Submitter : Andrew Stuart **Date:** 08/26/2005

Organization : Klingensmith HealthCare

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

There is an apparent discrepancy between the Federal Register posting and the companion document titled "Frequently Asked Questions: MAE NCD PMD Regulation and CMNs" just issued. The FAQ document (in Section III Header and again in A.3.3) states that "manual wheelchairs" and "all types of wheelchairs" are covered by the IFR. Is this accurate? Please reconcile this discrepancy.

Submitter : **Mr. Jeffrey Rose** **Date: 08/29/2005**

Organization : **Health System Services**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

CMS-3017-IFC seems to be in direct conflict with the paperwork reduction act. Why replace one piece of paper to determine medical necessity with potentially dozens of pages of still undefined "supporting documentation"?

Furthermore, the CMN is one of the few objective tools that a provider and CMS have to determine whether equipment is truly needed. It is CMS' own document. If it is not working in its present form why not revise it rather than abandon it? Surely whatever salient points CMS is trying to glean from the patient's medical record can be summed up in a few well-crafted questions. How about:

"Would the power mobility device enable the beneficiary to function more independently in ways not possible with a standard mobility device?"

or

"Would the power mobility equipment allow the beneficiary to perform mobility-related activities of daily living such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home?"

Answers to questions such as these clearly address CMS' stated coverage requirements. Shouldn't a physician's attestation to them be enough to qualify a beneficiary? Why complicate matters with an exceedingly vague, subjective policy that accomplishes nothing but confuse physicians, providers, CMS itself, and most importantly, the beneficiaries who benefit from this kind of equipment?

Jeffrey Rose
Vice President
Health System Services

Submitter : Susan Smith **Date:** 08/29/2005

Organization : Rehab Medical

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Clarify "PMD prescription must be in writing". Does this mean that the physician must list the basic equipment and all accessories ("a narrative description of a specific type of DME")the physician wants the patient to have, and that it must be "hand-written" not transcribed notes? When the patient comes to the DME supplier, will a detailed list be given to the supplier, or is the DME supplier to discern what is needed by the physician's hand-written notes? Because there are so many DME accessory options available, it would be very difficult for the physician to know all of the options and how they are used. As the DME supplier, we do not want to be in the position of decerning the notes and perhaps having Medicare not agree, therefore not funding the equipment.

Because the DME supplier will be held accountable for having all funding documentation, who is actually responsible for the in-home visit to determine that the equipment will fit in the client's environment? It appears from the CMS rules and regulations that CMS anticipates the physician will be scheduling "in-home" visits. This needs to be clarified.

Submitter : Mr. Thomas Van Berkel **Date:** 08/31/2005

Organization : Crown Medical Equipment Co. Inc.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

With the changes in Medicare and Medicaid it is very hard to process a POV or Electric wheelchair, first the codes for coverage are not clearly posted anywhere and if you do find a list of codes from Palmetto or other sources they are orginized in numerical order. This is great if you already know the code for example a manual wheelchair is a K code, however the electric wheelchair is not clearly listed, can anyone put together a simple query program on the Medicare and Medicaid website that allows users to enter a description of the item for example electric wheelchair, in plain english and get a set of codes listed alphbetically, instead of numerically. The information is already there but not sorted correctly. This causes DME suppliers to search for the correct code for hours. The other major problem is that there are too many variations for submission of the power assist vehicles. Does medicare require a cmn, or a pa for the wheelchairs, and or POV's? Does medicaid require a cmn or a PA or prior authorization for the same items? And if a substitution is permitted for a power wheelchair can a scooter be used in place of the chair? If so do we need to redo all the paperwork under a new code?
This system needs to be cleared up as it is extremely confusing. Then if a prior authorization is required, what is the PA form that is required for submission to medicare and medicaid? We submitted the original yellow form and it was rejected because of the color, now apparently the PA has to be white even though the yellow copies are from the government and standard forms that have been accepted.

Submitter : Ms. Angela Miller **Date:** 08/31/2005

Organization : Medical Auditing Solutions

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I would think if we can eliminate the CMN for power mobility then we should be able to eliminate all CMNs since the CMN is not accepted as the final document anyway. It has been proven the CMNs do not prevent unethical people from defrauding the government. With proper training, a supplier should be able to obtain testing and other information via referral's verbal order and fax then recite that information back on a physician's order for verification and signature. I was a compliance officer for 4.5 years and consulting engagements since with all training being --obtain copies of testing and medical records to support the order/CMN at the time of the order when it is not inexpensive and routinely purchased items. No matter what process is in place, if someone intends to defraud the government they will whether it is with CMN's or Physician Orders. The rules in place only delay the honest providers from obtaining paperwork faster because the unethical ones will just make it up and fill it out.

CMS-3017-IFC-6 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : **Dr. liang fan** **Date & Time:** **08/31/2005**

Organization : **SUNY at Buffalo**

Category : **Physician**

Issue Areas/Comments
GENERAL

GENERAL

Re: CMS-1502-P Teaching Anesthesiologists

Dear Sir/Madam:

I was profoundly disappointed that CMS officials did not appreciate the deleterious impact that CMS-1502-P has caused academic medical centers with respect to this disparity in payment among physicians in surgical specialties. The current Medicare teaching anesthesiologist payment rule has been shown to be unwise, unfair and unsustainable.

Quality medical care, patient safety and an increasingly elderly Medicare population demand that the United States have a stable and growing pool of physicians trained in anesthesiology. Right now, slots in anesthesiology residency programs are going unfilled because of ill-conceived Medicare policy that shortchanges teaching programs, withholding 50% of their funds for concurrent cases. At the University at Buffalo, we train 36 residents who fall victim to the inefficiencies in scheduling, personnel allocation, case assignments, and budget shortfalls that are directly attributed to the current Medicare teaching anesthesiologist policy. Anesthesiology teaching programs, caught in the snare of this trap, are suffering severe economic losses that cannot be absorbed elsewhere.

The CMS anesthesiology teaching rule must be changed to allow academic departments to cover their costs and meet their mission goals. Academic research in anesthesiology is also drying up as department budgets are broken by this arbitrary Medicare payment reduction.

A surgeon may supervise residents in two overlapping operations and collect 100% of the fee for each when certain requirements are met. A teaching anesthesiologist will only collect 50% of the Medicare fee if he or she supervises residents in two overlapping cases. This is not fair, and it is not reasonable. Medicare must recognize the unique delivery of anesthesiology care and pay Medicare teaching anesthesiologists on par with their surgical colleagues. Moreover, the Medicare anesthesia conversion factor is less that 40% of prevailing commercial rates. Reducing that lower payment by an additional 50% for teaching anesthesiologists results in revenue grossly inadequate to sustain the service, teaching and research missions of academic anesthesia training programs.

Anesthesiologists have made the delivery of anesthesia one of the safest medical practices in the nation. We have been cited by the Institute of Medicine as leading the way for patient safety reform. Ironically, if this rule is not changed, those programs that serve the sickest, poorest and oldest patients in our society will be forced to cut back or close their training sites reversing the century of progress made to reduce medical errors and deaths in the operating room.

Sincerely,

Submitter : Ms. CATHY REINER **Date:** 09/01/2005

Organization : DISABLED INDAVIGAL

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

WHAT HAPPENS WHEN MY MD.HAS ISSUED 2 PRESCRIBTIONS AND THE PROVIDER ECNORES 2 OF THEM AND TELL THE PATIENT THAT THEY DONT NEED THAT KIND OF CHAIR AND IS TOLD HE WILL ONLY PALCE A 400LB SEAT AND LEGG RAISERS ON A 300LBS BASE WHEN THE PATIENT WEIGHS 266 PLUS AND THE DOCTOR WANT A CHAIR WITH A MIN OF 350 WEIGHT CAPACITY.THE SUPPLIER TELLS THE PATIENT HE WILL PICK UP THE CHAIR REFUND MEDICARE AND THE PATIENT WHO IS CHAIR OR BED BOUND AND THEY WILL BE WITH OUT A CHAIR FOR UP TO 45 DAYS .HE SEEMS TO BE USING SCARE TACTICS TO MAKE THE PATIENT KEEP THE CHAIR AND LET THE PROVIDER ALTER THE CHAIR TO BE UNSAFE WHAT CAN THE PRESCRIBING DOCTOR DO?

Submitter : Mr. James Pazour **Date:** 09/06/2005

Organization : St. Luke's Hospital

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

After review of the conditions for payment document there appears to be a significant issue which CMS needs to address. This involves professionals used to document the need for MAE. The presented list is striking in that it does not list both occupational and physical therapists. It appears as though CMS is not using the most trained and/or appropriate invdividuals during the assessment process. Physicans, PA's, Nurse Practitioners, and Nurse Specialist have in most cases had minimal to no acedemic training in the area of MAE. In asking them to make this determination it is not unlike asking a heart surgeon to put in a total hip. While they might be able to do it, they certainly would not be the best person for the job. In direct contrast occupational and physical therapist not only are provided with introductory acedemic training, but have also choosen to specialize in this area of practice. Perhaps CMS needs to make better use of these rehabilitation professions who specialize in this area or address why they feel they are not integral to ensuring best practice.

Submitter : **Mrs. Laura Davis** **Date: 09/06/2005**

Organization : **Santa Rosa Memorial Hospital**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

This would be of great service to our neighborhood and community.

Submitter : Ms. Lois Tucker **Date:** 09/07/2005

Organization : Ms. Lois Tucker

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

The new CMS rule that providers are required to gather clinical information supplied by the doctor or practitioner that proves medical necessity before delivering a power wheelchair or scooter will make the process of getting a powered mobility device very difficult for the recipients. It will make getting the right piece of equipment nearly impossible. The major fault in this rule is that both physical and occupational therapists are not among the listed acceptable practitioners. The therapist's are licensed practitioners that are trained in wheelchair prescription and are the ones that are doing most of the evaluation and prescription. They are able to generate appropriate prescriptions and they gather and have all the necessary information needed to substantiate medical need. In all the major hospitals in NYC, patients receive there wheelchair evaluations in a designated wheelchair clinic that is either staffed by occupational and/or physical therapist. The therapist makes appropriate recommendations that is reviewed and confirmed by the patient's doctor. Therapists are well trained in recognition of the need for the chair based on the patients ability to perform Mobility Related ADL's, the patients physical needs in relationship to appropriate seating and the prescription of the most appropriate wheeled mobility base and electronic needs based on the clients level of function and physical/environmental limitations. They are updated on the changes in the technology made by the manufacturers and understand the clinical application of the products. If you mandate that the prescription and medical notes that are accepted for Medicare recipients only comes from the doctor, physican assistant or nurse practitioner you will create a situation where orders generated by these persons will be incomplete or inappropriate. Doctors and nurse practitioners are not educated or updated on product detail and configurations and do not know the detailed information that allow appropriate application of product as it relates to medical need. Please reconsider the designation of healthcare professionals to include the occupational and physical therapists. Allow the patient a full and thorough evaluation by the therapist. Once the recommendations are made, it would best serve the patient to allow that recommendation to be forwarded to the physician. When the patient has there face to face evaluation, the physician can review the recommendations and sign off on them if appropriate.

Allowing this document, generated by the therapist and co-singed by the physician to be the acceptable medical record to substantiate need would best serve the recipients. This is the standard practice for most private insurance companies as well as the state run Medicaid programs.

Submitter : **Mr. Kenneth Jelinek** **Date: 09/08/2005**

Organization : **University of Washington Medical Center**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am an occupational therapist and a certified assistive technology provider. I evaluate complicated patients with severe musculoskeletal and skin problems. I have been doing wheelchair seating and positioning, as a specialty, for over 15 years.

The physicians and ARNP's in our medical center are top notch; we are currently ranked the number one hospital based rehab center, and number three overall, in the country. There is one physician in our system that has enough experience to work with vendors (without a therapist) to evaluate and formulate plans for complicated seating patients; he is over 70 years old and just retiring. The physicians and ARNP's in our medical center depend on people like myself (there are a handful of us) for wheelchair and seating/positioning interventions; they simply do not have the specific knowledge base or detailed experience. If experienced therapists are not involved, I believe you will see a shift to the vendors leading the interventions. Having said that, we like our experienced vendors, but find that they too need our guidance.

I find it interesting that Medicare would reduce the role of therapists when the State of Washington increasingly requires patients to be evaluated by a therapist (rather than solely by a physician) to decrease over-utilization and over prescribing. Perhaps you'd like to telephone Diane Baum of Washington State DSHS (manager of the DME programs) and ask about therapists versus physician wheelchair issues? Her number is 1-360-725-1590. I am not at all sure what you would hear, but I imagine it is an opinion you will respect.

Regards, Ken Jelinek, OTR/L, ATP 1-206-579-7034 kenjel@u.washington.edu

Submitter : **Ms. Elizabeth Mccarty** **Date: 09/09/2005**

Organization : **United Cerebral Palsy**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I have evaluted individuals for 15 years for power mobility. This is a significant evaluation process and can take months to determine someones ability to safely use a power wheelchair. This is also significant as to the postural support or other medical needs that need to be evaluated for a clients ability to use power. A physician or PA(who has less years of schooling then a therapist) or a nurse rarely has time to take a medical history let alone provide the needed evaluation time it requires.
Currently many seating clinics include a doctor to review the progress of the client. It is the therapist that devotes the needed time to evaluated and train. Since Power w/c are so expensive, it is so important that the products be carefully evaluated and matched so as not to waist money or provide a product that the cleint is not able to use.

The other important issue is that physcians and PA and Nurses rarely have knowledge nor time to investigate products and rely on the expert advise of the therapist who have typically spent years learning and evaluating.

This is a very difficult area to just use a Doctors perscription for. It needs a careful plan with experienced individuals, who have typically been therapist.

I know so many individual doctors who just sign Rx and spend little time with the evaluation, leaving that to the experienced therapists. TO cut the therapist from this evaluation is a very bad direction to go. THis industry is already full of short cuts where vendors will get Dr. to sign perscriptions and the doctor does so without much investigation.

Requiring a client to participate in a seating clinic that is overseen by a Doctor or other qualified team member has been the most effect method to assure good product delivery.

I urge you not to decrease the professional input into such an important peice of equipment as power wheelchair that can be life improving or very dangerous to use.

Beth McCarty OTR/L Cincinnati Ohio

CMS-3017-IFC-13 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : Mrs. Ruth Bixby **Date & Time:** 09/13/2005

Organization : Lincoln Land community college

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I believe that ocupational therapists should be included in the bill. OTs have expertise in areas of physical and occupational asssessment,wheelchair evaluation and functional mobility isues that can assist in determining an individual's need for a powered mobilty device and insure that the device is appropriate and functional before dollars are spent on such a costly device.

Submitter : Mr. Dominic Rotella **Date:** 09/15/2005

Organization : Nichole Medical Equipment & Supply, Inc

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Why can't it be mandatory that any DME Provider of PMD's in order to receive payment for this item have a physical location within a 50 mile radius of the Geographic location they service or any other arbitrary distance as determined by CMS? This will help insure that the warranty & repairs can be maintained by the appropriate provider. Also if PT's or OT's or any other professional are considered to evaluate or recommend patients for PMD's other than the Physician's, they be subject to the same Anti-Kickback rules, penalties and fines as physicians. This will also help insure that everyone involved in the evaluation of the patient has only the patient's best interest in mind. Can CMS give us a form that we can use to give the physicians outlining all the items they would want to see as justification for a PMD. If a CMS form is used to obtain the pieces of the records you would want then it would by-pass our need to get a patient release first to obtain the records and physicians would give these records to us easier. The current proposal would mean we would have to gt an Rx first, then a patient release signed and then get the records. A CMS generated form requesting the records similar to the way the CMN would have been generated would allow us to get the records quicker and the PMD to the patient faster if they qualified.

Submitter : Mrs. kerry scudiero **Date:** 09/15/2005

Organization : Mediquick Inc

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

My questions are:
1. How will proof be provided to CMS/DMERC to show that the RX from the Dr. was received by the supplier within 30 days after the face to face eval?

2. How long will the RX be good for? IF the supplier receives the RX on 12/1/05, how long does he have to fill the order/RX and deliver the items to the patient?

3.IF the RX gets to the supplier with items that were not addressed, (ex: length of need or diagnosis codes) can the supplier call the physican and get those items over the phone or does the Dr. have to fill those items out personally?

4. In the Federal Register VOl. 70 No.165 dated 8/26/05, PAGE 50946, it states that, 'THE SUPPLIER OF DME WILL BE RESPONSIBLE TO ASSURE THAT PRESCRIPTIONS ARE VALID IN TERMS OF MEDICAL NECESSITY BEFORE THEY SUPPLY THE EQUIPMENT TO THE PATIENT.' However, CMS made it clear in the open door session on 9/13/05 that suppliers are not required to go over Dr's in their clinical assessments. Suppliers are not clinicians..Therefore, are suppliers required to look over progress notes and make sure medical necessity is met? And are suppliers then required to let the physician know that their patient can or can not have a power device?

5.

Submitter : Mrs. Jenny Sweeney **Date:** 09/16/2005

Organization : Mrs. Jenny Sweeney

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

It is important that occupational therapists and physical therapists are included as treating practitioners who can conduct the face to face exam to prescribe power mobility equipment. The physician, nurse practitioner, etc do not have the knowledge of equipment to ensure that the patient is prescribed the correct equipment by the supplier. They can determine need, but a therapist is necessary to bridge the gap between the physician and the supplier to ensure that the patient gets the most appropriate equipment, not the one that gives the supplier the most profit.

CMS-3017-IFC-17 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : **Pamela Daly** **Date & Time:** **09/16/2005**

Organization : **OOTA**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3017-IFC-17-Attach-1.TXT

September 9, 2005

CMS-3017- IFC
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8013
Baltimore, MD

I have had some concerns with seating and functional positioning of beneficiaries in mobility devices even prior to the new revisions. In reviewing the Federal Register 42 CRF 410 Interim Final Rule, it is clear that CMS has put much thought and conducted research into it's plan; however, my concerns have increased.

''Provisions of the Interim Final Rule'' - OCCUPATIONAL THERAPISTS COMPLETING THE EVALUATION It has been my unfortunate experience to find beneficiaries who have received Power Mobility Devices without an evaluation by an occupational therapist. This is very unfortunate because functional skills decline rapidly when beneficiaries are not able to participate in activities of daily living and/or mobility is limited by improper seating and positioning. For example, one case in point is a gentleman who received a wheelchair without height adjustable arm rests, lateral support or an elevating seat. This has caused a serious problem for him at work, as his wheelchair does not fit under his work table and his arms are positioned too low, causing excessive head flexion with shoulder protraction. The result is that he is no longer able to maintain his head in midline position and is unable to lift his head. His shoulders are extremely rounded and his arms have become very weak. Without the lateral support, his trunk falls to the left against his arm and limits mobility, which further increases his weakness. This could have been avoided if the wheelchair evaluation was completed by an occupational therapist. Occupational therapists have the clinical skills to evaluate the best seating and positioning for beneficiaries in all of their daily tasks and roles, within their own individual environments.

It is essential that the clinical skills of occupational therapists are utilized for evaluations of power wheelchairs and power-operated vehicles for beneficiaries. These skills are a crucial component of power chair evaluations and their evaluations should be part of the medical records that support medical necessity for power wheelchairs and power-operated vehicles. On many occasions, I arrived at a patient's home, who was new to me, to find that they had powered wheelchairs or scooters that only fit in one or two rooms of their home. The beneficiary was not able to access their bathtub, sink and sometimes their toilet, making them further dependent on caregivers/aides.

Pertinent medical information from the beneficiaries medical record and forward the information to the medical supplier. To eliminate waste, revisions to mobility devices and decompensation of skills, the physician should forward the medical information to the occupational therapist. In this manner, the therapist would be equipped with all of the pertinent information and skills necessary to complete a holistic and comprehensive evaluation for the best fit of a mobility device that matches the beneficiaries skills, needs and environmental and posture requirements.

This interim final rule would also requires physicians to travel to the beneficiary's home. This will greatly increase the cost to the physicians and decrease the clinical time that the physician is available to treat other patients, again increasing the costs of healthcare while occupational therapists already access patients in the community setting. Physicians prescribe medications and generally understand function as it relates with disease; however, they are not accustomed to determining and identifying the specific skills required to perform functional daily activities of feeding, bathing, dressing, grooming, toileting, housekeeping, meal prep, etc.

If the occupational therapist is excluded from the evaluation process, significant waste will occur to increase the costs of PMD's because the beneficiaries will, in

some situations, require aides and attendants (that they wouldn't have if the PMD evaluation had been completed by a therapist); increased costs to rehabilitate the consumer for lost muscle strength, diminished ADL performance; transportation costs (unable to exit home with PMD/PMD does not fit in current vehicle and wasn't considered during evaluation); and unnecessary revisions/modifications to the devices (to correct for needs not considered during the initial evaluation and ordering of the PMD). Again, some of the situations that I have seen that render the beneficiary dependent on a caregiver are:

beneficiary is unable to access their bathtub
beneficiary is unable to access their bathroom and/or kitchen
beneficiary is unable to vacate/enter their residence
unable to cook (improper height of wheelchair or lack of trunk support)
unable to enter vehicle (PMD does not fit)
not able to weight shift or pressure relieve in any manner

We also need to consider what the hidden costs would be to the beneficiary to adapt the home to accommodate the PMD if the evaluation was performed by a nontherapist. The beneficiary may require the installation of a ramp, the widening of a doorway(s), a new vehicle, adaptive equipment to transfer safely or perform ADL's from improper heights.

"BACKGROUND" - "IN THE HOME" REQUIREMENT: I would also like to comment on the "in home" requirements.

"Section 1861(n) provides that DME includes wheelchairs, including power operated vehicles that may appropriately be used as wheelchairs," . . ." "and are used in the beneficiary's home". "Section 414.202 of our regulations further defines DME" . . . "and is appropriate for use in the home". And also "We are revising § 410.38(c) of our regulations to specify the following: The definition of a 'power mobility …device (PMD)'. vehicles that a beneficiary uses in the home. This language appears to limit mobility coverage requirements, use and need to "in the home". Wheelchairs/PMD's should not be limited to "in the home". Many beneficiaries are homebound and socially isolated. Sometimes their only contact with the outside world is their Home Health Aid (HHA). A powered wheelchair/device would allow them a safe means of locomotion; to exit the home and visit neighbors and friends, schedule and maintain physician visits, make short trips to the local store; thereby, maximizing independence and avoiding long-term care placement. Without the ability to negotiate outside of the home and into the community, beneficiaries are not able to pursue meaningful activities in variety of social settings and maintain group ties.

It has been my experience that the difficulty with Power Mobility Device evaluations involves the direct ordering of the devices from the physician script to the supplier, without therapist input. In these situations, consideration of activities of daily living, transfer ability, adaptive equipment needs, home environment, cognitive abilities, caregiver assistance has been left out of the equation. CMS has determined that the physician should extract the ps decreased self esteem, depression, loneliness, and decreased quality of life, which translates to increased costs for the agency.

The restriction of thirty days for a beneficiary to see their physician, have a comprehensive evaluation completed and select a supplier is not adequate time. The patient's physical skills and abilities have to be assessed, as well as cognitive ability to operate a powered device. The patient's home has to be evaluated to determine the correct device to meet the beneficiaries needs. How and where the device will be stored/charged needs to be determined. Can the device fit through the doorways of the home? Can the beneficiary transfer from the tub/bed to the device and from the device to the tub/bed? Is there room for the device to turn around (end of hallway) each room to exit? Can the beneficiary access the stove, kitchen sink, bathroom sink, dresser drawers from the device? Does the beneficiary have a vehicle? Will the device fit in the vehicle? All of these questions are

important considerations that can not be answered in ten minutes.

Some times it takes two or three weeks to schedule an appointment with a supplier and often it can take a month or two to obtain a script from a physician. Then is the beneficiary becomes ill or is re-hospitalized during the process, this rule would require that the whole process be reinitiated. Additionally, PMD's would allow beneficiaries to engage in their work occupations outside of the home, complete IADL's of banking, shopping and driving.

In conclusion, my best recommendation to CMS to maximize cost containment while accentuating independence in the beneficiary, would be to have the physician write the script, the therapist complete the evaluation and the supplier order the equipmen: the supplier order the equipment, remove the "in home" restriction, remove the 30 days requirements. I have had some concerns with seating and functional positioning of beneficiaries in mobility devices even prior to the new revisions. In reviewing the Federal Register 42 CRF 410 Interim Final Rule, it is clear that CMS has put much thought and conducted research into it's plan; however, my concerns have increased.

''Provisions of the Interim Final Rule'' - OCCUPATIONAL THERAPISTS COMPLETING THE EVALUATION

It has been my unfortunate experience to find beneficiaries who have received Power Mobility Devices without an evaluation by an occupational therapist. This is very unfortunate because functional skills decline rapidly when beneficiaries are not able to participate in activities of daily living and/or mobility is limited by improper seating and positioning. For example, one case in point is a gentleman who received a wheelchair without height adjustable arm rests, lateral support or an elevating seat. This has caused a serious problem for him at work, as his wheelchair does not fit under his work table and his arms are positioned too low, causing excessive head flexion with shoulder protraction. The result is that he is no longer able to maintain his head in midline position and is unable to lift his head. His shoulders are extremely rounded and his arms have become very weak. Without the lateral support, his trunk falls to the left against his arm and limits mobility, which further increases his weakness. This could have been avoided if the wheelchair evaluation was completed by an occupational therapist. Occupational therapists have the clinical skills to evaluate the best seating and positioning for beneficiaries in all of their daily tasks and roles, within their own individual environments.

It is essential that the clinical skills of occupational therapists are utilized for evaluations of power wheelchairs and power-operated vehicles for beneficiaries. These skills are a crucial component of power chair evaluations and their evaluations should be part of the medical records that support medical necessity for power wheelchairs and power-operated vehicles.
On many occasions, I arrived at a patient's home, who was new to me, to find that they had powered wheelchairs or scooters that only fit in one or two rooms of their home. The beneficiary was not able to access their bathtub, sink and sometimes their toilet, making them further dependent on caregivers/aides.

Certificate of Medical Necessity (CMN)Discussion: It has been my experience that the difficulty with Power Mobility Device evaluations involves the direct ordering of the devices from the physician script to the supplier, without therapist input. In these situations, consideration of activities of daily living, transfer ability, adaptive equipment needs, home environment, cognitive abilities, caregiver assistance has been left out of the equation. CMS has determined that the physician should extract the ps decreased self esteem, depression, loneliness, and decreased quality of life, which translates to increased costs for the agency.

''Provisions of the Interim Final Rule'' - 30 DAYS FOR DETAILED SCRIPT and Certificate of Medical Necessity (CMN)Discussion "…a description of the item (for example, a narrative description of the specific type of PMD), the length of need, …" The restriction of thirty days for a beneficiary to see their physician, have a

comprehensive evaluation completed and select a supplier is not adequate time. The patient's physical skills and abilities have to be assessed, as well as cognitive ability to operate a powered device. The patient's home has to be evaluated to determine the correct device to meet the beneficiaries needs. How and where the device will be stored/charged needs to be determined. Can the device fit through the doorways of the home? Can the beneficiary transfer from the tub/bed to the device and from the device to the tub/bed? Is there room for the device to turn around (end of hallway) each room to exit? Can the beneficiary access the stove, kitchen sink, bathroom sink, dresser drawers from the device? Does the beneficiary have a vehicle? Will the device fit in the vehicle?

All of these questions are important considerations that can not be answered in ten minutes. Some times it takes two or three weeks to schedule an appointment with a supplier and often it can take a month or two to obtain a script from a physician. Then is the beneficiary becomes ill or is re-hospitalized during the process, this rule would require that the whole process be reinitiated. Additionally, PMD's would allow beneficiaries to engage in their work occupations outside of the home, complete IADL's of banking, shopping and driving.

In conclusion, my best recommendation to CMS to maximize cost containment while accentuating independence in the beneficiary, would be to have the physician write the script, the therapist complete the evaluation and the supplier order the equipment: he supplier order the equipment, remove the "in home" restriction, remove the 30 days requirements.

Again, thank you for this opportunity to express my thoughts and opinions. If you would like to discuss any of these issues further, please do not hesitate to contact me at 440-951-6677.

Respectfully submitted,

Pamela J. Daly, OTR/L
Third Party Reimbursement Chair, OOTA
PO Box 686
Mentor, Ohio
44061-0686440-951-6677

Submitter : Ms. Donna Hager **Date:** 09/18/2005

Organization : Sentara Home Health Care

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I do not feel Physicians, PA 's, Nurse Practioners can see the whole picture of why a person would require Power wheelchairs. Are they trained in knowing how power chairs would allow someone to complete ADL?; I don't think so!

Submitter : Greg Baird **Date:** 09/19/2005

Organization : DeltaMed, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3017-IFC-19-Attach-1.DOC

With regard to the interim final rule we have the following comments and concerns.

First, I appreciate the fact that CMS would like to capture the most relevant information possible to determine a beneficiary's need for mobility assistive equipment. We feel strongly that the interim final ruling has several serious shortcomings, however, as noted below.

1. <u>Beneficiary Access</u> to Medicare covered powered mobility devices will be seriously reduced.

By requiring a face to face physician exam for each beneficiary who wants a PMD, access is immediately greatly reduced. Most people who need such a device are severely disabled and typically immoble. It is clear to us that the beneficiaries who need these products the most would also be those least likely to physically get to a physicians office for this meeting.

It is important to remember that there is a relationship between physical disablities and income. Those with the fewest financial resources are often the same people with the most serious disablities because they haven't had equal access to quality preventative healthcare for most of their lives. In addition, they are often people with poorly connected social support systems such as rides to and from physician offices.

Furthermore, it is silly to assume that physicians will begin a national campaign of making home assessments for PMDs on their way home from work...Particularly when you consider that a large percentage of these beneficiaries live in sketchy neighborhoods typical of low income earners.

On another note:

It should come as no great surprise that CMS is receiving more claims for PMDs. While physical disabilities have always existed, only relatively recently have the benefits of PMDs gained widespread national attention. The DME industry is relatively small and has not been nearly as effective as pharmaceutical companies have been at educating caregivers and the public about the health benefits of their products. PMDs have the ability to help beneficiaries with severe mobility deficits to live more independent and rewarding lives. In addition, they are huge money savers! It is far more cost effective to help a person stay at home where cost of their care is quite low. Once that person has a fall, ambulance rides to the hospital, hip replacement surgeries, possible short-term nursing home stays and physical therapy can quickly become a large multiple of the cost of a $5,000 powered wheelchair.

A PMD can be to a person with severe functional limitations what a statin is to someone with high cholesterol or what Viagra is to a person with erectile dysfunction. Neither high cholesterol nor erectile dysfunction in the elderly are new phenomenon but effective medications for their treatment are. By the same token, an increase in the use of PMDs following improvements in their design and their abiltiy to facilitate an individuals abiltiy to perform activities of daily living is no more unusual and is to be expected.

Thank you for your kind attention.

- Greg Baird, DeltaMed, Inc.

Submitter : **Mr. Kasey Harris** **Date: 09/19/2005**

Organization : **Rider Pharmacy**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

As a provider, be you large or small, how do you think we should implement the new policy(ies) on Power Operated Vehicles? Providers should submit policy change guidelines as they relate to a fluid timeline of implementation. The guidelines are asking the providers to bench press 500 lbs on their first day of weight training instead of gradually building up to the accomplishment. CMS is going to strain and sprain alot of Provider's muscles and pocketbooks. Why not ask the providers the best way to gradually implement the changes a step at a time. Everyone wants to be the say-soer, the boss, the lawmaker. It is time that the focus of power operated mobility devices be adjusted by the industry that creates and provides them to the needy public. The patient, the beneficiary, the person, the individual that is suffering is the one suffering. Big business and Big government need to slow down and stop slapping the Providers and beneficiaries in the face with the mistakes and mismanagement of guidelines and rules. Conflict is becoming mainstage where teamwork should be standing.
Who is listening and who is plugging their ears with bottomlines and overbudget errors. Get together and drink from the same pot of coffee instead of gossiping at the fountain.

CMS-3017-IFC-21 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : Mrs. Melissa Tally **Date & Time:** 09/21/2005

Organization : UCP Perlman Center

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I think itis good that we are requiring physicains to see a patient within 30 days of an order for a power chair. However, what if the physicain does not know what is the most appropriate equipment or that the patient would benefit. What education would be provided to them. What about those doctors who rely on therapists who specialize in this equipment and refer to them to evaluate if a patient would benefit and what would be the most appropraite MAE. We have had clients who have seen their doctors for years and do not have essential adaptive equipment that would make their lives more functional. we have also had clients who have had very inappropriate equipment ordered for them. I think we need to look into who is the best source to evaluate the needs of these patients. There are so many options for adaptive equipment for those with a disabiltiy and there are thepraists and other professionals (including MDs) who are keeping up with the most up to date technology. Shouldn't we be working as a team to make sure these clients get the best care possible? Wouldn't that cut back on the fraud? Wouldn't that best serve those with a disabilty?

CMS-3017-IFC-22 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : Mr. Fazlyi Mustafa **Date & Time:** 09/23/2005

Organization : Preivat Person-familji

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

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CMS-3017-IFC-23 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : **Pippit Carlington** **Date & Time:** **10/01/2005**

Organization : **Pippit Carlington**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I have a systemic autoimmune disease called Sarcoidosis which significantly restricts my mobility and prevents me from living a normal life. There's no known cure for this disease, and its statistics sorely under-represent the toll it takes on those patients who have it. Most Sarcoidosis patients begin to become disabled around age 40-50 (if they are not already). Many people I know have died or are dying of this disease; often from cardiac arrhythmias, uncontrollable infection, or overwhelming pulmonary infiltrates. People's organs shut down as a result of severe and persistent inflammation. It's more devastating than cancer and less treatable, contrary to popular belief. Most people with Sarcoidosis eventually develop neurological manifestations involving cognitive impairment, nerve-conduction interference, motor difficulties, pain, and/or weakness, seizure, stroke, etc...

I'm unable to drive and have been since I was 19 years old.
I remain unable to work an 8-hour day, and I cannot walk reasonable distances that others can without suffering severe pain, becoming unsteady on my feet, and if I walk for too long I become disoriented, get blurred vision, and am at risk of falling. Sometimes I also develop difficulty breathing, and chest pain if I'm severely flaired-up. Currently I take a paratransit service when I have to run errands. I don't have help at home, and the few friends I have are not always able to take me where I need to go because of their work schedules. I avoid going places on the paratransit service because it's very taxing without a power wheelchair or scooter, and often after making a trip out I end up in bed and in severe pain for several days thereafter, unable to function even minimally. As I am writing this I am still in pain as a result of a trip I took on Thursday to the bank and the photo store. It is now Saturday.

I had to withdraw from college this past Spring Semester because the amount of walking required to get around the campus each day made me relapse. I developed kidney problems, and the more I pushed myself, the worse they got. This happened several months after my doctor had tried unsuccessfully to get me certified for a power chair or scooter, and found that I didn't qualify under Medicare's guidelines. He and I were told that in order to qualify I had to require the mobility device for use indoors (in my home). I had a prescription, but the company I consulted, The Scooter Store could not redeem the prescription because of this barrier. My doctor and I were stuck, so I just tried the best I could for as long as I could to make it around the campus, and that only worked for a semester and a half. Then my body collapsed. I don't have family support so it's imperative that I obtain an advanced degree so that I can eventually find a way to adequately support myself, and then buy long-term care insurance, as the life- expectancy for this disease is uncertain and Social Security Disability is just not enough to provide everything I need. By the way, the Scooter Store representative told me that I could buy a scooter out of pocket for "only $900", (yeah right; with what money?). My total SSDI amount is only $622/Month. The Americans With Disabilities Act was developed so that disabled citizens could do the same things as their non-disabled counterparts, so in keeping with the spirit of this Federal law I recommend this particular part of the Medicare guidelines by changed. I can't stay housebound and expect to survive. Just because I can walk inside my small ranch (one-story) house does not mean I should be unable to qualify for a mobility vehicle. Not all stores and other buildings have scooters available. When my body gives out it does so suddenly, so I can't predict or plan ahead for how much exertion I can handle from one day to the next. Without a scooter or powerchair it is doubtful I can return to school and

complete my requirements there.

CMS-3017-IFC-24 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : Mrs. Julie Wright **Date & Time:** 10/04/2005

Organization : Rocky Mountain Medical Equipment

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

The ATP requirements would be extremely difficult to meet in our area. I am currently managing a DME company in Colorado Springs, Co. As far as I am aware there are only 2 ATPs in our surrounding area. One works for us the other works for another DME company. We utilize our ATP not for Medical Necessity but for quality assurance over our ATS staff and for professional medical education within our community. The ATP educates the patient care providers in equipment availability and uses. To require an ATP to see all clients requiring power mobility would I believe not meet the patients best interest. They are in general doing an assessment in a couple visits. The patient care provider has better historical perspective and can more appropriately assist the DME company in getting the most appropriate equipment.

CMS-3017-IFC-25 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : Mr. Michael Aguilar **Date & Time:** 10/06/2005

Organization : Adorno-Rogers Technology

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

We are supportive of the new coverage policy and face-to-face requirement, however, we are extremely concerned that these initiatives will significantly disrupt access to power mobility devices as CMS rushes to implement. We are asking CMS to announce a short term delay in the implementation of certain initiatives to allow time to finalize key details and provide for a 90 day education and implementation period once all matters are final.

CMS must make major changes to local coverage policies and codes. The Interim Final Rule ?Conditions for Payment of Power Mobility Devices?, the DMERC Local Coverage Determination (LCD) policy, and the 63 new PMD HCPCS codes all require changes made to answer some significant questions. As of the end of September, there remain significant questions and concerns with these items and final answers are not available.

No physician education yet and DMERC systems are not ready. CMS is eliminating the ?Certificate of Medical Necessity? and instead requiring physicians to provide suppliers with copies of medical records that are to contain information related to medical need. CMS needs to conduct significant physician education about these changes, which is not feasible before the October 25 effective date. In addition, the billing and claims payment software required to implement the payment of claims will not, according to Medicare, be in place and operational until April of 2006.

Supporting details for new national coverage policy are not yet final. The DMERC LCD was just issued on September 14 to provide information for prescribing physicians and suppliers to comply with May 5 national coverage criteria in conjunction with the new PMD codes. It is expected that the regional policies will not be finalized until December 2005 at the earliest.

New product codes and pricing are not available. In February CMS issued a new set of 49 final codes for PMDs, which increased the number from 4. Manufacturers were required to test their products, and submit applications for the new final codes by September 1. On September 14, CMS announced a whole different set of 63 final codes to replace the 49 codes, and once again issued new and different testing requirements for the 63 new codes. We strongly recommend that CMS provide the same amount of time to adjust to the 63 new codes as was granted under the 49 final codes issued in February. In addition, the new allowable charges for these new codes are yet to be established and may not be available until December. This does not allow sufficient time to implement with an effective date of January 1.

The CMS fee setting method will result in inequitable fees. The gap-filling methodology that CMS will use to develop the new PMD Medicare fees is flawed and results in Medicare payment amounts for power wheelchairs that are not realistic and equitable. As a recent Muse and Associates report demonstrated, CMS should recognize that the historic trend in power wheelchair prices is not represented by the CPI-U component under the gap filling methodology. CMS should take into account the actual trend of pricing for power wheelchairs by using 1992 as the ?historic price? baseline year for gap-filling based on the data provided in the Muse and Associates report.

The opportunity remains to get it right. The most rational approach is to make substantive necessary changes, issue final policies and then allow at least a 90 day education period prior to implementation. Currently, some of these new rules go into effect prior to CMS receiving public comment.

CMS-3017-IFC-26 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : Katherine Olsen **Date & Time:** 10/06/2005

Organization : US Citizen with MS

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please remove the 'in the home' restriction on mobitity devices. This restriction causes people like me with MS and other nervous system problems to be confined to our homes. We can walk small amounts inside our homes but fatigue and other issue make impossible to get out into the community with the assistance of a mobility device.

Submitter : **Ms. Susan Farrell** **Date: 10/12/2005**

Organization : **Signature Healthcare, Inc.**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

I would like a requirement added to the Collection of Information Requirements. Over the past year, we have lost at least 10 manual wheelchairs because a less than scrupulous provider has delivered a power chair without informing the Medicare recipient that the manual wheelchair must be returned. When I contact the patient after receiving a denial for duplicate equipment - the patient refuses to return our manual wheelchair stating they need both. One patient received a power wheelchair from an out-of-state company that won't fit through her doorways and hallways in her home. We had no choice but to let her keep the manual wheelchair.

I feel if Medicare required the provider of the power wheelchair produce a copy of the manual wheelchair return that it would help deter fraud. Patients may refuse the power wheelchair when they are informed they cannot keep both wheelchairs.

September 9, 2005

CMS–3017– IFC
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8013
Baltimore, MD

I have had some concerns with seating and functional positioning of beneficiaries in mobility devices even prior to the new revisions. In reviewing the Federal Register 42 CRF 410 Interim Final Rule, it is clear that CMS has put much thought and conducted research into it's plan; however, my concerns have increased.

''Provisions of the Interim Final Rule'' - OCCUPATIONAL THERAPISTS COMPLETING THE EVALUATION It has been my unfortunate experience to find beneficiaries who have received Power Mobility Devices without an evaluation by an occupational therapist. This is very unfortunate because functional skills decline rapidly when beneficiaries are not able to participate in activities of daily living and/or mobility is limited by improper seating and positioning. For example, one case in point is a gentleman who received a wheelchair without height adjustable arm rests, lateral support or an elevating seat. This has caused a serious problem for him at work, as his wheelchair does not fit under his work table and his arms are positioned too low, causing excessive head flexion with shoulder protraction. The result is that he is no longer able to maintain his head in midline position and is unable to lift his head. His shoulders are extremely rounded and his arms have become very weak. Without the lateral support, his trunk falls to the left against his arm and limits mobility, which further increases his weakness. This could have been avoided if the wheelchair evaluation was completed by an occupational therapist. Occupational therapists have the clinical skills to evaluate the best seating and positioning for beneficiaries in all of their daily tasks and roles, within their own individual environments.

It is essential that the clinical skills of occupational therapists are utilized for evaluations of power wheelchairs and power-operated vehicles for beneficiaries. These skills are a crucial component of power chair evaluations and their evaluations should be part of the medical records that support medical necessity for power wheelchairs and power-operated vehicles. On many occasions, I arrived at a patient's home, who was new to me, to find that they had powered wheelchairs or scooters that only fit in one or two rooms of their home. The beneficiary was not able to access their bathtub, sink and sometimes their toilet, making them further dependent on caregivers/aides.

Pertinent medical information from the beneficiaries medical record and forward the information to the medical supplier. To eliminate waste, revisions to mobility devices and decompensation of skills, the physician should forward the medical information to the occupational therapist. In this manner, the therapist would be equipped with all of the pertinent information and skills necessary to complete a holistic and comprehensive evaluation for the best fit of a mobility device that matches the beneficiaries skills, needs and environmental and posture requirements.

This interim final rule would also requires physicians to travel to the beneficiary's home. This will greatly increase the cost to the physicians and decrease the clinical time that the physician is available to treat other patients, again increasing the costs of healthcare while occupational therapists already access patients in the community setting. Physicians prescribe medications and generally understand function as it relates with disease; however, they are not accustomed to determining and identifying the specific skills required to perform functional daily activities of feeding, bathing, dressing, grooming, toileting, housekeeping, meal prep, etc.

If the occupational therapist is excluded from the evaluation process, significant waste will occur to increase the costs of PMD's because the beneficiaries will, in some situations, require aides and attendants (that they wouldn't have if the PMD evaluation had been completed by a therapist); increased costs to rehabilitate the consumer for lost muscle strength, diminished ADL performance; transportation costs (unable to exit home with PMD/PMD does not fit in current vehicle and wasn't considered during evaluation); and unnecessary revisions/modifications to the devices (to correct for needs not considered during the initial evaluation and ordering of the PMD). Again, some of the situations that I have seen that render the beneficiary dependent on a caregiver are:

beneficiary is unable to access their bathtub
beneficiary is unable to access their bathroom and/or kitchen
beneficiary is unable to vacate/enter their residence
unable to cook (improper height of wheelchair or lack of trunk support)
unable to enter vehicle (PMD does not fit)
not able to weight shift or pressure relieve in any manner

We also need to consider what the hidden costs would be to the beneficiary to adapt the home to accommodate the PMD if the evaluation was performed by a nontherapist. The beneficiary may require the installation of a ramp, the widening of a doorway(s), a new vehicle, adaptive equipment to transfer safely or perform ADL's from improper heights.

"BACKGROUND" - "IN THE HOME" REQUIREMENT: I would also like to comment on the "in home" requirements.

"Section 1861(n) provides that DME includes wheelchairs, including power operated vehicles that may appropriately be used as wheelchairs," . . ." "and are used in the beneficiary's home". "Section 414.202 of our regulations further defines DME" . . . "and is appropriate for use in the home". And also "We are revising § 410.38(c) of our regulations to specify the following: The definition of a 'power mobility … device (PMD)'. vehicles that a beneficiary uses in the home. This language appears to limit mobility coverage requirements, use and need to "in the home". Wheelchairs/PMD's should not be limited to "in the home". Many beneficiaries are homebound and socially isolated. Sometimes their only contact with the outside world is their Home Health Aid (HHA). A powered wheelchair/device would allow them a safe means of locomotion; to exit the home and visit neighbors and friends, schedule and maintain physician visits, make short trips to the local store; thereby, maximizing independence and avoiding

long-term care placement. Without the ability to negotiate outside of the home and into the community, beneficiaries are not able to pursue meaningful activities in variety of social settings and maintain group ties.

It has been my experience that the difficulty with Power Mobility Device evaluations involves the direct ordering of the devices from the physician script to the supplier, without therapist input. In these situations, consideration of activities of daily living, transfer ability, adaptive equipment needs, home environment, cognitive abilities, caregiver assistance has been left out of the equation. CMS has determined that the physician should extract the ps decreased self esteem, depression, loneliness, and decreased quality of life, which translates to increased costs for the agency.

The restriction of thirty days for a beneficiary to see their physician, have a comprehensive evaluation completed and select a supplier is not adequate time. The patient's physical skills and abilities have to be assessed, as well as cognitive ability to operate a powered device. The patient's home has to be evaluated to determine the correct device to meet the beneficiaries needs. How and where the device will be stored/charged needs to be determined. Can the device fit through the doorways of the home? Can the beneficiary transfer from the tub/bed to the device and from the device to the tub/bed? Is there room for the device to turn around (end of hallway) each room to exit? Can the beneficiary access the stove, kitchen sink, bathroom sink, dresser drawers from the device? Does the beneficiary have a vehicle? Will the device fit in the vehicle? All of these questions are important considerations that can not be answered in ten minutes.

Some times it takes two or three weeks to schedule an appointment with a supplier and often it can take a month or two to obtain a script from a physician. Then is the beneficiary becomes ill or is re-hospitalized during the process, this rule would require that the whole process be reinitiated. Additionally, PMD's would allow beneficiaries to engage in their work occupations outside of the home, complete IADL's of banking, shopping and driving.

In conclusion, my best recommendation to CMS to maximize cost containment while accentuating independence in the beneficiary, would be to have the physician write the script, the therapist complete the evaluation and the supplier order the equipmen: the supplier order the equipment, remove the "in home" restriction, remove the 30 days requirements. I have had some concerns with seating and functional positioning of beneficiaries in mobility devices even prior to the new revisions. In reviewing the Federal Register 42 CRF 410 Interim Final Rule, it is clear that CMS has put much thought and conducted research into it's plan; however, my concerns have increased.

''Provisions of the Interim Final Rule'' - OCCUPATIONAL THERAPISTS COMPLETING THE EVALUATION

It has been my unfortunate experience to find beneficiaries who have received Power Mobility Devices without an evaluation by an occupational therapist. This is very unfortunate because functional skills decline rapidly when beneficiaries are not able to participate in activities of daily living and/or mobility

is limited by improper seating and positioning. For example, one case in point is a gentleman who received a wheelchair without height adjustable arm rests, lateral support or an elevating seat. This has caused a serious problem for him at work, as his wheelchair does not fit under his work table and his arms are positioned too low, causing excessive head flexion with shoulder protraction. The result is that he is no longer able to maintain his head in midline position and is unable to lift his head. His shoulders are extremely rounded and his arms have become very weak. Without the lateral support, his trunk falls to the left against his arm and limits mobility, which further increases his weakness. This could have been avoided if the wheelchair evaluation was completed by an occupational therapist. Occupational therapists have the clinical skills to evaluate the best seating and positioning for beneficiaries in all of their daily tasks and roles, within their own individual environments.

It is essential that the clinical skills of occupational therapists are utilized for evaluations of power wheelchairs and power-operated vehicles for beneficiaries. These skills are a crucial component of power chair evaluations and their evaluations should be part of the medical records that support medical necessity for power wheelchairs and power-operated vehicles.
On many occasions, I arrived at a patient‘s home, who was new to me, to find that they had powered wheelchairs or scooters that only fit in one or two rooms of their home. The beneficiary was not able to access their bathtub, sink and sometimes their toilet, making them further dependent on caregivers/aides.

Certificate of Medical Necessity (CMN)Discussion: It has been my experience that the difficulty with Power Mobility Device evaluations involves the direct ordering of the devices from the physician script to the supplier, without therapist input. In these situations, consideration of activities of daily living, transfer ability, adaptive equipment needs, home environment, cognitive abilities, caregiver assistance has been left out of the equation. CMS has determined that the physician should extract the ps decreased self esteem, depression, loneliness, and decreased quality of life, which translates to increased costs for the agency.

‘‘Provisions of the Interim Final Rule’’ - 30 DAYS FOR DETAILED SCRIPT and Certificate of Medical Necessity (CMN)Discussion “…a description of the item (for example, a narrative description of the specific type of PMD), the length of need, …” The restriction of thirty days for a beneficiary to see their physician, have a comprehensive evaluation completed and select a supplier is not adequate time. The patient’s physical skills and abilities have to be assessed, as well as cognitive ability to operate a powered device. The patient’s home has to be evaluated to determine the correct device to meet the beneficiaries needs. How and where the device will be stored/charged needs to be determined. Can the device fit through the doorways of the home? Can the beneficiary transfer from the tub/bed to the device and from the device to the tub/bed? Is there room for the device to turn around (end of hallway) each room to exit? Can the beneficiary access the stove, kitchen sink, bathroom sink, dresser drawers from the device? Does the beneficiary have a vehicle? Will the device fit in the vehicle?

All of these questions are important considerations that can not be answered in ten minutes. Some times it takes two or three weeks to schedule an appointment with a supplier and often it can take a month or two to obtain a script from a physician. Then is the beneficiary becomes ill or is re-hospitalized during the process, this rule would require that the whole process be reinitiated. Additionally, PMD’s would

allow beneficiaries to engage in their work occupations outside of the home, complete IADL's of banking, shopping and driving.

In conclusion, my best recommendation to CMS to maximize cost containment while accentuating independence in the beneficiary, would be to have the physician write the script, the therapist complete the evaluation and the supplier order the equipment: he supplier order the equipment, remove the "in home" restriction, remove the 30 days requirements.

Again, thank you for this opportunity to express my thoughts and opinions. If you would like to discuss any of these issues further, please do not hesitate to contact me at 440-951-6677.

Respectfully submitted,

Pamela J. Daly, OTR/L
Third Party Reimbursement Chair, OOTA
PO Box 686
Mentor, Ohio
44061-0686440-951-6677

Submitter : Mr. Carey Jinright **Date:** 10/15/2005

Organization : Precision Medical Solutions

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3017-IFC-28-Attach-1.DOC

I have been in this industry for nine years; I remember when lift chairs were abused in much the same way as power wheelchairs today. Wal-mart carried lift chairs, everybody carried lift chairs! The patients were marketed to at the expense of Medicare. This abuse lead to many claims being filed by patients that did not truly need the lift chairs, the solution was to stop paying for the chair all together. These details sound much like the situation that we find ourselves in today! I watched many of my patients that truly needed lift chairs go without them due to the change in coverage. The patients that did not really need them considered themselves lucky that they "cashed in" for their chair before the regulation was announced (never admitting that they were the reason for the regulation.) Medicare also never viewed these beneficiaries as unscrupulous; "they were just helpless victims."

My question is, in the year of 2005 with all of the technology that we have, why can't Medicare simply track us by our supplier number. I feel that this would be one of the reasons that we have supplier numbers, so that we can be treated independently of one another. I do not understand why it seems that the we are "all" viewed as unscrupulous DME providers as mentioned on page 50944, why could these particular DME companies not be located and punished independently? In our industry today we have two or three major companies that are turning the mobility industry into a retail market. They are removing the power from the physician to decide who needs a PMD by marketing directly to the patient and having their desires force the physician into ordering them the equipment they want. **If a car lot offered me a deal of acquiring a car, with a stipulation that it would paid for by someone else or it would be free to me, why would I not try to get the car? <u>It only makes sense that this would be a source of fraud and abuse!</u>** I have asked this question before and was told that, "they are not advertising to Medicare patients, which would be illegal," well I would like to know the ratio of private insurance beneficiaries to that of Medicare beneficiaries that were provided powered wheelchairs.

The new proposed regulation does not present any real solution to the problem. It seems to allude to the fact that if Medicare could just have these suppliers put "everyone" in a scooter instead of a power wheelchair then Medicare would save thousands! Medicare will still lose under the proposed regulation; it simply is not realistic! Suppliers that are certified (such as my self), that go to the patient's home and measure door ways, along with explaining realistic approaches to operating and transporting a PMD. Those of us that make sure that the patient qualifies and really needs the equipment that the physician ordered still cannot control what the physician records in his/her chart for progress notes. The new proposal makes the supplier more responsible for the physician's documentation skills; this is unacceptable. Medicare has never provided quantitative measures to determine who qualifies and who does not qualify for PMDs, this leaves even honest suppliers wondering exactly what to look for when evaluating a patient. The new regulation does not clear up the problem of what is acceptable documentation from a physician's chart and what is not.

Solution: I believe that Medicare should not allow any patient direct advertisement to be presented for medical equipment that is covered by Medicare. This will keep the control in the physician's hands! The Internet can offer patients a source of information if they desire it, this would at least make the patient invest time into the process. When a company that is named after one particular type of mobility aid does not even show the equipment that they are named after in their commercial a red flag should go up (think about this!)

Medical companies that have boxes in shopping malls that offer a chance to win a power wheelchair should be investigated! These companies are not geared towards answering a medical need!

Medicare could also regulate physician offices that are ordering a great volume of PMDs relative to their volume of patients. Medicare should have the right to know why their numbers are higher than other physicians.

Medicare should rely on trusted, certified providers for industry insight; these providers should not be grouped in with others to pay for others mistakes! If you ran a large company and you had a department that many of its employees came to work late, you would go and pull the time cards to see who was at fault. Surely you would not discipline the whole department (the innocent and the guilty), think of the resentment from those that had never been late. This is a good picture of our industry today. The new approach allows no reward for those that are doing a great job of providing needed equipment. There is no reward for becoming ATS certified, or being a NRRTS member, though many providers put years of their lives into obtaining these certifications, does that seem fair? In America we try to view every one as honest, **those that are committing fraud will continue to commit fraud until you put them out of our industry! No regulation will stop them, if they played by the listed rules there would be no problem to fix!**

Submitter : **Mrs. Angelein Daniel** **Date: 10/22/2005**

Organization : **Kaiser Permanente**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Proposing only RESNA-certified Assistive Technology Practitioners
ATPs) to conduct comprehensive evaluations of Medicare beneficiaries needing tilt and other high end power chairs will greatly affect access to care issues for patients. I strongly oppose the ATP - and urge the DMERCs to recognize that all occupational therapists have the requisite skills to conduct comprehensive evaluations. This provision potentially restricts equally competent therapists who are not ATPs and creates access to care issues.

Proposing provisions in 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 will also greatly affect quality patient care and treatment. Pateints will not receive adequate care in a timely manner because they will not be able to see their physician in a timely manner. This will overload the physician caseload making it hard for patients to access therapy services. This should specifically include the role of therapists in the treatment and evaluation process.

Thanks for your time and for taking my comments into consideration to help improve patient care from a rehab (occupational therapy) standpoint. Sincerely, Angelein Daniel

Submitter : Mr. samuel limon **Date:** 10/23/2005

Organization : Mr. samuel limon

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am submitting specific feedback regarding the following areas of interest:

* Permits only RESNA-certified Assistive Technology Practitioners (ATPs) to conduct comprehensive evaluations of Medicare beneficiaries needing tilt and other high end power chairs.

I strongly oppose ATP - only requirement I urge the DMERCs to recognize that all occupational therapists may have the requisite skills to conduct comprehensive evaluations. This provision potentially restricts equally competent therapists who are not ATPs and creates access to care issues. This is especially the case in Rural America. In my present location I have not seen access to ATP available.

* Implements provisions in CMS' draft interim final rule concerning 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.

I recommend that the interim and/or final rule or the DMERCs LCD specifically mentions the role of a therapist in the treatment and evaluation process. The final rule and or DMERC LCD should specifically include the role of therapists in the treatment and evaluation process. This is critical to ensure appropriate, efficient issue of PMD. Most physicians simply do not have the training or time to handle such detailed matters. This would most certainly lead to potentially expensive and or unecessary PMD perscriptions

* The required documentation of medical necessity for a wheelchair remains unclear in the interim final rule and in the LCD. For instance, if an occupational therapy evaluation identifies mobility needs and limits and is included in a beneficiary's medical record, it is unclear whether this would be sufficient documentation for wheelchair approval.

I urge the DMERCs to require documentation from occupational therapists as evidence of medical necessity and, at a minimum, recognize such documentation as sufficient to demonstrate medical necessity for a PMD.

* The timing of implementation for the interim final rule is confusing. As stated below, the comment period for the rule does not close until November 25, while implementation of the rule is scheduled for October 25. To add to the confusion, comments on the DMERCs LCD are due on October 31, and it is unclear when the LCD will be finalized.

I urge CMS to postpone the effective date of the rule to provide CMS with adequate time to fully educate providers and suppliers and ensure a smooth transition.

Submitter : Susan Powers **Date:** 10/25/2005

Organization : Susan Powers

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment for details.The government should have a certification of expertise in assessing need and provision for the seating and mobility needs of the disabled population . Then any health professional could qualify to assess power mobility devices.

CMS-3017-IFC-31-Attach-1.DOC

I am an Occupational Therapist and have been assessing the specifications and justifying component parts to power wheelchairs for the majority of 35 years. I have filled out the CMNs and provided the referring Physician with justifications for each part as well as the observation that the patient had demonstrated the ability to **safely use the equipment and the postural and pressure relief aspects of the accessories.** When appropriate, I requested the vendor to deliver a "demo" wheelchair to the patient's home in order to assure successful use in the home environment. The patient actively participated in the specification process tailoring the type of chair to the lifestyle. As I am not a vendor nor affiliated with one and has no motivating factor save the functional improvement to the patient's mobility status within the home.

Why have you not included occupational and physical therapists in your list of treating practitioners? Nurses and nurse practitioners and physician's assistants, yes even the physician themselves, do not possess the specified knowledge of what type of power chair is appropriate for each severely disabled person and what specialized accessories are **needed** (versus fraudulent padding).As the MD does not know what power chairs are appropriate for his patient he has had to rely on the vendor...and that's where the majority of abuses to your previous system occurred. The power should never have been with one who stands to profit from the transaction. As the government was paying for it, the sky was the limit.

. With all due respect, few office nurse, nurse practitioner or physician's assistants possess the knowledge of the physical impairments and spared skills of the disabled population. Where are the occupational and physical therapists in your Modernization Act?

The government should have a certification of expertise in assessing need and provision for the seating and mobility needs of the disabled population . Then any health professional could qualify to assess power mobility devices.

Susan Bowen Powers OTR/L RI License #7

Submitter : Mr. Phillip Lowe **Date:** 10/25/2005

Organization : Lowes Therapy

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

PT's or OT's should be involved in the decision process for needs determination and final WC prescription.

Submitter : Mrs. Lindsey Lawrence **Date:** 10/25/2005

Organization : NA

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I'd like to share a few comments concerning the Medicare Durable Medical Equipment Regional Carriers (DMERCs)draft of local coverage determination (LCD) concerning the governing of power mobility devices (PMDs) that is based on CMS' interim final rule and that limits the role of occupational therapists in evaluating beneficiaries for PMDs.

I'd like to strongly oppose the ATP - only requirement and urge the DMERCs to recognize that all occupational therapists may have the requisite skills to conduct comprehensive evaluations. This provision potentially restricts equally competent therapists who are not ATPs and creates access to care issues.

With regard to evalution for a PMD, I urge the DMERCs to specifically include the role of therapists in the treatment and evaluation process.

In the area of documentation, I urge the DMERCs to require documentation from occupational therapists as evidence of medical necessity and, at a minimum, recognize such documentation as sufficient to demonstrate medical necessity for a PMD. The timing of implementation for the interim final rule is confusing. The comment period for the rule does not close until November 25, while implementation of the rule is scheduled for October 25. To add to the confusion, comments on the DMERCs LCD are due on October 31, and it is unclear when the LCD will be finalized. I urge CMS to postpone the effective date of the rule to provide CMS with adequate time to fully educate providers and suppliers and ensure a smooth transition.

Thank you for the opportunity to share my concerns.
Sincerely,
Lindsey Lawrence, BGS, COTA/L, ROH Occupational Therapy Assistant

Submitter : **Ms. Charlene Simon** **Date: 10/26/2005**

Organization : **All Childrens Hospital**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am very concerned about the proposed requirement that therapists (now occupational therapists I understand) recommending high end power wheelchairs be ATP certified by Resna. I have been involved in wheelchair evaluations for 15 years, and feel that I have developed expertise in this area. I have not persued certification from Resna due to the expense of application, and the fact that the test includes multiple areas of inquiry, not just power and manual wheelchairs. The exam includes computer access and augmentative communication which is a very specialized field, often having no relationship to the wheelchair user. This requires study in an area I will never use as I will leave augmentative communication to professionals who have developed expertise in that area through practice. Having a cursory knowledge obtained thru hours of rote memorization from a study guide does not qualify a person to work in augmentative communication, nor in powered mobility. The ATP certification requirement would prevent me from working in seating and mobility (for the high end power wheelchairs) after 15 years of hands on experience. Implementing this proposal will restrict access to experts in the field for the end user, and will prevent me from practicing in one of my strongest areas of practice.

Submitter : Ms. KRISTINE GJERDE **Date:** 10/26/2005

Organization : MN CHAPTER, AMERICAN PHYSICAL THERAPY ASSOCIATION

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

"Provisions of the Interim Final Rule"
Regarding the face-to-face examination of the beneficiary.
Often, clients are obtaining their second or third power chair. These clients with preexisting conditions often have needs that are determined by the physical or occupational therapist involved in promotion of their functional activity. The client often has not seen the physician or treating practitioner as defined within 30 days and does not have a current need to do so. This face to face visit requirement actually adds cost to PMD requests, both to CMS and to the individual who must arrange transportation, time off of work, and/or escort requiring time off of work for family members. Requiring a prescription to endorse the request for PMD is reasonable, but to require an unnecessary additional face-to-face visit does not decrease expenses or validate the PMD request.
I am asking that this requirement be eliminated.

Submitter : **Ms. sharon malinowski** **Date: 10/27/2005**

Organization : **Beaumont Hospital**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I strongly oppose the ATP only requirement and feel it should be removed and urge you to recognize that all occupational therapists have the ability to evaluate the clients wheelchair needs. Also, documentation should be required from occupational therapists as evidence of medical necessity for a PMD.

Submitter : Mr. Matthew Kalifeh **Date:** 10/27/2005

Organization : Marian Respiratory Care, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please delay implementation of the Face-to-Face eaxam rule.

CMS-3017-IFC-38 Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)

Submitter : Mr. Brett Baker **Date & Time:** 11/25/2005

Organization : American College of Physicians

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

The American College of Physicians (ACP), representing over 119,000 doctors of internal medicine and medical students, is pleased to comment on this interim final rule.

BACKGROUND
ACP supports the payment to a physician for the work and resources involved in establishing and documenting the need for a PMD. The College believes that the payment rate, which is equivalent to a 99211, is appropriate if the documentation required to justify that the PMD is medically necessary is in the physician?s primary possession.

PROVISIONS OF THE INTERIM FINAL RULE
ACP recommends that CMS clarify the type of information that the physician is expected to submit in support of the PMD prescription and the sources from which the physician is expected to be able to draw that information. The supporting documentation listed in the actual amendments to Code of Federal Regulations (CFR) 410.38 (2)(iii), which reads: ?provides supporting documentation, including pertinent parts of the beneficiary?s medical record (e.g. history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans, and other information as appropriate?,? appears to be reasonable as it describes information to which the physician is likely to have primary access. However, the more expansive CMS description of the supporting documentation in this section, which reads: ? the parts of the medical record selected should be sufficient to delineate the history of the events that led to the request for the PMD; identify the mobility deficits to be corrected by the PMD; 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,? is likely to include documentation that a physician would have to obtain from an external source. ACP is concerned that a process that routinely requires physicians to submit documentation to which they do not have primary access will impose a significant administrative burden. Further, the CMS payment for establishing and documenting the need for a PMD is insufficient if physicians are expected to routinely obtain and submit documentation maintained by external sources.

Further, ACP recommends that CMS work with affected medical specialty organizations to develop a documentation template that would enable the physician to cogently capture the information that CMS determines necessary to justify the prescription.

ACP recommends that CMS make educational materials regarding establishing and documenting the need for a PMD available to physicians. These educational materials should include a quick-reference web-based guide. CMS should derive the educational materials from, in part, the Mobility Assistive Equipment (MAE) National Coverage Decision (NCD). In this section, CMS states that a physician?s knowledge of the provisions of the MAE NCD informs his or her discussion of the available options with the patient. However, ACP expects that few physicians are knowledgeable of the MAE NCD.

REGULATORY IMPACT STATEMENT

CMS estimates that physicians will prescribe 187,000 PMDs annually. Data from the Berenson-Eggers Type of Service (BETOS) code files at www.cms.hhs.gov indicate that Medicare paid for over 8 million prescriptions for the general ? wheelchair? category in 2004. ACP recommends that CMS to explain how the agency?s annual PMD prescription projection relates to the BETOS wheelchair data. Further, the College recommends that CMS provide an accounting of the expenditures with the dispensed wheelchairs so that physicians can understand the overall impact these expenditures have on the Medicare Part B program and to better understand their role in ensuring efficient use of scarce resources.

CMS-3017-IFC-39 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : **Sharon Hildebrandt** **Date & Time:** **11/25/2005**

Organization : **NCART**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3017-IFC-39-Attach-2.TXT

CMS-3017-IFC-39-Attach-1.DOC

NCART
National Coalition for Assistive and Rehab Technology

Attachment #39

1050 17th Street Northwest, Suite 600 Washington, DC 20036, 202-776-0652

November 25, 2005

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

The National Coalition for Assistive and Rehab Technology (NCART) is pleased to provide the following comments regarding the CMS Interim Final Rule on Conditions for payment of Power Mobility Devices. NCART is a coalition of suppliers and manufacturers of assistive and rehab technologies with a mission of ensuring proper and appropriate access to rehab and assistive technologies.

Introduction

The Interim Final Rule (IFR) intimates that one of the goals of this rule is to decrease fraud and abuse. NCART recognizes and supports this goal. Moreover, Congress appears to believe that requiring a face-to-face examination by a physician will facilitate this goal. There is reason to believe that having physicians examine their patients and assess their mobility needs provides a greater level of assurance that the physician understands the power mobility device that is being prescribed and has an intimate knowledge of their patient's need for the device. The breakdown in this concept centers on documentation and how it impacts access for the beneficiary and payment to the supplier.

CMS' reliance on the patient's medical record to substantiate medical need and the fact that physicians and many other professionals do not routinely document detailed information regarding the beneficiary's mobility deficit or resulting technology needs causes significant conflict for suppliers and beneficiaries. Beneficiaries may be denied access to necessary technology and suppliers may have reimbursement withdrawn based on insufficient documentation when in fact, this documentation does not adequately represent the true medical needs of the beneficiary at all. NCART members indicate, based on their experience, that physicians are not equally proficient at documenting mobility needs. They may routinely and appropriately provide notation in the chart notes regarding the primary diagnosis for which the physician is treating the patient, but provide very little of the necessary details regarding mobility related deficits or the need for a mobility device; even when the physician is providing a written

order for a mobility device. This leads to serious conflict between what Medicare requires the supplier to have on file and provide upon request and what physicians routinely document. The result is that based on information in the medical record, it may be determined that the beneficiary did not meet the coverage criteria, when in fact they do; the physician merely has not documented the need sufficiently.

CMS has taken tremendous steps to solve issues related to power wheelchair utilization. Significant effort continues to codify wheelchair technology in a manner consistent with current technology and clinical application. This code set will be a solid foundation for the development of a meaningful local coverage determination that can guide physicians, clinicians and suppliers regarding Medicare coverage for these products. In addition, this coverage policy will clearly inform Medicare beneficiaries regarding their eligibility for these devices.

NCART believes that the two most critical elements to meeting the desired goals surrounding this benefit are:

- **Comprehensive physician education**

  CMS must develop a comprehensive education plan to ensure that physicians and clinicians clearly understand their new role in the provision of power mobility devices (PMD) as well as Medicare coverage guidelines for all Mobility Assistive Equipment. The new NCD, draft LCD, revised LCD, IFR and myriad releases regarding this benefit has increased rather than decreased confusion in the marketplace. Many physicians still do not understand that they are required to conduct a face-to-face examination before prescribing power mobility devices and others are not aware of the new NCD.

- **Clear documentation requirements**

  CMS must provide clear guidelines regarding what qualifies as "sufficient documentation" to justify medical need. Physicians and clinicians are not consistent in their documentation styles or content. Since CMS continues to heavily rely on progress notes to determine medical need, it is imperative that clear and concise guidelines are provided.

II. Provisions of the Interim Final Rule

We acknowledge that CMS and the Durable Medical Equipment Regional Carriers (DMERC) have issued a number of instructions in an effort to provide clarification for items in this section where confusion and questions exist. However, we believe it is important for CMS to issue a Final Rule that clearly defines the provisions related to this regulation.

30-Day Timeframe

It is important for the 30 day timeframe to be clearly identified. Various publications have indicated when the 30 days count begins. This is critical information and should be included in a Final Rule.

Written Order

The IFR calls for the physician to provide "a narrative description of the specific type of PMD). It appears from other instructions provided by the DMERCs, that the physician's order can state "power wheelchair, power operated vehicle, or simply power mobility device". Physicians and suppliers need clear instructions for the content of the written order and this information must be clearly identified in the Final Rule.

Supporting Documentation

The IFR requires that the physician provide the supplier with a written order and sufficient documentation to justify medical necessity for the device prescribed. The IFR provides a fairly comprehensive list of information that the physician could provide. However, it is difficult to take that information and infer what qualifies as "sufficient to justify medical necessity" for a particular client in the case of an audit. The adjective "sufficient" is very subjective. What qualifies as sufficient to a physician who has intimate knowledge of the patient's medical condition, what is sufficient to the supplier who has the financial liability in the case of an audit and what is sufficient to a medical review person in the case of an audit could clearly be three different levels of documentation.

However, the IFR also states, "in most cases, the information recorded at the face-to-face examination will be sufficient". If this is the case, it would be extremely helpful to physicians and clinicians to have a list of questions or required informational elements. This would assist in guiding them through the mobility examination and ensure that the steps of the algorithm have been adequately followed. This could be developed into an 'evaluation form' format that the physician or clinician could actually document their findings as they stepped through the evaluation. It could also be useful as a guide for the examination. In this situation, the physician would either dictate his findings or document directly in the patient's progress notes. In any case, this type of tool would better ensure that the necessary information to support medical need will be in the patient's medical record in a manner that is consistent with the information CMS has requested.

Home Assessment

The IFR makes reference to the physician's understanding of the beneficiary's home environment. The draft LCD and revised LCD for power mobility, which were released after the IFR, indicate that it is the responsibility of the supplier to conduct a home assessment either before or at the time of delivery. The Draft supplier standards indicate that the supplier must do a home safety evaluation. The vast number of drafts and instructions related to PMD is part of the growing confusion surrounding this benefit.

Either way, it is unlikely that the physician will have sufficient knowledge of the home environment at the initial face-to-face exam unless it is provided by the beneficiary or responsible party. NCART believes it is the role of the supplier to gather information regarding the home environment, however, we believe it can be obtained from the beneficiary or caregiver at the time of the technology assessment. It is important for CMS to provide clarity regarding a home assessment in the Final Rule.

Summary

NCART members have worked closely with their referring physicians to educate them regarding the IFR and the NCD for power mobility. It continues to be a confusing time for all involved. CMS must develop a plan to educate all physicians and clinicians regarding their role in prescribing power mobility. CMS must also provide clear guidance regarding documentation requirements. It is imperative that physicians, suppliers and medical reviewers all have the same expectation regarding what is sufficient to justify medical need. There should not be situations where a person that has a medical need is denied a device or a supplier is denied payment for that device based purely on insufficient or inadequate documentation from a physician.

NCART appreciates the opportunity to provide these comments and would welcome the opportunity to work with CMS to develop an educational program and to further clarify documentation requirements.

Sincerely,

Sharon L. Hildebrandt

Executive Director

CMS-3017-IFC-40 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : **Mr. Donald Clayback** **Date & Time:** **11/25/2005**

Organization : **The MED Group**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachement.

CMS-3017-IFC-40-Attach-1.DOC

THE MEDGROUP

Attachment #40

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- "Conditions for Payment of Power Mobility Devices" CMS-3017-IFC

Dear Dr. McClellan:

I am writing on behalf of The MED Group (MED). MED is a nationwide network of independently owned home medical equipment and rehab technology companies. We have approximately 220 member companies with over 700 operating locations across the country.

We also are members of the American Association for Homecare (AAH), the National Coalition for Assistive and Rehab technology (NCART), and the Restore Access to Mobility Partnership (RAMP).

MED appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Interim Final Rule "Conditions for Payment of Power Mobility Devices" (IFR) issued August 26, 2005.

Comments and Recommendations

First off, MED fully supports the requirement that a beneficiary have a "face-to-face" examination prior to a physician prescribing a PMD. If properly designed and implemented, this safeguard will certainly assist in assuring that Medicare beneficiaries receive appropriate equipment based on their medical condition and needs. However, for this system to be effective, we offer the following comments and recommendations regarding the IFR:

1.) A grace period should be provided to allow for a rational and smooth transition to the changes being implemented.

The IFR has presented significant changes to the process of providing PMDs. There are many questions still outstanding at this date even though this regulation went into effect October 25.

There is also much education yet to be done. In light of these factors, a reasonable period of time should be announced providing for a "grace period" in which the providers will not be penalized as these changes are gradually implemented. This would allow physicians and providers to transition into the new regulations and not negatively impact the delivery of products and services to Medicare beneficiaries.

2.) A well-designed and executed physician education program must be conducted to allow for a better understanding in the physician community of their responsibilities under the new regulation.

From a practical standpoint, there has been NO physician education. While there have been some bulletins issued, several short memorandums do not constitute proper education. A better effort must be made and adequate time allowed for it to take place prior to the effective date of any new regulation.

CMS still needs to conduct extensive educational efforts - through newsletters (via 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. MED 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, MED strongly urges CMS to incorporate public comments, revise the regulation with significantly more detailed information directed at physicians.

3.) Documentation needs to be better defined. CMS should create specific questions that, if answered by the physician, will clearly document medical need and meet post-payment review requirements.

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, MED 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.

MED 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 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).

4.) The 30 day time frame from the face-to-face examination to the supplier receiving the paperwork should be extended to 60 days to allow sufficient time for the full process to take place.

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 30 day timeframe 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 allow up to 60 days from the date of the face-to-face examination.

5.) Inconsistencies between the IFR and the new Power Mobility LCDs must be resolved.

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 the mandatory nature of physicians' new prescribing responsibilities.

6.) <u>An optional prior approval process should be instituted so that providers can get approval in advance on the more complex power mobility systems.</u>

Medicare currently has a prior authorization process in place (Advanced Determination of Medical Coverage) for certain types of equipment such as an ultra light weight manual wheelchair, tilt in space manual wheelchair, and power wheelchair with power tilt and/or recline system. MED recommends CMS add a provision to allow providers the option to obtain ADMC for all PMDs. This option would allow for a pre-payment review for a PMD and improve beneficiary access to these products.

****

Thank you for your detailed review of these comments and inclusion of the recommendations in the near future. We stand ready to work collaboratively with CMS and the DMERCs on this matter and other Medicare DMEPOS issues. Please feel free to contact me directly if we can be of further assistance.

Sincerely,

Don Clayback

Donald E. Clayback
Senior Vice President- Networks
The MED Group
716-835-1728
dclayback@medgroup.com
www.medgroup.com

CMS-3017-IFC-41 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : **Dr. Sara Osman** **Date & Time:** **11/25/2005**

Organization : **Matheny School and Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3017-IFC-41-Attach-1.DOC

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

Subject Line: Medicare Program, Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles

I am writing this letter to comment on the proposed Interim Final Rule for Conditions for Payment of power Mobility Devices, file code CMS-3017-IFC. I am a physician working at the Matheny Medical and Educational Center, where our mission is to provide quality care for individuals with developmental disabilities. The individuals we serve typically have severe physical and cognitive impairments which affect their function, medical condition, and their quality of life. Many of our clients depend on manual and power wheelchairs with custom seating supports to enable participation in their activities of daily living.

At the Matheny Medical and Educational Center, we provide highly specialized clinical services to determine the most appropriate wheelchair system, including power mobility. Our Physical and Occupational Therapists are integral in providing the detailed assessments necessary in provision of power mobility in order to meet each client/ patient's functional and medical needs. Our Physical and Occupational Therapists receive extensive training and specialty certification in the field of Assistive Technology. At our facility, the Physical and Occupational Therapists are well suited to complete these power mobility assessments, provide the necessary in-depth clinical documentation, and conduct associated home/ environmental assessments.

Though the physician plays an important role in coordinating the rehabilitation team's efforts in the justification and provision of powered mobility, without the clinical assessments, expertise and involvement of Physical and Occupational Therapists, the client/ patient's care in this area would be significantly affected. It is for this reason, I request the *Interim Rule on the Conditions for Payment of Power Mobility Devices* be modified to acknowledge the essential role of the physical and/ or occupational therapist in assessing patients for power mobility devices. The language of the Rule should specify the ability of physicians to refer their patients to physical and occupational therapists for this service.

I appreciate your consideration in reviewing this clarification in the best interests of patient care and effective power mobility outcomes.

Sincerely,

Sara A. Osman, MD

CMS-3017-IFC-42 **Conditions for Coverage of Power Mobility Devices, including Powered Wheelchairs and Power-Operated Vehicles (Scooters)**

Submitter : **Dr. Susan Roeloffs** **Date & Time:** **11/25/2005**

Organization : **Matheny School and Hospital**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-3017-IFC-42-Attach-1.DOC

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

Subject Line: Medicare Program, Conditions for Payment of Power Mobility Devices, including Power Wheelchairs and Power-Operated Vehicles

I am writing this letter to comment on the proposed Interim Final Rule for Conditions for Payment of power Mobility Devices, file code CMS-3017-IFC. I am a physician working at the Matheny Medical and Educational Center, where our mission is to provide quality care for individuals with developmental disabilities. The individuals we serve typically have severe physical and cognitive impairments which affect their function, medical condition, and their quality of life. Many of our clients depend on manual and power wheelchairs with custom seating supports to enable participation in their activities of daily living.

At the Matheny Medical and Educational Center, we provide highly specialized clinical services to determine the most appropriate wheelchair system, including power mobility. Our Physical and Occupational Therapists are integral in providing the detailed assessments necessary in provision of power mobility in order to meet each client/ patient's functional and medical needs. Our Physical and Occupational Therapists receive extensive training and specialty certification in the field of Assistive Technology. At our facility, the Physical and Occupational Therapists are well suited to complete these power mobility assessments, provide the necessary in-depth clinical documentation, and conduct associated home/ environmental assessments.

Though the physician plays an important role in coordinating the rehabilitation team's efforts in the justification and provision of powered mobility, without the clinical assessments, expertise and involvement of Physical and Occupational Therapists, the client/ patient's care in this area would be significantly affected. It is for this reason, I request the *Interim Rule on the Conditions for Payment of Power Mobility Devices* be modified to acknowledge the essential role of the physical and/ or occupational therapist in assessing patients for power mobility devices. The language of the Rule should specify the ability of physicians to refer their patients to physical and occupational therapists for this service.

I appreciate your consideration in reviewing this clarification in the best interests of patient care and effective power mobility outcomes.

Sincerely,

Susan Roeloffs MD

43

Braxton, Shawn L. (CMS/OSORA)

From: Seatstafsol15@aol.com
Sent: Friday, November 25, 2005 11:27 AM
To: Braxton, Shawn L. (CMS/OSORA)
Subject: Comment for CMS 3017-IFC

I am a physical therpist with the certification of ATP in private practice. I am requesting CMS require DME providers of custom or rehab seating and wheeled mobility products to be listed on the NRRTS registry or submit documentation of their efforts to meet these standards. Insuring minimum standards will improve outcomes in many ways, helping to decrease excessive charges and inappropritate equipment prescription are but two improvements.
Thank you,
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