The SCOOTER Store®

December 15, 2011

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier CMS-10417
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

To Whom It May Concern:

On behalf of The SCOOTER Store (TSS), a nationwide provider of durable medical equipment headquartered in New Braunfels, Texas, we submit the following comments in response to a proposed new collection of information entitled "*Medicare Fee-for-Service Prepayment Medical Review.*" This collection was published in the Federal Register on December 8, 2011 by the Centers for Medicare and Medicaid Services (CMS).[1]

CMS is improperly seeking emergency review without providing any valid justification for depriving the public of the right to a proper notice and comment period. Dramatically reducing the normal 60 day time frame afforded citizens under the PRA, the agency is only allowing the public an opportunity to comment for seven days (until December 15th) and requesting Office of Management and Budget (OMB) approval by December 19, 2011, only two working days after submission. We note that CMS is seeking an 180 day approval for this emergency request even though OMB's own PRA emergency regulation, 5 CFR § 1320.13, only allows OMB to assign a control number valid for a maximum of 90 days after receipt of an agency emergency submission.

In its request, CMS references a "pilot prior authorization" program and a "pilot early [prepayment] review" program but provides no specifics. As will be set out in more detail below, it is believed CMS' emergency request is an attempt, in part, to gain OMB authority to implement a massive Demonstration Project involving 100% pre-pay and pre authorization review in seven large states, representing nearly ***fifty (50%)*** of the claims submitted for Power Mobility Devices (PMD). The Demonstration Project was announced on November 15, 2011 with a January 1, 2012 implementation date, a mere six weeks' notice to suppliers.

[1] 76 Fed. Reg. 76737.

While the issuance of this emergency request for a collection of information has immediately followed CMS's announcement of the PMD prepayment Demonstration Project, it is clear the broad language of this request could also impact a much larger group of providers and suppliers. Section 1893 of the Social Security, referenced as a legal authority for this proposed collection of information, creates the Medicare Integrity Program and allows for review of a wide range of providers and suppliers receiving payment under the Medicare program. If CMS is allowed approval of this broadly worded collection of information, the agency might attempt to create other massive "pilot" programs in other industries under this same authority. This could lead to an immeasurable increase in the paperwork burden placed on Medicare providers and suppliers without receiving proper review and inspection by the OMB and the public. Toward this end, the supporting documentation associated with this proposed collection of information references, among other things, an increase of 900,000 prepayment medical reviews each year to be imposed on various industries within the healthcare sector.

Congress enacted the PRA in part "to minimize the paperwork burden resulting from the collection of information by or for the Federal Government." To the contrary, this proposed collection of information will create a massive new paperwork burden on our nation's providers and suppliers, resulting in a substantial loss of jobs and loss of access to necessary equipment for Medicare beneficiaries.

Based on the significant issues set forth below, we respectfully request that CMS immediately withdraw this emergency PRA request. It is imperative that the agency undergo proper notice and comment and the affected parties have a full opportunity to have their voices heard.

I. CMS IS ATTEMPTING TO IMPLEMENT A MASSIVE GENERAL INVESTIGATION OF THE POWER MOBILITY INDUSTRY SCHEDULED TO BEGIN JANUARY 1, 2012

CMS references a "pilot prior authorization" program and a "pilot early [prepayment] review" program as part of this proposed collection of information, but provides no detail regarding such "pilot" programs. The agency is attempting to obtain *blanket* authorization from OMB to conduct "pilot" programs, now and in the future, without being held accountable for the specifics of the programs as they relate to paperwork clarity and burden.

It is believed this emergency OMB control number request is directly related to the November 15, 2011 announcement by CMS that it would be undertaking an unapproved general investigation of the power mobility device (PMD) industry, beginning January 1, 2012, through a Demonstration Project entitled *"Medicare's Prepayment Review and Prior Authorization*

Demonstration Project For Power Mobility Devices."[2] Traditionally a Medicare Demonstration Project tests a payment model on a small segment of the Medicare population across a limited area of the country in order to ensure beneficiaries are not adversely impacted on a broad scale. In addition, adequate notice is given to both beneficiary and business stakeholder before changes to a benefit or payment structure is implemented. However, the program announced by CMS on November 15, 2011 will purportedly cover nearly half of the current PMD benefit, with only 6 weeks' notice prior to implementation. This is an extraordinary departure from the normal demonstration process and is unfair to both beneficiaries and businesses alike.

Although this Demonstration Project constitutes a massive paperwork imposition on Medicare participants, CMS has failed to provide any basis to obtain OMB approval to conduct this demonstration project.[3]

*Proposed Demonstration Project - PHASE I - Initial **100% Prepayment Review** on the PMD Industry*

Under this three year "demonstration," CMS and its Durable Medical Equipment Administrative Medicare Contractors (DME MACs) would initially subject every power mobility device supplier to a 100% prepayment review for PMD claims involving a Medicare beneficiary in 7 largest Medicare reimbursement states – California, Florida, Illinois, Michigan, New York, North Carolina and Texas. These seven states represent almost 50% of the PMD claims submitted to Medicare nationally.

CMS released a December 1, 2011 document entitled *Provider Outreach and Education*[4] declaring that every Medicare supplier in the states of California, Florida, Illinois, Michigan, New York, North Carolina and Texas will receive an additional documentation request (ADR) for specific PMD codes. These ADR requests would include documentation from a beneficiary's face-to-face examination with his/her physician, seven element order, detailed product

[2] *See Medicare's Prepayment Review and Prior Authorization Demonstration Project for Power Mobility Devices*, available at https://www.cms.gov/apps/media/press/factsheet.asp?Counter=4168.

[3] The Department of Health and Human Services website acknowledges that compliance with the PRA must take place during a demonstration project. Responding to a frequently asked question (FAQ) as to whether the PRA applies to collections of information which are part of a pilot project or program, the agency stated "[t]he Paperwork Reduction Act is a law and must be complied with regardless of mode, or reason for the collection. In accordance with the PRA, OMB approval must be obtained prior to collecting information in any situation where 10 or more respondents are involved and the questions are standardized in nature." *Frequently Asked Questions About PRA/Information Collection*, available at http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html.

[4] *CMS Prepayment Review and Prior Authorization of Power mobility Devices (PMD) Demonstration, Provider Outreach and Education Posted December 1, 2011*, available at https://www.cms.gov/CERT/Downloads/PMD_powerpoint_v15_Final.pdf

description, home assessment, patient authorization and proof of delivery.[5] Stated CMS, the "DME MACs will send additional documentation request (ADR) on 100% of these claims to the billing suppliers....Failure to submit complete documentation = denial."[6] We note that the *Provider Outreach and Education* document was not provided to OMB nor was it included as part of the emergency PRA review.

CMS, in its December 1, 2011 document, made clear that every Medicare claim for the following codes in the states of California, Florida, Illinois, Michigan, New York, North Carolina, and Texas would receive an ADR and thus be subject to full prepayment review:

- All power operated vehicles (K0800-K0805, K0909-K0812)
- All standard power wheelchairs (K0813- K0829)
- All Group 2 complex rehabilitative power wheelchairs (K0835-K0843)
- All Group # complex rehabilitative power wheelchair without power options (K0848-K0855)
- All pediatric power wheelchairs (K0890-K0891)
- Miscellaneous power wheelchair (K0898)[7]

The ADR requests, on 100% of suppliers for 100% of Medicare PMD claims (for the specific codes referenced above) in almost 50% of the nation's PMD market, would pose an enormous burden on Medicare participants. No business could withstand this type of paperwork onslaught and routine delay of payment. Thousands of jobs will be lost within months of implementation. Further, seniors' access to this benefit will be severely restricted.

Proposed Demonstration Project PHASE II - Conversion from 100% Pre-Payment Review to ***100 % Prior Authorization*** *Program*

The second phase of the Demonstration Project would involve a prior authorization program in which physicians/practitioners would undergo a new requirement to submit documentation for every PMD claim to Medicare. Under current regulation, physicians/practitioners are not required to submit, as a matter of policy, PMD claims to Medicare. This substantive change in Medicare law requires proper notice and comment both within the PRA as well as the Administrative Procedure Act.[8]

Under this phase of the Demonstration Project, PMD claims for the codes listed above would require prior authorization before delivery of equipment.

[5] *Id* at 18.
[6] *Id* at 9.
[7] *Id.* at 4.
[8] 5 U.S.C. § 553

Prior authorization would be obtained by requiring the prescribing physician to submit documentation to a government contractor before the equipment was provided. CMS is proposing the creation of a new billing code and a small payment for physicians. Stated CMS in its December 1, 2011 *Provider Outreach and Education* document, "this compensates physician/practitioner for the additional time spent preparing and submitting a prior authorization request."[9]

CMS has provided no details in its emergency PRA submission regarding the prior authorization "demonstration." There is no explanation as to what type of paperwork will be required of the physician/practitioner. The fact that CMS is proposing a new billing code and a new fee to be paid to the provider is prima facie evidence that our nations' physicians/practitioners will be subjected to an entirely new paperwork/documentation standard.

II. ENACTMENT OF A 100% PREPAYMENT REVIEW AND PRIOR AUTHORIZATION IN SEVEN STATES WILL DESTROY BUSINESSES AND ACCESS TO NECESSARY MEDICAL EQUIPMENT

Power mobility has made a dramatic difference in the lives of our citizens. The development of new technology in the industry has made it possible for citizens to obtain smaller, more lightweight and maneuverable motorized wheelchairs for use inside the home. This allows people to move about in small places and complete their activities of daily living (ADLs) without being bed-bound or sent to nursing homes.

Payment Delays Will Cause Job Loss and Close Businesses, Limiting Beneficiary Access

As highlighted above, the prepayment review and prior authorization demonstration, if enacted, would have a dramatic impact on beneficiary access and the ability for legitimate health care businesses to remain in operation. The power mobility industry is very concerned that the demonstration project will stop payments on all new PMD claims for a minimum of 60 to 90 days. As a result, businesses must now obtain a minimum of 60 to 90 days ***additional*** working capital to survive CMS withholding these payments or risk business closure. The timing of this demonstration compounds cash flow problems stemming from Congress' decision to convert Medicare payments to a rental model on January 1, 2011, which already spreads payments over a 13-month period.

CMS' Purported High Error Rates Are Not Supported By Appeals Results

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[9] *CMS Prepayment Review and Prior Authorization of Power Mobility Devices (PMD) Demonstration, Provider Outreach and Education Posted December 1, 2011*, at 14.

CMS has typically cited high error with regard to PMD claims submitted to Medicare. However, this is not representative of the fact that a large number of claims are denied as a result of ADR requests are overturned during the appeals process, a process that often takes over eighteen months to complete. Few businesses can survive routinely waiting this long for payment.

Approval of this collection of information would cause unnecessary paperwork burdens on those participating in the Medicare program. In light of the jobs lost and health care access denied, CMS cannot rightfully claim that an emergency exists to impose such hardship on providers, suppliers and Medicare beneficiaries.

III. CMS PROVIDES NO RATIONALE TO JUSTIFY SUBMISSION OF THIS COLLECTION OF INFORMATION ON AN EMERGENCY BASIS.

Scope of Demonstration Project contradicts 100 claim "general investigation" parameters

There is no reference in the CMS emergency PRA submission regarding the 100% prepayment and prior authorization Demonstration Project to be conducted throughout the country. To the contrary, CMS specifically stated the following in its supporting documentation:

> In the case of a widespread "item or service-specific" problem, a larger sample of claims ***(generally 100 claims of the item or service in question)*** would be subjected to complex medical review. Performing medical review on a sample of claims for a specific billing code before placing the provider or supplier on non-random prepayment complex medical review allows for a determination as to whether a problem exists and ensures that contractor medical review resources are targeted appropriately and ***that providers and suppliers are not unnecessarily burdened*** and that contractor medical review resources are appropriately utilized. (emphasis added)[10]

CMS further stated that "this collection will not impact a substantial number of legitimate small businesses."

Similarly, current CMS regulation defines "Service-specific probe review" as "the complex medical review of a sample of claims, ***generally 100 claims***, across the providers or suppliers that bill a particular item or service to confirm that or determine whether the item or service is billed in error." 42 CFR § 421.501 (emphasis added). "Complex medical review" is defined as "all medical

[10] CMS-10417 Supporting Statement, p. 2, available at http://www.cms.gov/PaperWorkReductionActof1995/downloads/CMS-10417.zip.

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 likelihood of sustained or high level of payment error." *Id.*

Although CMS has proposed a full scale 100% industry prepayment and prior authorization review that would impact every provider and supplier of PMD in almost 50% of the PMD market nationwide, this collection was submitted to OMB under the guise that limited probe reviews would be conducted so that providers and suppliers "are not unnecessarily burdened."

CMS Failed to Comply with PRA Requirements By Failing to Describe the Demonstration Project

CMS did not comply with PRA requirements with regard to the demonstration project set to begin January 1, 2012. The PRA requires that all "collections of information" conducted or sponsored by an agency be approved by the Director of the OMB. [11]

CMS's December 8, 2011 Federal Register notice invites interested persons to "send comments regarding this [collection of information] burden estimate or any other aspect of this collection of information, including any of the following subjects:

(i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;
(ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;
(iii) enhance the quality, utility, and clarity of the information to be collected; and
(iv) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.[12]

The PRA requires federal agencies to obtain OMB approval for "collections of information" "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." 44 U.S.C. § 3518(c)(2).

[11] A "collection of information" is defined in the PRA as the "obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions, by or for an agency, regardless of form or format calling for...answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, 10 or more persons, other than agencies, instrumentalities, or employees of the United States." 44 U.S.C. §3502(3).
[12] 44 U.S.C. § 3506.

While the 100% prepayment and prior authorization proposal constitutes a significant general investigation of an industry "undertaken with reference to a category of individuals or entities such as a class of licensees or an entire industry," CMS avoided any discussion of these proposals when requesting emergency clearance from the OMB. CMS did not assess whether the Demonstration Project was necessary, did not provide any estimate of the burden associate with the Demonstration Project, did not discuss the quality, utility and clarity of the information to be collected during the Demonstration Project, nor did the agency assess how to minimize the burden of the Demonstration Project on those who are to respond.

The failure of CMS to offer any analysis required under the PRA for this Demonstration Project renders the entire collection of information submission invalid. CMS is seeking broad authority to develop any "pilot" program of its choosing without any checks and balances afforded the public through the PRA. This runs counter to the safeguards developed by Congress and the OMB when enacting the PRA.

OMB Has Previously Refused CMS's Request To Renew OMB Control Number 0938-0969

The Office of Information and Regulatory Affairs ("OIRA") website provides a detailed history of OMB control number 0938-0969. The control number was originally approved by the OMB on September 15, 2005 and OMB subsequently approved the control number with change on January 5, 2007. When the recent reapproval timeframe was reached, CMS sought and received an emergency extension on January 29, 2010. CMS than tried to obtain a second emergency extension on April 30, 2010 but this extension was formally disapproved by OMB on May 5, 2010 and removed from OIRA's Inventory of Active Information Collections.

CMS, recognizing the need to comply with the PRA, previously sought and received limited approval in January 2007 from the OMB to conduct "item or widespread or service-specific" reviews. The agency obtained OMB control number 0938-0969 to perform such reviews. When seeking such approval from OMB, CMS submitted a supporting statement to the OMB declaring, in part, that "[i]n the case of a widespread "item or service-specific" problem, a larger sample of claims (***generally 100 claims of the item or service in question***) would be subjected to complex medical review"[13] (emphasis added).

CMS previously acknowledged in its own Program Integrity Manual (PIM) the requirement that OMB control number 0938-0969 be utilized when conducting medical review. Pursuant to Chapter 3, Section 3.4 of the PIM,

[13] "Medicare Program: Termination of Non-Random Prepayment Review (CMS-6022-P)" (May 19, 2006), *available at* http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=200608-0938-003.

entitled "*Overview of Prepayment and Postpayment Review for MR Purposes,*" CMS explicitly informed contractors that they must notify suppliers of the OMB Paperwork Reduction Act collection number, which is 0938-0969. The agency mandated that this "number needs to be on every additional documentation request (ADR) or any other type of written request for additional documentation for medical review. It can be in the header, footer or body of the document. We suggest the information read "OMB #: 0938-0969" or "OMB Control #: 0938-0969."[14]

Even though OMB Control Number 0938-0969 was disapproved over 19 months ago, CMS contractors have continued to conduct the same widespread reviews and collection of documentation.

CMS cites as justification for this emergency request the following:

> *If Medicare is required to stop performing this type of review then it will severely impede the ability to ensure that the services provided were reasonable and necessary.*[15]

The above represents a tacit admission that the agency has been conducting industry reviews involving collections of information without obtaining proper approval from OMB. Further, if a real emergency existed to justify a new control number, the agency would not have waited 19 months prior to taking action.

IV. RECOMMENDATIONS

CMS describes the review of a claim in this collection of information as "the evaluation of medical records or any other documentation by a licensed medical professional prior to Medicare payment."[16] As stated above, while CMS has indicated in the past that a high error rate exists for Medicare claims involving PMDs and other products, this is misleading since a majority of denied claims are overturned on appeal. Further, we have had longstanding concerns regarding the manner in which documentation produced by a treating physician/practitioner during a congressionally mandated face-to-face examination is reviewed by licensed professionals working for the Medicare contractors.

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[14] "'Probe' Reviews," Medicare Program Integrity Manual, Ch. 3 § 3.11.1.2. After failing to obtain reapproval from OMB for control number 0938-0969, CMS removed the PRA language from its PIM. This of course does not mitigate the fact that the agency has failed to comply with federal law when attempting to enact this massive new paperwork burden on the entire PMD industry.

[15] *Request for Emergency Clearance of the Paperwork Reduction Act Package for Medicare Fee-for-Service Early Review of Medical Records*, Centers for Medicare and Medicaid Services.

[16] CMS-10417 Supporting Statement, p. 1

Congress, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), established the physician/treating practitioner as the gatekeeper when dealing with power wheelchairs covered by Medicare. [17] CMS subsequently developed regulations implementing the MMA power mobility device provisions. Pursuant to 42 C.F.R. § 410.38(c)(2), "Medicare Part B pays for a power mobility device (PMD) if the physician or treating practitioner...[c]onducts a face-to-face examination of the beneficiary for the purpose of evaluating and treating the beneficiary for his or her medical condition and determining the medical necessity..."

While the face-to-face examination is the event established by Congress and CMS to determine whether a beneficiary is qualified for a power wheelchair, we have long witnessed disregard by a Medicare contractor of the documentation produced by the physician/practitioner during the examination.

Prior to approval of any medical review collection of information or "pilot" medical review program impacting this industry, we propose that the lack of clarity and consistency during the claims review process be addressed head on. We propose regular meetings with representatives of CMS, OMB, Medicare contractors , and representatives of physicians, beneficiaries and Medicare Part B suppliers to iron out the specific information that must be contained in a power mobility device claim and the manner in which this information may be documented and recorded. An efficient documentation and recordkeeping process would reduce unnecessary costs while ensuring quality health care for our nation's elderly and disabled.

The following are specific recommendations governing the development of a clear and concise medical review standard.

- Validate that the face-to-face examination requirement established by Congress was designed to strengthen the role of the treating physician or practitioner in making medical necessity determinations regarding his/her patient.

- A finding of medical necessity during the face-to-face examination, based on professional medical judgment, shall constitute substantial evidence that the item or service is reasonable and necessary pursuant to Section 1862(a)(1) of the Social Security Act. The Secretary must present clear and convincing evidence to rebut any documented face-to-face examination finding of a physician, physician assistant, nurse practitioner, or a clinical nurse specialist.

[17] Codified at 42 U.S.C. § 1395m (a)(1)(E)(iv), the MMA states, in part, that "payment may not be made for such covered item [power wheelchairs] unless a physician..., a physician assistant, nurse practitioner, or a clinical nurse specialist...has conducted a face-to-face examination of the individual and written a prescription for the item

- Require the development of a comprehensive face-to-face examination medical necessity evaluation template/form for physicians and treating practitioners.

- Reduce unnecessary paperwork burdens on physicians and treating practitioners by focusing on the documentation produced as part of a congressionally mandated face-to-face examination.

- Ensure that the Secretary utilize appropriate resources to discover and combat fraud.

- Any change in current procedures must be developed with participation by all stakeholders in accordance with the Federal Advisory Committee Act, Administrative Procedure Act and Paperwork Reduction Act.

- Beneficiaries and suppliers must retain appeal rights in any system proposed by CMS. This includes appeals to a Qualified Independent Contractor, Administrative Law Judge, Departmental Appeals Board and judicial review should the beneficiary and/or supplier choose to pursue this course.

V. CONCLUSION

Based on the foregoing, we respectfully request that CMS retract this emergency collection of information. Should the agency continue to seek OMB approval, we contend that OMB must deny the agency's request to ignore longstanding notice and comment procedures.

We appreciate the opportunity to seek comments and thank you for your attention to this matter.

Very truly yours,

Michael B. Clark
General Counsel
The SCOOTER Store