The SCOOTER Store®

June 25, 2007

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

RE: CMS Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare Program; Conditions of Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles (CMS-3017-F); FR Vol. 72, No. 81/April 27, 2007

Dear Mr. Parham:

On behalf of The SCOOTER Store (TSS), I submit the attached comments on the collection of information associated with the Centers for Medicare and Medicaid Services (CMS) Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare Program; Conditions of Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles.

TSS comments submitted in our May 22, 2006, same subject, are enclosed in this letter and remain essentially correct today. In the current scenario, Medicare suppliers must collect and review medical records, thereby being placed in the position of overruling the judgment of the treating physician with regard to the medical need of the physician's own patient. The physicians must, at CMS demand, without specific guidelines or content standards from CMS, craft a long narrative prescription and select relevant medical records to support PMD prescriptions. Thus far the training provided by CMS to physicians, as to how to meet documentation standards to which they do not normally adhere, appears to be insufficient or non-existent. If a supplier fails to collect certain records that a reviewer later determines are needed, or if a claims reviewer disagrees with the medical judgments made by a treating physician, then the supplier risks substantial economic harm.

Regarding the burden from this information collection, the real-world experience of suppliers like TSS, operating under the Final Rule provisions is that:

- The physician's burden is 97 minutes (plus an additional one to two hours, if the physician visits the beneficiary's home, as the IFR indicated might be necessary;
- The supplier's burden for collection of the information is 2.5 hours for each claim; and
- The supplier's burden for having in-house medical personnel reviewing every claim is 1.1 hours per claim, and the cost of employing clinicians is at least $25 per hour.

The burden estimates provided in the enclosure to this letter have been by and large proven accurate. In addition to what was originally commented upon, CMS, through its contractors, is requiring suppliers to prepare a Detailed Product Description (DPD) listing the specific PMD base and all options and accessories that will be billed separately. This document was not reviewed or approved by the Office of Management and Budget (OMB) and yet creates an additional burden on providers and suppliers. Its burden is in excess of the timeframes stated above and is only included in the Local Coverage Determination for Power Mobility Devices and not the Federal Register postings by CMS.

For a detailed explanation of the actual burden being experienced by TSS, please refer to the attachment which was previously submitted on May 22, 2006 in the Executive Summary.

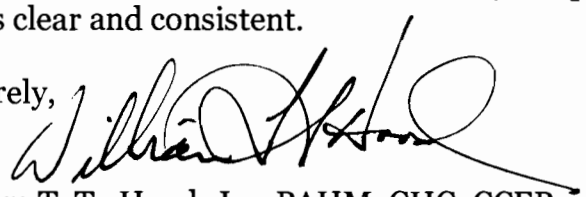
The Terms of Clearance issued October 16, 2006 set forth specific requirements to be adhered to by the agency. John F. Morrall, Acting Deputy Administrator of OMB's Office of Information and Regulatory Affairs, issued Terms of Clearance as follows: "The collection is approved contingent upon the following terms of clearance. We recognize the new paperwork requirements for suppliers and providers. After extensive review, OMB approves the collection for 12 months. During this period, CMS will monitor the paperwork burden required of providers and suppliers to determine if the paperwork requirements impose any unnecessary burden on the industry and/or need to be revised in order to improve the utility of the information. Upon resubmission to OMB, CMS will solicit public comments and report to OMB on its findings during the 12 month period." In the Federal Register notice governing this collection of information, CMS did not provide any data assessing the impact of the additional documentation collection burden imposed upon physicians and suppliers.

We ask that the OMB not grant this extension, but rather require CMS to perform the required monitoring of the paperwork burden, post the results, and allow the supplier and physician communities an opportunity to comment. After this has been done, then OMB should consider CMS's request for this data collection extension.

It is our fervent hope that CMS will work with providers and suppliers to develop a viable solution – one that allows the treating physician, not the supplier, to make the

medical determination on behalf of his/her patient under a documentation standard that is clear and consistent.

Sincerely,



William T. T. Hood, Jr. PAHM, CHC, CCEP
Vice President of Corporate Compliance

Enclosure: (1)

CC: Tim Zipp
Michael Clark, Esq.

The SCOOTER Store™

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May 22, 2006

Centers for Medicare and Medicaid Services
Office of Strategic and Regulatory Affairs
Division of Regulations Development—B
Attention: William N. Parnham, III
Room C4—26—05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS—3017—IFC, *Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles*, 70 Fed. Reg. 50,940; Form Number: CMS-10116 (OMB#: 0938-0971)

To Whom It May Concern:

On behalf of The SCOOTER Store (TSS), I submit the attached comments on the collection of information associated with 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), and final rule ("Power Mobility Device Rule" or "PMD Rule"), published at 71 Fed. Reg. 17,021 (April 5, 2006).

Because no meaningful comment period was provided before CMS finalized the Power Mobility Device (PMD) Rule, TSS greatly appreciates this opportunity to comment on the proposed collection of information. TSS is the nation's largest supplier of PMDs and has served over 200,000 Medicare beneficiaries and worked with over 100,000 physicians. TSS takes its role as a stakeholder very seriously and having changed its operations to comport with the PMD Rule's documentation requirements is well-positioned to comment on the inaccuracy of CMS' burden estimate and the lack of utility of the information sought. Also in these comments, TSS will recommend clear, consistent, and objective ways to substantially improve the Medicare claims reimbursement process, while protecting the Medicare trust fund and serving qualified Medicare beneficiaries.

Like the IFR, the PMD Rule replaces the Certificate of Medical Necessity (CMN)—a clear and objective document—with requirements that physicians draft lengthy prescriptions and suppliers collect and review physicians' medical records to determine if physicians properly prescribed PMDs. Specifically, Medicare suppliers must collect and review all medical records that CMS reviewers may later determine are necessary to verify a detailed written prescription from a treating physician. Also, physicians must, without specific guidelines or content standards from

Enclosure (1)

CMS, craft a long narrative prescription and select relevant medical records to support prescriptions. If a supplier fails to collect certain records that a reviewer later determines are needed, or if a claims reviewer disagrees with the medical judgments made by a treating physician, then the supplier risks substantial economic harm.

Although Medicare regulations should be designed to enhance clarity, fairness, and objectivity, the collections of information in the PMD Rule are:

- overly burdensome, far greater than CMS summarily estimated, because they impose open-ended paperwork and recordkeeping demands on suppliers and physicians;
- highly subjective, because they fail to provide clear benchmarks or standardized processes for suppliers and physicians, which decreases the utility of the information; and
- poorly designed, because they fail to advance the stated policy goals of CMS.

Because TSS is operating in compliance with the PMD Rule, TSS can provide evidence that CMS greatly underestimated the time and resource allocations necessary to fulfill these new requirements and greatly overestimated the utility of the information sought.

Unless CMS creates clear, fair, and objective documentation standards, TSS is concerned that the uncertainty and subjectivity resulting from implementation of PMD Rule will harm the Medicare program because it will punish suppliers, undermine physicians, and make it more difficult for qualified Medicare beneficiaries to get the equipment they need. In contrast, a clear and objective documentation standard will decrease the documentation burden currently imposed on the physicians and suppliers involved in the prescription of PMDs. As you know, the Paperwork Reduction Act (PRA) was enacted in order to prevent agencies from using paperwork demands as a way to coerce and punish those participating in federal programs, and the new CMS rule is clear example of the type of paperwork scheme that Congress intended to prohibit. As such, TSS respectfully requests that the Office of Management and Budget (OMB) not approve these information collection requirements.

TSS looks forward to working with OMB and CMS to develop paperwork and recordkeeping requirements that can help CMS serve qualified Medicare beneficiaries and realize the agency's stated goal of fraud and abuse prevention.

Very truly yours,

Mike Pfister

Enclosure

The SCOOTER Store Comments on
CMS—3017—IFC (70 Fed. Reg. 50,940); Form Number: CMS-10116 (OMB#: 0938-0971)

EXECUTIVE SUMMARY

In promulgating the Interim Final Rule (IFR) and Power Mobility Device (PMD) Rule, the Centers for Medicare and Medicaid Services (CMS) circumvented the requirements of the Administrative Procedures Act (APA); ignored the will of Congress; and greatly underestimated the burden of the collections of information contained in the IFR and PMD Rule. In addition, CMS overestimated the utility of the information sought by the burdensome paperwork and documentation requirements. Because The SCOOTER Store (TSS) changed its business operations to comport with the new requirements, the company is well-positioned to comment on the collections of information and the inaccuracy of CMS' estimated burdens. TSS is also well-positioned to make recommendations on ways to enhance the quality, utility, and clarity of the information to be collected, as well as ways to minimize the information collection burden.

Regarding the burden from this information collection, the real-world experience of suppliers, like TSS, operating under the IFR and the PMD Rule is that:

- The physician's burden is 97 minutes (plus an additional one to two hours, if the physician visits the beneficiary's home, as the IFR indicates might be necessary);
- The supplier's burden for collection of the information is 2.5 hours for each claim; and
- The supplier's burden for having in-house medical personnel reviewing every claim is 1.1 hours per claim, and the cost of employing clinicians is at least $25 per hour.

These are only the burdens addressed by CMS in the PMD Rule, and they are conclusory in nature. Burdens not considered by CMS include: training in-house medical clinicians; redacting documentation to meet HIPAA requirements; copying and filing of documentation; preparing privacy protected documents for transmission; preparation of documents for transmission to the durable medical regional carrier (DMERC); claims that were developed by the physician and supplier then denied by CMS; and CMS demands for "additional documentation" from suppliers.

Regarding utility of the information sought, the elimination of the certificate of medical necessity (CMN) removes objectivity from the claims process and the requirement that the physician attest to medical necessity under penalty of perjury. This decreases the utility and clarity of the information, undermining the goal of fraud and abuse prevention. According to Senator Charles Grassley, "Elimination of the [CMN] without a scripted form may open the door to fraud, confusion, and subjectivity."[1] As Senator Grassley stated, "CMS should consider a scripted prescription or similar form with open-ended questions that directly link to the NCD...CMS should include an attestation certification with reference to the False Claims Act to strengthen program integrity efforts."[2] TSS strongly supports Senator Grassley's recommendation and proposes a scripted prescription with attestation, as described in Section III below.

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[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) (emphasis added) (hereinafter "Grassley Letter").
[2] *Id.*

I. Questions that Illustrate that CMS Underestimated the Burden of the Information Collection and Overestimated the Utility of the Information Sought

TSS would like to take this opportunity to set forth three questions that highlight the flaws inherent in the proposed collections of information. Answers to these questions are critical to the effective functioning of the PMD Rule and to the success of suppliers and physicians attempting to operate under the PMD Rule.

First, holding in abeyance the burden placed on physicians and assuming the physician timely provides the seven-element prescription and the face-to-face examination report, both extensive documents addressing medical necessity, who decides how much, when, and what additional documentation is needed?

In the preamble to the PMD Rule, CMS explained that "a party engaged in healthcare-related businesses should ensure that it has adequate expertise to carry out its responsibilities, and should obtain the training necessary to achieve and maintain that level of expertise."[3] The PMD Rule further requires that suppliers "obtain as much documentation from the patient's medical as it determines that it needs to assure itself that the coverage criteria for payment have been met."[4] These explanations appear to require that suppliers train and employee medical review staff to determine whether observations recorded by treating physicians will be seen by DMERC review nurses as supporting a physician's prescription of particular equipment for patients.

Thus, how is the PMD Rule consistent with the statement of CMS' attorney before the U.S. District Court for the District of Columbia that the only burden on suppliers is that "they [suppliers] need to buy file cabinets to maintain these records"[5]? This statement was an explanation provided to the court in response to industry claims that the IFR was extremely burdensome, and the statement appears to be flatly inconsistent with the position of CMS in the PMD Rule.

Second, what is the utility of a supplier collecting, reviewing, and storing historical medical records—those records existing prior to the physician's face-to-face evaluation of the beneficiary? The new process requires that a doctor or treating practitioner:

- evaluate the beneficiary in the last 45 days to analyze mobility needs;
- document that the patient was evaluated for that purpose;
- conduct and document a face-to-face evaluation; and
- write a seven-element prescription.

Providing this information should sufficiently illustrate medical necessity and obviate the need for historical data contained in medical records, since those records were not charted for the purpose of determining medical necessity.

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[3] 71 Fed. Reg. 17,026 (April 5, 2006).

[4] *Id.*

[5] *Power Mobility Coalition v. Michael Leavitt*, C.A. No. 05-2027, Transcript of Proceedings before the Honorable Reggie B. Walton (Oct. 2005).

The collection, analysis, and storage of historical medical records is another new burden placed upon suppliers, and CMS greatly underestimated the time, financial, and human resources that must be dedicated to this task.

Third, one stated goal of CMS in promulgating new coverage rules was to reduce the number of claims that are denied through no fault of the supplier. CMS intends to achieve this goal by requiring a new array of documents from physicians and suppliers. The supplier must obtain a seven-element prescription, as well as a documented face-to-face examination report, from the physician or treating practitioner. What is not clear is at what point a supplier can reasonably rely upon the medical conclusions of a treating practitioner. If the supplier agrees with the treating practitioner that the documentation provided is sufficient 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)?

CMS addressed the limitation of liability issue in the PMD Rule, stating that unless a properly executed advance beneficiary notices (ABN) has been obtained from a beneficiary, a supplier will be liable for all denied claims.[6] This presents an impossible situation: If the supplier believes that it has done everything necessary to assure that coverage criteria for payment have been met, then it would be illegal for the supplier to execute an ABN. A properly executed ABN describes the reason for which the supplier believes the claim will be denied. If a supplier believes the claim will not be denied, then the supplier cannot execute an ABN. The only option would be to have each and every beneficiary complete an ABN stating that we do not know if CMS will pay this claim or not. That situation is specifically addressed and prohibited by the ABN language.

II. CMS Greatly Underestimated the Burden Imposed on Suppliers and Physicians Related to the Information Collections of the IFR and PMD Rule

A. Collection Burdens Under the IFR and PMD Rule

Before the promulgation of the IFR, the supplier obtained a physician-certified certificate of medical necessity (CMN), and CMS requested "additional documentation" only in the event of an audit or review. The new regulatory environment now requires the collection of "additional documentation" on 100 percent of claims, which drastically increases the burden on both suppliers and physicians. CMS identifies three distinct collections of information in the IFR and PMD Rule, 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 45 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.[7]

[6] 71 Fed. Reg. at 17,026.

[7] 70 Fed. Reg. 50,940, 50,944 (Aug. 26, 2005).

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.[8] This is in addition to writing and submitting the prescription to the supplier. While the IFR identifies that there is a burden associated with this requirement, CMS provides no precise estimate of this burden.[9]

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.[10]

Overall, CMS estimates that the combined burden on suppliers and physicians concerning medical records "will be no more than 10 minutes."[11] 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.[12]

Furthermore, the IFR and PMD Rule require an additional collection of information that has not been subjected to any burden analysis. Section 410.38(c)(5)(ii) of the IFR and PMD Rule 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."[13] 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."[14]

Despite the open-ended nature and significant scope of this "additional documentation" requirement, neither the IFR nor the PMD Rule include an estimate of the burden this places on suppliers. CMS attempts to address this concern in the PMD Rule by asserting that additional documentation will only be required during audits and will not be required for all claims.[15] However, no such limits are present in the regulatory language of the PMD Rule, and the express terms of the additional documentation provision authorize CMS claims reviewers to request additional documentation at any time and for any claim. This means that suppliers must collect "additional documentation" on every claim.

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[8] 70 Fed. Reg. 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.").
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] 71 Fed. Reg. at 17,030.
[14] 70 Fed. Reg. at 50,943.
[15] 71 Fed. Reg. at 17,024.

B. 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. In the PMD Rule, CMS states that the time figures are estimates and that time will vary based upon individual circumstances, but CMS still did not provide any evidence supporting the two minute and ten minute estimates.[16]

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.[17] Just drafting essays of this length would require 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 and PMD Rule.

TSS has worked with over 100,000 physicians and their staff. In consultation with medical professionals, nurses, and individuals familiar with the normal time burdens associated with medical paperwork, TSS 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 a face-to-face examination report: 10 minutes
- Write chart notes: 10 minutes
- Discuss/decide mobility assist required: 2 minutes
- Evaluate appropriate equipment using national coverage determination (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
- Copy pertinent portions of medical record: 10 minutes
- Redact records in order to ensure HIPAA compliance: 10 minutes
- Prepare HIPAA compliant fax cover sheet: 2 minutes
- Send Fax: 1 minute

[16] *Id.* at 17,023-24.
[17] 70 Fed. Reg. at 50,942.

This analysis indicates that the physician burden associated with the IFR and PMD Rule would be approximately 97 minutes, and those with whom we consulted stated that an additional one to two hours would be added if a physician is required to visit a patient's home, as the IFR suggests.

In addition to the burden described above, the IFR and PMD Rule impose additional physician burdens that greatly exceed even the prescription and the face-to-face examination requirements. The IFR explains that medical records submitted to a supplier to illustrate medical necessity must:

- track 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.[18]

Thus, in addition to the seven-element prescription and the face-to-face examination, CMS is requiring that the doctor track these requirements in his or her medical records, which presents two problems: 1) historical medical records that would be submitted will not chart this way, since those records pre-date the PMD Rule; and 2) CMS fails to estimate the burden associated with this recordkeeping requirement. CMS provides no burden analysis for the additional time and resources necessary to satisfy this requirement. Moreover, while the IFR contends that in most cases "the information recorded at the face-to-face examination will be sufficient,"[19] CMS clearly states that the burden is on suppliers to determine sufficiency and fails to provide any standard or guidance as to what is sufficient.

TSS has worked with over 100,000 physicians nationwide and has been operating under the IFR and the PMD Rule. 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 PMD Rule's actual burden than the unsupported estimate stated by CMS.

C. Burdens on Suppliers

The PMD Rule imposes new collection, review, and recordkeeping burdens on suppliers, which CMS greatly underestimated. The IFR explained that the supplier burden includes "receiving the documentation, reviewing the documentation to ensure it is complete, and storing the documentation."[20] Neither the IFR nor the PMD Rule properly accounts for the magnitude of the review burdens, and TSS respectfully requests that OMB reject this proposed collection of information and work with stakeholders and CMS to develop a clear, objective, and consistent process.

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[18] *Id.*
[19] *Id.*
[20] *Id.* at 50,944.

1. CMS Greatly Underestimated the Collection Burdens for Suppliers

Holding in abeyance the financial, time, and human resource burdens associated with reviewing documentation, the IFR and PMD Rule impose significant burdens solely attributable to collecting medical records. Simply collecting and transmitting the documents will take much longer than the 10 minutes that CMS summarily concluded will be required of suppliers.

Based upon TSS operations, which have been standardized and built around the most efficient processes and technologies available, the collection burden under the PMD Rule includes multiple burdens that, when combined, result in a significant overall financial, time, and human resources burden. The collection activities required of suppliers include:

1) Intake Process: Establishing Patient Files and Basic Information
2) Receive, Retrieve, and Account for Physician documents. Typically, this requires multiple contacts with the physician to collect all required information on the prescription, proof of a face-to-face examination and the related report, and explanation of areas where medical records are silent or unclear on coverage elements.
3) Identify Patient and Match Records
4) Review Documents for Non-Medical Requirements (*i.e.*, signature, names, etc.)
5) Requests for Additional Information
6) Review Additional Documents for Non-Medical Items

While individual circumstances require more time and human resources and others less, on average, the collection burden alone is 2.5 hours for each claim, which greatly exceeds CMS' ten minute estimate. Unlike CMS' estimate, these calculations are based on actual supplier operations and a history of responding to documentation requests from CMS contractors, making it far more realistic than the IFR assertion that the entire process will take less than ten minutes.

2. Review Burdens

The IFR contends that "there will be a shift in the burden of information collection from the supplier to the physician."[21] 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 and PMD Rule 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.

While this requirement may not have been clear under the IFR, CMS explains in the PMD Rule that they expect suppliers to have staff with medical expertise who are capable of reviewing detailed medical records in order to determine if a physician's prescription is supported by medical evidence.[22] Fulfilling this duty requires a complex analysis of the physician's diagnosis; all of the documentation and history regarding that diagnosis; and a determination if additional

[21] *Id.* at 50,942.
[22] 71 Fed. Reg. at 17,026.

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.

TSS, as the leader in the power mobility industry, has reorganized its business model to comply with these requirements and has found them to be extremely burdensome. TSS employs a staff of nurses for the purpose of reviewing every claim in an attempt to determine if a physician's documents sufficiently establish medical necessity for his/her patient. We found that, even when conducted with the utmost efficiency, the average amount of time it takes to complete this process is 1.1 hours per claim, and the cost of employing clinicians is at least $25 per hour. It is reasonable to assume that this burden will be even more significant for smaller suppliers and those who do not have the expertise, technology, and human resources available to TSS.

Given the scope of the collection and analysis required under the IFR and PMD Rule, 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 and PMD Rule state. The ten minute estimate is inconsistent even with past representations from CMS to OMB. 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."[23] 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.

CMS responded to this specific concern in the preamble to the PMD Rule, stating that the five hour estimate was an "extreme" rather than an average or representative figure.[24] Notwithstanding the fact that this assertion seems to be aimed at undermining the reliability of the agency's past estimate submissions to OMB, the argument that a ten minute estimate in the IFR and a five hour estimate in a past submission are consistent because they are simply estimates is disingenuous at best. As these comments explain, industry experience indicates that the five hour estimate is far closer to being an accurate burden estimate than the ten minute estimate.

3. Submission of Documents to Carrier

The IFR and PMD Rule also fail to properly account for the submission burdens imposed under the new documentation scheme. When CMS reviews claims, suppliers are required to undertake several activities and each of these activities entails its own burden under the PMD Rule. These activities and burdens include:

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[23] *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.

[24] 71 Fed. Reg. at 17,027.

1) Redact documentation to meet HIPAA requirements: 5 minutes
2) Copying and filing of documentation: 5 minutes
3) Preparing privacy protected documents for transmission: 10 minutes
4) Retrieval of documents from storage: 5 minutes (if on-site)
5) Preparation of documents for transmission to DMERC: 10 minutes

In sum, upon review by CMS, the information that has been collected is prepared for submission to the Program Safety Contractor with a total estimate of 35 minutes per claim. CMS has not accounted for these burdens in their estimates.

D. Burden Estimates in the IFR and PMD Rule 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 and PMD Rule 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 ten minute burden will be multiplied by 187,000 prescriptions per year.[25] 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 45-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 nor the PMD Rule consider these burdens.

2. Demands for Additional Documentation—As described earlier, language in the PMD 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 or the PMD Rule.

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 PMD Rule are likely to impose significant costs on both physicians and suppliers.

[25] 70 Fed. Reg. at 50,944.

III. CMS Should Utilize a Scripted Prescription with Attestation to Accomplish Fraud and Abuse Prevention Goals While Establishing Certainty and Objectivity in the Medicare Reimbursement Process

OMB has requested Comment on "...the use of... other forms of information technology to minimize the information collection burden." TSS proposes the use of a scripted prescription or form that captures all of the information deemed necessary by CMS and is subject to physician attestation.

TSS agrees with CMS that bad actors exist within the power mobility community, and TSS is committed to helping detect and prevent fraud and abuse. If CMS truly wants to adopt fraud prevention measures the agency must incorporate objective and consistent elements into the program as opposed to new, highly subjective elements. As Senator Grassley, Chairman of the Senate Finance Committee, points out in his letter to Secretary Leavitt and Administrator McClellan, "In the sprint to publish these requirements, CMS may have added an unnecessary degree of subjectivity to this process."[26] In particular, "Elimination of the [CMN] without a scripted form may open the door to fraud, confusion, and subjectivity."[27] 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 stated, "CMS should consider a scripted prescription or similar form with open-ended questions that directly link to the NCD...CMS should include an attestation certification with reference to the False Claims Act to strengthen program integrity efforts "[28] TSS strongly supports Senator Grassley's recommendation and proposes the prototype below. This form incorporates the nine components of the NCD algorithm and could be easily used by physicians, suppliers, and beneficiaries to determine if medical necessity exists and to document that need. TSS's scripted prescription prototype is presented below.

[26] *Grassley Letter supra* note 1.
[27] *Id.* (emphasis added).
[28] *Id.*

SUPPORTING DOCUMENTATION FOR A POWER MOBILITY DEVICE

Patient Name _____ **Patient SSN** _____

FACE TO FACE EXAMINATION

Date of face-to-face examination ____ / ____ / ____

1. Do you have access to the patient's medical records?	❑ Yes	❑ No
2. Did you examine this patient for the purpose of assessing their need for a power mobility device?	❑ Yes	❑ No
3. Are you this patient's physician or treating practitioner?	❑ Yes	❑ No
3. How long have you seen this patient?	❑ < 1yr.	❑ 1-3 yrs. ❑ >3 yrs.

In the patient's physical examination, I have evaluated the patient's weight, impairment of strength, range of motion, sensation, or coordination of the arms and legs; presence of abnormal tone or deformity of arms, legs or trunk; speed of ambulation and pain while ambulating or attempting to ambulate; neck, trunk, and pelvic posture and flexibility; sitting and standing balance.

4. Did you consider the patient's symptoms and related diagnoses in this evaluation?	❑ Yes	❑ No
5. Do the diagnoses support medical necessity for a power mobility device?	❑ Yes	❑ No
6. I have considered the patient's history as it related to his/her need for a power mobility device?	❑ Yes	❑ No

MEDICAL NECESSITY

1. Does the patient have a mobility limitation that significantly impairs his/her ability to participate in one or more mobility related activities of daily living such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home?	❑ Yes	❑ No
2. To your knowledge, has the patient tried other treatment plans to alleviate this mobility limitations?	❑ Yes	❑ No
3. Has this patient tried other mobility devices?	❑ Yes	❑ No
4. Can the patient's mobility limitation be sufficiently resolved by the use of an appropriately fitted cane or walker?	❑ Yes	❑ No
5. Will the use of the wheelchair significantly improve the patient's ability to participate in mobility related activities of daily living and the patient will use it on a regular basis in the home?	❑ Yes	❑ No
6. Does the patient have sufficient upper extremity function to self-propel an optimally-configured manual wheelchair in the home to perform the mobility related activities of daily living during a typical day?	❑ Yes	❑ No
7. Does the patient have the sufficient strength, postural stability and other physical or mental capabilities needed to safely operate a POV in the home?	❑ Yes	❑ No
8. Does the patient have the ability to safely operate a Power Wheelchair in the home?	❑ Yes	❑ No
9. Does the patient have the ability to transfer in and out of the power mobility device?	❑ Yes	❑ No

(over)

PATIENT HISTORY

1. Does the patient's medical record clearly support the need for a power mobility device? If not, please explain why?	❑ Yes	❑ No
2. Does the patient's medical record identify the mobility deficits to be corrected by the power mobility device? If not, please explain why?	❑ Yes	❑ No
3. Does the patient's medical record document that other treatments did not obviate the need of the PMD? If not, please explain why?	❑ Yes	❑ No

ENVIRONMENT

1. Has the patient expressed a willingness to use a mobility assistive device that is provided in their home?	❑ Yes	❑ No
2. Does the patient's home provide adequate access between rooms, maneuvering space, and surfaces for the operation of the POV?	❑ Yes	❑ No
3. Does the patient's home provide adequate access between rooms, maneuvering space, and surfaces for the operation of the power wheelchair?	❑ Yes	❑ No
4 Will the power mobility device be used only outside the home?	❑ Yes	❑ No

PHYSICIAN'S ATTESTATION

Based upon the face-to-face examination of the patient and my review of the patient's history, I have written a prescription for the appropriate mobility assistive device with all necessary accessories?	❑ **Yes**	❑ **No**

I consider this form to be the written report of my evaluation and will incorporate it into my patient's medical record as well as making it available to the supplier and MAC upon request. I certify that I am the treating practitioner or physician. I certify that the medical necessity information on this form is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to civil or criminal liability.

Treating practitioner or physician's signature

Date

The use of a scripted prescription with physician or treating practitioner attestation would provide all of the information sought by CMS, establish objectivity in the claims review process, and enhance the quality, clarity, and utility of the information to be collected. Using this or a similar template would greatly reduce the burden to collect the information requested.

IV. CMS Circumvented Legal Requirements and Ignored the Intent of Congress in Promulgating the Burdensome PMD Rule

The IFR was published absent stakeholder input; failed to comply with multiple legal requirements;[29] and imposed several new burdens on suppliers and physicians absent requisite

[29] 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.

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," 5 U.S.C. § 553(b), and then "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." *Id.*at § 553(c). 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. *See New Jersey Dep't of Envtl. Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980). Accordingly, although Congress established a handful of exceptions to the notice-and-comment requirement, it "expected, and the courts have held, that the various exceptions . . . will be narrowly construed and only reluctantly countenanced." *Id.*

CMS conceded in the IFR that it did not follow notice-and-comment procedures in promulgating the IFR. 70 Fed. Reg. at 50,943. That undisputed failure renders the IFR unlawful.

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." 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.

Second, although an agency may abandon notice and comment in "emergency situations" or when "delay could result in serious harm," 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.

analysis or support. Notwithstanding, CMS finalized the PMD Rule in April 2006 without addressing documentation issues raised by stakeholders, or Members of Congress.

A. CMS Ignored the Will of Congress

Congress has, on numerous occasions, expressed concern about the IFR and the documentation burdens associated with the new coverage standards. Notwithstanding these concerns, CMS has failed to modify their rules to account for the very serious reservations expressed by legislators.

The Chairman of the Senate Finance Committee, Senator Charles Grassley (R-IA), expressed his concern about CMS' approach to PMD coverage in a letter dated September 29, 2005. In that letter, Chairman Grassley noted that a lack of clarity and certainty in documentation requirements in PMD rules may unduly harm equipment suppliers and Medicare beneficiaries and create regulatory confusion that facilitates fraud. Furthermore, Chairman Grassley requested that CMS consider adopting standardized documentation requirements, such as utilizing a one-page "scripted prescription." Despite the Chairman's request for a response, he has not received any detailed answer from CMS.

A similar pattern of disregard for the concerns of legislators can be seen in the appropriations context. Section 222 of the FY2006 appropriations legislation providing funds to CMS precluded the agency from using any funds "to implement or enforce the interim final rule published in the Federal Register...on August 26, 2005 prior to April 1, 2006."[30] In the conference report accompanying the appropriations legislation, Congress made its intent clear. The conference report explicitly states that Congress intended for CMS to publish a new power mobility rule, allow for and consider input from stakeholders, and provide additional transition time for stakeholders to adapt to new CMS policies. H.R. Rep. No. 109-300, at 30 (Conf. Rep.). This language was designed to address many of the same concerns that motivated Chairman Grassley to contact CMS in September 2005.

Notwithstanding agency communications and the statutory language enacted at the end of last year, CMS did not propose a new rule, work with stakeholders to address the concerns regarding the original IFR, or address the documentation issues raised in Senator Grassley's letter to CMS. As Representative Ralph Regula, Chairman of the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, recently noted in a question directed to Secretary Leavitt, it appears that CMS is disregarding the intent of Congress by failing to adopt clear and consistent PMD guidelines.

Implementing the PMD Rule as if Congress has not spoken on the matter may harm Medicare beneficiaries by unduly burdening suppliers and manufacturers of PMDs and is in direct contravention of the express intent of Congress. TSS respectfully requests that OMB reject the collection of information and work with CMS, Members of Congress, and stakeholders to develop a collection of information that is clear, objective, and consistent.

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.

[30] Pub. L. No. 109-149.

B. The Proposed Methods of Information Collection Are Inconsistent With Statutory Mandates

Under the PMD Rule, 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.[31]

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 medical necessity for commercial purposes."[32] 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."[33]

The mandatory nature of the CMN has been confirmed in the judicial system. In *Maximum Comfort, Inc. v. Thompson*, 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.[34]

Despite the fact that Congress explicitly provided to suppliers the right to distribute a standardized form for purposes of demonstrating medical necessity, the PMD Rule 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.

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[31] 42 U.S.C. § 1395m(j)(2)(A)(i) (2004).
[32] *Id.*
[33] 42 U.S.C. § 1395m(j)(2)(B) (2004).
[34] 323 F. Supp. 2d 1060, 1074-75 (E.D. Cal. 2004) (emphasis added).

V. Contrary to CMS' Statements, the Agency Has Actually Increased the Risk that a Supplier Will be Denied Payment Through No Fault of Its Own

The IFR included a lengthy explanation of the justifications underlying adoption of the documentation scheme finalized by the PMD Rule. In the IFR, CMS states that the documentation requirements included in the PMD Rule facilitate the implementation of two different policy changes. First, CMS is acting on a congressional directive in the Medicare Modernization Act of 2003 (MMA) to implement a requirement that physicians conduct a "face-to-face" examination before prescribing mobility assistive equipment (MAE).[35] Second, the change is intended to update documentation standards to reflect new coverage standards set out by CMS in the May 5, 2005 National Coverage Decision (NCD) for MAE.[36] 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 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."[37]

Because CMS failed to adopt clear and objective documentation standards in the PMD Rule the agency has made it more difficult for coverage standards to be applied fairly, predictably, and with the minimum necessary burden on Medicare suppliers. If the PMD Rule required standardized documentation that clearly tracked the NCD's nine-step coverage algorithm CMS' aspirations could have been realized. 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 PMD Rule creates a maze of new documentation standards that bear no resemblance to the NCD. In particular, the PMD Rule eliminates the CMN requirement. The PMD Rule 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.[38] 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 PMD Rule are extremely burdensome and undermine the proper operation of the Medicare program by jeopardizing the viability of the power mobility benefit. The PMD Rule requires that physicians collect a vast array of information and draft expanded prescriptions without a standardized form. Moreover, the PMD Rule requires 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 PMD Rule. In sum, the scheme described in the IFR is subjective, burdensome, and rife with ambiguity.

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[35] 70 Fed. Reg. at 50,941.

[36] *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).

[37] 70 Fed. Reg. at 50,943.

[38] 71 Fed. Reg. at 17,022.

VI. Documentation Requirements Under the PMD Rule are Unclear and Unlikely to Facilitate the Proper Provision of Equipment to Medicare Beneficiaries

The collections of information offered by CMS in the PMD Rule 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.

A. Documentation Requirements are Vague and Arbitrary

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

The PMD Rule provides no measures upon which a supplier can rely to determine which of these records will be required in any particular situation. The PMD Rule broadly requires that suppliers provide to CMS primary medical records that "support" and "substantiate" the physician's conclusion that MAE is medically necessary.[39] 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

[39] *Id.* at 17,030 (§§ 410.38(c)(2)(iii) and 410.38(c)(5)(ii) of the rule).

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 PMD Rule fails to address this problem.

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

The documents that the PMD Rule 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 PMD Rule 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 historical 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.

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.[40] 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 PMD Rule, because the PMD Rule 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 PMD Rule is compounded by the nature of the prescription mandated by the rule. Pursuant to § 410.38(c)(1) of the PMD Rule, 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,

[40] 69 Fed. Reg. 47,487. 47,545 (August 5, 2004).

and the physician or treating practitioner's signature and the date the prescription was written.[41]

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

The lack of standardized forms, clear requirements that physicians document the elements of the NCD; and the reliance on inherently unclear medical records renders the information collected under the rule unclear and not useful in the effort to fairly administer the power mobility benefit. Many of these concerns were echoed in a recent letter sent by Senator Charles Grassley, Chairman of the Senate Finance Committee, which stated that "Elimination of the [CMN] without a scripted form may open the door to fraud, confusion, and subjectivity."[42]

VII. The Regulatory Impact Statement (RIS) in the PMD Rule is Insufficient

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

First, CMS claims that adoption of the PMD Rule 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."[43] 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 PMD Rule will result in a shift from power wheelchairs to POVs as a result of lifting the specialist requirements related to POV prescriptions.[44] 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 PMD Rule is an "economically significant" rule, there is scant discussion of likely impacts that the rule will have on suppliers as result of eliminating the

[41] 71 Fed. Reg. at 17,030.
[42] *Grassley Letter supra* note 1.
[43] 71 Fed. Reg. at 17,028.
[44] *Id.*

CMN.[45] While admitting that suppliers will have increased record-keeping burdens under the rule, there is no analysis of the overall cost of these burdens.[46]

Fourth, the PMD Rule claims that DME suppliers will actually benefit from the rule because the rule will "increase their ability to assure that their prescriptions are valid (in terms of medical necessity)."[47] 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 unlimited historical 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 PMD Rule 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.

VIII. Conclusion: The Threat Posed by the PMD Rule 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.[48] 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 PMD Rule, patients in need of PMDs will lose important sources of information about these devices and will have more difficulty obtaining them. Thus, the PMD Rule 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 PMD Rule will deny qualified patients access to medically necessary mobility devices. That is an issue of human safety and wellness, not just money. Expressed in economic terms, however, the PMD Rule may result in a net loss of consumer welfare, which is the aggregate difference of all

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[45] *Id.*
[46] *Id.* at 17,029.
[47] *Id.*
[48] 70 Fed. Reg. at 50,944-45.

consumers' valuations of a PMD and the price paid by all consumers, of between $93 million per year and $283 million per year.[49]

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.[50] Erecting artificial obstacles to reimbursement for eligible PMDs therefore is not even a rational way of curbing Medicare spending.

If clear, consistent and objective documentation standards were created to accompany the PMD it is likely that many of our concerns would be assuaged. Medicare suppliers must be able to trust treating practitioners, should have clear and objective paperwork to review, and should not be held financially liable when they had no reason to know that CMS claims reviewers would disagree with the medical conclusions reached by treating. We believe that the use of a scripted prescription such as the one offered in these comments would help accomplish these goals.

We appreciate our consideration of these comments.

[49] 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.

[50] 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).