to law under 5 U.S.C. § 706 because, among other things, they are inconsistent with the requirements of the Medicare statute and the agency failed to consider reasonable alternatives.

An oral hearing is requested, and a proposed order is attached.[1]

[1] Since promulgation of the new regulations last August, the Coalition and its members have engaged in discussions with HHS about alternatives to this litigation. Those discussions have been unsuccessful thus far.

STATEMENT OF THE CASE

1. Power Mobility Devices

Hundreds of thousands of elderly, disabled, or otherwise infirm Americans rely upon a motorized wheelchair or scooter to accomplish basic life tasks. *See* Zipp Decl. ¶ 4 (Exh. 7). These medical devices are known as power mobility devices, or "PMDs." In the last several years, PMDs have become more comfortable, easier to operate, and safer. *Id.* ¶ 5. Most new power wheelchairs have a tight turning radius, allowing their use in homes that older models could not navigate. *See id.*; 70 Fed. Reg. at 50,941. These improvements, together with the emergence of efficient new suppliers of PMDs (including members of the Coalition) and increased consumer awareness of the devices, drove a significant increase in demand for PMDs during recent years. Zipp Decl. ¶¶ 5-6. Demand for PMDs is expected to grow further as the average age of the American population increases. *Id.* ¶ 7.

PMDs are sophisticated and expensive items of medical equipment. Scooters cost approximately $2,000 at retail, while motorized wheelchairs cost approximately $5,000. *See* 70 Fed. Reg. at 50,945. The vast majority of PMD users could not afford to purchase or rent a device outside the Medicare program. Zipp Decl. ¶ 15; Sidak & Singer Decl. ¶¶ 17, 30 (Exh. 8).

2. The Medicare Act and Certificates of Medical Necessity

The Medicare Act, 42 U.S.C. §§ 1395-1395ggg, establishes a system of federal funding for certain medical care provided to eligible aged and disabled beneficiaries. The Medicare Act consists of several parts. Part B, *see id.* §§ 1395j–1395w-4, covers certain medically necessary equipment that is used primarily in the home, such as PMDs. Like

the rest of the Medicare program, Part B is administered by HHS's Centers for Medicare and Medicaid Services ("CMS"). CMS was formerly known as the Health Care Finance Administration, or "HCFA."

Under the Medicare statute and existing CMS regulations and guidelines, a beneficiary with a medical need for a PMD can obtain one through Medicare by following an established process that utilizes a Certificate of Medical Necessity ("CMN"). *See* 42 U.S.C. § 1395m(j)(2) (Exh. 2); 42 C.F.R. § 410.38 (2004) (Exh. 3). The CMN is a form that HCFA designed for use in obtaining reimbursement for "durable medical equipment" such as hospital-style beds, oxygen-therapy equipment, ventilators, and wheelchairs. *See* HCFA Form 843 (May 1997) (Exh. 4); 42 C.F.R. § 410.38(a). Congress has defined the CMN as a "form or other document containing information required . . . to be submitted to show that an item is reasonable and necessary for the . . . treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395m(j)(2)(B). The CMN enables the "efficient adjudication of claims by automating the submission of certain information needed to make medical necessity determinations." 70 Fed. Reg. at 50,944.

Under a process specifically authorized by statute, suppliers of PMDs provide physicians with CMN forms that can be used to establish whether Medicare reimbursement is available for a patient's use of the supplier's equipment. *See* 42 U.S.C. § 1395m(j)(2)(A)(i). If a physician determines that the patient has a medical need for a PMD, the physician fills out a CMN for particular equipment. The doctor or the patient then provides the CMN to the supplier of the equipment. *See* Zipp Decl. ¶ 10-12; DiLernia Decl. ¶ 6 (Exh. 9).

The patient ordinarily assigns his or her right to Medicare reimbursement for the PMD to the supplier, and is responsible for only a co-payment of 20% of the Medicare-allowable cost. The co-payment, moreover, is often covered by Medicaid or private insurance, provided that Medicare finds the claim to be reimbursable. *See* Zipp Decl. ¶ 11; DiLernia Decl. ¶ 3; Sidak & Singer Decl. ¶ 18. The supplier thus takes responsibility for submitting the claim for reimbursement and assumes the financial risk that the reimbursement claim will be denied. Zipp Decl. ¶ 13; Sidak & Singer Decl. ¶ 19.

Under the Medicare Act, the initial determination whether to provide reimbursement is made by one of a number of private firms known as Durable Medical Equipment Regional Carriers, or simply "carriers." Carriers are under contract with HHS to perform a variety of functions under the Medicare statute, including making coverage determinations, conducting audits, and determining reimbursement rates. *See* 42 U.S.C. § 1395u; 42 C.F.R. § 421.210. Carriers process CMNs and determine whether to provide the requested reimbursement.

In 1996, HCFA explained the role of the CMN during the course of developing and obtaining Administration approval for its CMN form:

> CMNs are used by Medicare and its contractors to verify that items and services provided are reasonable and necessary as required by [the Medicare Act]. In this way, CMNs are indispensable to the Medicare program. Without the use of these forms, the government would not be able to monitor utilization of certain items that are subject to frequent abuse, nor would the government be able to ensure that only appropriate payments are made. If the government did not use and evaluate the information provided in these forms, it would be very difficult to prevent inappropriate payments, and the Medicare Trust Fund would be vulnerable to abuse.

HCFA, *Supporting Statement for Paperwork Reduction Act Submissions [to the Office of Management and Budget] (Version 2)* at 7 (Nov. 5, 1996) at 4 (Exh. 5). CMNs play the same "indespensible" role today.

3. The 2003 Act and CMS's Notice of Proposed Rulemaking

In 2003, as part of the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (2003), Congress amended Medicare Part B to include a new provision specific to PMDs. Under that provision, Medicare reimbursement may be made for PMDs if a physician, or another specified medical professional, has at some time "conducted a face-to-face examination" of the patient and written a "prescription" for the PMD. 42 U.S.C. § 1395m(a)(1)(E)(iv). Prior to the MMA, a patient could obtain reimbursement for a medical scooter only if it was "ordered in writing" by a physician who was a "specialist." 42 C.F.R. § 410.38(c)(3). In this respect, the MMA made it easier for eligible Medicare recipients to obtain medical scooters.

Congress also directed the Secretary of Health and Human Services to "establish standards for clinical conditions for payment for" PMDs and other durable medical equipment. 42 U.S.C. § 1395m(a)(1)(E)(i). Congress further directed the Secretary, in promulgating those regulations, to "first establish standards" for types of equipment as to which "the Secretary determines there has been a proliferation of use, consistent findings of charges for [equipment] that [is] not delivered, or consistent findings of falsification of documentation to provide for payment of such [equipment]." *Id.* § 1395(m)(a)(1)(E)(iii).

These provisions of the MMA took effect on December 8, 2003. On December 22, 2003, the "Unified Agenda" published in the Federal Register indicated that CMS had

opened a rulemaking docket (RIN 0938-AM74), to "make the requirements to purchase [scooters] less stringent." Unified Agenda, 68 Fed. Reg. 72,904, 72,910 (Dec. 22, 2003). CMS, however, did not issue any substantive documents in that PMD rulemaking docket until the Interim Final Rule that is the subject of this case.

In August 2004, CMS issued a notice of proposed rulemaking in another docket (RIN 0938-AM90). The proposed rule in that docket addressed PMDs as one part of a comprehensive revision to CMS's payment policies under Medicare's physician fee schedule. *See* Proposed Rule, *Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005*, 69 Fed. Reg. 47,488, 47,575-76 (Aug. 5, 2004). Among the various changes proposed were some that would have implemented, for all durable medical equipment, the face-to-face examination and written-prescription requirements that the MMA established specifically for PMDs. In particular, the proposed rule would have provided that the physician's or prescribing practitioner's order must be dated and signed within 30 days after a face-to-face examination, and the physician or prescribing practitioner must document in the beneficiary's medical record the need for the durable medical equipment being ordered. *See id.* (proposed new 42 C.F.R. § 410.38(g)(4)-(5)). The proposed regulation also would have allowed CMS to establish additional payment criteria through instructions to Medicare carriers. *See id.* (proposed new 42 C.F.R. § 410.38(g)(6)).[2]

[2] In September 2003, CMS and the Office of the Inspector General had announced an initiative to address the explosive growth of Medicare payments for PMDs. CMS, *New Efforts Aimed at Stopping the Abuse of the Power Wheelchair Benefit in the Medicare Program* (Sept. 9, 2003), *available at* http://www.cms.hhs.gov/media/press/release.asp?Counter=843. After that announcement, Medicare carriers announced so-called "clarifications" of their policies concerning the review of documentation supporting reimbursement requests. The "clarifications," however, were never approved by the Office of Management and Budget and were withdrawn following enactment of the MMA. *See* HomeCare, *CMS Retracts Controversial Power Wheelchair Clarification* (Apr. 1, 2004), *available at* http://bg.homecaremag.com/ar/medical_cms_retracts_controversial.

Members of the Coalition and other interested parties filed Comments on the proposed rule. *See* Zipp Decl. ¶ 16. CMS issued a final rule in November 2004, but that rule did not implement any of the proposed changes to 42 C.F.R. § 410.38(g) with regard to PMDs and other durable medical equipment. Instead, CMS stated that, "[d]ue to the timeframe and the extensive number of public comments received," it would promulgate regulations implementing the face-to-face examination and written-prescription requirements in the MMA "at a later date" and would "address all public comments in a future Federal Register document." Final Rule, *Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005*, 69 Fed. Reg. 66,236, 66,336 (Nov. 15, 2004).

4. The Challenged Rule

On August 26, 2005, CMS took action to implement those provisions of the MMA and otherwise modify its reimbursement requirements for PMDs. But CMS did not follow the approach suggested in its proposed rulemaking, or even issue its new regulations in the same docket in which it had filed the notice of proposed rulemaking. Nor did CMS address the "extensive" public comments that had been submitted with respect to the rules the agency had proposed.

Instead, CMS returned to the previously inactive docket that it had opened on December 22, 2003, to ease the requirements for obtaining reimbursement for scooters. In that docket, CMS issued, without first filing a notice of proposed rulemaking, what it termed an "Interim Final Rule" addressing all PMDs. *See* 70 Fed. Reg. at 50,940. The Rule is scheduled to take effect on October 25, 2005. It is to remain in effect indefinitely

– until CMS completes a new notice-and-comment rulemaking that it initiated (also on August 26, 2005) to promulgate a Final Rule. *See id.*

In promulgating the new Rule, CMS asserted that notice and comment was unnecessary because the Rule, in part, implemented the face-to-face examination and prescription requirements of the MMA. *See id.* at 50,943. Yet the Rule adopts a host of new requirements that must be satisfied before a supplier (or a Medicare beneficiary) may obtain reimbursement for a PMD. Unlike the proposed rule put out for public comment in 2004, the Rule does away with the CMN as a standardized form for supporting a Medicare claim. Instead of the CMN, the Rule requires the PMD supplier (or the Medicare beneficiary) to support its claim for reimbursement by providing a prescription and "supporting documentation," including "pertinent parts" of the patient's medical records. *Id.* at 50,946. We refer to these changes, collectively, as the "Documentation Requirements."

By the terms of the Rule, a qualifying prescription is not a slip of paper from a doctor's standard prescription pad. Instead, CMS defined "prescription" as a "written order" that includes the beneficiary's name, the physician's name and signature, the date of the examination, "the diagnoses and conditions that the PMD is expected to modify, a description of the [PMD] (for example, a narrative description of the specific type of PMD)," and the "length of need." *Id.* at 50,941.

In addition to the prescription, the physician must provide the supplier with "pertinent parts of the medical record" that "clearly support the medical necessity for the PMD in the beneficiary's home." *Id.* at 50,942. According to CMS, "pertinent parts" "may include the [patient's medical] history," as well as details on the physician's

"physical examination, diagnostic tests, summary of findings, diagnoses, and treatment plans." *Id.* CMS envisions that these portions of the record would include "subjective" and "objective" components. The subjective component might summarize matters such as the patient's history, treatment, and request for a PMD. *See id.* The objective component might record circumstances like the patient's appearance and physical condition, including the functionality of the patient's extremities and the patient's ability to perform functions in his or her home environment. *See id.*

The Documentation Requirements also include procedural and record-keeping obligations. In order for a supplier to receive reimbursement for a PMD, it must receive from the doctor or treating practitioner, within 30 days of the face-to-face examination, the prescription and documentation that supports the determination of medical necessity. *See id.* at 50,946-47 (new 47 C.F.R. § 410.38(c)(2), (4)). Moreover, suppliers are required to "maintain the prescription and the supporting documentation" and must make those documents available "to CMS and its agents upon request." *Id.* at 50,947 (new 47 C.F.R. § 410.38(c)(5)(i)). If a Medicare carrier is not satisfied with the content of the prescription and medical records, it may require the supplier to obtain and present "additional documentation" from the medical professional. *Id.* at 50,943, 50,947 (new 47 C.F.R. § 410.38(c)(5)(ii)).

Although the effective date of the Rule is October 25, 2005, Medicare carriers will not be capable of processing the documents required by the Rule until April 2006. Between October 25, 2005, and April 2006, CMS will require suppliers to file an unsigned CMN form that the carriers are able to process, although that form will not carry any weight as proof of medical necessity and suppliers will have to comply with the

new Documentation Requirements. *See* HHS, *CMS Manual System, Pub. 100-08 Medicare Program Integrity*, Transmittal 124 (Sept. 23, 2005), *available at* http://www.cms.hhs.gov/manuals/pm_trans/R124PI.pdf.

DISCUSSION

A preliminary injunction against enforcement of the Rule is warranted because: (1) there is a likelihood (indeed, a strong likelihood) that the Coalition's challenge to the Rule will succeed on its merits; (2) members of the Coalition would suffer irreparable injury if the injunction is not granted; (3) the requested injunction would not substantially injure other interested parties; and (4) the public interest would be furthered by the injunction. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998). The Coalition need not demonstrate that all of the relevant considerations tilt in favor of relief. It is enough that the overall "balance[]" of these factors favors relief. *Id.*; *see Lee v. Christian Coal. of Am., Inc.*, 160 F. Supp. 2d 14, 26 (D.D.C. 2001) (preliminary injunction factors "interrelate on a sliding scale and must be balanced against each other") (internal quotation marks omitted). Nevertheless, as we demonstrate below, *all* of the relevant factors support issuing a preliminary injunction in this case. *Cf. World Duty Free Americas, Inc. v. Summers*, 94 F. Supp. 2d 61 (D.D.C. 2000) (preliminarily enjoining implementation of temporary regulation that was promulgated without notice and comment).

I. THE COALITION IS LIKELY TO SUCCEED ON ITS PROCEDURAL AND SUBSTANTIVE CHALLENGES TO THE RULE

The first relevant factor, whether the Coalition has shown a likelihood of success on the merits, tips the balance of all the factors strongly in favor of an injunction, because the Coalition is very likely to prevail on both its procedural challenge and its substantive

challenge to the Rule. *See generally Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843-45 (D.C. Cir. 1977) (discussing interrelationship of the four factors).

A. The Secretary Unlawfully Failed To Follow Notice-and-Comment Procedures

The APA, 5 U.S.C. § 553, generally requires that an agency wishing to change its substantive rules must do so through notice-and-comment rulemaking procedures. The Medicare Act likewise requires the use of notice-and-comment procedures in promulgating such rules. *See* 42 U.S.C. § 1395hh(b)(1). Under these procedures, a "notice of proposed rule making shall be published in the Federal Register," 5 U.S.C. § 553(b), and then "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation," *id.* § 553(c).

Notice-and-comment procedures represent Congress's compromise between the competing interests of agency efficiency and agency accountability. *See New Jersey Dep't of Envtl. Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980). Accordingly, although Congress established a handful of exceptions to the notice-and-comment requirement, it "expected, and the courts have held, that the various exceptions . . . will be narrowly construed and only reluctantly countenanced." *Id.*; *see Tennessee Gas Pipeline Co. v. FERC*, 969 F.2d 1141, 1144 (D.C. Cir. 1992) (same); *Analysas Corp. v. Bowles*, 827 F. Supp. 20, 23 (D.D.C. 1993) ("Courts in this circuit take a dim view of rule-making which has not been preceded by notice and comment.").

The Secretary of HHS conceded that he did not follow notice-and-comment procedures in promulgating the Rule. *See* 70 Fed. Reg. at 50,943. That undisputed failure renders the Rule unlawful.

1. The Documentation Requirements Are an Act of Agency Discretion, Not Statutory Interpretation or Ministerial Implementation

In promulgating the Rule, the Secretary attempted to justify his failure to follow notice-and-comment procedures in part on the basis that the Rule "conforms [CMS] regulations to section 1834(a)(1)(E)(iv) of the [MMA]." 70 Fed. Reg. at 50,943. That justification potentially invokes two exceptions to notice-and-comment requirements: the exceptions for "interpretive rules," 5 U.S.C. § 553(b)(3)(A), and for rules as to which "the agency for good cause finds . . . that notice and public procedure thereon are . . . unnecessary," *id.* § 553(b)(3)(B). *See* 42 U.S.C. § 1395hh(b)(2)(C) (incorporating exceptions to section 553). The interpretive-rule exception excuses notice-and-comment procedures when, instead of establishing any new legal requirements, a rule merely "advise[s] the public of the agency's construction of the statutes and rules which it administers." *American Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993) (internal quotation marks omitted). Similarly, the "good cause" exception for rules as to which notice and comment would be "unnecessary" includes "nondiscretionary ministerial action[s]" that the agency is required to take by virtue of a statutory command or some other requirement. *Metzenbaum v. FERC*, 675 F.2d 1282, 1284, 1291 (D.C. Cir. 1982) (per curiam). Neither exception applies here.

Section 1834(a)(1)(E)(iv) of the MMA, which the Rule implements in part, *see* 70 Fed. Reg. at 50,943, provides in full:

> Standards for power wheelchairs
>
> Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1395x(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

42 U.S.C. § 1395m(a)(1)(E)(iv).

The regulations at issue in this case plainly do more than implement the examination and prescription requirements of section 1834(a)(1)(E)(iv). The Secretary explained in promulgating the Rule that the Documentation Requirements are "*[i]n addition to* the prescription" required by Congress. 70 Fed. Reg. at 50,942 (emphasis added). And the "prescription" that the regulations require is itself more detailed than a normal prescription used in the medical profession, requiring the physician to include "the diagnoses and conditions that the PMD is expected to modify [and] a description of the item (for example, a narrative description of the specific type of PMD)." *Id.* at 50,941. As for the Secretary's elimination of CMNs, that action is not even *permissible* under the Medicare Act, 42 U.S.C. § 1395m(j)(2)(A)(i), much less *required*. *See generally Maximum Comfort, Inc. v. Thompson*, 323 F. Supp. 2d 1060, 1067-68 (E.D. Cal. 2004), *appeal pending*, No. 05-15832 (9th Cir. docketed May 4, 2004). The Rule promulgated by the Secretary therefore was not a discretionless, ministerial action that Congress required him to undertake.

Nor does the Rule satisfy the D.C. Circuit's criteria for an interpretive rule that is exempt from notice-and-comment requirements under section 553(b)(3)(A). *Cf. Komjathy v. NTSB*, 832 F.2d 1294, 1296 (D.C. Cir. 1987) (per curiam) (notice and

comment not required where regulation "merely reiterates the statutory language"). As a threshold matter, the Secretary cannot now rely on the interpretive-rule exception because he did not invoke that exception when adopting the Rule, and "an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

In any event, the new requirements have all the indicia of a legislative rule that generally must be subject to public comment. *See generally General Elec. Co. v. EPA*, 290 F.3d 377, 382-83 (D.C. Cir. 2002) (identifying characteristics of legislative rules); *Truckers United for Safety v. Federal Highway Admin.*, 139 F.3d 934, 938-39 (D.C. Cir. 1998) (same). The Documentation Requirements impose new, binding obligations on the Coalition's members and other suppliers of PMDs. The Secretary recognized that the Rule would have "substantial" effects on members of the public, 70 Fed. Reg. at 50,945, and was "economically significant" and a "major rule under the Congressional Review Act," *id.* *See generally* Sidak & Singer Decl. ¶ 31. The Secretary invoked his legislative rulemaking authority when imposing the Rule. 70 Fed. Reg. at 50,946 (citing 42 U.S.C. § 1302 as legal authority for the Rule). The requirements cabin CMS's own discretion in implementing the Medicare program with respect to PMDs. And they are to be published in the Code of Federal Regulations as amendments to prior Medicare rules. *See id.* (new 42 C.F.R. § 410.38(c)(2)(iii)).

As in *World Duty Free*, notice and an opportunity for public comment were required here because the new regulations go "beyond a mere recitation of the statutory language to . . . impose obligations and potential penalties." 94 F. Supp. 2d at 65

2. There Was No Other "Good Cause" for Bypassing Notice-and-Comment Procedures

The Secretary further posits that there was "good cause" under 5 U.S.C. § 553(b)(3)(B) for failing to undertake notice-and-comment procedures because "fraudulent billing practices for PMDs have been a substantial problem" and "it would be contrary to the public interest to delay a regulation intended to stem the abusive billing practices." 70 Fed. Reg. at 50,943. That statement amounts to little more than an assertion that a rulemaking is warranted. It is not even clear whether the Secretary meant to suggest that notice and comment was "impracticable," or "unnecessary," or "contrary to the public interest" under section 553(b)(3)(B). But it is of no matter which element of the test the Secretary meant to invoke, because the fraud justification fails under each one.

First, the Secretary cannot claim (and did not claim in the preamble to the Rule) that there was insufficient time to undertake notice and comment on the question of how fraud in the PMD program can best be addressed. CMS publicly announced its intent to consider reforms to the Medicare PMD program as early as September 2003. *See* note 2, *supra*. In December 2003, CMS opened a rulemaking on PMD reimbursement. In August 2004, CMS solicited comments on a proposed rule that contained provisions similar to some of the provisions of the instant Rule. Coalition members and other members of the public commented on the proposed rule. Then, in November 2004, CMS deferred considering comments on that proposed rule until a later date. *See* pp. 7-8, *supra*. CMS has been working toward its new Rule for at least two years. *See World Duty Free*, 94 F. Supp. 2d at 65 (lack of a congressional deadline for action and agency's two-year delay in promulgating regulations to implement a statutory change

"substantially undercut[]" agency's argument that "notice and publication was 'impracticable' and 'contrary to the public interest'").

The preamble to the Rule suggests no reason why the public could not have been included in CMS's lengthy deliberations. Indeed, there is every appearance that Secretary decided to proceed without notice and comment precisely so that he would not have to address the sort of record evidence developed on similar issues after the August 2004 notice of proposed rulemaking. The narrow exceptions in section 553 do not authorize that sort of "surprise switcheroo on regulated entities." *Environmental Integrity Project v. EPA*, Nos. 04-1083, 04-1243, 2005 U.S. App. LEXIS 21683, at *13 (D.C. Cir. Oct. 7, 2005) (under "logical outgrowth" rule, agency violated APA in adopting, without notice and comment, an interpretation of statutory language that was different than the interpretation in a proposed interim rule).

Second, although an agency may abandon notice and comment in "emergency situations" or when "delay could result in serious harm," *Jifry v. FAA*, 370 F.3d 1174, 1179-80 (D.C. Cir. 2004), neither circumstance is present here. Again, CMS's false-starts toward promulgating regulations through notice and comment belie any suggestion that an emergency precludes those procedures. The Secretary himself does not describe CMS's policy concerns or the Rule in those terms. *See* 70 Fed. Reg. at 50,941, 50,943-46; *see also Utility Solid Waste Activities Group v. EPA*, 236 F.3d 749, 754-55 (D.C. Cir. 2001) (relying on EPA's failure to establish "any threat to the environment or human health or that some sort of emergency had arisen").

Protecting program funds – through appropriate requirements that take account of all the relevant considerations – is indisputably a legitimate goal of CMS, but it lacks the

extreme urgency that has led courts to find good cause for bypassing notice and comment. *Cf. Jifry*, 370 F.3d at 1179 (upholding FAA regulations promulgated without notice and comment after the September 11, 2001, terrorist attacks to address an "imminent hazard" of further attacks) (internal quotation marks omitted). Indeed, because every agency rulemaking presumably is intended to serve the public interest, the good-cause exception would swallow the general rule of section 553 if an agency could avoid notice and comment merely by asserting that its rules will have some benefit. *See Utility Solid Waste Activities Group*, 236 F.3d at 754 (good-cause exception is not an "escape clause" and its use "should be limited to emergency situations") (internal quotation marks omitted).[3]

Third, this is not a "'a situation in which the interest of the public would be defeated by any requirement of advance notice,' as when announcement of a proposed rule would enable the sort of financial manipulation the rule sought to prevent." *Utility Solid Waste Activities Group*, 236 F.3d at 755 (quoting U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* at 31 (1947)). The Secretary has made no representation that notice and an opportunity to comment would have enabled evasion of the Rule. Nor could the Secretary press that argument, inasmuch as he made the new Rule effective two months after its promulgation. *See* 70 Fed. Reg. at 50,940.

[3] The preamble to the Rule also hints at impracticality in stating that the Rule was necessary to "operationalize" a National Coverage Decision ("NCD") for Mobility Assistive Equipment that CMS issued on May 5, 2005. *See* 70 Fed. Reg. at 50,943. Yet the Secretary evidently believed when he issued the NCD last May that it would be compatible with the CMN regime that was already in place; otherwise, he would have sought to modify the CMN requirements at that time. The preamble to the Rule, moreover, does not suggest that a conflict between the NCD and the CMN regime arose between May 2005 and August 2005. Instead, the Secretary suggests that the new Rule will improve compliance with the NCD. *See id.* That is an issue – concerning improvement of an existing agency program on which many members of the public depend – that notice-and-comment procedures are especially well-suited to examine.

The so-called "interim" status of the Rule also does not except it from the notice-and-comment requirements of section 553. Even interim regulations are subject to notice and comment, save those regulations that respond to a "rare 'emergency' situation." *American Fed'n of Gov't Employees, AFL-CIO v. Block*, 655 F.2d 1153, 1157-58 (D.C. Cir. 1981); *see also Tennessee Gas Pipeline*, 969 F.2d at 1145-46 (holding that an "interim rule" with "limited nature" was nevertheless subject to notice-and-comment requirements). As discussed above, the Secretary has not established that the Rule responds to any emergency. Furthermore, it is fatal to any "interim rule" rationale that the Secretary has not established a deadline or even a target date for promulgation of a final rule. *See Thrift Depositors of Am., Inc. v. Office of Thrift Supervision*, 862 F. Supp. 586, 593 (D.D.C. 1994) (interim status of rule did not warrant suspending notice and comment when the agency did not know when final rule would be promulgated); *Analysas Corp.*, 827 F. Supp. at 25 (same).

B. The Rule Is Arbitrary, Capricious, and Contrary to Law

The Coalition also is very likely to prevail on its substantive challenge to the Rule. "[N]otice-and-comment rulemaking is a primary method of assuring that an agency's decisions will be informed and responsive." *New Jersey Dep't of Envtl. Prot.*, 626 F.2d at 1045. It therefore is unsurprising that the Rule – which was never tested by that crucible – is fatally defective for lack of reasoned justification. *See Tennessee Gas Pipeline*, 969 F.2d at 1146 (deficiencies of interim rule demonstrate the "value of public participation in rulemaking" and the "wisdom of the APA's requirement that an agency have the benefit of informed comment before it issues regulations that have the force of law").

The Rule is subject to substantive judicial review under the familiar "arbitrary [and] capricious" standard of the APA. 5 U.S.C. § 706(2)(A); *see National Ass'n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 41 (D.D.C. 2000) (applying arbitrary-and-capricious standard to an Interim Final Rule). To be sure, the agency's failure to permit public comment prevents this Court from reviewing CMS's decision on "the whole record" before the agency. 5 U.S.C. § 706. Nevertheless, the Documentation Requirements must be struck down if CMS failed to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43 (internal quotation marks omitted); *see Tennessee Gas Pipeline*, 969 F.2d at 1146 (applying *State Farm* standard to agency's explanation for invoking good-cause exception notwithstanding the absence of a formal record). In particular, the Secretary was required either to consider "facially reasonable" alternatives to the Rule, or else to "give some reason . . . for declining to do so." *Laclede Gas Co. v. FERC*, 873 F.2d 1494, 1498 (D.C. Cir. 1989).

According to the preamble to the Rule, the reasons for issuing the new Documentation Requirements were: (1) increased Medicare payments for PMDs, *see* 70 Fed. Reg. at 50,941, 50,943; (2) the agency's conclusion that "inflated and falsified billings" are generally "a serious problem" in Medicare's durable medical equipment program, of which PMD reimbursement is a part, *id.* at 50,941; and (3) "the belief that the CMNs do not accurately reflect the contents of the physician's medical record" underlying a determination of medical necessity, *id.* at 50,944. None of these

considerations necessarily establishes the wisdom of the specific action that the Secretary took.

Increased Reimbursement Outlays. The Secretary states that Medicare payments for power wheelchairs "increased approximately 350 percent from 1999 to 2003." *Id.* at 50,941. The Secretary ignores that Medicare reimbursements for PMDs have *declined* by more than 30% since 2003. *See* Zipp Decl. ¶ 9. Furthermore, the increased utilization of PMDs before 2003 would suggest on its face that this equipment was increasingly beneficial to Medicare recipients during that period, not an increasing problem. (Research in fact bears this out. *See* pp. 33-34, *infra*).

There were several good reasons for the increase in physician prescriptions for PMDs from 1999 to 2003. Improvements in power wheelchairs and scooters made these devices useful for a greater number of patients, and suppliers worked hard to inform doctors and those patients who could benefit from these devices about their availability. More Americans in need of a PMD were receiving them. In addition, the increasing number of Americans aged 65 and older has increased the overall medical need for PMDs. *See* p. 7, *supra*.

The Secretary seemingly believes that too many Medicare dollars are being spent on PMDs. If so, the Secretary may review the eligibility criteria in the Medicare statute, *see* 42 U.S.C. § 1395y(a)(1)(A) (covered service or equipment must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member"), and CMS's implementing regulations, and ask for a legislative solution or public comment on a proposed regulatory fix. In May 2005, the Secretary and CMS issued a National Coverage Decision that attempts to clarify

eligibility for PMDs. *See* 70 Fed. Reg. 50,943 (noting the NCD); HHS, *CMS Manual System, Pub. 100-03 Medicare National Coverage Determinations*, Transmittal 37 (June 3, 2005), *available at* http://www.cms.hhs.gov/manuals/pm_ trans/r37NCD.pdf. What the Secretary may not do is use the Documentation Requirements as a back-door way of reducing Medicare spending on PMD reimbursements that are required under the program's eligibility criteria.

Fraud. The Secretary further cited findings of "fraud and abuse" by durable medical equipment suppliers. 70 Fed. Reg. at 50,941; *see id.* at 50,943-44. Specifically, the Secretary noted agency determinations of "inflated and falsified billings . . . among certain DME suppliers," *id.* at 50,941, and appeared to reference a report on Medicare fraud by the Office of the Inspector General of HHS. *See* HHS, Office of Inspector General, *Medicare Payments for Power Wheelchairs*, OEI-03-02-00600 (Apr. 2004) ("OIG Report"), *available at* http://oig.hhs.gov/oei/reports/oei-03-02-00600.pdf. The recommendations of the OIG Report, however, do not include the Documentation Requirements that the Secretary adopted.

The OIG Report identified two categories of unnecessary reimbursement by Medicare: (i) claims paid by Medicare despite the lack of a CMN or other inadequate documentation under existing regulations, and (ii) reimbursement for PMDs supplied to patients who are either ineligible for any type of PMD, or ineligible for the particular type of PMD supplied. *See* OIG Report at 9-12. The solution to overpayments in the first category lies with improved processing of claims by CMS and its Medicare contractors. Requiring additional paperwork will not help CMS to stop making payments when required documentation is missing.

As for PMDs furnished to ineligible patients, the OIG Report indicates that the main reason for such errors was physicians' lack of information about Medicare guidelines and the different types of mobility devices. *See id.* at 16-17. The Secretary has taken other actions to address those problems, including the issuance of an NCD in May 2005. The Secretary has failed to explain, particularly in light of those recent actions, how changing long-established reimbursement procedures reduces uncertainty, much less why the new procedures are the most appropriate way of correcting information shortfalls on the part of doctors and other treating professionals.

Documentation Gaps. Finally, CMS expressed the views that "CMNs do not accurately reflect the contents of the physician's medical record" and their "practical utility . . . is questionable," and, accordingly, that CMNs should be abandoned for PMD reimbursements. 70 Fed. Reg. at 50,944. This also is not sufficient justification for the Rule.

As an initial matter, the Eastern District of California has held that 42 U.S.C. § 1395m(j), which addresses the use and contents of CMNs, establishes Congress's intent "that whatever information may be required by carriers from suppliers to show the medical necessity and reasonableness of [durable medical equipment] must be contained in a CMN." *Maximum Comfort*, 323 F. Supp. 2d at 1068. For the reasons given in that case, *see id.* at 1067-75, the Rule is unlawful inasmuch as it replaces the CMN with a vague requirement of documenting medical necessity through medical records and allows carriers to require additional documentation beyond that expressly required by the Rule.

The Rule is also substantively deficient because the Secretary failed to consider other obvious approaches to gathering fuller information on medical-necessity determinations. In the Regulatory Impact Statement accompanying the Rule, the Secretary stated, without any explanation, that "[w]e do not believe that any reasonable alternatives [to the Rule] exist." 70 Fed. Reg. at 50,945. Yet public comments on the August 2004 proposed rule, which the Secretary has yet to address, discussed such alternatives. *See* Zipp Decl. ¶ 16. Furthermore, as recently as November 2004, CMS was considering one particularly obvious option – revising the CMN form to include additional information supplied by the medical practitioner. *See id.* ¶ 23. The Secretary utterly failed to explain why such "facially reasonable" alternatives to the Rule would not address his concerns. *Laclede Gas*, 873 F.2d at 1498.[4]

Similarly, the Secretary's adoption of the Rule appears to have been infected by grossly incorrect assumptions about its effect on suppliers of PMDs. The Secretary stated, for example, that "suppliers will face decreases in record-keeping requirements," 70 Fed. Reg. at 50,945, when in fact the Rule imposes new obligations to collect, review, and maintain supporting documentation. *See* Zipp Decl. ¶¶ 18-21; DiLernia Decl. ¶¶ 7-16. Coalition member The Scooter Store estimates that the Rule will require it to spend an additional $150,000 each year on document storage, in addition to the added expense of gathering and reviewing medical records to support reimbursement claims. Zipp Decl. ¶ 21. The Rule also is invalid due to this defective reasoning.

[4] In light of such concrete alternatives to the Rule, the Secretary's disregard of notice-and-comment requirements cannot be excused as harmless error. *See Utility Solid Waste Activities Group*, 236 F.3d at 755 (lack of comment period was not harmless error when a party "presented enough evidence to show that on remand they can mount a credible challenge to the amended rule and were thus prejudiced by the absence of an opportunity to do so before the amendment").

II. THE COALITION'S MEMBERS WILL SUFFER IRREPARABLE HARM IF ENFORCEMENT OF THE RULE IS NOT ENJOINED

A "strong showing of likely success on the merits may warrant issuance of preliminary injunctive relief even if the plaintiff makes a less compelling showing on the other three factors." *Lee*, 160 F. Supp. 2d at 26. In this case, however, the Coalition need not rely on that principle. Each of the other three factors, including the threat of irreparable injury to the Coalition's members if preliminary relief is not granted, also weighs in favor of preliminary injunctive relief.

The Rule will inflict irrecoverable, severe, and immediate economic loss upon Coalition members who depend upon timely and reliable Medicare reimbursement in their businesses. Under the CMN procedures that have been in effect since 1997, doctors record and attest to their determinations of medical necessity on the CMN form, which the supplier (or potentially the Medicare beneficiary herself) sends to the Medicare carrier to request reimbursement. Other medical information is not routinely requested by CMS or its carriers. *See* Zipp Decl. ¶ 22; DiLernia Decl. ¶ 8.

The "critical" role of the CMN in Medicare reimbursement, DiLernia Decl. ¶ 5, reflects, first, that the determination of medical necessity for a PMD is a judgment that treating physicians – not PMD suppliers or CMS – must make. In the CMS Administrator's words during his Senate confirmation process in 2004, "[t]he clinical criteria for deciding when a manual or power wheelchair is medically necessary and appropriate for a beneficiary has been and will continue to be a matter of clinical judgment by a physician," and a matter "best left to the physician's judgment." Answers for the Record to Questions from the Senate Finance Committee Hearing on the Nomination of Mark B. McClellan To Be Administrator of the Centers for Medicare &

Medicaid Services at 91 (Mar. 8, 2004) (response to question submitted by Sen. Kerry), *available at* http://finance.senate.gov/hearings/edmcquest.pdf.

The CMN process also meets a need to focus treating doctors on generating a written record that addresses the medical necessity of a particular device. In the ordinary course of their practices, physicians do not maintain medical records for the purpose of justifying their patients' need for particular medical equipment. For example, doctors may not record the considerations (such as upper-body weakness in a patient with no mobility below the waist) that led them to prescribe a PMD rather than other equipment such as a standard wheelchair, particularly when those considerations lack prospective significance for medical treatment. *See* DiLernia Decl. ¶¶ 10-11.

PMD suppliers are unable as a practical matter to educate all their customers' personal doctors on the need to keep such records for Medicare. DiLernia Decl. ¶ 12; *see* Zipp Decl. ¶ 19-20. Likewise, it would be infeasible for suppliers of PMDs to second-guess the records doctors generate in their practices. *See* DiLernia Decl. ¶ 13; Zipp Decl. ¶ 20. Instead, suppliers (as well as doctors) have relied on the CMN to ensure that a doctor who has prescribed a PMD has recorded findings that support that choice. *See* DiLernia Decl. ¶ 6; Zipp Decl. ¶ 22.

In a November 1996 submission to the Office of Management and Budget justifying adoption of the CMN, HCFA emphasized these factors, explaining that "CMNs are a standardized . . . way of communicating information needed to determine the medical necessity of the claim." HCFA, *Paperwork Reduction Act Submission: Durable Medical Equipment Regional Carriers, Certificates of Medical Necessity*, OMB Control No. 093800679, at 3 (Nov. 6, 1996) (Exh. 6). HCFA pointed out that this

standardized approach "presents less of a burden than requiring submission of individual medical records (which are non-standardized)." *Id.*

The Documentation Requirements represent an abandonment of this longstanding and workable approach that Congress incorporated into the Medicare Act. *See* 42 U.S.C. § 1395m(j)(2)(B). Under the new Rule, applicants for reimbursement may not rely on the standardized and familiar information the doctor provides on a CMN, but must instead assemble on an ad hoc basis, in addition to a prescription that meets CMS's requirements, other medical records "that clearly demonstrate medical necessity for the PMD." 70 Fed. Reg. at 50,942; *see id.* (documentation must "clearly support" medical necessity). Thus, the Rule seemingly establishes a new burden of proof (a "clear" evidence test), and requires suppliers to ensure that the doctor's medical records – whatever they may include – satisfy that standard. The Rule, however, provides no criteria, beyond two hypothetical examples of acceptable documentation that are discussed in the preamble, by which suppliers can reliably predict whether CMS and its contractors will find any particular documentation adequate. *See id.* at 50,492-43.

The combined consequence of (i) abolishing the CMN and (ii) failing to provide meaningful criteria for assessing the sufficiency of various sorts of medical records, is that suppliers – who, over time, have developed informed expectations as to how carriers are likely to view any particular CMN – have no significant guidance at all. In many instances, suppliers will not be able to make any educated prediction about whether they will be reimbursed for the cost of a PMD that fills a doctor's prescription, especially when the preamble to the Rule implies that the very purpose of the new requirements is to reduce the number of claims that Medicare reimburses. *See id.* at 50,941, 50,943 (citing

increased program outlays and "restraining the billing for PMDs" as justifications for the Rule); DiLernia Decl. ¶¶ 8-16; Zipp Decl. ¶¶ 24-25; Sidak & Singer Decl.¶ 25.[5]

Together with the increased record-gathering and record-keeping costs associated with the new Rule, and related delays in obtaining reimbursement, this uncertainty about whether claims will ever be paid is likely to put Coalition members (including small suppliers as well as large ones) out of business. *See* DiLernia Decl. ¶¶ 16-18; Sidak & Singer Decl. ¶¶ 22-27; Zipp Decl. ¶¶ 26-27. That extreme economic hardship constitutes irreparable injury. *See Express One Int'l, Inc. v. U.S. Postal Serv.*, 814 F. Supp. 87, 90-91 (D.D.C. 1992) (denial of the opportunity to service a government contract, with ensuing "loss of revenues and profits," was irreparable injury); *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (loss may be irreparable, even if recoverable, if it "threatens the very existence of the movant's business"); *McGregor Printing Corp. v. Kemp*, No. 91-3255, 1992 U.S. Dist. LEXIS 6717, at *16-*17 (D.D.C. May 14, 1992) (threat of closing down two plants with potential job loss of seven to 60 employees constituted irreparable injury).

The losses suffered by these suppliers, moreover, are irreparable because neither lost sales of mobility devices nor denied claims for reimbursement can be recouped from patients. *See* Zipp Decl. ¶ 13; DiLernia Decl. ¶¶ 16-18; Sidak & Singer Decl. ¶ 19, 30. There also is no mechanism, such as a suit for money damages, by which losses could be recovered from CMS after the fact. *See Department of the Army v. Blue Fox, Inc.*, 525 U.S. 255, 260 (1999) ("Absent a waiver, sovereign immunity shields the Federal

[5] When it audits suppliers' reimbursement claims, CMS commonly looks at a sampling of claims filed during a certain period of time. Depending on the results of the audit, CMS may extrapolate from the results of the audit to disallow a percentage of all claims filed by the supplier during that period. *See* 42 U.S.C. § 1395ddd(f)(3) (Supp. 2004). The consequence of this approach is a multiplier effect: for every claim that is found deficient after an audit, the supplier must repay CMS for many more claims.

Government and its agencies from suit.") (internal quotation marks omitted). Accordingly, because Coalition members would not be able to secure compensatory or other relief at a later date, their economic injury is irreparable. *See Wisconsin Gas*, 758 F.2d at 674-75.

Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20 (D.D.C. 1997), is illustrative. There, several manufacturers challenged the FDA's regulatory treatment of their products, where a competitor was allowed "to submit much less rigorous information and testing results." *Id.* at 23-24. The Court determined that the plaintiffs had shown "on-going and imminent harm" resulting from the more time-consuming and expensive regulatory requirements, that those greater financial costs could not be recouped, and that, although the plaintiffs' losses were purely economic, they had proved harm sufficient to warrant injunctive relief. *Id.* at 28-29; *see Armour & Co. v. Freeman*, 304 F.2d 404, 406 (D.C. Cir. 1962) (per curiam) (irreparable injury found when "enforcement of the [challenged] regulation" would "cause loss of profits which could never be recaptured"). Similar findings are warranted in this case.

Courts have found irreparable harm under circumstances involving far less economic injury than the Rule would inflict on Coalition members. In *World Duty Free*, for example, the Court concluded that an interim rule that affected one-third of company's business constituted irreparable harm. 94 F. Supp. 2d at 67; *see also National Ctr. on Missing & Exploited Children v. Horner*, 699 F. Supp. 333, 337 (D.D.C. 1988) (potential loss of $166,000 in contributions to a charitable organization constituted "irreparable harm"); *Bracco Diagnostics*, 963 F. Supp. at 29 & n.9 ($1.5 million in additional expenses). In this case, by comparison, the Rule could wipe out supplier

businesses of all sizes and imperil Medicare-reimbursed sales of PMDs that total approximately $864 million annually for the industry. *See* 70 Fed. Reg. at 50,945 (providing FY 2004 sales figures).[6]

Coalition members also have been unlawfully deprived of their opportunity to participate, through the public-comment process, in CMS's decisionmaking on the Rule. Coalition members have participated in other rulemaking proceedings concerning CMS's reimbursement regulations for PMDs, and they would have participated in a notice-and-comment proceeding to consider whether the Documentation Requirements are lawful and sound policy. *See* Zipp Decl. ¶ 17. That denial of an opportunity to participate in the agency's administrative processes constitutes irreparable harm, independent of the economic effect of the Rule. *See Community Nutrition Inst. v. Butz*, 420 F. Supp. 751, 757 (D.D.C. 1976) ("[T]he harm suffered by those who would otherwise participate in agency rulemaking under the APA is to be considered irreparable when the agency fails to afford them their rights to such participation.").

III. A PRELIMINARY INJUNCTION WOULD NOT CAUSE THE SECRETARY OR INTERESTED PARTIES SERIOUS HARDSHIP

In marked contrast to the irreparable harm that Coalition members will suffer absent the issuance of a preliminary injunction, the Secretary has only a minimal interest in enforcing the Rule as of October 25, 2005.

---

[6] Because the Documentation Requirements are likely to cause Coalition members to close their businesses and withdraw entirely from the Medicare program, and because remaining suppliers will face severe penalties if they fail to comply with the Rule, Coalition members have no practical means of obtaining relief through the administrative process. *See* DiLernia Decl. ¶ ¶17-18; Zipp Decl. ¶¶ 26-27; Sidak & Singer Decl. ¶¶ 16, 27, 30. In this situation, access to the courts is available under 42 U.S.C. § 405(h) because denying access would "mean no review at all." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 19 (2000). *See American Lithotripsy Soc'y v. Thompson*, 215 F. Supp. 2d 23, 28-29 (D.D.C. 2002); *National Ass'n of Psychiatric Health Sys.*, 120 F. Supp. 2d at 38-39.

CMS's two-year delay in promulgating a Rule, and its continuing failure to take any relevant regulatory action pursuant to the August 2004 notice of proposed rulemaking, cast serious doubt on any claim of imminent harm if the Documentation Requirements do not take effect on October 25. CMS's asserted interests in enforcing the Rule also must be discounted insofar as they include illegitimate considerations (such as reducing Medicare expenditures for PMDs that are reimbursable under the applicable eligibility criteria), or could be addressed as effectively, or more effectively, in some other way (such as by improving the CMN form).

A preliminary injunction would not disrupt CMS's regulatory program because the Documentation Requirements have not taken effect. This is not a circumstance in which entering a preliminary injunction would disrupt a current regulatory regime, *cf. EMILY's List v. Federal Election Comm'n*, 362 F. Supp. 2d 43, 58-59 (D.D.C. 2005) (preliminary injunction would throw the "present system of regulations into disarray"), but rather one in which the injunction would preserve the status quo pending adjudication of the merits, *see Graphic Scis., Inc. v. International Mogul Mines Ltd.*, 397 F. Supp. 112, 117 (D.D.C. 1974) ("[T]he primary use of temporary relief is to preserve the status quo until more deliberate investigation can better determine the rights of the parties.").

Furthermore, Medicare carriers do not have in place the systems necessary to process reimbursement claims under the new documentation guidelines, and they will not have such systems in place before April 2006 – more than five months from now. *See* pp. 10-11, *supra*. Thus, whatever benefits the Documentation Requirements might ultimately have will be realized only incompletely (and perhaps not at all) until April 2006 at the earliest. During that same period, however, the Documentation Requirements

will cause Coalition members to suffer immediate and certain economic loss. For all these reasons, the balance of these hardships tilts decidedly in favor of granting the Coalition's motion for preliminary injunctive relief.

IV. THE PUBLIC INTEREST LIES IN ISSUING A PRELIMINARY INJUNCTION

The final factor pertinent to this motion for preliminary relief is the public interest. This factor also weighs heavily on the side of granting relief.

There is a substantial public interest in ensuring that Medicare beneficiaries are not denied access to medically appropriate mobility devices. *See International Long Term Care, Inc. v. Shalala*, 947 F. Supp. 15, 20 (D.D.C. 1996) (the public interest in serving the needs of the "elderly and infirm" warranted preliminary injunction preventing termination of a nursing home from Medicare); *Libbie Rehab. Ctr., Inc. v. Shalala*, 26 F. Supp. 2d 128, 132 (D.D.C. 1998) ("The interest of the Government in administering the Medicare . . . program[] is to ensure that the recipients of benefits are receiving adequate treatment and care.").

In Fiscal Year 2004, medical professionals prepared 187,000 certifications of medical necessity for PMDs, which were submitted for Medicare reimbursement. *See* 70 Fed. Reg. at 50,944-45. Each of those CMNs represents an opportunity for an American to live a safer, richer, and more independent life. Yet, as physicians and suppliers withdraw from or reduce their participation in the Medicare program in response to the Rule, patients in need of PMDs will lose important sources of information about these devices and will have more difficulty obtaining them. Thus, the Documentation Requirements will reduce the public's access to medically necessary mobility devices beginning on October 25, 2005. That outcome is contrary to the public interest. *See FTC*

v. Freeman Hosp., No. 95-5015-CV-SW-1, 1995 U.S. Dist. LEXIS 4020, at *11 (W.D. Mo. Feb. 28, 1995) (identifying public interest in access to "effective medical care"); *St. Jude Med., Inc. v. Intermedics, Inc.*, 623 F. Supp. 1289, 1293 (D. Minn. 1984) (public interest favored granting preliminary junction in order to ensure patient access to heart valves).

HHS's desire to reduce Medicare spending comes nowhere close to outweighing this public interest in providing medically necessary mobility equipment. *Cf. Cordis Corp. v. Medtronic, Inc.*, No. 4-86-820, 1986 U.S. Dist. LEXIS 17091, at *42-*43 (D. Minn. Dec. 1, 1986) (public interest in ensuring sufficient public access to life-saving devices outweighs possible costs to integrity of the patent system). As already explained, the growth in Medicare reimbursements for PMDs between 1999-2003 has stopped, and reflected several factors that have nothing to do with fraud or unjustified payments. *See* p. 21, *supra*. Nor can it be assumed that eliminating the CMN in favor of more subjective and cumbersome documentation requirements is a sound way of enforcing Medicare's eligibility requirements. *See* pp. 21-22, *supra*.

What *can* be expected that the Rule will deny qualified patients access to medically necessary mobility devices. That is an issue of human safety and wellness, not just money. Expressed in economic terms, however, the Rule may result in a net loss of consumer welfare (which is the total difference between the value of PMDs to consumers and their cost) in the range of $93 to $283 million per year. Sidak & Singer Decl. ¶ 29.

Furthermore, research indicates that the provision of PMDs under Medicare *saves* program funds. PMDs make patients more independent, better able to care for themselves, and less prone to falls and other accidents, and thus reduces Medicare

expenditures for home healthcare and inpatient care at hospitals and skilled nursing facilities. *See* Clifford L. Fry, Ph.D., *et al.*, *Powered Vehicles for the Mobility Impaired: The Net Benefits to Medicare* (2005), *available at* http://www.cms.hhs.gov/mcd/publiccomment_popup.asp?comment_id=227 (concluding that the provision of a PMD to an eligible Medicare recipient saves the program more than $5,300 over three years – after deducting the cost of the PMD). Erecting artificial obstacles to reimbursement for eligible PMDs therefore is not even a rational way of curbing Medicare spending.

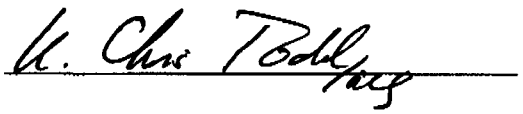
Finally, courts have recognized a weighty public interest in enforcing the requirements of the APA. *See Bracco Diagnostics*, 963 F. Supp. at 30. Here, the public – including physicians, suppliers, and Medicare beneficiaries and their families – has a substantial interest in ensuring CMS's compliance with the deliberative requirements of the APA, before the agency significantly overhauls an important component of the Medicare program.[7]

CONCLUSION

A preliminary injunction enjoining defendants from enforcing the challenged Rule (new 42 C.F.R. § 410.38(c)) should be entered.

[7] For the same reasons that the balance of harms and the public interest support entering a preliminary injunction in this case, the appropriate permanent relief will be vacatur of the Rule and a remand to the agency. *See, e.g.*, *CropLife Am. v. EPA*, 329 F.3d 876, 884-85 (D.C. Cir. 2003); *Sprint Corp. v. FCC*, 315 F.3d 369, 377 (D.C. Cir. 2003); *see also American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001) (remedy for a violation of the APA "normally will be a vacatur of the agency's order").

Respectfully submitted,



Eric W. Sokol
D.C. Bar No.: 434592
Power Mobility Coalition
919 18th Street, N.W.
Suite 550
Washington, D.C. 20006
(202) 296-3501

K. Chris Todd
D.C. Bar No.: 284455
David C. Frederick
D.C. Bar No.: 431864
Austin C. Schlick
D.C. Bar No.: 540042
Andrew M. Hetherington
D.C. Bar No.: 490434
Kellogg, Huber, Hansen, Todd
Evans & Figel, P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900

Counsel for the Power Mobility Coalition

Dated: October 13, 2005

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

POWER MOBILITY COALITION Plaintiff, v. MICHAEL O. LEAVITT, Secretary, United States Department of Health and Human Services, and MARK B. McCLELLAN, Administrator, Centers for Medicare and Medicaid Services, Defendants.	)	Civil Action No. _____

[PROPOSED] ORDER GRANTING MOTION FOR PRELIMINARY INJUNCTION

The Court has considered the motion of the Power Mobility Coalition for a preliminary injunction against defendants' implementation and enforcement of the proposed amendments to 42 C.F.R. § 410.38(c) promulgated in Interim Final Rule, *Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles*, 70 Fed. Reg. 50,940 (Aug. 26, 2005), and the responses thereto.

Plaintiff has shown that: (1) it is likely to succeed on the merits of its procedural and substantive claims to the Interim Final Rule; (2) its members would be irreparably harmed if the amendments promulgated in the Interim Final Rule are not enjoined; (3) defendants and other interested parties would not be burdened by an injunction against enforcement of the new regulations; and (4) the public interest would be served by enjoining the regulations.

For the foregoing reasons, IT IS ORDERED that the motion is hereby GRANTED.

IT IS FURTHER ORDERED that plaintiffs are not required to post bond or other security as a condition for obtaining this order.

United States District Judge

Dated: October ___, 2005

Independence Through Enhancement of Medicare and Medicaid
COALITION

Comments Submitted by the
ITEM COALITION

On November 25, 2005

To the
Centers for Medicare and Medicaid Services
(CMS)

Regarding the Interim Final Rule with Comment Period
Released on August 26, 2005

"Medicare Program; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power Operated Vehicles"

1875 Eye Street N.W., 12th Floor • Washington, D.C. 20006
(202) 349-4260 (phone) • (202) 785-1756 (facsimile) • www.itemcoalition.org

Introduction:

These comments are being submitted on behalf of a national, consumer-led coalition known as the "ITEM" Coalition, an acronym for Independence Through Enhancement of Medicare and Medicaid. The ITEM Coalition was formed in 2003, and its 74 member organizations include a diverse set of disability groups, aging organizations, other consumer groups, labor organizations, voluntary health associations, and non-profit provider associations.

The ITEM Coalition's purpose is to raise awareness and build support for policies that will improve access to assistive devices, technologies, and related services for people of all ages with disabilities and chronic conditions. From coverage for hearing aids to augmentative communications devices (AACs) to advanced artificial limbs to screen readers for people with vision impairments, the Coalition's mission is a broad one with implications for virtually every person with a disability who relies on assistive devices to be healthy, functional, and independent.

These comments will focus on many provisions in the August 26th Interim Final Rule on Power Mobility Devices (PMDs). The ITEM Coalition recognizes the value associated with the face-to-face examination requirement. Additionally, the ITEM Coalition applauds the Centers for Medicare and Medicaid Services (CMS) for attempting to decrease provider and supplier reliance on the Certificate of Medical Necessity. However, ITEM Coalition members are concerned that several provisions in this regulation may threaten access to PMDs for people with disabilities. Generally, we find that the Interim Final Rule fails to recognize the complexity of the PMD prescription and acquisition process. The ITEM Coalition encourages CMS to take into greater consideration the Medicare beneficiaries impacted by this rule who depend on Mobility Assistance Equipment (MAE) to live healthy and independent lives.

Additionally, members of the ITEM Coalition continue to oppose CMS' current interpretation of the "used in the patient's home" language. Although this regulation attempts to improve the prescription and acquisition processes for PMDs, the ITEM Coalition feels that by confining any assessment to beneficiary needs only within the home, CMS is restricting itself from making any true improvements to the benefit. There continues to be no clinical basis for the "in the home" restriction and by asking treating practitioners to document medical need only within the home setting, CMS is severely restricting patients from receiving the most appropriate devices to meet their mobility needs.

I. Background

Specialist's Assessment for POV Prescription

The August 26th regulation states that a specialist is no longer required by Medicare to assess an individual for a power operated vehicle (POV) as previously required by

regulation *57 FR 57688*. The ITEM Coalition does not oppose this change for the prescription of POVs and, in fact, recognizes that this change may improve access for beneficiaries to this type of device. However, ITEM Coalition members encourage CMS to invest in education and outreach to those physicians who have not historically been prescribing POVs. Even for those physicians who have been prescribing POVs for many years, the new requirements and regulations issued over the last several months are at a minimum overwhelming, and we are concerned that without proper outreach, providers who are unfamiliar with the process will refrain from prescribing POVs to beneficiaries or improperly do so.

Development of New G Code

The ITEM Coalition commends CMS for recognizing the additional burden associated with the preparation of a written prescription and pertinent parts of the medical record for submission to the supplier in order to establish medical need for the PMD. As stated in the regulation, CMS finds that in prescribing a mobility device, there is an increased burden on physicians above and beyond the evaluation and management (E&M) code corresponding to the history and physical examination of the patient. Thus, creates a new G code for such reimbursement purposes.

However, members of the ITEM Coalition are concerned that the proposed G code value of $21.60 will not provide sufficient incentive for physicians to participate in the prescription of PMDs, which, under the new requirements, will be more complex and time-consuming than under the old rules. ITEM Coalition members believe that the PMD assessment/prescription process is much more complex than laid out in this regulation and commonly includes other professionals such as physical therapists and other clinicians. A G code of $21.60 not only fails to take into account the additional burden that physicians will face under the new regulations, but completely ignores the important role of clinicians in the assessment process.

If physicians and clinicians are not provided an incentive to participate in the Medicare process established for the prescription of a PMD, members of the ITEM Coalition fear that Medicare beneficiaries with disabilities may have difficulty finding a physician and clinician willing to assess them for these important devices. Therefore, the ITEM Coalition encourages CMS to create a payment structure that will provide an incentive not only to physicians but also to clinicians involved in this complex and time consuming process.

II. Provisions of the Interim Final Rule

30-Day Face-to-Face Examination Requirement

Members of the ITEM Coalition recognize that the Medicare Modernization Act of 2003 (MMA) requires CMS to implement a face-to-face examination requirement for the prescription of PMDs. The ITEM Coalition recognizes the value of this requirement and

believes that for the prescription of most devices, this is already standard practice. However, members of the ITEM Coalition are concerned by this regulation's requirement that 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 recognize that additional documents have subsequently been released further clarifying the 30-day face-to-face examination requirement. However, the Interim Final Rule on which we are commenting, the only *regulation* that addresses this requirement, clearly states that a supplier must receive the written prescription 30 days after the face-to-face examination.

As written, members of the ITEM Coalition believe the 30-day requirement for the face-to-face examination does not take into account the complex process of prescribing a PMD. To obtain an appointment with a physician, attend a session or a series of sessions with a therapist and have complete and accurate medical records to the supplier within a 30-day timeframe can be a difficult task for the average consumer, especially those in more rural settings. However, the individuals to whom this requirement is applicable have severe mobility impairments, low incomes, and likely few resources. Many of these individuals face the difficult task of arranging suitable transportation to coincide with the appointments. Additionally, some of these beneficiaries may face literacy issues or have conditions that impair their motor skills, making it necessary for them to rely on others to assist them with handling, reading, and signing of any documentation. Taking these additional factors into account, the 30-day requirement seems simply impracticable.

The timeframe laid out in the August 26th regulation would create a significant barrier to access to PMDs. Therefore, the ITEM Coalition encourages CMS to recognize through regulations the complex process associated with the acquisition of a PMD for a Medicare beneficiary and issue more appropriate regulations.

Additionally, the ITEM Coalition encourages CMS to review current requirements that prevent billing for multiple codes associated with PMD assessment in a single day. Such restrictions may hinder access by creating an unnecessary delay in the assessment process as patients are required to return to the clinician's office on several occasions.

Documentation Requirements

With the removal of the Certificate of Medical Necessity (CMN), CMS is now requiring an extensive amount of readily available documentation from the physician via the supplier in order to establish medical necessity for a PMD. Although the regulation explains by example the type of documentation to be used in the prescription process (patient history, physical examination, diagnostic tests, summary of findings, diagnoses, and treatment plans) it does not provide the level of specificity or clarity that physicians, clinicians and suppliers need as they transition from the CMN. Members of the ITEM Coalition are concerned that an increased level of confusion and a subsequent reluctance

to participate on the part of the treating practitioners, including the clinicians, and suppliers will create a barrier to access to PMDs for individuals with disabilities.

Additionally, the removal of the CMN and new documentation requirements laid out in this regulation place a new burden of proof on the suppliers. Suppliers are now required to make the final decision as to whether medical necessity has been established by the physician's and clinician's documentation or whether additional information is needed before a PMD can be granted. In the current environment, this is a daunting responsibility for a supplier and creates a disincentive to participate in the Medicare program. Without clear guidelines and requirements for establishment of medical necessity, we believe that suppliers, especially smaller suppliers or those with less experience in the Medicare program, will be reluctant to provide PMDs to Medicare recipients, thereby reducing access to PMDs for people with disabilities.

Assessment Process

In an attempt to illustrate the type of information that might justify medical need, the Interim Final Rule provides two examples of what CMS considers appropriate and comprehensive evaluations. The ITEM Coalition is extremely concerned that in both examples CMS fails to include a clinical evaluation by a therapist, a common and integral part of the prescription process. ITEM Coalition members feel that this omission again illustrates a disconnect between CMS' view of the prescription process for PMDs and what really occurs in the field.

One of the provided examples includes a home visit by the physician to assess the home environment of the patient. Members of the ITEM Coalition find this scenario unrealistic and far from standard practice. Additionally, both examples repeatedly refer to the physicians' knowledge of the recent National Coverage Determination (NCD) for Mobility Assistance Equipment (MAE). We find it very unlikely that the average physician will be familiar with the coverage standards established by the new NCD, especially without a final Local Coverage Determination (LCD) in existence.

Therefore, ITEM Coalition members encourage CMS to reconsider it vague requirements for the establishment of medical necessity and create a process in which physicians, clinicians, suppliers and, of course, consumers, will be well-served. We believe such a system is essential to ensure access to PMDs for people with disabilities.

III. Response to Comments

Implementation/Timing

Members of the ITEM Coalition are extremely disappointed by CMS' decision to waive the Notice of Proposed Rule Making and implement the new requirements established by this regulation prior to the end of the comment period.

Over the last several months, stakeholders have been inundated with new regulations and requirements on the prescription, coding, payment, and coverage of wheelchairs and POVs under Medicare. This series of events began with CMS' interest in reducing waste, fraud and abuse in the system while improving access to the most appropriate devices for people with disabilities. However, the ITEM Coalition believes that the new regulations have only served to complicate further the MAE Medicare benefit and, in fact, stand to hinder access to MAE for beneficiaries.

By implementing these new regulations without first considering the input of all stakeholders, ITEM Coalition members believe that CMS is missing an important chance to create a truly appropriate and comprehensive prescription process. We believe that the established processes for public comment are not simply formalities but rather opportunities for CMS to learn from experts in the field and the consumers on which such regulations have real-life implications. The changes outlined in the Interim Final Rule are significant yet underdeveloped, representing a superficial view of the assessment process for PMDs. We regret that CMS did not find it necessary to consider the public's comments before implementation of this important rule and we encourage the agency to revise this rule in proposed form.

Sincerely,

The ITEM Coalition Steering Committee:

Kim Ruff-Wilbert
United Spinal Association

Peter W. Thomas
Consortium for Citizens with Disabilities Health Task Force

Mark Richert (ETM)
Mark Richert
American Foundation for the Blind

Lee Page
Paralyzed Veterans of America

(EAN)
Eva DuGoff
Medicare Rights Center

Attachments: ITEM Coalition Member List

1875 Eye Street N.W., 12th Floor • Washington, D.C. 20006
(202) 349-4260 (phone) • (202) 785-1756 (facsimile) • www.itemcoalition.org

ITEM Coalition Members

Adapted Physical Activity Council

Advancing Independence

Advanced Medical Technology Association

Alexander Graham Bell Association for the Deaf and Hard of Hearing

Alpha One

American Academy of Audiology

American Academy of Neurology

American Academy of Physical Medicine and Rehabilitation

American Association for Homecare

American Association of People with Disabilities

American Association on Health and Disability

American Congress of Community Support and Employment Services

American Congress of Rehabilitation Medicine

American Foundation for the Blind

American Medical Rehabilitation Providers Association

American Music Therapy Association

American Network of Community Options And Resources

American Occupational Therapy Association

American Physical Therapy Association

American Speech-Language-Hearing Association

American Therapeutic Recreation Association

Amputee Coalition of America

Assistive Technology Industry Association

Association for Education and Rehabilitation of the Blind and Visually Impaired

Association for Persons in Supported Employment

Association of Tech Act Projects

Association of University Centers on Disabilities

Blinded Veterans Association

Brain Injury Association of America

Center for Disability Issues and Health Professionals

Center for Independent Living Inc., Berkeley, California

Center for Medicare Advocacy, Inc.

Christopher Reeve Paralysis Foundation

Consortium of Developmental Disabilities Councils

Council of Citizens with Low Vision International

Council of State Administrators of Vocational Rehabilitation

1875 Eye Street N.W., 12th Floor • Washington, D.C. 20006
(202) 349-4260 (phone) • (202) 785-1756 (facsimile) • www.itemcoalition.org

Disability Service Providers of America

Easter Seals

Epilepsy Foundation

Families USA

Goodwill Industries International, Inc.

Helen Keller National Center

Inclusion Research Institute

Long Island Center for Independent Living

Medicare Rights Center

The Miami Project to Cure Paralysis

National Association for Home Care and Hospice

National Association for the Advancement of Orthotics and Prosthetics

National Association of Councils on Developmental Disabilities

National Association of Protection and Advocacy Systems

National Association of Rehabilitation Research and Training Centers

National Campaign for Hearing Health

National Coalition for Disability Rights

National Council on Independent Living

National Family Caregivers Association

National Multiple Sclerosis Society

National Organization on Disability

National Rehabilitation Hospital – Center for Health and Disability Research

National Respite Coalition

National Spinal Cord Injury Association

National Stroke Association

National Vision Rehabilitation Association

NISH

Paralyzed Veterans of America

Research Institute for Independent Living

Rehabilitation Engineering and Assistive Technology Society of North America

Self Help for Hard of Hearing People

Service Employees International Union

Spina Bifida Association of America

The Arc of the United States

Topeka Independent Living Resource Center

United Cerebral Palsy Associations

United Spinal Association

1875 Eye Street N.W., 12th Floor • Washington, D.C. 20006
(202) 349-4260 (phone) • (202) 785-1756 (facsimile) • www.itemcoalition.org

AMERICAN
ASSOCIATION
FOR
HOMECARE

Supporting Quality Health Care Services at Home

Via Hand Delivery and Federal Express

November 23, 2005

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-3017-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS Interim Final Rule on Conditions for Payment of Power Mobility Devices, CMS-3017-IFC[1]

Dear Dr. McClellan:

The American Association for Homecare (AAHomecare) submits these comments on the Centers for Medicare and Medicaid Services' (CMS') interim final rule (IFR) on conditions for payment of power mobility devices (PMDs).[2] AAHomecare is the only national trade association that represents every line of service in the homecare community. Our members include home health agencies and providers and manufacturers of rehab and assistive technologies and services as well as pharmacies providing home infusion and inhalation therapies. These comments are informed by the experience of the AAHomecare Rehab and Assistive Technology Council (RATC), which is composed of providers and manufacturers who serve the needs of Medicare beneficiaries with disabilities or chronic conditions that require them to use PMDs. Consequently, AAHomecare is uniquely qualified to comment on the IFR.

AAHomecare generally supports the requirements of the IFR including the requirement for a face-to-face evaluation of the beneficiary. We remain concerned, however, because a successful transition to the procedures dictated by the IFR depend mostly on the willingness of physicians and other practitioners to properly document the medical needs of the beneficiary in a way that is consistent with CMS' national coverage guidelines for mobility assistive equipment. As a threshold matter, we are concerned that the supporting documentation requirements contained in the IFR are overly broad, making it difficult for a physician to understand the scope of what CMS expects. Further, CMS has done little to educate physicians about their new responsibilities under the IFR. We recommend that CMS engage in an aggressive education campaign targeting the clinical community to

[1] 70 F.R. 50940 (August 25, 2005).
[2] PMDs include both power wheelchairs and power operated vehicles (POVs).

625 Slaters Lane, Suite 200 Alexandria, VA 22314-1171
tel: 703.836.6263 fax: 703.836.6730 www.aahomecare.org

address these concerns. We are also concerned that the 30-day window for documenting the face-to-face evaluation in the written order is too short and should be extended to at least 60 days. We address these and other issues in further detail below.

I. INTRODUCTION

As you know, earlier this year CMS published a national coverage determination (NCD) for mobility assistive equipment. CMS also announced 49 new power wheelchair codes. The NCD contains a complicated algorithm for determining when a Medicare beneficiary who needs mobility assistive equipment may qualify for a PMD. The IFR, in turn, governs the prescription, documentation, and delivery of PMDs. The IFR requires that beneficiaries receive a "face-to-face" evaluation by the physician or treating practitioner; eliminates the certificate of medical necessity (CMN); and imposes extensive new documentation requirements on suppliers and physicians.

In place of the CMN, the rule would require physicians to provide suppliers with a prescription and extensive documentation from the patient's medical record to substantiate medical necessity for the PMD. Medical necessity is determined in reference to the algorithm contained in the NCD. The IFR requires suppliers to maintain this documentation on file in the event of a Medicare audit. If the documentation submitted by the physician does not adequately address the required elements of the algorithm based on the supplier's review, the supplier must request additional documentation from the physician or face an overpayment on audit. The supplier should not have to make a clinical judgement regarding the completeness of the physician's documentation.

On September 14, 2005, following publication of the IFR, the DMERCs published a proposed local coverage determination (LCD) that defines the specific coverage criteria for the power wheelchair codes. The LCD also attempts to further define the documentation requirements in the IFR. The draft LCD announced new codes and included testing requirements for product code verification. After manufacturers raised concerns about the impact of the new codes and testing requirements, CMS announced a delay in the implementation of the codes until CMS has an opportunity to sit down with stakeholders and determine how to proceed. The delay in the codes necessitated a change in the LCD to reflect the current codes. CMS plans to issue a new LCD when the codes are finalized next year.

II. PROVISIONS OF THE IFR

A. CMS Must Engage Physicians in an Aggressive Education Campaign to Ensure Compliance with the IFR

The IFR requires physicians to: write a prescription for a PMD, document in the medical record the results of a "face-to-face" examination of the beneficiary, and provide the prescription and the supporting documentation to the supplier within 30 days of the face-to-face examination. The prescription must contain the following elements: the beneficiary's name; the date of the face-to-face evaluation; the diagnosis and condition

that the PMD is intended to modify; a description of the item, i.e., a narrative description of the PMD; the length of need; the physician or treating practitioner's signature and the date the prescription was written. 42 C. F. R. § 410.38 (c) (1).

While the IFR is highly specific about the requirements for the written prescription, the supporting documentation requirements in the rule are meaninglessly broad. For example, the preamble states only that the physician or treating practitioner prepares pertinent parts of the medical record for submission to the DME supplier. 70 FR at 50942. The rule, in turn, states that the physician is to provide "supporting documentation, including pertinent parts of the beneficiary's medical record (e.g., physical examination, diagnostic test, summaries of findings, diagnoses, treatment plans and/or other information as may be appropriate) that supports the medical necessity for the PMD. . . ." 42 C.F.R. § 410.38 (c) (2) (iii). CMS has not given physicians guidance on what *information* substantiates medical necessity for the PMD.

AAHomecare appreciates the need for CMS to collect information that supports the medical necessity for a PMD. The IFR, however, does not tell physicians what information will support medical necessity. There is no guidance with respect to the content or format of the documentation. Rather, the rule lists various pieces of the patient record that *could* contain relevant information, depending on the circumstances. Our members' experience proves that physicians do not usually chart with the level of descriptiveness that CMS appears to require in the IFR.

We recommend that CMS engage in an aggressive campaign to educate physicians about the requirements of the IFR. Importantly, the education campaign must extend beyond the physician community to include the many medical centers and rehab facilities that serve individuals who require PMDs. All stakeholders must participate in this process so that the outcome for the clinical community is a clear understanding of the practitioner's central role in under the requirements of the IFR. There is precedent for this kind of outreach to physician and DME provider stakeholders. During the approval process for the CMNs in 1995, CMS (then HCFA) engaged physicians and suppliers as stakeholders in addressing their documentation concerns with respect to the CMN.

This type of forum could be held nationally or could be held at the carrier level to ensure the participation of a greater number of physicians. These sessions would give providers and physicians or other practitioners the opportunity to raise specific questions and get timely responses. The education campaign should also produce concise written materials that providers could distribute to physicians. These materials would at least be easier for physicians to digest than the LCD and the NCD, which they must now wade through. CMS' preparation of the materials will ensure their accuracy and credibility in the eyes of physicians and other practitioners.

We also recommend that CMS significantly increase the payment to physicians for preparing the documentation. As we discussed in comments AAHomecare submitted on the paperwork burdens imposed by the IFR, the CMS estimate that it will take physicians and suppliers a combined total of only 10 minutes to prepare and collect the

documentation grossly underestimates the paperwork burden of these new requirements. Physicians are more likely to take their time and provide adequate documentation if they are appropriately reimbursed for the effort.

B. CMS Should Require the DMERCs to Develop Clear Evaluation Criteria that can be Used by Clinicians to Document Medical Necessity

As we noted above, one of AAHomecare's primary concerns is that the documentation physicians provide be adequate to support a medical necessity determination for the PMD. To achieve this goal, it would be useful to have at least a consistent format for the patient assessment. As part of the education campaign we described above, we recommend that CMS work with the DMERCs, PMD providers, and the physician community to develop an evaluation form that physicians and practitioners could use when they assess patients and prescribe PMDs. The discussion pertaining to documentation in the draft LCD provides a good basis for the development of such a form.

The draft LCD suggests questions that the physician or practitioner must address in order to meet the thresholds for medical necessity under the policy. The draft LCD also identifies the types of information that the DMERCs expect to see when reviewing the medical necessity for PMD claims. AAHomecare recommends that CMS work with the other stakeholders to further develop these questions so that physicians and practitioners can use them as a template for the evaluation. This will ensure consistency in the way the clinician documents the decision-making process. Because the forms would reflect the physician's/clinician's work product, they should be accepted as part of the patient's medical record. This approach to education and documentation will serve to underscore for physicians the important role they have in assuring that their patients maintain appropriate access to PMDs.

C. CMS Must Expand the Thirty-Day Window for the Written Prescription

The IFR states that the physician must furnish the provider with a written prescription and supporting medical documentation within 30 days of the face-to-face examination. This timeframe may not provide adequate time for the process to be completed. Under previous policy, providers would routinely need to follow up with physicians on numerous occasions just to obtain a prescription and completed CMN. In order to allow sufficient time for the physician to provide the prescription and supporting documentation to the provider, CMS should extend the timeframe in the IFR to 60 days.

D. CMS Should Harmonize Differences between the LCD and the IFR

There are some inconsistencies between the terms of the DMERC LCD and the IFR. The IFR states the supplier may not dispense the PMD until it has received the PMD prescription and supporting documentation from the physician or treating practitioner. 42 C.F.R. § 410.38 (c) (4). The DMERC LCD at least implies that receipt of the supporting

documentation is discretionary. DMERC instructions should be clear that the supporting documentation is not optional. Further, as we emphasized above, aggressive physician and practitioner education on the required elements of the IFR would serve to minimize problems of inconsistent interpretation on the content or format of the documentation that the clinician submits.

III. CONCLUSION

The American Association for Homecare sincerely appreciates the opportunity to submit these comments. We want to stress our support for the IFR's core requirement of a face-to-face evaluation of the beneficiary by a physician or other qualified practitioner before ordering a PMD. We believe that many of the concerns our members have raised with respect to the new requirements can be addressed through appropriate and aggressive education of the clinical community to provide clear guidance on what specific elements are necessary to substantiate medical necessity. We urge CMS to finalize the IFR in a manner that addresses the concerns we have raised. AAHomecare is committed to working with CMS to address these concerns. Please feel free to contact me if you have any questions.

Sincerely,

Kay Cox

Kay Cox
President and CEO

The SCOOTER Store™

1650 Independence Drive. ♦ New Braunfels, TX 78132 ♦ (830) 608-9200 ♦ www.thescooterstore.com

November 23, 2005

Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS—3017—IFC, Comments on *Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles*, 70 Fed. Reg. 50,940 (Aug. 26, 2005).

To Whom It May Concern:

On behalf of The SCOOTER Store (TSS), I submit the attached comments on the Centers for Medicare and Medicaid Services (CMS) interim final rule (IFR), *Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles*, published at 70 Fed. Reg. 50,940 (Aug. 26, 2005). TSS shares CMS's objective of preventing fraud and abuse related to the power mobility benefit and applauds CMS for working to address this and many other issues important to the power mobility community. TSS looks forward to partnering with the government to better serve the growing population of Medicare beneficiaries and protect the Medicare trust fund.

CMS, industry, and the multiple Members of Congress who have weighed in on the IFR, all agree that certainty is needed to create a workable and efficient Medicare reimbursement system for power mobility devices (PMDs). Perhaps foremost, there is a need for certainty that the power mobility benefit is being administered in a way that best prevents fraud and abuse. To this point, TSS provides three recommendations for fraud and abuse prevention in the attached comments. Second, there is a need for certainty that PMDs will continue to be made available to qualified Medicare beneficiaries. And, finally, there is a need for certainty that suppliers can rely on a clear and objective physician's prescription in supplying PMDs. TSS's attached comments address each recommendation in detail.

While TSS sincerely hopes that the IFR will accomplish its stated objectives without punishing legitimate suppliers, the company must take this opportunity to preserve future legal options related to this rulemaking. The IFR was published absent stakeholder input and failed to comply with multiple legal requirements. The IFR also imposes several new burdens on suppliers and physicians absent requisite analysis or support. Thus, TSS's attached comments address these issues as well.

TSS believes that CMS acted in good faith in trying to reform the power mobility benefit, and TSS has always acted in good faith in dealing with the federal government and Medicare beneficiaries. We hope that these good faith efforts continue, so TSS and CMS can best serve Medicare beneficiaries and protect the power mobility benefit.

Very truly yours,

Mike Pfister

Enclosure

The SCOOTER Store Comments on CMS—3017—IFC

November 23, 2005

I. Executive Summary

Founded in 1991, The SCOOTER Store (TSS) is the nation's largest supplier of power mobility equipment. TSS has worked with over 97,000 physicians and served over 200,000 Medicare beneficiaries. In this time, TSS employees have reviewed thousands of medical records for geriatric power mobility customers. Our experience indicates that few, if any, physicians document their medical records to the level of specificity and detail outlined in the examples in the Interim Final Rule (IFR). TSS applauds the Centers for Medicare and Medicaid Services (CMS) for recognizing that substantial physician education efforts are required for physicians to meet the new IFR mandates and encourages CMS to undertake those initiatives as quickly and extensively as possible. Already, TSS has witnessed some improvement in physician documentation, which is an encouraging development, but the prevalence of this practice is yet unknown.

While TSS will take this opportunity to make recommendations on strengthening the IFR, at a minimum, TSS and CMS share the view that the physician is the ultimate arbiter of medical necessity. Two steps in the right direction on this front are the implementation of the new face-to-face examination requirement and the new payment for physician documentation of power mobility devices (PMDs). These developments, however, will not change the content and quality of historical medical records, which as described below, rarely chart the way outlined in the IFR. TSS, like all suppliers, must be assured that the new and improved physician documentation practices will ultimately substantiate the written orders that suppliers fill when the durable medical equipment carriers (DMERCs) review claims.

TSS also shares the view with CMS that fraud and abuse exist within the power mobility community. TSS is committed to helping detect and prevent fraud and offers three fraud prevention recommendations: 1) a scripted prescription with attestation; 2) mandatory accreditation and supplier standards; and 3) serial number tracking. Each recommendation is described in detail in Section II below. Following the TSS recommendations, these comments then address: 1) the new documentation standards in the IFR; 2) the viability of the power mobility benefit under the IFR; and 3) the legality of the IFR.

Not addressed below is the 30-day limitation. For the geriatric mobility market, this requirement provides adequate time to ensure that physicians document the face-to-face evaluation, complete an order, and deliver the order to a professional supplier. While TSS understands the specific cycle times of the high-end rehabilitation products, this requirement does not appear to present a problem for TSS.

Finally, TSS would like to take this opportunity to set forth three questions the answers to which are critical to the effective functioning of the IFR and to the success of suppliers attempting to operate under the IFR.

First, when the physician provides the prescription and the face-to-face examination report, both extensive documents addressing medical necessity, who decides how much additional documentation is needed?

Second, what is the relevance of historical medical records—those existing prior to the face-to-face evaluation—to the patient's current need for mobility assistance? The new process requires that a doctor or treating practitioner:

- evaluate the beneficiary in the last 30 days to analyze mobility needs;
- document that the patient was evaluated for that purpose;
- conduct and document a face-to-face evaluation;
- write a seven-element prescription; and
- acknowledge consideration of the mobility algorithm.

Aren't these the issues relevant to a coverage determination rather than historical data in medical records that were not charted for the purpose of determining medical necessity?

Third, one stated goal of the IFR is to reduce the number of claims that are denied through no fault of the supplier. The supplier must obtain a seven-element prescription, as well as a documented face-to-face examination report. If the supplier agrees with the treating practitioner that additional documentation provided is adequate, and subsequently, a DMERC reviewer decides differently, will the supplier be held liable for the claim? Or, is a supplier protected by the limitation of liability provision provided to suppliers by Congress at 42 U.S.C. § 1395pp(a)?

II. Reasonable Alternatives to the IFR Requirements Exist and TSS Recommends Adopting Alternative Fraud and Abuse Prevention Measures

In the IFR, CMS cites fraud and abuse of the power mobility benefit as one reason for reforming the procedures related to obtaining, prescribing, and supplying PMDs. However, the procedures promulgated through the IFR will not prevent fraud and abuse of the system. In fact, the new procedures may "...open the door to fraud, confusion, and subjectivity,"[1] as Senator Charles Grassley, Chairman of the Senate Finance Committee, stated in his letter to Secretary Leavitt of the Department of Health and Human Services and Dr. Mark McClellan, Administrator of CMS.

TSS agrees that fraudulent and abusive practices exist within the power mobility industry but proposes eliminating these practices through means different than voluminous documentation requirements. There are two categories of unnecessary reimbursement by Medicare, as noted by the Office of Inspector General: 1) claims paid by Medicare despite the lack of a CMN, and 2) reimbursement for PMDs supplied to patients who are either ineligible for any type of PMD, or ineligible for the particular type of PMD supplied. To address these concerns, TSS encourages CMS to adopt or implement the following: 1) a scripted prescription with attestation; 2)

[1] Letter from Sen. Charles E. Grassley, Chairman, U.S. Senate Committee on Finance, to The Honorable Michael O. Leavitt, Secretary, Department of Health and Human Services, and Dr. Mark McClellan, Administrator, Centers for Medicare & Medicaid Services (Sept. 29, 2005).

mandatory supplier accreditation and standards; and 3) serial number audits. Each is discussed in more detail below.

A. Scripted Prescription with Attestation

As Senator Grassley also stated in his letter to Secretary Leavitt and Administrator McClellan, "CMS should consider a scripted prescription or similar form with open-ended questions that directly link to the NCD."[2] TSS strongly supports Senator Grassley's recommendation and proposes two prototypes below. Each incorporate similar elements, but one is styled to more closely resemble a Certificate of Medical Necessity and the other is a "Face-to-Face Evaluation Report." Each incorporates the nine components of the NCD algorithm. Either of these thorough forms could be easily used by physicians, suppliers, and beneficiaries to determine if medical necessity exists and to document that need.

TSS agrees with CMS that bad actors exist within the power mobility community and is committed to helping detect and prevent fraud and abuse. If CMS truly wants to adopt fraud prevention measures, then the agency must incorporate objective and consistent elements into the program as opposed to new, highly subjective elements. As Senator Grassley points out, "In the sprint to publish these requirements, CMS may have added an unnecessary degree of subjectivity to this process."[3] In particular, "Elimination of the [CMN] without a scripted form may open the door to fraud, confusion, and subjectivity."[4] The elimination of the CMN not only removes objectivity, but also it removes the requirement that the physician attest to medical necessity under penalty of perjury. As Senator Grassley noted, "CMS should include an attestation certification with reference to the False Claims Act to strengthen program integrity efforts."[5] TSS's scripted prescription prototypes, presented below, address this issue as well.

---

[2] *Id.*
[3] *Id.*
[4] *Id.* (emphasis added).
[5] *Id.*

DEPARTMENT OF HEALTH & HUMAN SERVICES
FORM APPROVED
HEALTH CARE FINANCING ADMINISTRATION

May 18, 2005

OMB NO.

DMERC

CERTIFICATE OF MEDICAL NECESSITY

MANUAL WHEELCHAIRS, POVS, MOTORIZED WHEELCHAIRS

SECTION A Certification Type/Date: INITIAL ___/___/___ REVISED ___/___/___

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER (___)___-____ HICN		SUPPLIER NAME, ADDRESS, TELEPHONE and NSC NUMBER (___)___-____ NSC# _____
PLACE OF SERVICE _____ NAME and ADDRESS of FACILITY if applicable (See Reverse)	HCPCS CODE _____ _____ _____ _____	PT DOB ___/___/___ : Sex ____(M/F); HT.____ (In.); WT.____ (lbs.) PHYSICIAN NAME, ADDRESS, TELEPHONE and UPIN NUMBER (___)___-____ UPIN# _____

SECTION B Information in This Section Must Be Completed by the Prescribing Physician.**

EST. LENGTH OF NEED (# OF MONTHS): 1-99 (99=LIFETIME) DIAGNOSIS CODES (ICD-9): _____ _____ _____

ITEM ADDRESSED	ANSWERS	ANSWER QUESTIONS 1, 2, 3, 4, 5 AND 6 FOR ALL DEVICES, 7 FOR MANUAL WHEELCHAIRS, 8 FOR POV/SCOOTER AND 9 FOR WHEELCHAIR OPTIONS/ACCESSORIES. (Circle Y for Yes, N for No, or D for Does Not Apply, unless otherwise noted.)
Any Mobility Device	Y N D	1. Does the beneficiary have a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living in the home?
Any Mobility Device	Y N D	2. Are there other conditions that limit the beneficiary's ability to participate in mobility-related activities of daily living at home?
Any Mobility Device	Y N D	3. If other limitations exist, can they be ameliorated or compensated sufficiently such that the additional provision of mobility equipment will be reasonably expected to significantly improve the beneficiary's ability to participate in mobility-related activities of daily living in the home?
Any Mobility Device	Y N D	4. Does the beneficiary or caregiver demonstrate the capability and the willingness to consistently operate the device safely?
Cane or Walker	Y N D	5. Can the functional mobility deficit be sufficiently resolved by the prescription of a cane or walker?
Manual or Power Wheelchair or POV/Scooter	Y N D	6. Does the beneficiary's typical environment support the use of a wheeled mobility device? (i.e. manual wheelchair, power-operated vehicle/scooter, or power wheelchair)
Manual Wheelchair	Y N D	7. Does the beneficiary have sufficient upper extremity function to propel a manual wheelchair in the home to participate in mobility-related activities of daily living during a typical day?
Any POV/Scooter or Power Wheelchair	Y N D ___/___/___	8. A physician who prescribes a power mobility device must have performed a face-to-face examination of the beneficiary within the previous 30 days. Have you performed a face-to-face examination within the last 30 days? If so, when?
POV/scooter	Y N D	9. Does the beneficiary have sufficient strength and postural stability and is their home environment adequate for them to operate a power-operated vehicle/scooter safely and effectively while conducting mobility-related activities of daily living?
Power Wheelchair	Y N D	10. Are the additional features provided by a power wheelchair needed to allow the beneficiary to participate in one or more mobility-related activities of daily living?

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):
NAME: TITLE: EMPLOYER:

** This Section cannot be completed by a supplier. More detailed information can be completed in Section E.

SECTION C	Narrative Description of Equipment and Cost

(1) Narrative description of all items, accessories and options ordered; (2) Supplier's charge; and (3) Medicare Fee Schedule Allowance for each item, accessory, and option. (See instructions on back.) If additional space is needed, list wheelchair base and most costly options/accessories on this page and continue on HCFA Form 854.

☐ CHECK HERE IF ADDITIONAL OPTIONS/ACCESSORIES ARE LISTED ON ATTACHED HCFA FORM 854

SECTION D	Physician Attestation and Signature/Date

I certify that I am the treating physician identified in Section A of this form. I certify that I have conducted an in-office examination of this beneficiary. I have received Sections A, B and C of the Certificate of Medical Necessity (including charges for items ordered). Any statement on my letterhead attached hereto has been reviewed and signed by me. I certify that the medical necessity information in Section B is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in this section may subject me to civil or criminal liability.

PHYSICIAN'S SIGNATURE _____ DATE: ____/____/____ (SIGNATURE AND DATE STAMPS ARE NOT ACCEPTABLE)

ORM HCFA 843 (5197)

Mobility Assistive Equipment – Face to Face Examination Report

Patient Information					
Name:					(HICN)#:
Mailing Address:					Telephone:
City:	State:	Zip:	DOB:	Age: 85	
Physician or Treating Practitioner Information					
Name:					UPIN:
Mailing Address:					Telephone:
City:			State:		Zip:

Current Symptoms, Related Diagnoses, and History

Please describe the reason for this office visit:

Please identify previously diagnosed conditions and any other issues relating to the patient's mobility needs:

Physical Exam				
Ht:	Wt:	B/P:	Pulse (resting):	Respiratory: Normal Labored at times Is O2 required? Y N

Any current pressure sores? Y N Location: _____

Poor Balance: Y N History or risk of Falls: Y N Poor Endurance: Y N

Cachexia (severe weakness): Y N Obesity: Y N Significant Edema: Y N

Holds to furniture/walls for mobility: Y N

Neck, Trunk and Pelvic Posture and Flexibility: ____ Good ____ Limited ____ Severely Limited

Pain when ambulating or attempting to ambulate: ____ Low ____ Moderate ____ Severe

Mobility Assistive Equipment – Face to Face Examination Report (Page 2)

Functional Assessment

Question	Your Answers below must be justified by your narrative responses.	
1.Does your patient have a mobility limitation that impairs participation in Mobility Related Activities of Daily Living (MRADLs) in the home? If YES, why: _____ _____ _____	☐ YES ☐ NO	GO TO QUESTION 2 STOP—NO MAE
2.Can their limitations be compensated by the addition of MAE to improve the ability to participate in MRADLs in the home? If YES, why: _____ _____ _____	☐ YES ☐ NO	GO TO QUESTION 3 STOP—NO MAE
3.Is your patient or their caregiver capable and willing to operate the MAE safely in the home?	☐ YES ☐ NO	GO TO QUESTION 4 STOP—NO MAE
4.Can their mobility deficit be safely resolved by a cane or walker? If NO, why: _____ _____	☐ YES ☐ NO	STOP—ORDER CANE OR WALKER GO TO QUESTION 5
5.Does your patient's home environment support use of a wheelchair or POV?	☐ YES ☐ NO	GO TO QUESTION 6 STOP—NO MAE
6.Does your patient have the upper extremity function to safely propel a manual wheelchair to participate in MRADLs in the home? If NO, why: _____ _____ _____	☐ YES ☐ NO	STOP—ORDER MANUAL WHEELCHAIR GO TO QUESTION 7

Mobility Assistive Equipment – Face to Face Examination Report (Page 3)

7. Does your patient have sufficient strength and trunk stability to operate a POV (Scooter) in the home? (A POV/Scooter is a 3 or 4 wheeled device with tiller steering, limited seat modification capabilities and requires the upper body strength to keep arms fully extended) Please explain: _____ _____ _____	☐ YES ☐ NO	GO TO QUESTION 8 GO TO QUESTION 9
8. Is your patient able to safely maneuver a POV in their home? (A POV requires large maneuvering space/even surfaces for effective operation due to its extended length and wide turning radius.)	☐ YES ☐ NO	GO TO QUESTION 9 GO TO QUESTION 9
9. Does your patient need the additional features of a power wheelchair to participate in MRADLs in the home? (ie. Joystick Control, Additional Maneuverability, Special Seating Options, ELRs) If YES, why: _____ _____ _____	☐ YES ☐ NO	GO TO QUESTION 10 IF QUESTION 8 IS YES, ORDER POV IF QUESTION 8 IS NO, NO MAE
10. Is your patient able to safely maneuver a power wheelchair in the home?	☐ YES ☐ NO	STOP—ORDER PWC STOP

I certify that the information provided is a true and accurate representation of my patient's current condition. I hereby incorporate this document into my patient's medical record. This document is supported by additional medical records in my patient's file.

Physician or Treating Practitioner Signature: _____ **Date:** _____

B. Mandatory Supplier Accreditation and Standards

TSS recommends that CMS require accreditation for all Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers and that an independent accreditation commission be formed to conduct evaluations. TSS sought and received third-party accreditation two years ago from the Accreditation Commission for Health Care, Inc. (ACHC).

An accreditation requirement will provide improved quality of care for beneficiaries and ensure that only the highest quality and highest integrity suppliers will participate in the industry. There are national accreditation commissions that offer DMEPOS suppliers accreditation, such as the ACHC, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and Community Health Accreditation Program (CHAP). These accreditation commissions offer programs for suppliers of all sizes, as long as they are committed to providing the required levels of service. This requirement for accreditation would do more to eliminate fraud from the DMEPOS industry than many of the previous steps taken by CMS or than the documentation requirements of the IFR. It would also require an independent, non-profit organization to review and approve the quality of service, policy and procedures, and compliance with federal guidelines of all suppliers submitting claims to CMS for DMEPOS. In fact, accreditation is already required by most managed care organizations as a condition of contract.

Accreditation results in numerous benefits for Medicare beneficiaries, CMS, and suppliers, as described below.

Benefits for Medicare Beneficiaries:

- Accreditation provides assurance that the supplier is committed to providing quality healthcare.
- Accreditation provides confidence that a supplier has been reviewed by an independent accrediting commission.
- Customer Satisfaction Surveys required by accredited suppliers provide opportunities for improvement in their business processes, ensuring suppliers are responding to the needs of Medicare beneficiaries.

Benefits for CMS:

- An accreditation requirement will provide additional protection against fraudulent practices and reduce the number of suppliers who engage in fraud.
- Accreditation ensures that the supplier has met a unified set of standards for operations.
- Accreditation is a demonstration of the organization's professional leadership and commitment to ethical business operations.
- Accredited status offers objective assurance that the supplier is in compliance with separate standards covering all of its operations, including the 21 Supplier Standards established by CMS.
- Accreditation provides CMS an independent verification of the supplier's compliance with all federal requirements.

- The accreditation process includes a review of the supplier's policies and procedures and compliance with those policies and procedures during an initial on-sit visit.
- Accreditation commissions reserve the right to make announced or unannounced on-site visits at any time during the accreditation cycle.

Benefits for DMEPOS Suppliers:

- Accreditation provides the supplier with external validation of their commitment to providing quality healthcare.
- Accreditation requirements involve quality improvement programs that will improve business processes.
- Provide suppliers with a high quality standard set of business practices/guidelines that will ensure they are delivering appropriate service levels.

TSS supports CMS's decision to propose quality standards for DMEPOS suppliers, and TSS incorporates by reference its comments on the draft quality standards filed on November 28, 2005.

C. Serial Number Audits

TSS recommends that CMS audit the serial numbers of the PMDs. This simple audit would help eliminate supplier submission of bills for equipment never provided or lesser/different equipment provided, and it would provide CMS with a simple mechanism to detect criminal behavior quickly. First, manufacturers/importers of power mobility devices would submit to CMS the serial numbers of devices with the corresponding supplier purchases. Next, suppliers would include this serial number as part of a Medicare claim for PMDs. Lastly, CMS could contact the beneficiary to obtain the particular PMD's serial number and compare that to the claim information submitted by the supplier and manufacturer. If these three did not match, then CMS could further investigate.

III. Documentation Standards Under the IFR are Unreasonable and Unlawful

CMS states that the documentation requirements included in the IFR facilitate the implementation of two different policy changes. First, CMS is acting on a congressional directive in the Medicare Modernization Act of 2004 (MMA) to implement a requirement that physicians conduct a "face-to-face" examination before prescribing MAE.[6] Second, the change is intended to update documentation standards to reflect new coverage standards set out by CMS in the May 5, 2005 NCD for MAE.[7] According to the IFR, the end result of these changes should be to "operationalize the NCD requirements and statutory changes in ways that will not

[6] 70 Fed. Reg. 50,940, 50,941 (August 26, 2005).

[7] *Id.* at 50,943. *See also Pub 100-03 Medicare National Coverage Determinations*, CMS Manual System, Transmittal 37, § 280.3, June 3, 2005, at 19-20. (Describing the nine-step algorithm establishing Medicare coverage for MAE).

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."[8]

If the IFR required standardized documentation that clearly tracked the NCD's nine-step coverage algorithm this aspiration could have been realized, as discussed above. However, rather than clearly codifying the elements included in the NCD and creating a documentation process that allows suppliers to reasonably rely on the medical conclusions reached by treating physicians, the IFR creates a maze of new documentation standards that bear no resemblance to the NCD. In particular, the IFR eliminates the CMN requirement. The IFR replaces the standardized CMN form with a mandate that suppliers obtain and maintain a written prescription and the correct "supporting documentation, including pertinent parts of the medical record" from treating physicians.[9] These actions raise concerns because TSS's experience indicates that absent clear guidance from CMS, DMERCs will often implement inconsistent and ambiguous documentation requirements.

The collections of information required under the IFR are extremely burdensome and undermine the proper operation of the Medicare program by jeopardizing the viability of the power mobility benefit. The IFR requires that physicians collect a vast array of information and draft expanded prescriptions without a standardized form. Moreover, it appears on the face of the IFR that the IFR may require that suppliers collect and review medical records in order to determine if a physician's prescription is sufficiently supported by diagnostic examinations and notes recorded by the physician. These requirements are unnecessary, inconsistent with statutory language, and the burdens associated with these demands are severely underestimated by CMS in the IFR. In sum, the scheme described in the IFR is subjective, burdensome, and rife with ambiguity.

A. Collections of Information Under the IFR

CMS identifies three distinct collections of information in the IFR, including:

1. Prescription—Section 410.38(c)(2)(ii). States that Medicare Part B will pay for a PMD if the physician or treating practitioner writes a prescription that is received by the supplier within 30 days after the date of the face-to-face examination of the beneficiary. CMS estimates that it will take approximately 2 minutes for the physician or treating practitioner to prepare and submit the prescription.[10]

2. PMD Evaluation—Section 410.38(c)(2)(iii). Requires that physicians and treating practitioners collect and submit to suppliers supporting documentation from the beneficiary's medical records that demonstrate that the item being provided is medically necessary.[11] This is in addition to writing and submitting the prescription to the supplier.

---

[8] 70 Fed. Reg. at 50,943.
[9] *Id.* at 50,946-50,947.
[10] *Id.* at 50,944.
[11] *Id.* at 50,942 ("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.").

While the IFR identifies that there is a burden associated with this requirement, CMS provides no precise estimate of this burden.[12]

3. Supplier Obligations—Section 410.38(c)(5)(i). Requires that suppliers maintain a copy of the PMD prescription and supporting documentation to support a claim for reimbursement and make this information available to CMS and its agents upon request. According to the IFR, the burdens associated with this provision include receiving the documentation; reviewing the documentation to ensure it is complete; and storing the documentation. The IFR does not include a specific estimate of the burden associated with this requirement.[13]

Overall, CMS estimates that the combined burden on suppliers and physicians concerning medical records "will be no more than 10 minutes."[14] However, CMS provides no calculations or analyses to determine how this estimate was reached, other than an assertion in the IFR that physicians will no longer need to independently record items on a CMN.[15]

Furthermore, the IFR requires an additional collection of information that has not been subjected to any burden analysis. Section 410.38(c)(5)(ii) of the IFR requires that "a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the power mobility device."[16] The IFR explains that this requirement includes a duty to collect, maintain, and provide to CMS a range of additional medical documents, including "physician office records, home health agency records, records from other healthcare professionals, and test reports."[17] Despite the open-ended nature and significant scope of this requirement, the IFR includes no estimate of the burden this places on suppliers.

B. The Proposed Collection Scheme is Inconsistent with Statutory Mandates

Under the IFR, the CMN is eliminated and replaced with a requirement that suppliers collect and decipher prescriptions and medical records that will vary significantly from physician to physician. By limiting the right of suppliers to provide a standardized form to facilitate collection of information, or rendering such a form meaningless in terms of claims review, CMS is acting in direct contravention to statutory language governing the Medicare program.[18]

The CMN is not a creature of regulation, but is instead specifically provided for by statutory language. Congress created the CMN as the tool that suppliers are permitted to use to facilitate smooth and uniform collection of information regarding medical necessity. Congress did not leave this option to the discretion of CMS or the Department of Health and Human Services (HHS). Rather, Congress explicitly provided that "a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of

---

[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.* at 50,947.
[17] *Id.* at 50,943.
[18] 42 U.S.C. § 1395m(j)(2)(A)(i) (2004).

medical necessity for commercial purposes."[19] The purpose of this document is also clear: Congress stated that a CMN is designed "to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[20]

The mandatory nature of the CMN has been confirmed in the judicial system. In *Maximum Comfort, Inc. v. Thompson*, the only case confronting the issue directly, the federal district court explained,

> the plain language of [42 U.S.C.] § 1395m(j)(A)(2)(i) supports the plaintiff's position that it may only use a CMN to provide the necessary information for the determination of medical necessity and reasonableness. The Secretary cannot require that DME suppliers, such as plaintiff, obtain Medicare beneficiaries' medical records and make a judgment as to whether the equipment is medically necessary and reasonable. It is clear from the plain text of the Medicare Act that, while Congress granted the Secretary broad discretion over medical necessity and billing criteria and procedures, it did not do the same regarding medical necessity documentation. Instead, Congress addressed that issue itself and established that any and all information required from suppliers to make a medical necessity determination must be contained in a CMN.[21]

Despite the fact that Congress explicitly provided to suppliers the right to distribute a standardized form for purposes of demonstrating medical necessity, the IFR purports to eliminate the CMN altogether. CMS will replace the CMN with no common form or other tool that suppliers may provide to physicians. This is flatly inconsistent with the statutory language governing the Medicare program. CMS must allow suppliers to generate and provide a form containing all the information required by CMS and its agents.

C. Documentation Standards Under the IFR are Burdensome

1. Burdens on Physicians

The IFR summarily states that a physician will take two minutes to complete a prescription, and ten minutes to determine which medical records are relevant to the determination of medical necessity and prepare those documents for submission. CMS then concludes that this process requires the same amount of time (12 minutes) to fill out the one-page standardized CMN form. This statement, which is not supported by any evidence, is obviously incorrect.

A review of the sample prescriptions included in the IFR reveals that the CMS burden estimate regarding physicians is far from correct. When written in lay terminology, which would be necessary for the prescriptions to be analyzed by non-medically trained suppliers, the sample prescriptions are 262 and 580 words long.[22] Just drafting essays of this length would require

---

[19] *Id.*
[20] 42 U.S.C. § 1395m(j)(2)(B) (2004).
[21] 323 F. Supp. 2d 1060, 1074-75 (E.D. Cal. 2004)(emphasis added).
[22] 70 Fed. Reg. at 50,942.

more than the 10 minutes provided for in the CMS estimate and that is not the end of the burdens imposed on physicians under the IFR.

TSS, in consultation with medical professionals, nurses, and individuals familiar with the normal time burdens associated with medical paperwork found the following estimates of the burdens on physicians.

1) The Face-to-Face Exam and Report
   Schedule appointment--10 minutes
   Nurse Assessment prior to exam--10 minutes
   See patient/exam--15 minutes
   Write chart notes--10 minutes
   Discuss/decide mobility assist required--2 minutes
   Evaluate appropriate equipment using NCD algorithm--4 minutes
   Write detailed prescription--3 minutes

2) Preparation and Transmission of Medical Records
   Research medical record and files for relevant information--10 minutes
   Redact records in order to ensure HIPAA compliance--10 minutes
   Prepare HIPAA compliant FAX cover sheet--2 minutes
   Send Fax--1 minute

This analysis indicates that the physician burden associated with the IFR would be approximately 67 minutes, and those with whom we consulted stated that an additional one to two hours would need to be added to that total if a physician is required to visit a patient's home, as the IFR suggests.

However, there are additional burdens imposed on physicians that appear to go above and beyond normal documentation procedures. The IFR explains that medical records submitted to a supplier must delineate a patient's medical history, identify mobility deficits, document the failure of other treatment methods, document that a patient lives in a PMD-appropriate environment, and document that a beneficiary is capable of using the PMD.[23] The IFR contends that in most cases "the information recorded at the face-to-face examination will be sufficient."[24] Therefore, it appears the rule is requiring that the doctor, in addition to conducting a face-to-face examination craft new medical records that track these five requirements. This burden is not sufficiently explained by the IFR, and no burden analysis considers the additional time and resources necessary to satisfy this requirement.

TSS has worked with over 97,000 physicians nationwide. While the short timeframe for comment precludes TSS from contacting and interviewing each of these physicians and their staff, our analysis is informed by input from individuals with extensive experience working with physicians and physicians' offices and represents a much more realistic estimate of the IFR's actual burden than the unsupported estimate stated by CMS. At a minimum, simple logic leads

[23] *Id.*
[24] *Id.*

one to the conclusion that this entire process will take longer than filling out one form, contrary to CMS's conclusion.

2. Burdens on Suppliers

The IFR imposes both collection and review burdens on suppliers. The IFR notes that the supplier burden includes "receiving the documentation, reviewing the documentation to ensure it is complete, and storing the documentation."[25] The IFR does not properly account for the magnitude of the review burdens, and as such it is important that those burdens are evaluated carefully.

a. Review Burdens

The IFR contends that "there will be a shift in the burden of information collection from the supplier to the physician."[26] This statement is inaccurate because in order for a supplier to determine if documentation is "complete," according to CMS instructions, they must do more than simply ensure that they have received particular forms from the physician. Although this may not have been CMS's intent, the IFR seems to task suppliers with analyzing the content of medical records and reports to determine if the data in those documents sufficiently supports the conclusions memorialized in the physician prescription. The IFR anticipates that this review may lead the supplier to determine that the physician's documentation does not satisfy CMS's requirements.[27] Fulfilling this apparent duty would require a complex analysis of the physician's diagnosis; all of the documentation and history regarding that diagnosis; and a determination if additional documentation is necessary to confirm the diagnosis and prescription. If CMS officials disagree with the supplier's judgment about "completeness," then the supplier will be financially responsible for the cost of the equipment.

Given the scope of the collection and analysis required under the IFR, it is difficult to understand how, under any scenario, the entire collection and review process could be completed by a supplier in ten minutes, as the IFR states. In fact, a review of medical documentation to determine support for medical necessity can take several hours per patient. As CMS explained in a 2003 Paperwork Reduction Act (PRA) submission, "it can take up to 5 hours for an office clerk to review a documentation request, find and review the file (either from the supplier's own records or through the ordering physician's office), and make copies."[28] Even this estimate is conservative given that it only considers office clerks, does not include detailed medical review, fails to account for the time associated with collecting paperwork, and also does not account for the time associated with determining what additional examinations or records are necessary. Given the resources available to CMS, it is inconceivable that suppliers would be expected to conduct a collection and review of records 30 times faster than CMS.

---

[25] *Id.*at 50,944.
[26] *Id.*at 50,942.
[27] *Id.* at 50,944.
[28] *Supporting Statement for Paperwork Reduction Act Submission, Durable Medicare Equipment Regional Carrier, Certificate of Medical Necessity and Supporting Documentation Requirements—Motorized Wheel Chair*, CMS 843, Submission to Office of Management and Budget, March 21, 2003, at 5.

TSS is concerned that any estimate of the review burden cannot properly gauge the amount of time and resources required of suppliers. The rule includes open-ended language requiring additional documentation; does not set objective standards to determine when documentation is sufficient or complete; and fails to provide any standardized forms to facilitate the recording of physician observations and conclusions. Thus, it is likely that review of documentation will take substantially longer than even the five hour estimate provided by CMS under the existing regulatory regime.

b. Collection Burdens

Notwithstanding the enormous burdens associated with reviewing documentation, there remain significant burdens solely attributable to collecting medical records under the IFR. Even aside from the time required to review and interpret the medical content of records, simply collecting and transmitting the documents will take much longer than the 10 minutes that CMS summarily determined will be required of suppliers.

Based upon TSS operations, which have been standardized and built around the most efficient processes and technologies available, the following time estimates can be properly attributed to the collection process.

1) Intake process (establishing patient files and basic information)-30 minutes
2) Receive/retrieve/account for Physician documents-5 minutes
3) Identify patient and match records-2 minutes
4) Review documents for non-medical requirements (signature, names, etc.)-30 minutes
5) Requests for Ask additional information-10 minutes
6) Review additional documents for non-medical items-15 minutes
7) Redact documentation to meet HIPAA requirements-5 minutes
8) Copying and filing of documentation-5 minutes
9) Preparing privacy protected documents for transmission-10 minutes
10) Retrieval of documents from storage-5 minutes (if on-site)
11) Preparation of documents for transmission to DMERC-10 minutes

Therefore, a supplier can reasonably expect to spend at least 127 minutes per claim simply acquiring and preparing documentation for submission. Given that these estimates are based on actual supplier operations and a history of responding to documentation requests from CMS contractors, this estimate is far more realistic than the assertion in the IFR that the entire process will take less than 10 minutes.

3. Burden Estimates in the IFR are Unsupportable and Incorrect

The lack of analysis and supporting evidence for CMS's burden estimate makes it difficult to precisely determine how the burdens estimates under the IFR were reached. Nonetheless, it is clear that the following will amplify record-keeping and review burdens:

1. The Number of Prescriptions—The IFR presumes that the 10 minute burden will be multiplied by 187,000 prescriptions per year.[29] However, CMS does not clarify how this number was derived, and it does not appear that the 187,000 number takes into account claims that will be denied by CMS or prescriptions that are improperly written, or claims for which doctors do not or are unwilling to supply supporting documentation prior to the 30-day time limit. Suppliers acting lawfully and consistent with program requirements must collect and review documentation for claims that are denied and prescriptions that are not supported, but the IFR does not consider these burdens.

2. Demands for Additional Documentation—As described earlier, language in the new rule requires that suppliers collect, review, and provide to CMS a long list of documents, in addition to the documents explicitly required to be provided in connection with the prescription. The collection and review of these documents imposes significant burdens on suppliers, and neither the number of claims subject to this requirement, nor the time required of physicians, suppliers, and third parties such as nursing homes to satisfy this mandate are analyzed by the IFR.

When these factors are considered in light of a more complete analysis of burdens imposed on physicians and suppliers, it is clear that the new documentation standards under the IFR are likely to impose significant costs on both physicians and suppliers.

D. Documentation Requirements Under the IFR are Unclear and Unlikely to Facilitate the Proper Provision of Equipment to Medicare Beneficiaries

The collections of information offered by CMS in the IFR are not written using plain, coherent, and unambiguous terminology and thus will significantly compromise the quality, utility and clarity of the information that is collected. CMS has provided no form or format with regard to the medical record requirement, and there is no uniform measure as to what will constitute sufficient documentation.

1. The Documentation Requirements are Vague and Arbitrary

The IFR is unclear in regard to what documents that must be submitted to CMS and the content that is required to be contained in those documents. Suppliers were required to submit a single standardized form to CMS, the CMN. Under the IFR, any or all of the following documents may be required of suppliers, in addition to the prescription from the physician.

- Patient histories;
- Progress notes;
- Physical examinations;
- Diagnostic tests (potentially including cardiologist notes, echocardiogram and cardiac stress test results, and arterial blood test results);
- Summaries of findings;
- Diagnoses;

[29] 70 Fed. Reg. at 50,944.

- Treatment Plans;
- Physician office records;
- Hospital records;
- Nursing home records;
- Home health agency records; and
- Records from "other healthcare professionals"

The IFR provides no measures upon which a supplier can rely to determine which of these records will be required in any particular situation. The IFR broadly requires that suppliers provide to CMS primary medical records that "support" and "substantiate" the physician's conclusion that MAE is medically necessary.[30] To determine sufficiency, suppliers will have to review medical records, decipher individual notes made by physicians (many of which are illegible), analyze medical examinations, and determine if additional documents are necessary to support a physician's medical necessity determination. This process is highly subjective and extremely burdensome, in terms of time, human, and financial resources.

Suppliers are not physicians. Suppliers do not have the specialized education required to analyze medical records, nor do they have clinical relationships with the beneficiaries for whom physicians have prescribed equipment. Absent a complete medical analysis of the records in question by a medical specialist, suppliers will never know if they have collected enough documentation or if the content of the documentation is sufficient to support a medical necessity conclusion. Expecting a supplier to perform such an analysis is unreasonable, and the IFR fails to address this problem.

2. The Documentation Requirements Undermine Fair and Objective Claims Processing and Review

The documents that the IFR requires physicians and suppliers to collect and submit to CMS are of limited utility because they are inherently ambiguous, subjective, and not suited for uniform review. Additionally, because the prescription mandated by the IFR does not require physicians to certify the specific coverage listed in the NCD, it will not be possible for either suppliers or claims reviewers at CMS to predictably and fairly evaluate medical necessity.

Collection of primary medical records will not be useful to either suppliers or CMS because these medical records are not crafted for the purpose of establishing reimbursement criteria, and they are highly subjective. Physicians do not typically document specific Medicare coverage criteria in their medical records, and the records are not created with an intention that they will be reviewed by third parties who are not familiar with the patient and his/her medical conditions. When TSS has attempted to review these records in the past, we have found that the ambiguity inherent in medical records will often result in multiple reviewers reaching inconsistent conclusions after reviewing the same documents. And, illegible medical records result in automatic denial. Because these records are open to multiple interpretations or are illegible, they are of limited utility in the effort to verify medical necessity and ensure that CMS will reimburse suppliers for equipment before it is delivered to beneficiaries.

[30] 70 Fed. Reg. at 50,946-47 (§§ 410.38(c)(2)(iii) and 410.38(c)(5)(ii) of the rule).

CMS has previously acknowledged the fact that medical records are not standardized or capable of uniform interpretation. In fact, on August 5, 2004, as mentioned above, CMS attempted to address this very issue by proposing to amend 42 C.F.R. § 410.38 to require that physicians document in their medical records the need for the DMEPOS being ordered.[31] Although CMS sought comments from Medicare stakeholders, including physicians and clinicians, CMS never finalized this proposal. As a result, physicians have never been instructed to include any specific content in their records establishing medical necessity for Medicare coverage purposes. Even if this practice changes on a going-forward basis, it will not address the underlying problems with the IFR, because the IFR requires analysis of medical records created in the past in order to establish a medical history.

The limited utility of the medical records required to be collected under the IFR is compounded by the nature of the prescription mandated by the rule. Pursuant to § 410.38(c)(1) of the IFR, a prescription under the rule must include the following items:

> 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.[32]

These requirements do not track either the form or content of the nine-step coverage algorithm included in the NCD. Additionally, there is no standardized form or template that physicians can use to document their medical conclusions. As a result, physicians are not required to explicitly certify any of the specific medical issues identified in the NCD in their prescription, and suppliers and CMS claims reviewers are charged with conducting an independent analysis of complex narratives and medical records in order reach their own conclusions about whether coverage criteria are satisfied.

The lack of standardized forms, clear requirements that physicians document the elements of the NCD; and the reliance on inherently unclear medical records renders the information collected under the rule unclear and not useful in the effort to fairly administer the power mobility benefit. Many of these concerns were echoed in a recent letter sent by Senator Charles Grassley, Chairman of the Senate Finance Committee, which stated that "Elimination of the [CMN] without a scripted form may open the door to fraud, confusion, and subjectivity."[33]

IV. The IFR Threatens the Viability of the Power Mobility Benefit

A. The IFR Creates a Hostile Risk Environment That Will Harm Suppliers and Beneficiaries

---

[31] 69 Fed. Reg. 47,487. 47,545 (August 5, 2004).

[32] 70 Fed. Reg. at 50, 946.

[33] Letter from Sen. Charles E. Grassley, Chairman, U.S. Senate Committee on Finance, to The Honorable Michael O. Leavitt, Secretary, Department of Health and Human Services, and Dr. Mark McClellan, Administrator, Centers for Medicare & Medicaid Services (Sept. 29, 2005).

The IFR creates a regulatory environment that will lead to unpredictable denials of claims and overwhelming financial uncertainty for suppliers of power mobility equipment. As a result, qualified Medicare beneficiaries will have significantly less access to medically necessary power mobility equipment.

CMS states that the new documentation standards in the IFR codify the NCD and reduce the risk that suppliers will have their Medicare "claims denied through no fault of their own." This claim is fundamentally incorrect: the new IFR documentation standards place the increased risk of denial liability squarely on the shoulders of suppliers. The IFR language does not incorporate the objective functional ambulation standards listed in NCD. Rather than creating a system that allows suppliers to trust the clearly stated medical conclusions of a physician, whether included on a CMN or a prescription, the IFR makes suppliers responsible for collecting, reviewing, and determining the sufficiency of medical records and a physicians' medical decision. The IFR massively expands the regulatory duties of suppliers and allows CMS agents to assign fault to suppliers for a wide range of highly subjective and specialized judgments about the sufficiency and content of medical records. As such, suppliers will face significant denial rates because CMS officials could interpret medical documents differently than the non-medically trained suppliers have. CMS will make suppliers strictly liable for what CMS believes are wrong (or insufficiently documented) determinations by physicians. This result will drive down utilization rates, and contrary to the claims of the IFR, it will do so by driving suppliers out of the market.

The IFR eliminates the only manner of documenting medical necessity in a standardized form, the CMN, and instead requires that physicians draft long prescriptions answering subjective questions. Then, suppliers review all relevant medical records to determine if a treating physician is correct in his/her conclusion that those records include the elements of medical necessity listed in the NCD.

If a non-medically trained supplier decides that despite the physician's prescription, medical records are insufficient, they cannot provide the equipment. If suppliers decide that the documentation is sufficient, than suppliers will be strictly financially liable if CMS officials differ in their interpretation of highly individualized and subjective documents, *i.e.* physician notes, exam results, and narratives about patients. Under this system, suppliers will never have a predictable benchmark for determining what documents they must collect or what specific language must be in those documents, and hence suppliers will have no reasonable assurance their claims will paid by CMS. This is a hostile risk environment in which no business could reasonably function.

The threat posed by the IFR to the viability of the power mobility benefit is not small. Experienced economists recently analyzed the likely impacts of the IFR on Medicare beneficiaries and power mobility suppliers. They came to the following conclusion:

> We conclude that the CMS's Interim Final Rule would irreparably harm the Scooter Store and any other supplier of power mobility devices (PMDs)...We also conclude that the Interim Final Rule would irreparably harm all consumers of PMDs, including those consumers who purchase through the Medicare channel

> and those who are fully privately insured... [Even if t]he Scooter Store could continue to operate profitably by raising the price of its PMDs and selling directly to high-income seniors only...such an outcome...would destroy the current benefits of enhanced mobility enjoyed by thousands of seniors who are not independently wealthy or fully privately insured.[34]

B. The Regulatory Impact Statement (RIS) in the IFR is Insufficient

CMS's brief discussion of regulatory impacts suggests that adoption of the IFR will achieve a variety of seemingly inconsistent results. However, these claims cannot withstand scrutiny.

First, CMS claims that adoption of the IFR will not "significantly alter the number of prescriptions for PMDs" and that "the impact of these changes will have minimal net impact on the Medicare Program."[35] Notwithstanding the fact that these claims seem to stand in bold contrast the rationale provided for bypassing normal notice-and-comment procedures, CMS provides no support or analysis for the claim that the new documentation requirements will not impose new and significant costs on PMD suppliers.

Second, CMS claims that the IFR will result in a shift from power wheelchairs to POVs as a result of lifting the specialist requirements related to POV prescriptions.[36] However, this analysis completely ignores the fact that POVs are unsuitable for many Medicare beneficiaries, regardless of who prescribes the equipment. POVs require more room to operate, are less stable than power wheelchairs, and are much more difficult to use in accessing areas of homes such as bathrooms and closets. As a result, it is difficult to understand the support for the claim that increased POV prescriptions will offset a decrease in power wheelchair prescriptions.

Third, while admitting that the IFR is an "economically significant" rule, there is scant discussion of likely impacts that the rule will have on suppliers as result of eliminating the CMN.[37] In fact, the IFR summarily claims that suppliers will have a decreased documentation burden as a result of the IFR, relying upon the PRA discussion in the IFR. This IFR section provides absolutely no analysis or evidence to support the assertion that the collection and review of primary medical documents will impose a smaller burden on suppliers than ensuring that a complete and accurate CMN is submitted.[38] As discussed earlier, and in the PRA comments submitted by The SCOOTER Store, the PRA analysis in the IFR is incomplete and inaccurate.

Fourth, the IFR claims that DME suppliers will actually benefit from the rule because the IFR will "increase their ability to assure that their prescriptions are valid (in terms of medical necessity)."[39] This claim is misleading. The only way for suppliers to test the validity of physicians' prescriptions is through the newly required collection and analysis of virtually

---

[34] Declaration of J.Gregory Sidak and Hal J. Singer, *The Power Mobility Coalition v. Michael O. Leavitt*, Civil Action No. 1:05CV02027 (RBW) (D.C. Dist. Oct. 13, 2005).
[35] 70 Fed. Reg. at 50,945.
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.* at 50,946.

unlimited primary medical records. Even this analysis cannot "assure" medical necessity. Moreover, the time and expense required to conduct a thorough medical review is significant and likely to force many suppliers out of business. Furthermore, DME suppliers are not medical experts and should not be charged with determining whether an item, which has been prescribed by a treating physician, is medically necessary. Such an analysis, when combined with the fact that CMS reviewers can disagree with the suppliers conclusions and impose substantial economic costs, creates an unacceptable amount of uncertainty and risk. This is not an opportunity; it is an obligation and a burden.

In sum, the RIS is insufficient. Implementation of the IFR is inconsistent with the laws governing regulatory development, and CMS would be well-served by developing rules in closer consultation with the regulated community and in compliance with the law.

C. The Threat Posed by the IFR to the Power Mobility Benefit Outweighs any Benefits

There is a substantial public interest in ensuring that Medicare beneficiaries are not denied access to medically appropriate mobility devices. In Fiscal Year 2004, medical professionals prepared 187,000 certifications of medical necessity for PMDs, which were submitted for Medicare reimbursement.[40] Each of those CMNs represents an opportunity for an American to live a safer, richer, and more independent life. Yet, as suppliers withdraw from or reduce their participation in the Medicare program in response to the IFR, patients in need of PMDs will lose important sources of information about these devices and will have more difficulty obtaining them. Thus, the IFR will reduce the public's access to medically necessary mobility devices. That outcome is contrary to the public interest.

CMS's desire to reduce Medicare spending comes nowhere close to outweighing this public interest in providing medically necessary mobility equipment. It can be expected that the IFR will deny qualified patients access to medically necessary mobility devices. That is an issue of human safety and wellness, not just money. Expressed in economic terms, however, the IFR may result in a net loss of consumer welfare, which is the aggregate difference of all consumers' valuations of a PMD and the price paid by all consumers, of between $93 million per year and $283 million per year.[41]

Furthermore, research indicates that the provision of PMDs under Medicare saves program funds. PMDs make patients more independent, better able to care for themselves, and less prone to falls and other accidents, and thus reduces Medicare expenditures for home healthcare and inpatient care at hospitals and skilled nursing facilities.[42] Erecting artificial obstacles to reimbursement for eligible PMDs therefore is not even a rational way of curbing Medicare spending.

---

[40] *Id.* at 50,944-45.

[41] Declaration of J.Gregory Sidak and Hal J. Singer, *The Power Mobility Coalition v. Michael O. Leavitt*, Civil Action No. 1:05CV02027 (RBW) (D.C. Dist. Oct. 13, 2005) at ¶29.

[42] Clifford L. Fry, Ph.D., et al., Powered Vehicles for the Mobility Impaired: The Net Benefits to Medicare (2005) (concluding that the provision of a PMD to an eligible Medicare recipient saves the program more than $5,300 over three years – after deducting the cost of the PMD).

V. The IFR Does Not Comply with Legal Requirements

In promulgating the IFR, CMS failed to comply with multiple provisions of the Administrative Procedures Act (APA) and the Medicare Act. This renders the IFR fatally flawed, and CMS should not implement its provisions.

A. CMS Bypassed Statutorily Required Notice-and-Comment Processes

The APA, 5 U.S.C. § 553, requires that administrative agencies promulgate legislative rules after following a notice-and-comment process. Under these procedures, a "notice of proposed rule making shall be published in the Federal Register,"[43] and then "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation."[44] Likewise, the Medicare Act, 42 U.S.C. § 1395hh(b)(1), contains an explicit notice-and-comment requirement applicable to regulations implementing the substantive provisions of the Medicare Act. The IFR was promulgated without notice-and-comment and does not qualify for any of the limited exceptions to the notice-and-comment requirement in either 5 U.S.C. § 553(b) or 42 U.S.C. § 1395hh(b), and therefore violates both the APA and the Medicare Act.

Notice-and-comment procedures represent Congress's compromise between the competing interests of agency efficiency and agency accountability.[45] Accordingly, although Congress established a handful of exceptions to the notice-and-comment requirement, it "expected, and the courts have held, that the various exceptions . . . will be narrowly construed and only reluctantly countenanced."[46]

CMS conceded in the IFR that it did not follow notice-and-comment procedures in promulgating the IFR.[47] That undisputed failure renders the IFR unlawful.

1. The Documentation Requirements Are an Act of Agency Discretion, Not Statutory Interpretation or Ministerial Implementation

In promulgating the IFR, CMS attempted to justify its failure to follow notice-and-comment procedures in part on the basis that the IFR "conforms [CMS] regulations to section 1834(a)(1)(E)(iv) of the [MMA]."[48] That justification potentially invokes two exceptions to notice-and-comment requirements: the exceptions for "interpretive rules,"[49] and for rules as to which "the agency for good cause finds . . . that notice and public procedure thereon are . . . unnecessary."[50] The interpretive-rule exception excuses notice-and-comment procedures when, instead of establishing any new legal requirements, a rule merely "advise[s] the public of the

---

[43] 5 U.S.C. § 553(b).
[44] *Id.*at § 553(c).
[45] *See New Jersey Dep't of Envtl. Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980).
[46] *Id.*
[47] 70 Fed. Reg. at 50,943.
[48] *Id.*
[49] 5 U.S.C. § 553(b)(3)(A).
[50] *Id.*at § 553(b)(3)(B).

agency's construction of the statutes and rules which it administers."[51] Similarly, the "good cause" exception for rules as to which notice and comment would be "unnecessary" includes "nondiscretionary ministerial action[s]" that the agency is required to take by virtue of a statutory command or some other requirement.[52] Neither exception applies here.

Section 1834(a)(1)(E)(iv) of the MMA, which the IFR implements in part,[53] provides in full:

> Standards for power wheelchairs
>
> Effective on the date of the enactment of this subparagraph, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1395x(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.[54]

The IFR plainly does more than implement the examination and prescription requirements of section 1834(a)(1)(E)(iv). CMS explained in promulgating the IFR that the documentation requirements are "*[i]n addition to* the prescription" required by Congress.[55] And the "prescription" that the regulations require is itself more detailed than a normal prescription used in the medical profession, requiring the physician to include "the diagnoses and conditions that the PMD is expected to modify [and] a description of the item (for example, a narrative description of the specific type of PMD)."[56] As for CMS's elimination of CMNs, that action is not even *permissible* under the Medicare Act[57] much less *required.*[58] The IFR promulgated by CMS therefore was not a discretionless, ministerial action that Congress required the agency to undertake.

Nor does the IFR meet the test for an interpretive rule that is exempt from notice-and-comment requirements under section 553(b)(3)(A). As a threshold matter, the interpretive-rule exception was not invoked when adopting the IFR. In any event, the new requirements have all the indicia of a legislative rule that generally must be subject to public comment.[59] The documentation requirements impose new, binding obligations on suppliers of PMDs. CMS recognized that the IFR would have "substantial" effects on members of the public,[60] and was "economically

---

[51] *American Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993) (internal quotation marks omitted).
[52] *Metzenbaum v. FERC*, 675 F.2d 1282, 1284, 1291 (D.C. Cir. 1982) (per curiam).
[53] *See* 70 Fed. Reg. at 50,943.
[54] 42 U.S.C. § 1395m(a)(1)(E)(iv).
[55] 70 Fed. Reg. at 50,942 (emphasis added).
[56] *Id.* at 50,941.
[57] 42 U.S.C. § 1395m(j)(2)(A)(i).
[58] *See generally Maximum Comfort, Inc. v. Thompson*, 323 F. Supp. 2d 1060, 1067-68 (E.D. Cal. 2004), *appeal pending*, No. 05-15832 (9th Cir. docketed May 4, 2004).
[59] *See generally General Elec. Co. v. EPA*, 290 F.3d 377, 382-83 (D.C. Cir. 2002) (identifying characteristics of legislative rules); *Truckers United for Safety v. Federal Highway Admin.*, 139 F.3d 934, 938-39 (D.C. Cir. 1998) (same).
[60] 70 Fed. Reg. at 50,945.

significant" and a "major rule under the Congressional Review Act."[61] CMS invoked its legislative rulemaking authority when imposing the IFR.[62] The requirements cabin CMS's own discretion in implementing the Medicare program with respect to PMDs. And they are to be published in the Code of Federal Regulations as amendments to prior Medicare rules.[63]

Notice and an opportunity for public comment were required here because the new regulations go "beyond a mere recitation of the statutory language to . . . impose obligations and potential penalties."[64]

2. There Was No Other "Good Cause" for Bypassing Notice-and-Comment Procedures

CMS posited in the IFR that there was "good cause" under 5 U.S.C. § 553(b)(3)(B) for failing to undertake notice-and-comment procedures because "fraudulent billing practices for PMDs have been a substantial problem" and "it would be contrary to the public interest to delay a regulation intended to stem the abusive billing practices."[65] That statement amounts to little more than an assertion that a rulemaking is warranted. It is not even clear whether CMS meant to suggest that notice and comment was "impracticable," or "unnecessary," or "contrary to the public interest" under section 553(b)(3)(B). But it is of no matter which element of the test CMS meant to invoke, because the fraud justification fails under each one.

First, there was ample time to undertake notice and comment on the question of how fraud in the PMD program can best be addressed. CMS publicly announced its intent to consider reforms to the Medicare PMD program as early as September 2003. In December 2003, CMS opened a rulemaking on PMD reimbursement. In August 2004, CMS solicited comments on a proposed rule that contained provisions similar to some of the provisions of the IFR. TSS and other members of the public commented on the proposed rule. Then, in November 2004, CMS deferred considering comments on that proposed rule until a later date. CMS has been working toward its new rule for at least two years.[66]

The preamble to the IFR suggests no reason why the public could not have been included in CMS's lengthy deliberations. Indeed, there is every appearance that CMS decided to proceed without notice and comment precisely so that the agency would not have to address the sort of record evidence developed on similar issues after the August 2004 notice of proposed rulemaking. The narrow exceptions in section 553 do not authorize that sort of "surprise switcheroo on regulated entities."[67]

---

[61] *Id.*
[62] *See id.* at 50,946 (citing 42 U.S.C. § 1302 as legal authority for the IFR).
[63] *See id.* (new 42 C.F.R. § 410.38(c)(2)(iii)).
[64] 94 F. Supp. 2d at 65.
[65] 70 Fed. Reg. at 50,943.
[66] [FIX] *See World Duty Free*, 94 F. Supp. 2d at 65 (lack of a congressional deadline for action and agency's two-year delay in promulgating regulations to implement a statutory change "substantially undercut[]" agency's argument that "notice and publication was 'impracticable' and 'contrary to the public interest'").
[67] *Environmental Integrity Project v. EPA*, 2005 U.S. App. LEXIS 21683, at *13 (D.C. Cir. Oct. 7, 2005) (under "logical outgrowth" rule, agency violated APA in adopting, without notice and comment, an interpretation of statutory language that was different than the interpretation in a proposed interim rule).

Second, although an agency may abandon notice and comment in "emergency situations" or when "delay could result in serious harm,"[68] neither circumstance is present here. Again, CMS's earlier steps toward promulgating regulations through notice and comment belie any suggestion that an emergency precludes those procedures. The IFR does not describe CMS's policy concerns or the IFR in those terms.[69]

Protecting program funds—through appropriate requirements that take account of all the relevant considerations—is indisputably a legitimate goal of CMS, but it lacks the extreme urgency that has led courts to find good cause for bypassing notice and comment.[70] Indeed, because every agency rulemaking presumably is intended to serve the public interest, the good-cause exception would swallow the general rule of section 553 if an agency could avoid notice and comment merely by asserting that its rules will have some benefit.[71]

Third, this is not a "'a situation in which the interest of the public would be defeated by any requirement of advance notice,' as when announcement of a proposed rule would enable the sort of financial manipulation the rule sought to prevent."[72] Contrary to any such argument, CMS made the IFR effective two months after its promulgation.[73]

The so-called "interim" status of the IFR also does not except it from the notice-and-comment requirements of section 553. Even interim regulations are subject to notice and comment, save those regulations that respond to a "rare 'emergency' situation."[74] The IFR does not establish any emergency. Furthermore, it is fatal to any "interim rule" rationale that CMS has not established a deadline or even a target date for promulgation of a final rule.[75]

B. The IFR Illegally Eliminates the Certificate of Medical Necessity as Evidence of Medical Necessity

The Medicare Act gives suppliers a statutory right to utilize a CMN in seeking reimbursement for PMDs provided to Medicare beneficiaries.[76] Congress also provided that a supplier that submits a properly completed CMN cannot be required to submit additional information to

---

[68] *Jifry v. FAA*, 370 F.3d 1174, 1179-80 (D.C. Cir. 2004),

[69] *See* 70 Fed. Reg. at 50,941, 50,943-46; *see also Utility Solid Waste Activities Group v. EPA*, 236 F.3d 749, 754-55 (D.C. Cir. 2001) (relying on EPA's failure to establish "any threat to the environment or human health or that some sort of emergency had arisen").

[70] *Cf. Jifry*, 370 F.3d at 1179 (upholding FAA regulations promulgated without notice and comment after the September 11, 2001, terrorist attacks to address an "imminent hazard" of further attacks) (internal quotation marks omitted).

[71] *See Utility Solid Waste Activities Group*, 236 F.3d at 754 (good-cause exception is not an "escape clause" and its use "should be limited to emergency situations") (internal quotation marks omitted).

[72] *Utility Solid Waste Activities Group*, 236 F.3d at 755 (quoting U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* at 31 (1947)).

[73] *See* 70 Fed. Reg. at 50,940.

[74] *American Fed'n of Gov't Employees, AFL-CIO v. Block*, 655 F.2d 1153, 1157-58 (D.C. Cir. 1981).

[75] *See Thrift Depositors of Am., Inc. v. Office of Thrift Supervision*, 862 F. Supp. 586, 593 (D.D.C. 1994) (interim status of rule did not warrant suspending notice and comment when the agency did not know when final rule would be promulgated).

[76] 42 U.S.C. § 1395m(j)(2)(A)(i).

substantiate a claim for reimbursement.[77] The IFR eliminates the CMN as evidence of medical necessity and permits Medicare carriers to insist on additional information to substantiate claims for reimbursement. Thus, the IFR violates 42 U.S.C. § 1395m(j)(2) and 5 U.S.C. § 706.

See Section above for a full discussion of the illegality of the elimination of the CMN.

C. CMS Established Arbitrary and Capricious Reimbursement Requirements in the IFR

The reimbursement requirements established in the IFR are arbitrary, capricious, and not in accordance with law, in violation of 5 U.S.C. § 706(2)(A). CMS failed to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made."[78] In particular, CMS was required either to consider "facially reasonable" alternatives to the IFR, or else to "give some reason . . . for declining to do so."[79]

According to the preamble to the IFR, the reasons for issuing the new documentation requirements were: (1) increased Medicare payments for PMDs;[80] (2) the agency's conclusion that "inflated and falsified billings" are generally "a serious problem" in Medicare's durable medical equipment program, of which PMD reimbursement is a part;[81] and (3) "the belief that the CMNs do not accurately reflect the contents of the physician's medical record" underlying a determination of medical necessity.[82] None of these considerations necessarily establishes the wisdom of the specific action that CMS took.

Increased Reimbursement Outlays. The IFR states that Medicare payments for power wheelchairs "increased approximately 350 percent from 1999 to 2003."[83] This ignores that Medicare reimbursements for PMDs have *declined* since 2003. Furthermore, the increased utilization of PMDs before 2003 would suggest on its face that this equipment was increasingly beneficial to Medicare recipients during that period, not an increasing problem.

There were several good reasons for the increase in physician prescriptions for PMDs from 1999 to 2003. Improvements in power wheelchairs and scooters made these devices useful for a greater number of patients, and suppliers worked hard to inform doctors and those patients who could benefit from these devices about their availability. More Americans in need of a PMD were receiving them. In addition, the increasing number of Americans aged 65 and older has increased the overall medical need for PMDs.

---

[77] 42 U.S.C. § 1395m(j)(2)(B).
[78] [FIX] *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43 (internal quotation marks omitted); *see Tennessee Gas Pipeline*, 969 F.2d at 1146 (applying *State Farm* standard to agency's explanation for invoking good-cause exception notwithstanding the absence of a formal record).
[79] *Laclede Gas Co. v. FERC*, 873 F.2d 1494, 1498 (D.C. Cir. 1989).
[80] *See* 70 Fed. Reg. at 50,941, 50,943.
[81] *Id.* at 50,941.
[82] *Id.* at 50,944.
[83] *Id.* at 50,941.

Fraud. CMS also cited findings of "fraud and abuse" by durable medical equipment suppliers.[84] Specifically, CMS noted agency determinations of "inflated and falsified billings . . . among certain DME suppliers,"[85] and appeared to reference a report on Medicare fraud by the Office of the Inspector General of HHS.[86] The recommendations of the OIG Report, however, do not include the documentation requirements that CMS adopted.

The OIG Report identified two categories of unnecessary reimbursement by Medicare: (i) claims paid by Medicare despite the lack of a CMN or other inadequate documentation under existing regulations, and (ii) reimbursement for PMDs supplied to patients who are either ineligible for any type of PMD, or ineligible for the particular type of PMD supplied. The solution to overpayments in the first category lies with improved processing of claims by CMS and its Medicare contractors. Requiring additional paperwork will not help CMS to stop making payments when required documentation is missing.

As for PMDs furnished to ineligible patients, the OIG Report indicates that the main reason for such errors was physicians' lack of information about Medicare guidelines and the different types of mobility devices.[87] CMS has taken other actions to address those problems, including the issuance of an NCD in May 2005. The IFR failed to explain, particularly in light of those recent actions, how changing long-established reimbursement procedures reduces uncertainty, much less why the new procedures are the most appropriate way of correcting information shortfalls on the part of doctors and other treating professionals.

See Section II above for recommendations on fraud prevention measures.

Documentation Gaps. Finally, the IFR stated that "CMNs do not accurately reflect the contents of the physician's medical record" and their "practical utility . . . is questionable," and, accordingly, that CMNs should be abandoned for PMD reimbursements.[88] This also is not sufficient justification for the IFR.

As an initial matter, the Eastern District of California has held that 42 U.S.C. § 1395m(j), which addresses the use and contents of CMNs, establishes Congress's intent "that whatever information may be required by carriers from suppliers to show the medical necessity and reasonableness of [durable medical equipment] must be contained in a CMN."[89] For the reasons given in that case,[90] the IFR is unlawful inasmuch as it replaces the CMN with a vague requirement of documenting medical necessity through medical records and allows carriers to require additional documentation beyond that expressly required by the IFR.

The IFR is also substantively deficient because CMS failed to consider other obvious approaches to gathering fuller information on medical-necessity determinations. In the Regulatory Impact

---

[84] 70 Fed. Reg. at 50,941; *see id.* at 50,943-44.
[85] *Id.* at 50,941.
[86] *See* HHS, Office of Inspector General, *Medicare Payments for Power Wheelchairs*, OEI-03-02-00600 (Apr. 2004) ("OIG Report"), *available at* http://oig.hhs.gov/oei/reports/oei-03-02-00600.pdf.
[87] *Id.* at 16-17.
[88] 70 Fed. Reg. at 50,944.
[89] [FIX] *Maximum Comfort*, 323 F. Supp. 2d at 1068.
[90] *See id.* at 1067-75

Statement accompanying the Rule, the Secretary stated, without any explanation, that "[w]e do not believe that any reasonable alternatives [to the Rule] exist."[91] Yet public comments on the August 2004 proposed rule, which CMS has yet to address, discussed such alternatives. Furthermore, as recently as November 2004, CMS was considering one particularly obvious option—revising the CMN form to include additional information supplied by the medical practitioner. CMS utterly failed to explain why such "facially reasonable" alternatives to the IFR would not address CMS's concerns.[92]

Similarly, CMS's adoption of the IFR appears to have been infected by grossly incorrect assumptions about its effect on suppliers of PMDs. The Secretary stated, for example, that "suppliers will face decreases in record-keeping requirements,"[93] when in fact the Rule imposes new obligations to collect, review, and maintain supporting documentation. *See* Section III, above for a detailed discussion of the financial impact of the IFR. TSS estimates that the IFR will require it to spend an additional $270,000 each year on document storage, in addition to the added expense of gathering and reviewing medical records to support reimbursement claims. The IFR also is invalid due to this defective reasoning.

[91] 70 Fed. Reg. at 50,945.

[92] *Laclede Gas*, 873 F.2d at 1498. In light of such concrete alternatives to the IFR, CMS's disregard of notice-and-comment requirements cannot be excused as harmless error. *See Utility Solid Waste Activities Group*, 236 F.3d at 755 (lack of comment period was not harmless error when a party "presented enough evidence to show that on remand they can mount a credible challenge to the amended rule and were thus prejudiced by the absence of an opportunity to do so before the amendment").

[93] 70 Fed. Reg. at 50,945.

PHYSICIANS FOR AMERICA'S MOBILITY IMPAIRED

Advocates for the Rights of Medicare Beneficiaries

November 23, 2005

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Room 314-G
Washington, DC 20201

RE: Implementation of the New Conditions of Coverage for Power Mobility Devices, 70 Fed. Reg. 50,940 (August 26, 2005).

As mentioned in previous correspondence, we represent an informal consortium of physician specialists across the country who treat patients who need mobility assistance due to disability or related impairment. We again write to raise our serious concerns regarding the Interim Final Rule on Conditions for Payment for Power Mobility Devices.

From a clinician's standpoint, we believe the new Rule won't resolve the potential for fraud, which we assume was the original impetus for these revisions, and won't assure that our patients with demonstrable need will get mobility assistance. We simply do not see how this attempt at compiling medical records and other unspecified documentation, in an unrealistic time frame, will serve any purpose other than to unnecessarily complicate the diagnostic process, set up both suppliers and providers with catch-22 retrospective reviews, and inevitably reduce the number of medically necessary devices prescribed and delivered to those in need.

As physicians, we have experienced similar oversight schemes in managed care settings where the underlying purpose of—in effect, retrospective review and ridiculous documentation requirements—is to reduce the medical loss ratio in favor of the payor to the detriment of the patient. Doctors will quickly see the impediments and risks of attempting to prescribe a PMD under the new Rule and try to refer the patient to an increasingly smaller pool of physicians who can afford to manage the care of this fragile patient population. As we have emphasized before, the delay or denial of this kind of care leads to the progressive deterioration of those patients' health, and, perversely, increases the cost of their care in other acute settings.

The impractical aspects of the Rule can be fixed. We have read the comments submitted by industry experts who deal with our colleagues on a daily basis and concur with several of their suggestions that would make this new system more rational, efficient, and compassionate.

First, what is it exactly that CMS and the DMERCs want from us? Our medical records likely will not be compiled in the fashion contemplated by the rule, and there is little

guidance as to what your regulators are looking for in the way of adequate documentation. Further, due to HIPAA regulations, physicians would be required to redact their medical records, make copies of them and send them in to suppliers to fill a PMD prescription. This creates a record-keeping burden for physicians. The reimbursement for these exercises, like other federal schemes, does not reflect the actual costs. In that respect this is yet another unfunded silent mandate on daily medical practice.

We understand this has little to do with our medical judgment and more to do with screening for medically necessary care. If we are to avoid regulatory "gotchas," the rule needs to be very specific as the content of our "documentation." This can be remedied by returning to an earlier proposal regarding local coverage determinations and adding specificity to those criteria. That September 14th draft outlined the proper elements:

- Symptoms
- Related diagnoses
- History
    - How long the condition has been present
    - Clinical progression
    - Interventions that have been tried and the results
    - Past use of walker, manual wheelchair, POV, or power wheelchair [21]and the results
- Physical exam
    - Weight
    - Impairment of strength, range of motion, sensation, or coordination of arms and legs
    - Presence of abnormal tone or deformity of arms, legs, or trunk
    - Neck, trunk, and pelvic posture and flexibility
    - Sitting and standing balance
- Functional assessment – any problems with performing the following activities including the need to use a cane, walker, or the assistance of another person
    - Transferring between a bed, chair, and PMD
    - Walking around the home – to bathroom, kitchen, living room, etc. – provide information on distance walked, speed, and balance

A format that follows this logic, and asks the physician a series of questions associated with preparing the documentation, will better serve your agency's intended purposes, and will help us better prepare our prescription. Previously the Certificate of Medical Necessity (CMN) served as a tool to help the physician determine medical need. We would recommend an expanded CMN with more questions or a more scripted form or template that provides numerous yes/no questions with some narrative to explain why physicians answered "yes." This would be given equal weight and would be a significant part of the medical record.

Secondly, pulling together records and reformatting for the agency's purposes will often take twice as long as the 30-day requirement. This rule assumes a level of compliance at the document level that is unrealistic in many settings. It also assumes a level of communication in very busy and already overburdened medical practices with the supplier, who is now in the untenable position of second guessing our documents and judgment, and will probably result in many cross communications. These kinds of communication dysfunctions happen in far simpler transactions between us and pharmacists, and are about to get more complicated with the rollout of Part D. How do you expect the collaboration between us and the PMD supplier to be any simpler, and be accomplished in a 30-day span? This can at least be partially addressed by doubling the time frame to 60 days so the physician and supplier are not technically in violation of the rule because of normal kinks and delays in these kinds of communications.

Third, and equally important, how is CMS going to retrain physicians to this new format? In our experience, change and adaptation come slowly in medical practices. As CMS is well aware, physicians who write these kinds of prescriptions don't fall into neat, tidy packages, or even in readily organized large groups. A significant number of these prescriptions come from small group or solo practices, including primary physicians, who will not be equipped to quickly accommodate these new—and we still believe unnecessary—reporting burdens. There must be a vigorous, collaborative effort with organized medicine at every level, and reasonable forbearance on the part of CMS when still large numbers of physicians are technically non-compliant, due in large part to the slow and cumbersome nature of physician education on regulatory matters. We are concerned that this cumbersome, multi-layer communication process will be detrimental to the very real needs of our mobility-impaired patients, who typically are elderly and disabled.

As we have emphasized in previous letters, the new Rule as adopted will not work, unless it is the agency's express intent to delay or deny medically necessary care and sort out the disputes on the back end. It does not acknowledge the real world of medical practice and, as currently configured, will result in many doctors shying away from these services. We respectfully urge that these and many other comments are taken into consideration so our mutual interest in assuring patients with a medical need for mobility support get the care to which they are entitled.

Sincerely,

Mark Race

Mark Race, MD
Co-Chair

George Rodgers, JR

George Rodgers, MD
Co-Chair

Cc: Michael O. Leavitt
Secretary of Health and Human Services
U.S. Department of Health and Human Services