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June 26, 2012

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier CMS-10417 (OMB 0938-0969)
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 comments regarding the extension of the collection of information, entitled "*Medicare Fee-for-Service Prepayment Medical Review,*" published for review on April 27, 2012. 77 Fed. Reg. 25181.

This collection of information perpetuates several aspects of medical review that continue to be of concern. In particular, we are concerned that the broad and vague description of medical review places a significant burden on responding providers, suppliers and beneficiaries. Prepayment medical review is an onerous process requiring Medicare suppliers to obtain a significant amount of ill-defined documentation and then submit such documentation to a Medicare contractor for review. Based on prior history, contractors deny nearly all the claims (80-90 percent) during medical review only to have a large amount of these denied claims overturned during a lengthy and costly Medicare appeals process.

We urge CMS to delay submission of this control number for OMB review until a well-defined medical review process is established with proper input from the provider, supplier and beneficiary community.

I. History of OMB Control Number 0938-0969

The Office of Management and Budget (OMB) Office of Information and Regulatory Affairs 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. CMS sought and received an emergency extension on January 29, 2010. CMS tried to

obtain a second emergency extension on April 30, 2010 but this extension was formally disapproved by OMB on May 5, 2010 and the control number was removed from OIRA's Inventory of Active Information Collections.

CMS did not seek or request an OMB Control Number for a period of 19 months after its emergency extension request was rejected. On December 8, 2011, CMS requested emergency approval of a medical review proposed collection of information and attempted to combine this collection with several demonstration projects.[1] On December 15, 2011, the Office of Management and Budget (OMB) determined that the collection of information was Improperly Submitted. OMB instructed CMS to *"[p]lease submit this information collection request as a reinstatement with change to OMB Control Number 0938-0969*."

CMS, without informing the public and without seeking any public comment, subsequently issued the same supporting documentation submitted on December 8, 2011 to OMB in an attempt to obtain **immediate** "reinstatement with change" of OMB Control Number 0938-0969. On March 19, 2012, OMB gave emergency approval to reinstate Control Number 0938-0969 for six months, with Terms of Clearance. Specifically CMS was instructed as follows:

> When CMS renews this collection, the 60-day Federal Register notice will specifically seek public comments to inform the burden estimates associated with this collection. CMS will revise the burden estimate if public comments include persuasive data to suggest that the estimates are insufficient.[2]

The present request for comments has been published by CMS in order to extend this information collection beyond the six month approval.

II. Given the Broad Policy Implications, Codification of "Prepayment Review" Requires a Separate Rulemaking

OMB control number 0938-0969 was sought in conjunction with a September 26, 2008 CMS final rule entitled *Medicare Program: Termination of Non-Random Prepayment Review*.[3] As the title of the regulation describes, the final rule limits contractor behavior once a provider or supplier has already been placed on prepayment review, but does not establish the specific conduct of the prepayment review process.

We note that CMS does not acknowledge the final rule governing this control number but rather the Supporting Statement accompanying this control number relies solely on manual guidance not subject to formal notice and comment rulemaking.

In its Supporting Statement, CMS describes far reaching and broad medical review activities set forth in agency Program Integrity Manual (PIM) guidance rather

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[1] 76 Fed. Reg. 76737.
[2] *Notice of Office of Management and Budget Action,* OMB Control Number 0938-0969 (Mar. 19, 2012).
[3] 73 Fed. Reg. 55753.

than formal regulation. The following are some examples of broad policy cited by CMS in its Supporting Statement without properly undergoing a formal rulemaking process .

- CMS references contractors employing "data analysis procedures to identify claims that may be billed inappropriately" [4]but provides no specific detail as to how these "data analysis procedures" will be established.

- CMS states that prepayment medical review determinations "require the reviewer to make a clinical judgment about whether an item or service is covered",[5] thereby calling into question the role of the physician practitioner in the medical necessity process. Under this system, the physician's medical judgment is superseded and by a government contractor reviewer who has never treated or examined the beneficiary in question. Further, an error rate is assessed without any rebuttal opportunity by the physician. Often an error rate is assessed on a supplier even though the supplier relied upon the professional medical judgment of the treating physician.

- CMS authorizes a contractor to request supporting medical record documentation "[w]hen a contractor identifies a likelihood of sustained or high level of payment error." CMS references examples of a high level of payment error to include "unusual patterns such as prescribing the same items and/or services for a high number of patients, consistently prescribing inappropriate treatments, unexplained increases in volume when compared to historical or peer trends, or any other reasons as determined by the Secretary or their designees."[6] This broad authority, developed without any formal input from the public, suggests that a Medicare contractor could impose medical review on any company at any time for any reason. This lack of accountability and transparency is harmful to the Medicare population and companies that provide necessary and equipment and services to our nation's elderly and disabled.

CMS manual guidance is not sufficient authority to impose this significant burden on Medicare providers, suppliers and beneficiaries. The medical review process must undergo proper notice and comment as required by federal law.[7] Because these instructions have not been formally vetted through the rulemaking process, affected providers and suppliers have not been able to provide comments. Further, the PIM provisions are created by the agency and can be changed without any public notice or input.

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[4] *Medicare Fee-for-Service Prepayment Review of Medical Records,* Centers for Medicare and Medicaid Services, Supporting Statement Part A, CMS-10417, OMB: 0938-0969, 2 (Apr. 27, 2012).
[5] *Id.*
[6] *Id.*
[7] 5 U.S.C. § 553

III. The Documentation Requirements Underpinning "Complex Medical Review" Are Unclear and Unreasonable

Under the Paperwork Reduction Act (PRA), an agency must certify, and provide a record supporting that certification, that each collection of information submitted to the Office of Management and Budget "reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency"[8] and "is written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond."[9] Contrary to this clear statement from Congress, the "additional supporting documentation" proposed by CMS in this submission dramatically increases the burden on individuals participating in the Medicare program and create a paperwork requirement that the entities expected to participate do not comprehend.

The medical review process for this collection of information will require providers and suppliers to furnish a wide range of medical documents without ever fully defining their use. For example, CMS references the Program Integrity Manual definition of "additional documentation" in its Supporting Statement:

> The term "additional documentation" refers to medical documentation and other documents such as supplier/lab/ambulance notes and includes:
>
> - Clinical evaluations, physician evaluations, consultations, progress notes, physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation is maintained by the physician and/or provider.
>
> - Supplier/lab/ambulance notes include all documents that are submitted by suppliers, labs, and ambulance companies in support of the claim (e.g., Certificates of Medical Necessity, supplier records of a home assessment for a power wheelchair".
>
> - ***Other documentation include any records needed from a biller in order to conduct a review and reach a conclusion about the claim***.[10]

The additional documentation review inherent in medical review continues to be ambiguous and undefined. Medical documentation obtained as part of "complex medical review" that results in disagreements — between the CMS contractor clinical reviewers and the treating physician/practitioners — undermines the role of the treating

[8] 44 U.S.C. § 3506(c)(3)(C)
[9] 44 U.S.C. § 3506(c)(3)(D)
[10] *Verifying Potential Errors and Taking Corrective Actions,* Medicare Program Integrity Manual, Ch. 3 § 3.2.3.

physician and the purpose of the face-to-face examinations required for Medicare coverage of several items and services.

Further, this should not result in liability for suppliers who must rely upon the medical expertise of others. Congress provided a limitation of liability for suppliers when the supplier "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services…"[11] The current medical review" process is inconsistent with the statutory guarantee that suppliers can safely rely upon the reasonable judgments of the beneficiary's treating physician.

IV. CMS Discounts the True Burden Faced by Providers and Suppliers

CMS stated in October 2005 that the "burden associated with this action is the time and effort necessary for the provider or supplier of services to locate and obtain the supporting documentation for the claim to Medicare and to forward the materials for submission to Medicare contractors for review."[12] When the proposed rule was issued, CMS maintained that the burden would amount to ten minutes per case, only half as much as they now allocate.[13] CMS later stated "it will take the supplier or provider no longer than 20 minutes to locate, photocopy and transmit this information to the contractor upon request."[14] Despite comments received from providers stating the burden ranged from 30-185 minutes, CMS has elected to increase the burden estimate to 30 minutes.[15] CMS provides little explanation as to how this number was selected and clearly ignores the real burden associated with this collection of information.

Provided as an example, as highlighted in previous comments, these are burdens placed on providers and suppliers with regard to power mobility device (PMD) claims.

Burden on Physicians/treating Practitioners

TSS has worked with physicians/treating practitioners (and their staff) throughout the country. In consultation with medical professionals, nurses, and individuals familiar with the normal time burdens associated with the medical paperwork, we have previously estimated, and continue to estimate, the following burdens on physician offices regarding this collection of information:

1) The Face-to-Face Exam and Report

   Schedule appointment
   Nurse assessment prior to exam

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[11] 42 U.S.C. § 1395pp(a)(2)
[12] *Id.*
[13] *See* 70 Fed. Reg. 58652.
[14] *Medicare Program: Termination of Non-Random Prepayment Review*, Centers for Medicare and Medicaid Services, Supporting Statement CMS-6022-P(August 25, 2006)
[15] *Medicare Fee-for-Service Prepayment Review of Medical Records,* Supporting Statement Part A, CMS-10417, OMB: 0938-0969, 7.

See patient/exam
Write a face-to-face examination report
Discuss/decide mobility assist required
Evaluate appropriate equipment using national coverage determination (NCD) algorithm
Write detailed prescription

2) Preparation and Transmission of Additional Medical Records

Research medical record and files for relevant information
Copy pertinent portions of medical record
Redact records in order to ensure HIPAA compliance
Prepare HIPAA compliant fax cover sheet
Send fax

This analysis indicates that the physician/treating practitioner burden associated with this collection of information would take several hours.

Burden on Suppliers

The Medicare PMD regulation imposes significant collection, review and recordkeeping burdens on suppliers which are greatly underestimated by CMS. The collection activities required of suppliers include the following:

- Intake process: Establishing patient files and basic Information
- 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 if medical records are silent or unclear on coverage elements.
- Requests for additional information
- Storage of documents collected

We estimate the timeframe to collect, review and store medical records to be roughly 2.5 hours for each PMD claim. These calculations are based on actual operations and a history of responding to documentation requests from CMS contractors. In addition to this timeframe, denied claims result in a lengthy and costly appeals process impacting Medicare providers/suppliers/beneficiaries and the entire Medicare program.

V. RECOMMENDATIONS

Prior to approval of any medical review collection of information, 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, treating practitioners beneficiaries and Medicare Part B suppliers to iron out the specific information that must be retained to

document the claims subject to this collection of information. An efficient documentation and recordkeeping process would reduce unnecessary costs while ensuring quality health care for our nation's elderly and disabled.

VI. CONCLUSION

Based on the foregoing, we respectfully request that CMS immediately withdraw this collection of information. Should the agency continue to seek OMB approval, we contend that OMB must deny the agency's request to ignore necessary rulemaking procedures under the Administrative Procedure Act.

Very truly yours,

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Eastwood & Azia, PLLC
Counsel to The SCOOTER Store

cc: The SCOOTER Store
Valerie J. Eastwood, Esq. (firm)

Via Electronic Submission
http://www. regulations.gov

June 26, 2012

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Policy Analyst
Office of Management and Budget
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725 17th Street NW
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Re: **Medicare Fee-for-Service Prepayment Review of Medical Records**
CMS-10417, OCN: 0938-0969

Dear Ms. Dooling:

The American Association for Homecare (AAHomecare) submits the following comments on the Centers for Medicare and Medicaid Services' (CMS) request for Office of Management and Budget (OMB) approval of the above referenced information collection request (ICR). CMS' Paperwork Reduction Act (PRA) submission states that the collection is required for the Agency and its contractors to perform prepayment review of claims submitted for Medicare payment. OMB has requested comments on the collection, especially with respect to the necessity, utility, and burden of collection.

AAHomecare represents durable medical equipment (DME) providers, manufacturers, and others in the homecare community that serve the medical needs of millions of Americans who require oxygen systems, wheelchairs, medical supplies, inhalation drug therapy, and other medical equipment and services in their homes. Members operate more than 3,000 homecare locations in all 50 states. In light of our members' expertise and experience, AAHomecare is uniquely qualified to comment on the request for OMB approval of the ICR.

AAHomecare strongly supports vigorous program integrity actions to protect Medicare and its beneficiaries. We agree that Medicare must be vigilant to ensure that benefit dollars are not diverted to abusive or fraudulent providers. The Social Security Act (SSA) requires the Secretary

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to pay only for covered items and services that are "'reasonable and necessary' for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]"[1] While the statute gives the Secretary the discretion to determine what is "reasonable and necessary," she is nonetheless bound by the procedural and substantive laws and rules, such as the PRA, that temper what could otherwise result in unfettered administrative power. The underlying purpose and goals of the PRA are to minimize the burden of paperwork requested by or for the Federal government.[2] To that end, the law requires that all paperwork collections requested by agencies or their contractors be approved by OMB.

In this case, AAHomecare recognizes CMS' authority to identify and correct improper payments or fraudulent activity. However, the manner in which the Agency has exercised that authority in the recent past runs counter to the standards established by the PRA, especially with respect to the burden imposed on providers by the prepayment review activities of CMS and its contractors. We discuss our concerns in more detail below.

I. Background

CMS may contract with others to administer Medicare program functions such as processing and paying claims. Medicare Administrative Contractors (MAC) pay claims, develop local coverage determinations (LCD), offer provider education, and perform complex medical reviews to identify and recover overpayments. MACs are third-party administrators who perform the routine administrative tasks necessary for the day-to-day operation of the program. CMS also engages other contractors in more targeted roles to perform Medicare Integrity Program (MIP) activities. These contractors, known as Medicare Integrity Contractors (MIC), have a narrower scope of work.

CMS' authority to engage Medicare contractors is based on different provisions of the SSA depending on the contractor's scope of work, but all of the contractors can perform complex medical reviews to carry out their duties. Zone Program Integrity Contractors (ZPIC), Program Safeguard Contractors (PSC), and DME MACs conduct both pre- and post-payment audits. Prepayment audits are especially burdensome because they have the potential to stifle a provider's cash flow, jeopardizing its solvency and ability to care for patients.

II. CMS Grossly Underestimated the Collection Burden of Prepayment Complex Medical Review

Contractors may conduct service-specific prepayment complex medical review when they have evidence of a high level of payment errors associated with a Medicare-covered service. If the contractor identifies a provider problem, it has the ability to put the provider on provider-specific prepayment complex medical review. Complex prepayment medical review means that

[1] §1862, Social Security Act.
[2] 44 U.S.C §3502(3).

the contractor requests additional documentation to support a claim after the claim is submitted but before payment is made. This documentation includes physician and/or inpatient medical records and copies of test results as well as physical therapist (PT) or occupational therapist (OT) assessments.

Contrary to the assertion in the Agency's submission, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) providers are not required to and do not typically collect this type of detailed medical documentation at the time they initiate service. Except for a small number DMEPOS items, providers may deliver a DME item to a beneficiary based on the physician's verbal order. Providers must have an appropriate written order in their files before submitting the claim to Medicare. This long-standing policy strikes a balance between a beneficiary's need to receive equipment quickly and the Agency's need to protect Medicare monies. Simply stated, providers do not get paid unless they have a valid written order when they submit a claim to Medicare.

Consequently, most providers will have basic medical documentation to support a claim but not the extensive documentation required for complex medical review. This is an important point because contractors cannot deviate from LCD and national coverage determination (NCD) documentation requirements in an audit. What this means is that providers must document in nearly implausible detail every element of the coverage criteria in an LCD. Some contractors have even requested documentation for ancillary LCD provisions that in themselves do not affect coverage for the DMEPOS item. CMS' submission estimates that the time and cost burdens for collecting this information is no more than 30 minutes per claim at an hourly rate of $16.83 plus taxes and benefits for a total of $33.66. The estimate grossly underestimates the time and money burden of CMS' current strategy of conducting widespread service-specific or provider-specific prepayment complex medical reviews.

As we noted above, CMS' estimates assume that providers have on hand the type of detailed medical record documentation required to defend a claim in an audit. Not only is the information not immediately available to providers, who must call multiple facilities and practitioners to obtain it, but providers must also take time to ***review*** the records in order to confirm that they satisfy the documentation burden imposed by the contractors. Moreover, because most conditions treated with DME are chronic and long term, providers often have to search a patient's entire medical history to locate records that meet the burden given that many LCDs require evidence that "other treatments have been tried and failed."

Further, CMS has embarked on a program of aggressive prepayment complex medical review, especially for DMEPOS, such that the prepayment reviews are ***routine*** in all four DME MAC jurisdictions. This means that service-specific widespread prepayment reviews often overlap with provider-specific prepayment reviews in any given DME MAC jurisdiction at any given time. It is also important to remember that providers ***do not get paid*** if a claim is denied in a prepayment review even though the beneficiary received and is using the equipment. The provider's recourse is to appeal the denial, a process that can take a year or more. So in

addition to other costs, the cost of the outstanding receivables must be included in the Agency's burden estimates. Our members report that, at a minimum, an accurate time burden would be two hours to collect, review, organize, and send in the documentation at total cost of $ 67.32.

The cost and time burden associated with these audits escalates when the ZPIC contractors perform the audit. It is not uncommon for the ZPIC to impose 100% prepayment complex medical review on providers. This means the providers bear the cost and time burden of responding to the review and the added burden of having little or no cash flow to support its operations and – most importantly – patient care. While it may be possible for very large providers to weather this burden for a time, we are aware of many small providers who have closed their business because of the financial burdens created by these reviews.

III. The Paperwork Collection Does Not Enhance the Quality or Utility of the Information

AAHomecare recognizes that the Secretary has the authority to perform pre- and post-payment complex medical reviews and that they can be a useful tool to identify and correct instances of incorrect payment. However, the Agency's aggressive strategy of widespread prepayment reviews calls into question the necessity and utility of the information providers are required to collect. The following examples highlight this point:

The DME MACs audit the same patient's claims for the same piece of equipment repeatedly over the course of the rental period even though the claim has been audited and paid in full in a preceding rental month. Because DME is paid on a monthly fee schedule, providers submit consecutive monthly claims for the item during the rental period. Although a beneficiary's claim was audited and paid early in the rental period, contractors will continue to audit that beneficiary's claims for the remainder of the rental period.

There is no consensus on the documentation required to support medical necessity among the contractors. Contractors frequently change the standards providers must meet in order to document medical necessity. These changes are announced in informal forums such as website bulletins or contractor conference calls without notice to providers based on the contractor's assertion that the change is a "clarification" not a "modification" of existing standards.

Providers are required to recreate existing documentation that may already be a part of their files when coverage for a patient's equipment transfers from private insurance to Medicare. One example is that providers must have "proof of delivery" for the equipment they furnish to a beneficiary. If the beneficiary received the equipment before enrolling in Medicare, the contractors require a new proof of delivery as of the date of enrollment – even though the equipment was delivered to the beneficiary before then. Practically, the only ways to accomplish this are to either "make-up" a new delivery ticket with a different date, or pick-up the equipment and "re-deliver" it as of the Medicare enrollment date. Either way, the provider

has to make a costly and wasteful trip to the beneficiary's home to document something that is already in their files.

Providers are required to submit extensive medical necessity documentation when the prepayment complex medical review in fact audits only compliance with "technical" documentation requirements. In an effort to meet CMS' targets for increased prepayment reviews, contractors are performing "technical" reviews that focus on whether the documentation the provider submits conforms to the technical requirements of an LCD, not whether it supports medical necessity. However, providers are nonetheless required to submit voluminous records to show medical necessity for the claim under review. In an over-simplified example, if an LCD requires the provider to have an order, the contractor looks for the order but does not assess whether the order shows the beneficiary's medical need for the equipment. If the order is present, then the contractor approves the claim. Because providers do not know this beforehand, they must submit the level and quality of records that would otherwise support prepayment complex medical review.

ZPIC audits that should be used to address fraud and abuse are deployed for routine matters such as patient complaints or small dollar value claims. We have an example where the ZPIC made an audit request for an item that is not even covered by Medicare.

Providers are required to obtain either an attestation or signature log when a physician's signature is Illegible on a document and the physician's name is not printed on the document even though all other documentation submitted in support of the claim in fact bears the physician's printed name and the signature matches the signature on the order. Cleary, if all the other documentation submitted by a provider identifies the physician, they should not have to jump through hoops to obtain physician signature attestations.

III. Conclusion

CMS must do a better job of improving its prepayment complex medical review process in order to reduce the burden associated with audits and improve the quality and utility of the information its contractors collect. OMB should require CMS to implement a process to accomplish this before it approves the ICR under review. To this end, we recommend:

- Require contractors to develop, officially publish, and adhere to consistent documentation standards that apply prospectively in the four DME MAC jurisdictions.
- Require contractors to request only the level and quality of information necessary to perform a review.
- Require contractors to implement procedures to prevent repeat audits of a beneficiary's claims for the same piece of equipment.

- Allow contractors to rely on documentation available in a provider's records to verify physicians' signatures or proof of delivery.

We appreciate the opportunity to submit these comments. Please feel free to contact me if you have any questions or comments regarding the above.

Sincerely,

Walter J. Gorski
Vice President of Government Affairs

Federation of American Hospitals

Charles N. Kahn III
President and CEO

June 26, 2012

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RE: Agency Information Collection; Centers for Medicare & Medicaid Services; Medicare Fee-for-Service Prepayment Medical Review; CMS-10417; 77 Fed. Reg. 25181

Dear Ms. Jones:

The Federation of American Hospitals ("FAH") is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States, providing a wide range of ambulatory, acute and post-acute services. Our members include teaching and non-teaching, short-stay community hospitals in urban and rural America, as well as inpatient rehabilitation, psychiatric, cancer and long-term care hospitals. We appreciate the opportunity to comment to the Centers for Medicare & Medicaid Services ("CMS") regarding the information collection governing the Medicare Fee-for-Service Prepayment Review of Medical Records.

The FAH and its members are strongly committed to and share CMS' goal of protecting the Medicare trust fund from vulnerabilities and reducing the payment error rate. However, as previously stated in comments submitted regarding the Recovery Audit Prepayment Review Demonstration, the FAH questions the efficacy of prepayment complex medical review for hospital services as a means to achieve this goal. The Supporting Statement notes that, "The priority for Medicare Administrative Contractors (MACs) is to minimize potential future losses to the Medicare Trust Funds through targeted claims review while using resources efficiently and treating providers and beneficiaries fairly." It is unclear how prepayment review of over two million claims at a cost of nearly $34 million (as stated in the Supporting Statement Summary

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Table: Annual Burden Estimate & Cost) is deemed an efficient use of resources for both the Medicare Program as well as providers, or how this burden is viewed as fair to providers.

Targeting Review - CMS must ensure that the scope of MAC prepayment review of hospital claims is limited and carefully targeted to circumstances and providers where "aberrant billing patterns or other information that may present a vulnerability to the Medicare program" has been identified. MACs must be transparent regarding the methods and standards applied to determine where aberrant billing patterns have been discovered.

In addition, the FAH opposes across-the-board pre-payment reviews of certain MS-DRGs as they do not distinguish providers who have put in place significant safeguards and processes to comply with coverage, coding and documentation guidelines. Permitting MACs to apply prepayment review only to those providers whose data is suggestive of aberrant billing patterns is an appropriate and efficient way to reinforce CMS' policy without creating unnecessary burden on all providers and penalizing those who have strong compliance programs in place.

Transparent/Consistent Review Standards - Furthermore, the standards used by MACs for pre-payment review must be transparent to providers and open to comment. Currently, the MACs set their own criteria for documentation required to support payment. For example, in the case of many MS-DRGs subject to pre-payment review, there is no National or Local Coverage Decision or Medicare program manual provision that governs the documentation necessary for coverage. NCDs and LCDs are required to be posted in draft form, and providers may comment on the standards before they are finalized and published, giving providers time to develop compliance programs to adhere to the requirements before they go into effect.

For example, we are aware of one MAC that denied a significant number of joint replacement surgery claims because the hospital medical record did not contain sufficient documentation of failed prior conservative treatment despite the fact that such a requirement is not contained in a NCD nor does this MAC have a joint replacement LCD. While we recognize that failing prior conservative treatment is a logical pre-cursor to any surgery, this information may be contained in the physician office records or in the records of an initial treating physician, physical therapist or other provider who referred the patient for surgery but who does not document in the hospital medical record because that provider is not part of the surgical team. Our members have been advised that a summary statement from the surgeon that the patient failed prior conservative treatment is not sufficient. Hospitals are then faced with a difficult decision: to proceed with the procedure and risk non-payment or to refuse to schedule the procedure until the documentation is gathered, potentially delaying or denying care to beneficiaries who did receive prior conservative treatment.

CMS must put in place measures that provide consistency among the reviews performed by their MACs. Our providers have experienced a wide variance in the denial rates for the same services by different MACs. For example, for the same MS-DRG, we are aware of one contractor denying approximately 82% of the claims requested, while another contractor denies only 29%. While there may be some variance by region, it is unreasonable to believe that provider practice varies to this extent.

MAC Accountability - CMS must enforce the Program Integrity Manual requirement that MACs track appeals and take corrective actions when claims are routinely reversed on appeal. Continuing to perform pre-payment review on services that are routinely reversed on appeal is not an efficient use of resources for the Medicare Program or providers. Since the MACs compute the claims error rate prior to appeal, a provider can be placed on continued pre-payment review without regard to the fact that claim denials may be overturned on appeal, effectively lowering the error rate. This is inefficient, subjects the provider to unnecessary reviews, and creates more work for both providers and Contractors.

Information regarding prepayment reviews should be made public by all MACs. This information should include the services under review (MS-DRGs), as well as the percentage of claims reviewed, selection criteria and review outcomes. This will help improve program accountability and provider trust regarding the equitable application of pre-payment review. There is currently a wide variation in the amount of information published by MACs regarding their pre-payment reviews. Some MACs are very diligent, publishing the MS-DRGs under review, the selection criteria, percentage of claims reviewed and denial percentages while others do not have any information published. We also anticipate that there will be confusion for both providers and contractors as to the prepayment reviews being performed by RACs and MACs. We witnessed this confusion when the demand letter process moved from the RAC to the MAC. To assist providers in properly responding and tracking these reviews, distinct reason codes must be used by each contractor. In addition, prepayment reviews should be clearly distinguished from all the other types of reviews that contractors typically conduct.

CMS must ensure that the credentials of those individuals performing reviews at the MACs are sufficient to conduct credible medical necessity determinations. Providers have received medical necessity denials from MACs that appear to have been performed by a non-physician. A non-physician, even a registered nurse, lacks the credentials to make broad medical necessity determinations. It is also inconceivable that the MACs have adequate and appropriately trained staff, including physicians and non-physicians to manage the increasing number of reviews and appeals.

Record review limits - CMS has not set forth any restrictions regarding a limit to the number of records that can be requested by a MAC for prepayment review. Other review programs, such as those performed by RACs, do have such limits. CMS must limit the number of records that can be requested from a single provider and should take into account the various concurrent review programs to which a provider may be subject.

Hospital cash flow/costs – Pre-payment reviews substantially stretch out the payment period and negatively affect hospital cash flow. Providers submitting proper claims are penalized by a delay of up to 60 days while waiting for completion of the medical record review by the MAC. Cash flow concerns combined with the fact that hospitals generally experience a high rate of success in appealing payment denials demonstrate that for hospitals, prepayment review must be the exception, rather than the rule. Given the long appeal process and the delays hospitals are experiencing with contractors adhering to the appeals response timeframes, cash flow could become an even greater concern. MACs are already overwhelmed with first level

appeals from the RAC program. The addition of pre-payment reviews will only add to this burden, which has been openly acknowledged by CMS contractors.

The Supporting Statement estimates the average time for a provider to respond to medical record requests to be 30 minutes, at an average hourly rate of $16.83, and a loaded rate of $33.66. To the extent pre-payment reviews are not targeted to those potentially problematic providers, some of these costs will be borne unfairly by compliance-minded providers. According to industry statistics on RACs, 55% of all hospitals spent more than $10,000 in the first quarter of 2012 managing the RAC process. Another third spent more than $25,000. Hospitals also reported that the time devoted to managing the demanding RAC process is increasing, a burden that the addition of prepayment review will certainly exacerbate.

CMS should consider reimbursing providers for medical records selected as part of MAC pre-payment reviews. Reimbursement is provided as part of the RAC permanent program and the process of submitting records is no different for MAC prepayment reviews.

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Thank you for the opportunity to provide these comments. If you have any questions or need further information, please contact me, Jeff Micklos, or Steve Speil of my staff at 202-624-1500. We would welcome an opportunity to discuss them with you.

Sincerely,

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Docket: CMS-2012-0054
Medicare Fee-for-Service Prepayment Medical Review (CMS-10417)
Comment On: CMS-2012-0054-0001
Medicare Fee-for-Service Prepayment Medical Review (CMS-10417)
Document: CMS-2012-0054-0002
NY

Submitter Information
Name: Christopher Sullivan
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General Comment
For any program to improve itself, it must constantly be monitoring it's performance. For a program like Medicare Advantage, the only true way to measure performance is to measure these types of health metrics. However, the whole program must be standardized under these metrics. The data is not particularly useful if it is spotty around the country. Ture action can only be taken if these metrics are agreed upon and measured through a long period of time. Only then can the program improve itself to provide the best care possible to the public.

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June 26, 2012

VIA ELECTRONIC DELIVERY:
http://www.regulations.gov

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10417 (OCN 0938-0969)
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Comments on Form Number CMS-10417 (OCN 0938-0969):** Agency Information Collection Activities: Proposed Collection; Comment Request

COMMENTS ON THE 30-MINUTE BURDEN ESTIMATE FOR PREPAYMENT REVIEWS

Dear Sir or Madam:

We write on behalf of Hoveround Corporation ("Hoveround" or "Company") to provide our comments to the referenced information collection activities by the Centers for Medicare & Medicaid Services ("CMS" or the "Agency") for Fee-for-Service Prepayment Medical Review.[1] Hoveround is a leading manufacturer and longstanding Medicare supplier of power wheelchairs, a benefit that has been the subject of heightened scrutiny by the Agency, including prepayment reviews. The Company addresses in this comment letter its experiences with the amount of time necessary to respond to Additional Documentation Requests ("ADRs") by suppliers of power mobility devices ("PMDs"), which has been profoundly underestimated in CMS's Supporting Statement.

Because CMS cross-references this prepayment review collection in its estimates of the burden anticipated for the Agency's proposed demonstration on PMDs (scheduled to be launched this summer), Hoveround at this juncture believes it is necessary to underscore that the burden for suppliers of PMDs in fact is quite substantial. The 30-minute estimate identified by CMS for prepayment reviews simply does not adequately take into account the efforts required by suppliers to review ADRs, train personnel to respond, obtain documentation (including medical records from sources other than ordering physicians

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[1] *See* CMS, *Agency Information Collection Activities: Proposed Collection; Comment Request*, 77 Fed. Reg. 25181 (April 27, 2012) ("PRA Notice"); CMS, Supporting Statement, Part A, Medicare Fee-For-Service Medicare Fee-for-Service Prepayment Review of Medical Records (CMS-10417; OCN: 0938-0969) (April 27, 2012) ("Supporting Statement"), *available at* http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS1254586.html.

and providers), and ensure the completeness of the documentation before transmitting their responses to Medicare contractors. For the reasons addressed more fully in this comment letter and Attachment A, Hoveround therefore requests that the Agency revisit and modify its estimates, including, if appropriate, separating the burden estimate for suppliers of PMDs, who, unlike clinics and hospital providers (to name a few), often must seek additional documentation and other information not only from other providers—that is, from the ordering physicians or practitioners—but also from other sources that would not typically transmit such documentation to the PMD supplier during the ordinary course of ordering PMDs.

CMS Must Objectively Re-evaluate the Burden Estimate for Suppliers of PMDs

This collection, as CMS notes in its notice for comments, is for an extension of OMB's 6-month approval; specifically, OMB's 6-month approval terms required the Agency to "specifically seek comments to inform the burden estimates" for prepayment reviews and "revise the burden estimate" in light of persuasive data in public comments.[2] Prior to submitting the collection of information request to OMB for an extension, the Paperwork Reduction Act ("PRA") requires CMS to establish a specific, objectively supported estimate of the burden associated with the collection.[3] CMS has already increased its estimates from 20 to 30 minutes. This revised estimate, however, is the lowest amount of time previously submitted by commenters. The range commenters identify is 30 to 185 minutes, which is based on the burdens experienced by all commenters, not just those who rely on medical records that must be maintained by other entities for much of the documentation requested during prepayment reviews.

First, we believe that CMS should select some weighted median rather than the very lowest time estimate submitted by commenters. Moreover, we believe CMS should address PMD burdens separately from the prepayment review experienced by other suppliers and providers. Hoveround's experience has been that the amount of time needed to evaluate and respond to ADRs for PMD claims is about six times the 30-minute estimate. This is because the current practice by the four Durable Medical Equipment Medicare Administrative Contractors ("DMACs"), as well as other contractors conducting reviews, has been to require substantially more medical record documentation than the supplier is required to maintain under the four corners of the local coverage determination ("LCD") for PMDs. The LCD documentation requirements remain some of the most onerous documentation requirements for a Medicare device benefit, yet the expectation during a record review is that the supplier collect and submit substantial *additional* information, including medical records not only from physicians, providers and other entities that have ordered the PMD—as identified by the LCD—but also from providers that treated and/or diagnosed the patient. Most notably, the LCD requires that before a claim is submitted, a report of the face-to face examination is obtained from the ordering physician. During the ADR process, the DMACs expect medical record documentation to include more than that single report; suppliers responding to ADRs must submit a longitudinal picture of the beneficiary's medical history. The expectation is that the ordering physician or practitioner provides additional medical records of prior treatment for the beneficiary's condition and the supplier would gather documentation from other providers' medical records as well. For most claims undergoing ADR, the supplier therefore must make multiple telephone calls to the ordering physician's office and other providers to gather additional information from all relevant sources. Simply, because the documentation sought during ADRs generally is not otherwise routinely submitted to the supplier during the ordinary process of information sharing (*i.e.*, information

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2 OMB, OIRA Conclusion, Medicare Fee-for-Service Early Review of Medical Records, OMB Control No. 0938-0969 Terms of Clearance (Mar. 19, 2012), available at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201112-0938-008 ("When CMS renews this collection, the 60-day Federal Register notice will specifically seek public comments to inform the burden estimates associated with this collection. CMS will revise the burden estimate if public comments include persuasive data to suggest that the estimates are insufficient.")

3 *See* 44 U.S.C. § 3506(c)(1)(A)(iv); 5 C.F.R. § 1320.8(a)(4).

submitted to the supplier within 45 days of the face-to-face examination), the time spent gathering additional information is substantial.

The Agency's proposed estimate of the burden—30 minutes—is supported by the statement that "CMS previously estimated it will take the provider or supplier on average no longer than 20 minutes to locate, photocopy and transmit this information to the contractor upon request" and that the 20 minutes is being increased to 30 minutes "to account for increased emphasis of inpatient hospital claims, for which the medical records are typically large."[4] This breakdown does not take into account a supplier's processing time to review the Medicare contractor's request or some of the other steps associated with a typical review, including the "additional documentation" collection described above. Indeed, the PRA regulation CMS itself cites in its Supporting Statement provides that the "burden" includes reviewing instructions, collecting, validating, training personnel and searching data sources.[5] One example of some of these steps is the "Quick Resource Tool" developed by CGS Administrators, LLC for home health and hospice claims undergoing Medicare reviews. The contractor's tool recognizes tasks not otherwise described by CMS, including a review of the request for additional documentation, evaluating the documentation to ensure completeness, and the monitoring of the entire process, among other things.[6] Although the CGS document does not identify a time associated with each step, it does outline a multi-step approach for certain groups of claims undergoing development (home health and hospice claims).

CMS acknowledges that there would be "great variation" for completing the required tasks depending on the type of claim, but the Agency otherwise minimizes or disregards outright the variations in deriving a single burden estimate.[7] Specifically the Agency acknowledges that supplier claims may require additional involvement from providers who ordered the item being dispensed; yet, without offering any further rationale, CMS concludes that the additional collection was taken into account when the 30-minute estimate was derived: "The information being collected already exists in the medical record when the provider ordered an item or performed a medical service for the beneficiary they were treating."[8] An objective analysis must explore the respective responsibilities of suppliers and physicians and other practitioners or providers that create and maintain medical records. At Attachment A, Hoveround's list of the tasks and associated time frames based on its experience with gathering, examining, copying and submitting documentation during the prepayment review process. We urge the Agency to examine carefully the tasks in that attachment, which shows the specific burdens placed on specialty suppliers—that is, suppliers that rely on physicians, other practitioners and providers to create and maintain medical record documentation.

Only An Objectively Derived ADR Burden Estimate for Suppliers of PMDs May Be Crossed-Referenced for the Proposed PMD Prior Authorization Burden Estimate

Far from being an objectively-supported estimate of the burden of all prepayment reviews, the CMS estimate relies on the lowest amount of time of previous commenters a prepayment review burden estimate that OMB recently singled out for further examination and comment. We are particularly concerned with the use of a lowest common denominator approach because of the ramifications not only with the issue at hand—the burden associated with prepayment reviews—but also the cross-reference included in the burden estimate for CMS's currently-proposed demonstration PMD prior authorization demonstration. For that demonstration, there remain many unknown tasks. CMS nonetheless estimated a

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4 CMS Supporting Statement at p.7.

5 *See* Supporting Statement at p.7, *citing* 5 C.F.R. § 1320.3(b)(1).

6 *See* http://www.cgsmedicare.com/hhh/medreview/adr_process.html.

7 *See* CMS Supporting Statement at p.7.

8 CMS Supporting Statement at pp.7-8.

30-minute burden for the submitter of a prior authorization request. Even assuming that the burden on suppliers submitting a prior authorization request is the same as the prepayment review burden, there can be no question that the 30-minute estimate is flawed. This is demonstrated both through Hoveround's own experience and through recent surveys undertaken by American Association for Homecare, which show the prepayment review process to be closer to 82 minutes for standard wheelchair claims and 92 minutes for complex wheelchair claims.

We respectfully urge the Agency to consider this submission as it deliberates to meet the PRA requirement of providing an objectively supported estimate of the burden.

* * *

Thank you for considering Hoveround's comments regarding the Agency's proposed information collection. Should you have any questions or comments, please feel free to contact me at 202-637-2169.

Sincerely,

Stuart S. Kurlander/ERS

Stuart S. Kurlander
of LATHAM & WATKINS LLP

cc: Hoveround Corporation
Esther R. Scherb, Latham & Watkins LLP
Eric C. Greig, Latham & Watkins LLP

ATTACHMENT A

Comments on CMS-10417 (OCN 0938-0969)
Time Burden Estimate for Suppliers to Complete Additional Document Request

Activity	Activity Description	Time in Minutes
Process Receipt of ADR Letter	Time/date stamp letter, log receipt of letter into patient's electronic file, image a copy of the letter into the patient's electronic file, assign work activity to staff.	15
File Preparation	Create paper chart and print all documents in patient's file including written order, progress notes, other medical documentation, Detailed Product Description (DPD), Delivery Ticket, Assignment of Benefits, Home Evaluation, Home Safety Survey, Capped Rental Agreement, 1500 Form, and product brochures.	15
Clinical Reviews	Clinician on staff reviews all documentation in the chart. Outline additional physician requests for supporting documentation.	15
Contact other Health Care Providers for Supporting Documentation	Clerical staff contacts physician and other health care providers seeking additional supporting documentation. (Average of 5 telephone calls placed lasting an average of 10 minutes each.)	50
Process Receipt of Additional Supporting Documentation	Log receipt of documentation into patient's chart, image a copy of the documentation into the patient's electronic record, insert copy of additional documentation into paper file.	10
Detailed Clinical Review	Conduct extensive chart review including creation of a letter outlining the PMD algorithm and the supporting documentation contained in the patient chart.	60
Prepare ADR Packet for Mailing to Contractor	Image a copy of the completed ADR packet into the patient's electronic medical record, document completion of the process in the notes, create mailing envelope including mail tracking receipt, document tracking number in the patient's file.	20
	TOTAL MINUTES	185