CMS-6022-P-1 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Mr. Robert Ferry** **Date & Time:** **11/29/2005**

Organization : **Quality Health Care Corp. dba Home Care Plus**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-6022-P-1-Attach-1.DOC

Attachment #1

November 29, 2005

To: Federal Register
Re: File Code CMS-6022-P

To Whom It May Concern:

The requirements and error rating system for termination of non-random prepayment review in the Medicare Program should:

- Protect the financial integrity of the Medicare Program.
- Protect the Medicare Beneficiaries from under utilization and over utilization of the Medicare benefit.
- Reflect equity in the review process at each review level up to and including appeals to the Administrative Law Judge at HHS.

The proposed 70% decrease in error rate should only apply to non-clinical aspects of error determination i.e. technical billing code errors not related to clinical judgments.

The following changes to the termination proposal are requested:

- For clinical decision-making outcomes of error rate, we propose a 51% decrease as a threshold for termination of review. This will accomplish two goals:
    - It will improve the mathematical probability of termination when subjective clinical judgments from reviewers are influenced by mostly documentation and cannot be clinically verified at the point of care.
    - The smaller population samplings for small to medium-sized providers will have a fair opportunity of successful termination.

- The termination error rate should apply by consecutive summation at each appeal review level. If the error rate drops to less than 50% at the redetermination review level, at the reconsideration level or at the ALJ level, then the termination of non-random prepayment review should be enacted.

Thank you very much for your time and consideration.

Yours truly,

Robert Ferry, RN, BSN, CLNC

CMS-6022-P-3 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Ms. Jane Dunne** **Date & Time:** **12/06/2005**

Organization : **Ms. Jane Dunne**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-6022-P-3-Attach-1.TXT

CMS-6022-P-4 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Ms. Carol Frerman** **Date & Time:** **12/06/2005**

Organization : **AdminaStar Federal**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

We have several question/comments on the proposed changes to the Federal Register regarding non-routine prepay complex reviews.

1) The description of a nonrandom prepayment review process (as discussed on page 58651) assumes that following a probe review, a nonrandom prepayment edit is initiated for targeted providers that continuously edits claims until it it removed by the contractor. Does CMS expect all nonrandom prepayment review edits to be selecting 100% of a provider or service for at least 1 year? If the contractor selects only 20-40 claims for the non-random prepayment review, then terminates the edit, how would the 1 year timeframe be calculated? Is this 1 year time frame for each provider in a PCA case or for the PCA case itself?

2) If the probe review shows that a provider is submitting claims for a service that is not a Medicare benefit, would a 100% nonrandom prepayment review of that provider and service be appropriate until the situation is corrected?

3) Is it acceptable to have a provider on an intermittent non-random prepayment review for longer than one year if quarterly evaluation of the sample of claims shows that provider specific education has not resulted in significant improvement? Can the referral to the benefit integrity PSC be delayed while additional provider education and validation is performed?

4) System security regulations will prevent most contractors from discontinuing an edit in 2 business days. While changes are made as quickly as possible, this timeframe is too short. Can you please lengthen it a few days?

CMS-6022-P-5 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Ms. Anne Marie Bicha** **Date & Time:** **12/06/2005**

Organization : **Alliance of Specialty Medicine**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-6022-P-5-Attach-1.DOC

Alliance of Specialty Medicine

A Coalition of 13 Medical Societies Representing 200,000 Specialty Physicians in the United States

Gordon Wheeler, Chair
gwheeler@acep.org
(202) 728-0610

Lucia DiVenere, Vice-Chair
ldivenere@acog.org
(202) 863-2510

Attachment #5

December 6, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-6022-P
P.O. Box 8012
Baltimore, MD 21244-8012

RE: Medicare Program; Termination of Non-Random Prepayment Review

Dear Dr. McClellan:

Founded in 2001, the Alliance of Specialty Medicine (the Alliance) represents over 200,000 physicians in 13 medical specialty organizations and serves as a strong voice for specialty medicine. The Alliance appreciates the opportunity to comment on CMS' proposed rule setting forth the requirements for terminating a provider or supplier from non-random complex pre-payment medical review, in accordance with section 934 of the Medicare Modernization Act.

The Alliance commends CMS' proposal to terminate in most cases a provider or supplier from non-random prepayment complex medical review no later than one year from the initiation of the review or when the provider's or supplier's error rate decreases by 70 percent from the initial error rate. We agree with CMS' assessment that a higher rate reduction than 70 percent is impracticable. We also support CMS' proposal that a contractor could extend a non-random prepayment complex review beyond the one-year limit in certain situations such as if the provider or supplier begins billing another inappropriate code to change the error rate of the original code in question. The Alliance recommends that CMS' recommendations be implemented in the final rule.

If the Alliance of Specialty Medicine may provide any additional comments or assistance to CMS on this proposed rule, please contact Anne Marie Bicha, Director of Regulatory Affairs, American Gastroenterological Association at 240-482-3223 or abicha@gastro2.org.

Sincerely,

American Academy of Dermatology Association
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Obstetricians and Gynecologists
American Gastroenterological Association
American Society for Therapeutic Radiology and Oncology
American Society of Cataract & Refractive Surgery
American Urological Association
Congress of Neurological Surgeons
National Association of Spine Specialists
Society of Thoracic Surgeons

CMS-6022-P-6 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Mr. Robert Falk** **Date & Time:** **12/06/2005**

Organization : **Powell Goldstein LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

Attached, please find commments submitted on behalf of Mobility Products Unlimited, LLC.

CMS-6022-P-6-Attach-1.DOC

MOBILITY
PRODUCTS•UNLIMITED, LLC

Attachment #6

December 6, 2005

Via Electronic Submission

William N. Parham, III
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Regulations Development Group
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Rule on Termination of Non-Random Prepayment Review
CMS-6022-P

Dear Mr. Parham:

Mobility Products wishes to provide a limited comment on the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) on October 7, 2005 entitled *Medicare Program; Termination of Non-Random Prepayment Review.*[1] Mobility Products Unlimited is a Medicare Part B supplier that provides Medicare beneficiaries with medically necessary motorized wheelchairs, power operated vehicles (POVs) and oxygen services. Based in South Daytona, Florida, Mobility Products Unlimited provides medically necessary Part B items to beneficiaries in numerous states throughout the country.

Our particular concern does not focus on the substance of the proposed regulation itself, but rather the fact that the preamble contains language that does not appear to reflect guidance publicly available elsewhere in the Medicare program. More specifically, the passage of concern states:

> *Providers and suppliers may supply additional documentation not explicitly listed by the contractor. This supporting information may be requested by CMS and its agents on a routine basis in instances where diagnoses on the claims do not clearly indicate medical necessity. For example, documentation supporting the medical necessity of a power wheelchair would not be requested in the vast majority of cases where patients have definite medical conditions such as neurological spinal cord injury, cerebral*

[1] 70 Fed. Reg. 58649-58654.

Mobility Products Unlimited, LLC
2400 S. Ridgewood Avenue, Suite #48, South Daytona, FL 32119
Phone 386.255.2388 or Toll Free 1.888.224.2482 Fax 386.255.3481

palsy, multiple sclerosis or stroke with residual myoplegia (not all inclusive). On the other hand, it is more likely that documentation would be requested for patients whose diagnoses are limited to non-neurological conditions such as chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, arthritis or obesity (not all inclusive).[2]

We do not believe that CMS has issued any guidance either through the National Coverage Determination for Power Mobility Devices ("PMDs"), through any manual instructions, DMERC local medical review policies or even Medlearn programs that indicates that the documentation requirements for PMDs vary by the patient's diagnosis.

Mobility Products, like other suppliers, is anxious to have additional guidance regarding what constitutes proper documentation for PMDs and has repeatedly offered its assistance to CMS to develop a workable solution. However, it should be clear to the public when CMS is developing additional guidance on PMD documentation. We strongly believe that establishing new standards affecting PMDs is outside the scope of this rule-making process. Because the passage of concern does not reflect any currently available public guidance, we ask that this point be clarified in the final rule's preamble.

* * *

Mobility Products is happy to serve as an on-going resource as these standards are modified. If you have questions or need further information, please contact Trienah Gorman at tgorman@mpullc.com or (386) 271-1335 or Rob Falk at rfalk@pogolaw.com or 202-624-7318.

::ODMA\PCDOCS\WSH\372579\1

[2] 70 Fed. Reg. 58651.

CMS-6022-P-7 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Mr. Mike Fuller** **Date & Time:** **12/06/2005**

Organization : **Fuller Rehabilitation Independent Living Aids**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6022-P-7-Attach-1.TXT

CMS-6022-P-8 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Ms. Kay Cox** **Date & Time:** **12/06/2005**

Organization : **American Association for Homecare**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached comments from the American Association for Homecare.

CMS-6022-P-8-Attach-1.PDF

#8

AMERICAN ASSOCIATION FOR HOMECARE

Via Electronic Transmission

December 6, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445 G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Termination of Non-Random Prepayment Review [CMS-6022-p] RIN 0938-AN31

The American Association for Homecare (AAHomecare) submits the following comments in response to the Centers for Medicare and Medicaid Services' (CMS') request for comments on the proposed rule on termination of non-random prepayment review.[1] AAHomecare is the only national association that represents every line of service within the homecare community. Our members are providers and suppliers of durable medical equipment and services, infusion and respiratory care therapies, home health services, and rehabilitative and assistive technologies as well as manufacturers and state associations. AAHomecare and its members are committed to advancing the value and practice of quality health care services at home.

Section 934 of the Medicare Modernization Act (MMA) included a requirement that CMS establish by regulation procedures for terminating non-random prepayment review as it applies to a specific provider or supplier. The proposed rule would implement the requirements of §934 by amending 42 C. F. R. 421 and defining terms related to medical review. Specifically, the proposed rule would add definitions for "allowed charges," "complex medical review," "and non-random prepayment complex medical review." For example, the proposed rule would define "complex medical review" as follows:

> *Complex Medical Review* means review of claim information and medical documentation by a licensed medical professional for a billed item or service identified by data analysis techniques or a probe review to have a likelihood of a sustained or high level of payment error.[2]

[1] 70 Fed. Reg. 58649 (October 7, 2005).
[2] 70 Fed. Reg. 5860.

American Association for Homecare
625 Slaters Lane, Suite 200
Alexandria, VA 22314

The proposed rule would define "non-random prepayment complex medical review" as follows:

> *Non-random prepayment complex medical review* means the prepayment medical review of claim information and medical documentation by a licensed medical professional for a billed item or service identified by data analysis techniques or probe review to have a high likelihood of sustained or high level of payment error.[3]

Under the scheme proposed by CMS, providers and suppliers would be subject to non-random prepayment complex medical review following a determination that the provider's or supplier's Medicare billing is subject to high level of payment error. This determination is made following a complex medical review of a small sample of claims, or a probe review as defined in the proposed rule.

Non-random prepayment complex medical review begins when the contractor notifies the provider or supplier that it is initiating the prepayment review. Under the proposed rule, non-random prepayment complex medical review would continue for up to one year, subject to certain caveats. Medicare contractors would be required to evaluate the provider's or supplier's payment error rate on a quarterly basis. The non-random prepayment complex medical review would terminate in any quarter where the provider or supplier error rate has achieved a 70% decrease from the initial error rate that resulted in the non-random prepayment complex medical review.

COMMENTS

The proposed rule only establishes the procedures for terminating non-random prepayment complex medical review. It does not address the process CMS or its contractors will use to make the determination that a provider or supplier has a high level of payment error. CMS cites the Program Integrity Manual instructions to contractors on performing medical review activities as authority for its prepayment medical review activities. The manual provisions, in turn, provide little concrete guidance on the decision-making process contractors should follow in placing a provider or supplier on non-random prepayment complex medical review.

For example, the use of non-random prepayment complex medical review is discussed in Chapter 3 of the Program Integrity Manual under progressive corrective action. Non-random prepayment complex medical review is identified as one of the options that Medicare contractors can use to address identified high payment error rates.[4] The manual identifies the formula for establishing the payment error rate, but does not provide criteria for evaluating when the error rate is sufficiently high to trigger the use of non-random prepayment complex medical review as a progressive corrective action remedy. The manual includes a number of examples or "vignettes," that include the application of different remedies to address billing errors, but these fail to identify the thresholds that warrant the imposition of non-random prepayment complex medical review except for some very limited examples.

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[3] *Id.*
[4] Program Integrity Manual, Chapter 3 §3.11.

CMS acknowledges in the preamble to the proposed rule that requiring non-random prepayment complex medical review is burdensome for the provider or supplier. Responding to this type of medical review requires the provider or supplier to furnish documentation from the patient record to establish the medical necessity for the item. The preamble estimates that obtaining this documentation should consume no more than 10 minutes of the provider's or supplier's time. AAHomecare strongly questions that estimate. Our members report that it take much more than 10 minutes to follow-up on a request for medical records from physicians or inpatient facilities. Earlier this year we submitted the results of an informal survey of DMEPOS providers showing that the time to collect medical necessity information from physicians far exceeded the 10-minute burden estimate proposed by CMS[5]. Although the subject of that survey was documentation for power mobility devices, the results are generally consistent with our members' experience in obtaining medical necessity documentation.

Consequently, we strongly recommend that CMS further define the decision making process for contractors. Medicare contractor discretion to determine when payment error rates are "high" should be subject to closer oversight and guidance from CMS. For example, providers and suppliers should be afforded an opportunity to show, during a rebuttal period following the initial probe review, that Medicare payment for an item or service was proper. In a probe review, providers and suppliers must respond with medical necessity documentation within a limited timeframe usually no more than 30 days. While the contractor may give the provider or supplier an extension, whether to do so is discretionary. Often, the provider or supplier is faced with obtaining records dating back several years. This is not easy to accomplish within a 30 or 45 day period. If the provider or supplier establishes within a rebuttal period that Medicare payment for the claims was proper, the additional documentation submitted at that time should be considered in establishing the error rate. The Program Integrity Manual does not address this type of process; and it is our understanding based on member reports that some contractors do not consider information submitted during the rebuttal in establishing the error rate.

AAHomecare recommends this type of process as a way of preserving CMS and contractor resources consistent with the principles underlying progressive corrective action. AAHomecare appreciates the opportunity to submit these comments and remains available to discuss them with you in greater detail. Please contact me at (703) 535-1888 or kayc@aahomecare.org should you have any questions or concerns.

Sincerely,

Kay Cox

Kay Cox
President and CEO

[5] *See* AAHomecare comments on the paperwork burdens of the Interim Final Rule on Conditions of Coverage for Mobility Assistive Devices, submitted on September 26, 2005.

CMS-6022-P-9 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Mr. Eric Sokol** **Date & Time:** **12/06/2005**

Organization : **Power Mobility Coalition**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-6022-P-10 **Termination of Non-Random Prepayment Medical Review**

Submitter : Mrs. Mary St.Pierre **Date & Time:** 12/06/2005

Organization : National Association for Home Care & Hospice

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-6022-P-11 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Dr. JAMES H. SCULLY** **Date & Time:** **12/06/2005**

Organization : **THE AMERICAN PSYCHIATRIC ASSOCIATION**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

PLEASE SEE ATTACHMENT

CMS-6022-P-11-Attach-1.DOC

American Psychiatric Association

1000 Wilson Boulevard
Suite 1825
Arlington. VA 22209
Telephone 703.907.7300
Fax 703.907.1085
E-mail apa@psych.org
Internet www.psych.org

December 12, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6022-P
P.O. Box 8012
Baltimore, MD 21244-8012

RE: Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 37,000 psychiatric physicians, nationwide, appreciates the opportunity to submit these comments concerning the proposed rule, under 45 C.F.R. Part 421, published in the Federal Register on October 7, 2005, with the title, "Medicare Program; Termination of Non-Random Prepayment Review"[1] (referred to herein as PCM review).

APA is highly concerned about several aspects of this proposed rule. CMS' proposed triggers for when a CMS Medicare claims contractor can place a physician on this intense level of prepayment review and for termination from that review are problematic in methodology.[2] This type of claims review is both administratively and

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[1] CMS Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P [Federal Register: October 7, 2005 (Volume 70, No. 194)].

[2] Government Accounting Office (GAO) Report, "MEDICARE Call Centers Need to Improve Responses to Policy-Oriented Questions from Providers;" July 16, 2004, pg. 2:

"The contractors that process Part A claims, which cover inpatient hospital, skilled nursing facility, hospice, and certain home health services, are referred to as fiscal intermediaries. The contractors that process Part B claims, which include physician services, diagnostic tests, durable medical equipment, and related services and supplies, are referred to as carriers."

financially burdensome to physicians. They must provide patients' medical records to substantiate each claim under review, which is time-intensive and costly. In addition, payment on claims subject to this level of review is delayed until the contractor determines that the billed service or item passes both tests. The review has a two-part test: 1. is the billed service or item covered? and 2. was the billed service or item "reasonable and necessary"?

CMS explains that, "(t)here are three types of non-random prepayment medical review: Automated, routine, and complex."[3] Automated review is done by computer. Routine medical review is performed by non-clinical review staff. In complex medical review a licensed medical professional evaluates medical records. "This type of review delays payment until the contractor is able to make a determination that the items or services billed are covered and are reasonable and necessary."[4]

Due to the attendant administrative requirements and delayed payment, being on this level of review constitutes a substantial burden and disadvantage to a provider, including an individual physician. For those reasons, it is imperative that a CMS contractor be prevented from doing two things: 1. placing a physician on PCM review status without solid evidence for it; and 2. keeping a physician on PCM review status any longer than absolutely necessary to correct the identified billing problem. We do not find that CMS' proposed rule meets the criteria for either appropriate initiation or termination of PCM review.

CMS proposes in this rule to "terminate . . . a provider or supplier from non-random prepayment complex medical review no later than 1 year from the initiation of the review or when the provider's or supplier's error rate decreases by 70 percent from the initial error rate. The initial error rate would be calculated based on the probe review

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[3] CMS Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P [Federal Register: October 7, 2005 (Volume 70, No. 194)], at 58650:

"Automated and routine non-random prepayment medical review does not create an administrative burden on the provider or supplier since additional medical documentation does not need to be submitted for these types of medical reviews."

[4] CMS Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P [Federal Register: October 7, 2005 (Volume 70, No. 194)], at 58651:

"There are three types of non-random prepayment medical review: Automated, routine, and complex. . . . A non-random prepayment routine medical review is limited to rule-based determinations performed by specially trained non-clinical medical review staff.[4]. . . (N)on-random prepayment complex medical review is the evaluation of medical records or any other documentation by a licensed medical professional prior to Medicare payment. Complex medical review determinations require the reviewer to make a clinical judgment about whether an item or service is covered, and is reasonable and necessary. In order for this determination to be made the provider or supplier would submit a copy of the medical records that indicate that the items or services billed are covered, and are reasonable and necessary for the condition of the patient. This type of review delays payment until the contractor is able to make a determination that the items or services billed are covered and are reasonable and necessary."

prior to the initiation of non-random complex prepayment medical review.[5] APA maintains that there is an alternative approach to this issue that better balances the need to maintain integrity for Medicare billing, while minimizing the burden on physicians. Recommendations set forth, below, detail this approach.

A. Initiation of Non-Random Prepayment Complex Medical Review

Since a number of contractors' determinations relate to the calculation of the "initial error rate"[6] that is a reference point for termination of prepayment complex medical review (PCM review), they are essential and should be defined with more specificity.

Contractors have Excessive Discretion

From CMS' description, it appears that the contractor has an exceptional, excessive degree of latitude to determine whether and when a provider is placed on complex medical review. This is especially problematic since the complex medical reviewer is not required to be a physician, who could at least make what is likely to be a more accurate peer judgment as to the physician's billing code determinations. Instead, the reviewer is just required to be a "licensed medical professional," whose clinical judgment is unlikely to match that of a physician.[7] This disparity of experience and judgment between the reviewer and billing physician can result in a lower degree of statistical agreement in billing code choices, hence, inflated billing error rates that lead to PCM review. This review level is highly burdensome. It requires that the provider supply supportive medical records for each claim and payment is delayed until the reviewer completes the determination.

Moreover, claims samples may be quite small from which PCM review can be initiated. The small claims sample is first analyzed either by a computer program or non-medical review staff in data analysis "probe," to determine whether there appears to be

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[5] CMS Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P [Federal Register: October 7, 2005 (Volume 70, No. 194)], at 58651.

[6] CMS Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P [Federal Register: October 7, 2005 (Volume 70, No. 194)], at 58650-58651:

"Initial error rate means the calculation of an error rate based on the results of a probe review prior to the initiation of non-random prepayment complex medical review. . . . "

"(w)e are proposing to terminate in most cases a provider or supplier from non-random prepayment complex medical review no later than 1 year from the initiation of the review or when the provider's or supplier's error rate decreases by 70 percent from the initial error rate."

[7] CMS Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P [Federal Register: October 7, 2005 (Volume 70, No. 194)], at 58651.

any billing error. The contractor has the discretion to prompt such a probe for any reason it deems fit.[8]

Another problem is that the definition of the second test, "reasonable and necessary" is within the contractor's discretion. The non-physician reviewer second-guesses the physician as to what is appropriate for the patient. If the "licensed medical professional" who reviews the claim disagrees with the physician's assessment of what is "reasonable and necessary" for the patient, the service/item can be denied coverage and considered a billing "error" on that basis alone.

There would appear to be an undue potential for contractors to "game" the system for financial gain with little restraint or oversight by CMS. This is more than speculative; there is historical documentation of such problems. Since the 1990s, GAO and OIG have been identifying areas where contractors abuse the system to their own advantage and have alerted CMS to this problem.[9]

Criteria to Trigger Complex Medical Review are Poorly Defined

In this proposed rule, CMS does not describe specific criteria for a given provider's claims that are required to trigger complex medical review, such as statistical thresholds, error rates, dollar amounts of errors, or others. Instead, CMS allows the contractors to decide what these are. This affords far too much discretion to the contractors, power that is not balanced by protections for providers. One aspect is that the sample size of claims that a contractor can use as a basis for placing a provider on complex medical review can be very small, as few as 20-40 claims (over an unspecified time period) for a single, specific billing code. It is within the contractor's discretion to use a larger claims sample, although CMS states that this is "generally 100 claims of the item or service in question."[10] Errors found within that sample may still be relatively

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[8] CMS Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P [Federal Register: October 7, 2005 (Volume 70, No. 194)], at 58650.

"The contractor employs data analysis procedures to identify claims that may be billed inappropriately. These procedures may be based on claims data (national and local) beneficiary complaints, and alerts from other organizations (for example, Office of Inspector General and Government Accountability Office)."

[9] Government Accounting Office (GAO) Report, "MEDICARE CONTRACTORS Further Improvement Needed in Headquarters and Regional Office Oversight;" March 23, 2000, pg. 5:

"Beginning in the early 1990s, we designated the Medicare program as a high-risk area, and so it remains. For years, we and the Office of Inspector General (OIG) in the Department of Health and Human Services have been concerned about appropriate oversight by HCFA of Medicare contractors to ensure they pay claims accurately and prevent fraud and abuse.3 Concerns about the effectiveness of HCFA's monitoring efforts have been heightened by recent evidence that some contractors—who are responsible for checking and auditing claims to ensure that providers do not defraud Medicare—have themselves defrauded the program."

[10] CMS Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P [Federal Register: October 7, 2005 (Volume 70, No. 194)], at 58650.

insignificant from a statistical viewpoint, either in number or dollar amount. Unless and until a statistically meaningful verification of billing error is performed by a licensed medical reviewer through a complex review probe, a provider should not be placed on non-random prepayment review status.

The contractor then has further discretion to "request supporting medical record documentation" when the contractor "identifies a likelihood of sustained or high level of payment error."[11] Again, these terms ("likelihood," "sustained," and "high level") are not defined and are within the discretion of the contractor to define and apply. CMS does not explain what mathematical probability or range constitutes a "likelihood." What time period and intensity of billing errors meets a definition for "sustained"? What error rate is equivalent to a "high level"?

Recommendation: CMS is charged with fairly balancing the need for Medicare billing integrity with the rights of providers to remain unburdened by the administrative and financial implications of a PCM review. It is also imperative to promote consistency within the review process across contractors. For these reasons, CMS should improve the balance of those involved. CMS should specifically define all relevant terms and implement statistical criteria, wherever possible, that allow contractors to determine through review whether there are billing errors. The criteria should be structured to identify true billing errors, not just reasonable differences in coding judgment, and the errors should be of sufficient magnitude to warrant placing providers on non-random PCM review in the first place.

B. Triggers for Termination of Non-Random Prepayment Complex Medical Review are Excessively High Hurdles

CMS states that, "we are proposing to terminate in most cases a provider or supplier from non-random prepayment complex medical review no later than 1 year from the initiation of the review or when the provider's or supplier's error rate decreases by 70 percent from the initial error rate."[12] Despite CMS' language, the one-year mark for termination is not necessarily a true calendar year for all cases under such review. Contrary to its own statement, CMS proposes, per 42 C.F.R., Sec. 421.405(a)(2), to have contractors make code-specific error rate determinations on a quarterly basis. Rolling averages are not allowed. They are not required to calculate error rates at the one-year anniversary mark after the provider is sent notice of PCM review status.[13] That means that a provider whose anniversary falls at the beginning of a quarter can remain on PCM review status almost three months longer than a calendar year. That delay has a

[11] CMS Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P [Federal Register: October 7, 2005 (Volume 70, No. 194)], at 58650.

[12] CMS Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P [Federal Register: October 7, 2005 (Volume 70, No. 194)], at 58651.

[13] CMS Proposed Rule: "Medicare Program; Termination of Non-Random Prepayment Review;" CMS-6022-P [Federal Register: October 7, 2005 (Volume 70, No. 194)], at 58651-58654.

substantial financial and pragmatic impact upon a provider. APA maintains that it is appropriate for the contractor to calculate the error rate quarterly but the last error rate should be calculated no longer than one calendar year (365 days) after the notice date to the provider.

The requirement for an error rate decrease of 70 percent to trigger termination for PCM review seems excessive. The burden of PCM review for physicians and other providers is high and quality improvements of 70 percent in billing methods may be difficult to reach, depending upon the nature of the billing discrepancy. When providers seek clarification about proper billing methods from CMS contractors, they are unlikely to receive accurate information that could assist them in improving their "error rates."

A July 2004 Government Accounting Office (GAO) report found a substantial percentage of either incorrect or only partly correct/incomplete responses from CMS contractors' call center staff when queried about Medicare billing issues. In fact, only "(o)nly 4 percent of the responses GAO received in 300 test calls to 34 call centers were correct and complete." According to the graph in this report on "Provider Call Centers' Responses to Four Policy-Oriented Questions for Billing Medicare," even the relatively simple and seemingly common questions, i.e., about billing for a patient's office visit and procedure in the same day, resulted in approximately 35%-50% of incorrect responses and an additional approximately 20%-35% of partly correct/incomplete responses.[14] The study period covered September 2003 through June 2004, so results are quite recent.[15]

More troubling is the fact that this GAO study reflects an increased, rather than a decreased, level of CMS call center errors, despite that the 2002 GAO study of reference in the 2004 report had already alerted CMS to the high error rate at call centers. In the 2002 study, GAO "reported that the responses we received to 85 percent of 61 calls we made across five carrier call centers posing policy-oriented questions were incorrect or incomplete."[16] These results raise a serious question as to how well providers can be expected to improve contractor-calculated "error rates," when guidance from the primary source, CMS contractors themselves, is so unreliable.

Recommendation: APA strongly urges CMS to mandate that contractors calculate the provider's one-year error rate no later than one calendar year (365 days) after the notice date of PCM review status to the provider, rather than at the end of the quarter within which the anniversary date for that notice falls.

APA further urges CMS to create a more balanced and fair method of PCM review termination, such as a tiered system that depends upon the degree of improvement

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[14] Government Accounting Office (GAO) Report, "MEDICARE Call Centers Need to Improve Responses to Policy-Oriented Questions from Providers;" July 16, 2004, pg. 2; 11.

[15] Government Accounting Office (GAO) Report, "MEDICARE Call Centers Need to Improve Responses to Policy-Oriented Questions from Providers;" July 16, 2004, pg. 8.

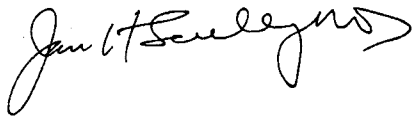
[16] Government Accounting Office (GAO) Report, "MEDICARE Call Centers Need to Improve Responses to Policy-Oriented Questions from Providers;" July 16, 2004, pg. 6.

in a provider's error rate. For instance, a 50 percent drop in error rate could trigger termination of PCM review, followed by random review probes over two quarters. A 60 percent drop could trigger termination with random probes for one following quarter.

CONCLUSION AND RECOMMENDATIONS

APA is concerned with the high level of discretion afforded to CMS' Medicare claims contractors, with respect to both their ability to initiate and terminate a provider's being on PCM review. APA maintains that CMS can better balance the respective needs for Medicare billing integrity with the burden on providers when they are unduly placed on PCM review. CMS can effectuate this balance by developing specific criteria for the following: statistically meaningful calculations of initial and subsequent billing error rates; triggers for initiation of PCM review; and triggers for termination of such review. There should be a definite one calendar year maximum period for PCM review and a more reasonable error rate decrease threshold for termination. CMS can also contribute to integrity of the program by thorough oversight of CMS contractors, which has historically proven to be problematic, including with regard to accuracy of billing information they relate to providers.

Thank you for your consideration of these comments.



James H. Scully Jr., M.D.
Medical Director and C.E.O., American Psychiatric Association

CMS-6022-P-12 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Mr. Eric Sokol** **Date & Time:** **12/06/2005**

Organization : **Power Mobility Coalition**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see prior attachment, we are sending this to insure that you receive it.

CMS-6022-P-12-Attach-1.DOC

Attachment #12

December 6, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6002-P
PO Box 8012
Baltimore, MD 21244-8012

Re: CMS-6022-P

To Whom It May Concern:

On behalf of the Power Mobility Coalition (PMC), a nationwide association of manufacturers and suppliers of motorized wheelchairs and power operated vehicles (POVs), we are submitting comments regarding the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) on October 7, 2005 entitled *Medicare Program; Termination of Non-Random Prepayment Review.*[1] The proposed rule seeks to define the medical review process and outlines the process by which a supplier may be removed from "non-random prepayment medical review." The proposed rule, however, raises several concerns for power mobility beneficiaries and suppliers and promotes ambiguity which will allow Medicare contractors, who process power wheelchair claims, the discretionary authority to inappropriately deny claims from beneficiaries that meet eligibility criteria for power mobility devices (PMDs).

Some of the PMC concerns are outlined below:

The Proposed Rule Unfairly Singles Out Certain Diagnosis Codes for Increased Scrutiny

Although the power mobility benefit is based on the functional ability of the beneficiary to perform activities of daily living, this proposed rule would treat beneficiaries differently based solely on their diagnosis. As CMS stated in the proposed rule:

> Providers and suppliers may supply additional documentation not explicitly listed by the contractor. This supporting information may be requested by CMS and its agents on a routine basis in instances where diagnoses on the claims do not clearly indicate medical necessity. For example, documentation supporting the medical necessity of a power wheelchair would not be requested in the vast majority of cases where patients have definite medical conditions such as neurological spinal cord injury, cerebral palsy, multiple sclerosis or stroke with residual myoplegia (not all inclusive). On the other hand, it is more likely that documentation would be requested for patients whose diagnoses are limited to non-neurological

[1] 70 Fed. Reg. 58,649-58,654.

> conditions such as chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, arthritis or obesity (not all inclusive).[2]

CMS recently issued a National Coverage Determination (NCD) for Mobility Assistive Equipment (MAE) which declared that the benefit would be dependent on the functional capability of the beneficiary. As set forth in the new NCD:

> [E]vidence is adequate for to determine that MAE is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations within the home. Determination of the presence of a mobility deficit will be made by an algorithmic process, Clinical Criteria for MAE Coverage, to provide the appropriate MAE to correct the mobility deficit.

In a prior May 5, 2005 CMS decision memo, entitled "*Coverage Decision Memorandum for Mobility Assistive Equipment (canes, crutches, walkers, manual wheelchairs, power wheelchairs, scooters)*" CMS acknowledged that "several commenters commended CMS for not setting the coverage conditions on diagnosis codes."

As drafted, however, this proposed rule directly prejudices a class of patients who have lawfully paid into the Medicare program in that the standard for receiving power mobility equipment will be based on their diagnosis and not their functional ability to conduct activities of daily living. Further, such action directly contradicts the national coverage criteria governing power mobility.

We further note that an agency, pursuant to 44 U.S.C. § 3518(c)(2), is required to obtain approval from the Office of Management and Budget (OMB) for information collected "during the conduct of general investigations...undertaken with reference to a category of individuals or entities such as a class of licensees or an entire industry." This general investigation, in the form of additional documentation imposed on a class of individuals with certain diagnoses, has not been submitted to OMB for approval and thus is illegal.

Medical Records and Chart Notes Should Not Be Relied Upon to Determine Medicare Eligibility

The medical records that a supplier must collect and submit in order to be removed from "non-random prepayment medical review" are inherently ambiguous, subjective, and not suited for uniform review. Physicians do not typically document specific Medicare coverage criteria in their medical records, and the records are not created with an intention that they will be reviewed by third parties who are not familiar with the patient and his/her medical conditions.

Medical record content has never been the standard by which Medicare coverage is determined. As an example, CMS previously proposed to amend 42 C.F.R. § 410.38 to require that physicians document in their medical records the need for the prosthetic, orthotic, durable medical equipment, and/or supplies ("DMEPOS") being ordered.[3] CMS acknowledged in their proposed rule that the physician documentation of medical need for DMEPOS constitutes a

[2] 70 Fed. Reg. 58,651.
[3] 69 Fed. Reg. 47487-47730 (August 5, 2004).

"collection of information" and is subject to approval from OMB per the PRA. Although CMS and OMB sought comments from Medicare stakeholders, including physicians and clinicians, CMS never finalized this proposal and OMB never issued an OMB control number concerning this proposed collection of information. It is unrealistic to suggest physicians will somehow document in their medical records according to a standard that has not existed previously.

Despite the fact that no OMB control number has ever been issued governing the requirement that physicians record specific information in their medical records, CMS continues to maintain that the content of medical records will determine medical necessity and continues to maintain that such content will determine the liability of the *supplier* when submitting a claim.

Suppliers Must Not Be Put Into a Position to Make Clinical Decisions Concerning Beneficiary Eligibility

The proposed rule also suggests that the supplier will suffer penalties should the medical record content not satisfy a Medicare contractor's reviewer who has never seen or treated the Medicare beneficiary.

Suppliers are not qualified, nor should they be qualified, to review the treating physicians' medical records in order to make an independent medical decision. In fact, CMS defines "nonrandom prepayment complex medical" review in this proposed rule as the "evaluation of medical records or any other documentation by a ***licensed medical professional*** prior to Medicare payment" (emphasis added), thereby acknowledging that a non medical professional should not be entrusted to review medical records.

In short, power mobility suppliers are not in the position to properly review, analyze and interpret medical records. If a CMS is requiring such analysis from suppliers they should specifically state so in the proposed rule. Further, reliance on the judgment of our nations' physicians is a paramount tenet within the Medicare program.[4] CMS Administrator Mark McClellan, confirmed that the Medicare program relies on the professional medical judgment of the physician. In a written submission to the United States Senate, Dr. McClellan stated the following:

> The clinical criteria for deciding when a manual or power wheelchair is medically necessary and appropriate for a beneficiary has been and will continue to be a matter of clinical judgment by a physician. It's also my understanding that CMS does not want to list specific condition-based criteria since the decision to determine the appropriateness of providing a manual or power wheelchair is best left to the physician's judgment.[5]

Consistent with Dr. McClellan's written testimony before Congress, there is no requirement in Medicare law, and no indication that Congress contemplated, that the role of the supplier is to substitute its "medical judgment" for that of a treating physician. Toward that end, the Medicare statute requires that the supplier be waived from liability if the supplier "did not know, and could

[4] *See* 42 U.S.C. § 1395 which provides that "Nothing in this subchapter shall be construed to authorize a Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided."

[5] S. Hrg. 108-422 at 192 (March 8, 2004).

not reasonably have been expected to know, that payment would not be made for such items or services...[6] In light of this congressional protection, CMS must explain how a supplier can be held liable for relying on the treating physician when such supplier is not authorized or qualified to supersede the judgment of the patient's treating physician.

Any Error Rate Should Take Into Account Reversals During Appeal Process

The proposed rule, per 42 C.F.R. 421.4101, defines an "error rate" as the dollar amount of allowable charges for a particular item or service billed in error as determined by complex medical review, divided by the dollar amount of allowable charges for that medically reviewed item or service."[7] "Initial error rate" is defined as the "calculation of an error rate based on the results of a probe review prior to the initiation of non-random prepayment complex medical review."[8]

Claims billed in "error," however, are often overturned during all levels of the appeals process and thus a supplier or provider should not be penalized for a claim that results in payment by the Medicare program. For this reason, the PMC recommends that the "error rate" definition be revised to ensure that reversals during the appeals process will result in an adjustment to such rate.

Collection of Information Requirements

In this proposed rule, CMS is seeking comments on the following proposed collections of information contained in 42 CFR 421.405:

> Under complex medical review the provider or supplier must submit a copy of the medical records that support the items or services billed. The burden associated with this section is the time and effort necessary for the provider or supplier of services to locate and obtain the supporting documentation for the claim to Medicare and to forward the materials for submission to Medicare contractors for review. We expect that this information would generally be maintained by suppliers and/or providers as a normal course of business and that this information will be readily available.[9]

CMS estimates that the "burden associated with this action is the time and effort necessary for the provider or supplier of services to locate and obtain the supporting documentation for the claim to Medicare and to forward the materials for submission to Medicare contractors for review."[10] CMS further estimates that "the burden associated with this requirement is estimated to be 10 minutes per provider or supplier, to locate, photocopy and transmit this information to the contractor upon request."[11]

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[6] 42 U.S.C. § 1395pp(a); 42 C.F.R. §§ 411.400-411.406.
[7] 70 Fed. Reg. 58,653.
[8] *Id.*
[9] 70 Fed. Reg. 58,652.
[10] *Id.*
[11] *Id.*

PMC's analysis differs dramatically with CMS' analysis. Specifically, the PMC breakdown on physician and suppliers paperwork burdens, as required in this proposed rule and the recently issued interim final rule concerning power mobility devices,[12] is as follows:

Physicians

Prescription – Physicians are required, under the recently implemented interim final rule for PMDs,[13] to create a prescription with several specific components, all of which are currently included in the Certificate of Medical Necessity form. Without a form or format, the new prescription will create a larger burden on physicians as they attempt to document free-hand all of the components contained in the interim final rule.

Chart Notes and Evaluations - Physicians are required, under the interim final rule, to prepare, maintain and provide a record of the face to face examination of the beneficiary for the power mobility device. According to the preamble of the interim final rule, "the parts of the medical record selected [by the physicians] should be sufficient to delineate the history of events that led to the request for the PMD; identify the mobility deficits to be corrected by the PMD; and document that other treatments do not obviate the need for the PMD, that the beneficiary lives in an environment that supports the use of the PMD and that the beneficiary or caregiver is capable of operating the PMD...."[14] Physicians do not currently, nor have they in the past, charted according to these standards and thus the new burden placed on them will be substantial. Further, there is no established mechanism to determine if the physician's medical records comply with these requirements. CMS must consider these requirements in their burden estimate.

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

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

Supplier Requirements

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

The most common request for "additional documentation" is for copies of chart notes. To underscore the burden associated with the collection of this information, one of our members

[12] 70 Fed. Reg. 50,942
[13] *Id.*
[14] *Id.*

collected "additional documentation" in 1999 primarily consisting of chart notes for 283 claims. The total project required 1334 man-hours, or 4.71 hours per claim.

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

Sincerely,

Stephen M. Azia
PMC Counsel

Eric W. Sokol
PMC Director

CC: William N. Parham, III, CMS
Christopher Martin, OIRA

CMS-6022-P-13 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Mr. William Dombi** **Date & Time:** **12/06/2005**

Organization : **National Association for Home Care & Hospice**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6022-P-13-Attach-1.DOC

CMS-6022-P-13-Attach-2.DOC

Ruth L. Constant
Chairman of the Board

HOMECARE & HOSPICE
NATIONAL ASSOCIATION FOR HOME CARE & HOSPICE
228 Seventh Street, SE, Washington, DC 20003 • 202/547-7424 • 202/547-3540 fax

Val J. Halamandaris
President

December 6, 2005

Centers for Medicare and Medicaid Services
Attention: CMS-6022-P
PO Box 8012
Baltimore, MD 21244-8012

Electronically Submitted to:
http://www.cms.hhs.gov/regulations/ecomments.

Re: File code CMS-6022-P Medicare Program; Termination of Non-Random Prepayment Review

To Whom It May Concern:

The National Association for Home Care & Hospice (NAHC) is the largest trade association representing the interests of home health and hospice providers. NAHC"s membership encompasses all types and sizes of providers. The proposed regulation, "Termination of Non-Random Prepayment Review," will directly affect NAHC's members. Therefore, we appreciate the opportunity to comment on this rule.

NAHC has concern about the three issues related to the proposed rule. They are:

- Lack of specific quantitative measures for triggering placement of providers on non-random prepayment complex medical review.
- Failure to identify a minimum number of claims to be reviewed within a quarter upon which improvement measurement is based.
- Failure to consider denial reversals through the appeal process in determining initiation and continuation of non-random prepayment complex medical review.

Lack of Non-Random Prepayment Review Triggers and Failure to Identify Minimum Number of Claims

Issue: The Centers for Medicare & Medicaid Services (CMS) requires its contractors to place providers on non-random prepayment complex medical review when a probe confirms that "billing errors present a likelihood of sustained or high level of payment error." However, CMS does not provide national criteria, such as specific error rates, in its guidance to contractors. Although CMS recommends limiting agency probe edits to

20-40 claims and limiting topic probe edits to 100 claims, CMS does not provide guidance to its contractors as to a minimum number of claims to be reviewed when determining whether a provider is likely to have a sustained high error rate.

Recommendations:

- Establish 30% as the national probe denial rate for triggering non-random prepayment review.
- Create criteria for a minimum number of records to be reviewed before determining that a provider has a likelihood of sustained or high level of payment error. This should be no fewer than 10 claims on a particular probe for a quarter.
- Drop providers from non-random prepayment review when fewer than 10 claims were reviewed in the quarter.

Rationale: Lack of a CMS established error rate as the basis for placing a provider on prepayment review gives contractors too much flexibility. Home health and hospice providers, especially small providers with small numbers of claims that meet probe edit criteria, are often placed on non-random prepayment review based on denial rates calculated on very few claims. Review of a limited sample of claims increases the likelihood of higher error rates than would result if a larger sample of claims were reviewed. Furthermore, this same effect will also result when small numbers of claims are reviewed during non-random prepayment review, thus reducing the chances of impacted providers ever achieving a 70% improvement rate.

Failure to Consider Appeal Decisions

Issue: The proposed rule does not address consideration of reversals of denials on appeal. Furthermore, although CMS policy suggests that its contractors consider appeals that result in reversal of payment denials when targeting providers for nonrandom prepayment review, policy does not carry the weight of regulation.

Recommendation: Include consideration of appeal decisions when targeting providers for nonrandom prepayment review and when determining whether nonrandom review should be terminated because a provider has corrected its billing errors by 70%. This result can be accomplished in either of two ways

1. When calculating a provider's error rate for a quarter, reduce the error rate by the amount of money the provider was paid based on favorable appeal decisions in that quarter, or
2. Calculate error rates based solely on denials that have completed the appeal process.

Rationale: Basing non-random prepayment review and continuation of such review upon erroneous medical review decisions is unfair. To ensure prompt payment of claims favorable appeal decisions should be included in the calculation of error rates.

Thank you for consideration of our comments. Please feel free to contact if you wish to discuss any points in our recommendations that require clarification.

Sincerely,

Mary St.Pierre
Vice President for Regulatory

William A Dombi
Vice President for Law

CMS-6022-P-14 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Mr. Tim Zipp** **Date & Time:** **12/06/2005**

Organization : **The SCOOTER Store**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

see attached comments and previous comments on IFR which are part of these comments

CMS-6022-P-14-Attach-1.DOC

CMS-6022-P-14-Attach-2.DOC

The SCOOTER Store

December 6, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6002-P
PO Box 8012
Baltimore, MD 21244-8012

File Code CMS- 6022 -P

To Whom It May Concern:

On behalf of The SCOOTER Store (TSS), a nationwide supplier of power mobility equipment headquartered in New Braunfels, Texas, we appreciate the opportunity to submit comments in response to the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) on October 7, 2005 entitled *Medicare Program: Termination of Non-Random Prepayment Review*.[1] TSS's commitment to ethical and legal business practices resulted in third-party accreditation from the Accreditation Commission for Health Care, Inc. (ACHC).

The proposed rule defines the process by which a supplier or provider may be removed from "non random prepayment medical review." Generally, we are supportive of efforts to provide certainty and uniformity in the termination process, and we are encouraged that CMS is taking steps towards this goal. However, the proposed rule appears to codify several aspects of medical review that raise concerns. In particular, we are concerned that entrenching the use of primary medical records, as opposed to standardized forms, will lead to ambiguity and confusion that will harm Medicare beneficiaries who rely on power mobility equipment to conduct their activities of daily living. Below, our comments proceed in two parts. Part I addresses the collateral implications of the proposed rule, which includes the codification of an overly-subjective and punitive medical review process. Part II discusses TSS positions on the termination and extension provisions.

I. Collateral Implications of the Proposed Rule Harm Durable Medical Equipment Suppliers and Medicare Beneficiaries

Ostensibly, the proposed rule seeks to promulgate regulations that establish the process by which non-random prepayment reviews are terminated or extended. In doing so, CMS is also codifying several new definitions, which have significant implications far beyond the scope of this rule. These definitions have never been established before through rulemaking, so TSS is taking this opportunity to comment upon them. Moreover, the preamble to the rule indicates that certain diagnosis codes will trigger increased scrutiny, which is contrary to law and CMS policy.

[1] 70 Fed. Reg. 58649-58654

A. Given the Broad Policy Implications, Codification of "Complex Medical Review" Requires a Separate Rulemaking

The proposed rule defines "complex medical review" as including a review of "medical documentation by a licensed professional."[2] This definition codifies an approach that TSS and other suppliers have strenuously and repeatedly opposed because the process is subjective, ambiguous, punitive towards suppliers, and contrary to law.

"Complex medical review" has significant and broad implications far beyond the scope of this rulemaking and has not been previously defined. Thus, TSS urges CMS to propose a rule on the "complex medical review" process, clearly articulating the roles and liabilities of suppliers. Through notice-and-comment rulemaking, CMS could resolve much of the ambiguity surrounding the claims reimbursement process and diminish the number of claims wrongly denied by CMS contractors, 70 percent of which are ultimately paid through the administrative law process. This simple step could save the federal government and taxpayers significant funds and enable suppliers to continue serving Medicare beneficiaries who qualify for power mobility equipment.

A notice-and-comment rulemaking on "complex medical review" should address the following:

- Should suppliers employ licensed medical review professionals to review medical records and make professional medical judgments, potentially overriding the determination of the beneficiary's treating physician?

- If a licensed medical professional determines that the item is not medically necessary, does the treating physician have an opportunity to rebut the findings of the government's licensed medical professional prior to an error rate being assessed? Is there a formal process by which this will be governed?

- What is the liability of the treating physician if the government determines that such physician prescribed this equipment in error?

- Can the government impose an error rate on a supplier if the supplier relied upon the professional medical judgment of the treating physician prior to delivering an item to a Medicare beneficiary?

The additional documentation review inherent in "complex medical review" is a poor alternative to the use of standardized forms such as a scripted prescription or a Certificate of Medical Necessity (CMN). Even if CMS contractors can request and review medical documentation as part of "complex medical review," disagreements between medical professionals—the CMS contractor clinical reviewers and the treating physician—should not result in liability for suppliers who relied upon the medical expertise of others. In fact, 42 U.S.C. § 1395pp(a)(2) provides a limitation of liability for suppliers when the supplier "...did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services...."[3]

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[2] 70 Fed. Reg. at 58,653.
[3] 42 U.S.C. § 1395pp(a)(2).

CMS must ensure that "complex medical review" is not inconsistent with the statutory guarantee that suppliers can safely rely upon the reasonable judgments of treating physicians.

Given the significant and far-reaching implications of codifying "complex medical review," TSS recommends that CMS undertake a separate rulemaking to define this term and clearly articulate the related process.

B. The Documentation Requirements Underpinning "Complex Medical Review" Are Unreasonable and Unlawful

The discussion of the medical review process in the proposed rule explains that reviewers will require that suppliers provide a wide range of primary medical documents to CMS for the purpose of determining whether beneficiaries qualify for coverage. Underpinning the complex medical review process with flawed documentation requirements will taint the entire process, and CMS should work with stakeholders to resolve documentation issues first. Building complex medical review and subsequent error rate analysis on a flawed documentation process undermines the legitimacy of error rate calculations and unfairly punishes suppliers. As TSS stated in our attached comments on the *Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles*, submitted on November 26, 2005, this approach is unworkable and unduly burdensome.[4] This is particularly true given the new documentation requirements placed on physicians and suppliers.

Additionally, TSS is concerned that the standards for document retention prior to "complex medical review" are ambiguous. Suppliers are not in a position to accurately predict which claims will be subject to heightened documentation standards, yet the complex review requirements demand retention and production of an expansive universe of documents. CMS should state clearly what documents suppliers must have immediately available if claims are subjected to review. Moreover, CMS must ensure that those document collection, retention, and production requirements comply with the mandates of the *Paperwork Reduction Act*.

C. The Medical Review Process Unfairly Singles Out Certain Diagnosis Codes for Increased Scrutiny

The preamble to the proposed rule endorses treating beneficiaries differently during the medical review process based solely on their diagnoses. Pursuant to national coverage standards, Medicare beneficiaries qualify for coverage under the power mobility benefit based upon a "functional" analysis designed to determine if the beneficiary needs power mobility equipment in order to perform one or more activities of daily living.

In the preamble, CMS uses a power wheelchair example to explain that CMS intends to audit individuals who receive power wheelchairs differently based upon their diagnosis.[5] This is in direct conflict with the recent work of the 19-member federal employee Interagency Wheelchair Work Group (IWWG) which declared that this benefit would be dependent on the functional

[4] CMS – 3017 – IFC, TSS Comments on *Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles*, 70 Fed. Reg. 50,940 (Aug. 26, 2005)
[5] 70 Fed. Reg. 58,651

capability of the beneficiary.[6] Likewise, it is in conflict with the coverage policies codified in the recent National Coverage Decision (NCD), which states, "[F]or beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations within the home."[7] CMS, in the May 5, 2005 CMS decision memo entitled *Coverage Decision Memorandum for Mobility Assistive Equipment (canes, crutches, walkers, manual wheelchairs, power wheelchairs, scooters)*, acknowledged that this approach stands in contrast to a focus on diagnosis codes and noted that "several commenters commended CMS for not setting the coverage conditions on diagnosis codes."

A focus on diagnosis codes unfairly prejudices a class of patients who have paid into the Medicare program. Instead, reviewers should strictly focus on a functional analysis that seeks to determine whether or not power mobility equipment is necessary for beneficiaries to carry out one or more activities of daily living.

II. TSS Comments on Termination and Extension of Non-Random Prepayment Review

TSS is encouraged that the proposed rule seeks to codify a predictable and reasonable termination and extension process pursuant to the requirements of the *Medicare Modernization Act*. Certainty is critical for business operations and planning. The following comments address the terms set forth by the proposed rule.

A. The Termination Provision, One Year or 70 Percent Reduction in Initial Error Rate, Provides Certainty for Suppliers and CMS

TSS shares CMS's belief that a "90-95 percent reduction in a provider or supplier's error rate would be impracticable." While the proposed rule provides no analysis supporting the 70 percent reduction figure, TSS agrees that a reduction rate of 70 percent "would protect the financial integrity of the Medicare program and allow the provider or supplier a realistic opportunity to be terminated from non-random prepayment complex medical review."[8] TSS's position on this provision is conditioned upon a reasonable and narrow construction of the extension provisions and an objective and fair medical review process.

The other termination trigger, the one year time limit, provides sufficient time for DMERCs to complete necessary reviews, barring unusual circumstances. However, the language of the provision appears to indicate that the minimum time a supplier could be subject to non-random prepayment review is three months:

> A contractor must review claims for a specific billing code aberrancy for the quarter and calculate the quarterly error rate for those claims medically reviewed in that quarter.[9]

[6] NCD for Mobility Assistive Equipment (MAE)(280.3).
[7] *Id.*
[8] 70 Fed. Reg. 58,651
[9] 70 Fed. Reg. at 58,654.

If CMS intends to establish a minimum time period for non-random prepayment review, TSS disagrees with this timeframe. Suppliers could meet the other trigger for termination of non-random prepayment review by reducing error rates by 70 percent earlier than a three-month period. Thus, CMS should remove any language establishing a minimum time that suppliers are subject to review, if the other trigger is met. Finally, as noted below, the integrity of the one-year provision must not be compromised by overly-broad extension language.

B. The Extension Provisions Must Be Clarified and Narrowly Construed

The extension provision of the proposed rule seeks to prevent suppliers from code-shifting as a way to circumvent operation of the rule. TSS supports this position but urges CMS to construe this provision strictly. CMS should direct contractors that non-random prepayment review must be terminated under the rule—upon attaining the 70 percent reduction rate or the one year time limit—unless the specific conditions requiring an extension are satisfied. It is essential that extensions be rare, and that contractors be prohibited from using the extension authority to contravene CMS's efforts and Congress' mandate to provide reliability and predictability to the termination process.

C. Error Rate Calculations Should Consider Reversals During the Appeals Process

The proposed rule defines an "error rate" as the dollar amount of allowable charges for a particular item or service billed in error as determined by complex medical review, divided by the dollar amount of allowable charges for that medically reviewed item or service.[10] "Initial error rate" is defined as the "calculation of an error rate based on the results of a probe review prior to the initiation of non-random prepayment complex medical review."[11]

Claims billed in "error," however, are often overturned during the appeals process. Thus, a supplier or provider should not be penalized for a claim that results in payment by the Medicare program. For this reason, TSS recommends that the "error rate" definition be revised to ensure that reversals during the appeals process will result in an adjustment to calculated error rates.

[10] 70 Fed. Reg. 58653.
[11] *Id.*

We appreciate the opportunity to comment on the proposed rule and look forward to working with CMS toward our shared goal of increasing the quality of service provided to Medicare beneficiaries by the DME industry.

Sincerely,

Tim Zipp
Executive Vice President,
Government Relations
The SCOOTER Store

ATTACHMENT 1
TSS IFR Comments submitted November 28, 2005

CC: William N. Parham, III, CMS
Christopher Martin, OIRA

The SCOOTER Store™

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

December 12, 2005

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

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

To Whom It May Concern:

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

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

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

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

Very truly yours,

Mike Pfister

Enclosure

The SCOOTER Store Comments on CMS—3017—IFC

November 23, 2005

I. Executive Summary

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A. Scripted Prescription with Attestation

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

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

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

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

May 18, 2005

OMB NO

DMERC

CERTIFICATE OF MEDICAL NECESSITY

MANUAL WHEELCHAIRS, POVS, MOTORIZED WHEELCHAIRS

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

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

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

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

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

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

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

SECTION C	Narrative Description of Equipment and Cost

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

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

SECTION D	Physician Attestation and Signature/Date

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

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

DRAFT

DRAFT HCFA 843 (E197)

Mobility Assistive Equipment – Face to Face Examination Report

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

Current Symptoms, Related Diagnoses, and History

Please describe the reason for this office visit:

_____

_____

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

_____

_____

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

Any current pressure sores? Y N Location: _____

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

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

Holds to furniture/walls for mobility: Y N

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

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

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

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

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

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

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

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

B. Mandatory Supplier Accreditation and Standards

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

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

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

Benefits for Medicare Beneficiaries:

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

Benefits for CMS:

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

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

Benefits for DMEPOS Suppliers:

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

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

C. Serial Number Audits

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

III. Documentation Standards Under the IFR are Unreasonable and Unlawful

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

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

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

only bring more certainty to all participants, but also greatly reduce the risk that a supplier will be denied payment through no fault of its own."[8]

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

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

A. Collections of Information Under the IFR

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

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

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

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[8] 70 Fed. Reg. at 50,943.
[9] *Id.* at 50,946-50,947.
[10] *Id.* at 50,944.
[11] *Id.* at 50,942 ("Pertinent parts from the documentation of the beneficiary's PMD evaluation may include the history, physical examination, diagnostic tests, summary of findings, diagnoses, and treatment plans.").

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

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

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

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

B. The Proposed Collection Scheme is Inconsistent with Statutory Mandates

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

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

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

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

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

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

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

C. Documentation Standards Under the IFR are Burdensome

1. Burdens on Physicians

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

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

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

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

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

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

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

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

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

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

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

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

2. Burdens on Suppliers

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

a. Review Burdens

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

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

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

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

b. Collection Burdens

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

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

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

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

3. Burden Estimates in the IFR are Unsupportable and Incorrect

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

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

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

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

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

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

1. The Documentation Requirements are Vague and Arbitrary

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

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

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

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

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

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

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

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

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

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

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

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

> the beneficiary's name, the date of the face-to-face examination, the diagnoses and conditions that the PMD is expected to modify, a description of the item (for example, a narrative description of the specific type of PMD), the length of need, and the physician or treating practitioner's signature and the date the prescription was written.[32]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

V. The IFR Does Not Comply with Legal Requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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[61] *Id.*

[62] *See id.* at 50,946 (citing 42 U.S.C. § 1302 as legal authority for the IFR).

[63] *See id.* (new 42 C.F.R. § 410.38(c)(2)(iii)).

[64] 94 F. Supp. 2d at 65.

[65] 70 Fed. Reg. at 50,943.

[66] [FIX] *See World Duty Free*, 94 F. Supp. 2d at 65 (lack of a congressional deadline for action and agency's two-year delay in promulgating regulations to implement a statutory change "substantially undercut[]" agency's argument that "notice and publication was 'impracticable' and 'contrary to the public interest'").

[67] *Environmental Integrity Project v. EPA*, 2005 U.S. App. LEXIS 21683, at *13 (D.C. Cir. Oct. 7, 2005) (under "logical outgrowth" rule, agency violated APA in adopting, without notice and comment, an interpretation of statutory language that was different than the interpretation in a proposed interim rule).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[76] 42 U.S.C. § 1395m(j)(2)(A)(i).

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

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

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

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

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

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

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

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

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

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

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

See Section II above for recommendations on fraud prevention measures.

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

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

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

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

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

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

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

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-6022-P-15 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Date & Time:** **12/06/2005**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-6022-P-16 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Date & Time:** **12/06/2005**

Organization :

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-6022-P-16-Attach-1.DOC

Comments on CMS 6022-P
"Medicare Program; Termination of Non-Random Prepayment Review"

Comments on Section 4 "Collection of Information Requirements"
According to the proposal it is estimated that the "burden associated with this requirement is estimated to be 10 minutes per provider..."

- Based upon experience, Probe Review data collection takes significantly more time than what is estimated.
- In order to ensure appropriate information is sent and timeline requirements are met, the provider needs to complete the following tasks: review of medical record, organization and sorting of medical record to include appropriate pieces of documentation and timeframe, labeling, photocopying, packaging, mailing, and tracking of the claim. In our experience, approximately 30-35 minutes per record.

Comments on Section 2B "Termination of Non-Random Prepayment Complex Medical Review"

- Having a 70% decrease in the initial error rate as a cut-off for termination of this type of review is appropriate.
- It would also be appropriate to have in place an option that would remove a provider from this type of review when they meet a threshold of 10% or less overall error rate. This would give additional criteria allowing providers who may be placed on this type of review for relatively low initial error rates.
- Updated error rate reports from the contractor to the provider need to be timely and specific demonstrating individual claims decisions (paid or unpaid), and then show a detailed accounting of how the quarterly error rate was calculated or updated.

General comments:

- Based on prior experience with Prepayment Medical Review (for a period of 2 years), we would request clarification regarding how error rate % is determined, for example is it based upon dollar ($) amounts? Days of coverage? Does it depend upon the type of service being billed?
- There should be some ability for a provider to appeal a Probe Review determination which places a provider on Medical Review. CMS currently has an appeal process in place regarding Fiscal Intermediary decisions on covered services. Based on the potential financial burden incurred during Prepayment Review, a similar process would be warranted to appeal Probe Review decisions.

CMS-6022-P-17 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Dr. Mark Race** **Date & Time:** **12/06/2005**

Organization : **Physicians for America's Mobility Impaired**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-6022-P-17-Attach-1.DOC

PHYSICIANS FOR AMERICA'S MOBILITY IMPAIRED

Advocates for the Rights of Medicare Beneficiaries

December 6, 2005

William N. Parham, III
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Regulations Development Group
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Christopher Martin
Office of Information and Regulatory Affairs
Office of Management and Budget
CMS Desk Officer CMS 6022-P
New Executive Office Building
Room 10235
Washington, DC 20503

Dear Mr. Parham and Mr. Martin:

We represent an informal consortium of physician specialists across the country that treats patients with physical disabilities. We appreciate the opportunity to submit comments in response to the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) on October 7, 2005 entitled *Medicare Program; Termination of Non-Random Prepayment Review*. We wish to add to other professionals' comments you may have received concerning the anticipated disruptions in care to those patients who need power mobility to perform their daily living activities.

As presently constituted, it appears to us that this proposed rule retrospectively places non clinicians between the patient and the prescribing physician and imposes a new and relatively unfamiliar documentation scheme. Throughout this retooling of CMS' system for approving prescriptions for PMDs we have continued to emphasize to this agency that this approach, if not greatly simplified, will inevitably reduce appropriate utilization. This agency is also well aware that further mobility restrictions on this vulnerable population will result in the rapid deterioration of health and its ensuant higher costs.

Brief Summary of Proposed Rule

The proposed rule would amend 42 C.F.R. 421 and define terms related to medical review. For example:

> Nonrandom prepayment complex medical review is the "evaluation of medical records or any other documentation by a licensed medical professional prior to Medicare payment. Complex medical review determinations require the reviewer to make a clinical judgment about whether an item or service is covered, and is reasonable and necessary. In order for this determination to be made the provider or supplier would submit a copy of the medical records."

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> Medical records include "any medical documentation, other than what is included on the face of the claim that supports the item or service that is billed. For Medicare to consider coverage and payment for any item or service, the information submitted by the supplier or provider (that is, claims) must be supported by the documentation in the patient's medical records. The patient's medical records include – (1) physician's office records; (2) hospital records; (3) nursing home records; (4) home health agency records; (5) records from other healthcare professionals; and (6) diagnostic reports and other supporting documentation."[1] 70 Fed. Reg. 56851.

The proposed rule further makes clear that beneficiaries will be treated differently based on their diagnosis. CMS states in the proposed rule:

> Providers and suppliers may supply additional documentation not explicitly listed by the contractor. This supporting information may be requested by CMS and its agents on a routine basis in instances where diagnoses on the claims do not clearly indicate medical necessity. For example, documentation supporting the medical necessity of a power wheelchair would not be requested in the vast majority of cases where patients have definite medical conditions such as neurological spinal cord injury, cerebral palsy, multiple sclerosis or stroke with residual myoplegia (not all inclusive). On the other hand, it is more likely that documentation would be requested for patients whose diagnoses are limited to non-neurological conditions such as chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, arthritis or obesity (not all inclusive).

The Proposed Rule Subverts the Role of the Physician in the Medicare Program

The proposed rule not only relies on a physician recordkeeping standard, but also suggests that the beneficiary would have their claim wrongfully denied should medical record content not satisfy a carrier reviewer who has never seen or treated the patient.

Power mobility device suppliers are not qualified, nor should they be qualified, to review the treating physicians' medical records in order to make an independent medical decision. They should rely upon the treating physician's prescription to fill a mobility device claim. This feature seems to contradict CMS's stated intent, and that of Dr McClelland's, that a licensed physician should make these determinations.[2][3]

This proposed rule must distinguish between the medical role of the physician and t the collaborative role of the supplier. We strongly hold that it is not the role of the supplier to review, analyze and interpret medical records to fill the treating physician's prescription. I ilt is not in the best interest of the Medicare beneficiary for the supplier to overturn the judgment of the patient's treating physician.

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[1] *Id.*

[2] CMS defines "Nonrandom prepayment complex medical" review in this proposed rule as the "evaluation of medical records or any other documentation by a ***licensed medical professional*** prior to Medicare payment" (emphasis added), thereby acknowledging that a non-medical professional should not be entrusted to review medical records.

[3] . In a March 8, 2004 written submission to the United States Senate, Dr. McClellan stated the following: The clinical criteria for deciding when a manual or power wheelchair is medically necessary and appropriate for a beneficiary has been and will continue to be a matter of clinical judgment by a physician. It's also my understanding that CMS does not want to list specific condition-based criteria since the decision to determine the appropriateness of providing a manual or power wheelchair is best left to the physician's judgment.

The Proposed Rule Creates an Illegal Barrier for Power Mobility for Beneficiaries with Certain Diagnoses

CMS recently issued a National Coverage Determination (NCD) for Mobility Assistive Equipment (MAE) in which they declared that the benefit would be dependent on the functional capability of the beneficiary. Stated CMS:

> Effective May 5, 2005, CMS finds that the evidence is adequate to determine that MAE is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations within the home. Determination of the presence of a mobility deficit will be made by an algorithmic process, Clinical Criteria for MAE Coverage, to provide the appropriate MAE to correct the mobility deficit.

In a prior May 5, 2005 CMS decision memo, entitled "*Coverage Decision Memorandum for Mobility Assistive Equipment (canes, crutches, walkers, manual wheelchairs, power wheelchairs, scooters)*" CMS acknowledged that "several commenters commended CMS for not setting the coverage conditions on diagnosis codes."

Although the power mobility benefit is based on the functional ability of the beneficiary to perform activities of daily living, this proposed rule would treat beneficiaries differently based solely on their diagnosis. As referenced earlier in these comments, CMS declared the following in the proposed rule:

> Providers and suppliers may supply additional documentation not explicitly listed by the contractor. This supporting information may be requested by CMS and its agents on a routine basis in instances where diagnoses on the claims do not clearly indicate medical necessity. For example, documentation supporting the medical necessity of a power wheelchair would not be requested in the vast majority of cases where patients have definite medical conditions such as neurological spinal cord injury, cerebral palsy, multiple sclerosis or stroke with residual myoplegia (not all inclusive). On the other hand, it is more likely that documentation would be requested for patients whose diagnoses are limited to non-neurological conditions such as chronic obstructive pulmonary disease, congestive heart failure, coronary artery disease, arthritis or obesity (not all inclusive).

We are concerned that proposed action directly prejudices a class of patients who have lawfully paid into the Medicare program in that the standard for receiving power mobility equipment will be based on their diagnosis and not their functional ability to conduct activities of daily living. Further, such action directly contradicts the national coverage criteria governing power mobility.

A Scripted Prescription Would Ensure that a Review Process Is Undertaken in a Manner that is Clear and Consistent

You are aware that Senator Charles Grassley has suggested that CMS consider a scripted prescription or similar form with open-ended questions that directly link to the NCD. We support such a process to help decrease the already heavy workload on America's physicians. We recommend that CMS develop an expanded version of the current Certificate of Medical Necessity or a template that employs several open-ended questions that could be easily used by physicians, suppliers, and beneficiaries to determine if medical necessity exists and to document that need.

There are a number of concerns we have recognized in the delivery system fostered by this proposed regulation that have already been noted by other organizations. While the extensive new documentation is still unclear in a number of areas, it sets up a three-way conflict between the prescriber, intermediary (DMERC) and the supplier. As noted above, the supplier must infer from the medical record an implied medical necessity. Additionally, under the current proposal, there is no assurance that a treating physician's prescription will be correctly filled by a supplier. There is uncertainty regarding the selection process of the specific type of power mobility product and accessories for the patient. We are concerned that replacing an objective form (the CMN) with the subjective standard (collection and analysis of physicians' notes) also will create ambiguity in the claims approval process, which seems counter to the ostensible objectives of this revamping of the current system. This approach also appears to undermine our clinical role as physicians in providing sound medical treatments for our patients.

While we agree that CMS should employ all possible strategies to eliminate fraud and abuse within the Medicare program, there should be a level of confidence in the Federal Government that physicians are working with credible suppliers to fill their prescriptions. We too are committed to helping detect and prevent fraud and abuse. If CMS truly wants to adopt fraud prevention measures, then the agency must incorporate objective and consistent elements into the program as opposed to new, highly subjective elements.[4]

Documentation Standards In the Proposed Rule are Unduly Burdensome

Physicians are required, under a recently implemented interim final rule for power mobility devices, to create a prescription with several specific components, all of which are currently included in the Certificate of Medical Necessity form. Without a form or format, the new prescription will create a larger burden on physicians as they attempt to document free-hand all of the components contained in the interim final rule.

Physicians are required, under this new regulation, to prepare, maintain and provide a record of the face-to-face examination of the beneficiary for the power mobility device. According to the preamble of the interim final rule, "The parts of the medical record selected [by the physicians] should be sufficient to delineate the history of events that led to the request for the PMD; identify the mobility deficits to be corrected by the PMD; and document that other treatments do not obviate the need for the PMD, that the beneficiary lives in an environment that supports the use of the PMD and that the beneficiary or caregiver is capable of operating the PMD...." Physicians do not currently nor have they in the past charted according to these standards and thus the new burden placed on them will be substantial. Further, there is no established mechanism to determine if the physician's medical records comply with these requirements. CMS must consider these requirements in their burden estimate.

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

All requirements are applicable to 100% of all PMD prescriptions, which is not current practice and will thus place new and substantial burdens on our nation's physicians. This burden must be calculated by

[4] As Senator Grassley also pointed out, "elimination of the [CMN] without a scripted form may open the door to fraud, confusion, and subjectivity." Elimination of the CMN not only removes objectivity, but also removes the requirement that the physician attest to the accuracy of medical necessity information subject to civil and criminal liability. Stated Senator Grassley, "CMS should include an attestation certification with reference to the False Claims Act to strengthen program integrity efforts."

CMS and not summarily dismissed as current medical practice. Current medical practice is for physicians to consider their patient's condition and complete a Certificate of Medical Necessity to prescribe, document, and establish the need for PMDs.

Our informal consultation with medical professionals, nurses, and individuals familiar with the normal time burdens associated with medical paperwork found the following rough estimates of the burdens on physicians:

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

Our analysis suggests that the physician burden solely associated with gathering medical records to be approximately 23 minutes. This, of course, does not take into account additional Medicare requirements imposed on physicians including the face-to-face examination necessary for power mobility equipment and the preparation of the medical records themselves.

As we have noted in previous comments, this proposed regulation hits the medical profession just as several provisions in the Medicare Modernization Act land in their offices, along with a possible fee reduction or possibly, at best, a modest one-time update in reimbursement. Recent surveys of practicing physicians suggest this will force even more of them to close their practices to Medicare beneficiaries because of sheer economic reality. The implementation of Part D alone, and the complex prescription drug program, most certainly will generate added confusion for beneficiaries and prescribers alike. As a result, the timing to radically alter the delivery system of sophisticated power mobility devices, which require careful collaboration among several highly trained professionals, could not be worse.

The net result, regardless of regulatory intent, will be to reduce valid utilization by discouraging physicians from working through an arduous process and thus shrink the pool of specialists able and willing to persist in this endeavor. By default, many patients with a legitimate need for mobility support will be stranded, atrophied by a regulatory scheme.

Sincerely,

Mark Race, MD
Co-Chair

George Rodgers, MD
Co-Chair

CMS-6022-P-18 **Termination of Non-Random Prepayment Medical Review**

Submitter : **Dr. Gail Whitelaw** **Date & Time:** **12/06/2005**

Organization : **American Academy of Audiology**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached comment letter.

CMS-6022-P-18-Attach-1.PDF

AMERICAN ACADEMY OF AUDIOLOGY

11730 Plaza America Drive, Suite 300, Reston, VA 20190-4798 • 1-800-AAA-2336

December 6, 2005

BY ELECTRONIC MAIL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6022-P
P.O. Box 8012
Baltimore, MD 21244-8012

Re: CMS-6022-P

Dear Sir or Madam:

The American Academy of Audiology is pleased to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS) proposed rule on the termination of non-random prepayment complex medical review.

The Academy represents nearly 10,000 audiologists practicing nationwide in private practices, hospital, nursing homes, schools, clinics, and other settings. We are concerned that the proposed rule does little to limit the virtually unfettered discretion of Medicare contractors to determine the scope and duration of non-random prepayment reviews.

The proposed rule is intended to implement § 934 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA). That provision was clearly intended to place limitations on the discretion of Medicare administrative contractors in the conduct of non-random prepayment reviews. Specifically, it requires that non-random prepayment review be initiated only if there is "a likelihood of sustained or high level of payment error." It also requires the Secretary to "issue regulations relating to the termination, including termination dates, of non-random prepayment review." 42 U.S.C. §1395kk-1(h)(2)(A), (B).

The Academy believes there is a need for limitations on the duration of non-random prepayment complex medical reviews of Medicare providers' and suppliers' claims. In the past, the Academy has received complaints from members about seemingly open-ended prepayment reviews. In some cases, these reviews can be so burdensome that hospitals may simply cease billing Medicare for covered services, because the amount of reimbursement does not equal the administrative costs of responding to a Medicare contractor's requests for documentation.

The Academy is concerned, however, that the proposed rule does little to restrict a contractor's discretion in deciding when to terminate non-random prepayment review. The proposed rule provides that contractors "may" terminate non-random prepayment review if either of two criteria are met: (1) one year has passed since initiation of the review; or (2) calculation of the error rate indicates the provider or supplier has reduced its initial error rate by 70 percent or more. If the review is terminated after one year but the contractor determines that the provider or supplier continues to have a high error rate, the contractor must consider further actions, including initiating post-payment review or referring the provider or supplier to the Benefit Integrity Program Safeguard Contractor. In addition, the contractor must periodically re-evaluate the provider's or supplier's bills to see if its error rate justifies placing the provider or supplier back on non-random prepayment review.

The Academy believes the proposed rule should be revised to require that the contractor "must" terminate non-random prepayment review if either of the specified criteria are met. After one year or a 70 percent reduction in the initial error rate, there should be a presumption in favor of terminating the review. If a provider or supplier continues to have a sustained or high level of payment error following termination, the appropriate procedure should be placing the provider or supplier back on non-random prepayment review. However, at that point, the burden of proof should shift to the contractor. While we appreciate the need to safeguard the Medicare Trust Fund, the intent of § 934 of the MMA was to limit contractor discretion, and the proposed rule does not appear to effectuate that intent.

We also request that CMS provide some guidance as to what level of billing errors constitutes a "high level of payment error." The proposed rule indicates that a 70 reduction in the initial error rate is grounds for terminating prepayment review, but it does not indicate what error rate would justify initiation of prepayment review. In addition, we request further explanation as to how CMS arrived at the figure of a 70 percent reduction in the initial error rate needed to terminate review, as this percentage appears to be relatively high.

The Academy appreciates the opportunity to submit these comments.

Respectfully submitted,

Gail M. Whitelaw

Gail Whitelaw, Ph.D.
President