



April 28, 2015

William N. Parham, III
Director, Paperwork Reduction Staff
Center for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier CMS-1696/CMS-10417
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Paperwork Burdens Associated with Prepayment Medical Review

Dear Mr. William N. Parham,

The American Association for Homecare (AAHomecare) submits the following comments regarding the Centers for Medicare and Medicaid Services' (CMS) request for Office of Management and Budget (OMB) approval of a collection of information. 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.

AAHomecare is the largest national association representing durable medical equipment (DME) suppliers, manufacturers, and others in the homecare community. Our members 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. In light of our members' expertise and experience, AAHomecare is uniquely qualified to comment on the request for OMB approval of the proposal.

The underlying purpose and goals of the PRA are to minimize the burden of paperwork

requested by or for the Federal government.¹ To that end, the law requires that all paperwork collections requested by agencies or their contractors be approved by OMB. AAHomecare recognizes CMS' authority to identify and correct improper payments and 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 suppliers by the prepayment review activities of CMS and its contractors. We discuss our concerns in more detail below.

I. CMS underestimated the collection burden of prepayment complex medical review.

A. Prepayment medical reviews are a cost containment strategy, not a fraud prevention tool.

AAHomecare questions CMS' rationale that contractors use prepayment reviews as a way to target suppliers and providers that present a vulnerability to the Medicare program. CMS' indicates that prepayment reviews are the result of contractor data analysis that identifies suppliers and providers with suspicious billing patterns. DME MAC contractors perform widespread probe prepayment reviews that are not supplier specific and would not indicate that an individual DMEPOS supplier has engaged in suspicious or aberrant billing. These widespread probe reviews target a HCPCS code and not individual suppliers. Although data analysis might suggest that a specific HCPCS code may have seen an increase in utilization, probing widespread payment reviews targeting HCPCS codes does not, by itself, indicate wrong doing by individual suppliers or providers. Therefore, not all prepayment medical review is a response to fraud or abusive behavior by suppliers or providers.

The comments suggest that prepayment review is primarily a fraud prevention strategy. Although prepayment review can be a fraud prevention strategy, CMS currently uses prepayment reviews as a cost containment strategy. The Agency deploys these audits aggressively, 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 supplier-specific prepayment reviews in any given DME MAC jurisdiction at any given time.

The cost and paperwork burden of routine prepayment reviews far exceed the estimates CMS puts forth in its submission to the OMB. AAHomecare believes that the time and financial burden of responding to CMS prepay reviews will increase dramatically if the Agency increases the number of prepayment audits as it proposes to do.

¹ 44 U.S.C §3502(3).

B. CMS cost estimates must include the compliance and documentation costs that are necessary for responding to prepay reviews.

DMEPOS suppliers are different from other Medicare providers because Medicare pays for most DMEPOS items as recurring rentals or on-going purchases of supplies. Beneficiaries typically receive DMEPOS as part of an ongoing service, not a distinct episode of care. The documentation suppliers collect when they initiate service applies to claims that can span for as long as 60 months or the remainder of a patient's life. There are additional tasks required to respond to a prepay audit that are specific to DMEPOS suppliers. We are outlining those steps with a time estimate below. Although CMS suggests in its time estimates that the documents themselves are easily accessible (assuming a supplier has a copy of the beneficiary's medical records in his or her files), responding to prepayment reviews requires far more than simply printing or gathering documents and faxing or sending them electronically. The DMEPOS supplier must begin to prepare for prepayment audits, well before he or she even submits a claim. Often, the first (and typically recurring step) thing suppliers do is educate physicians about Medicare requirements. Our members report that they must perform the following steps as part of every Medicare prepayment audit:

1. **[45 minutes]** Prior to delivery, educate physician/referral source regarding the documentation that will be required to provide service to include. Education includes, but is not limited to:
 - a. The need for clear and legible chart notes from face-to-face visit substantiating necessity for equipment and/or supplies prescribed.
 - b. The requirements of a Detailed Written Order Prior to Delivery (DWOPD) for items that fall under the Affordable Care Act (ACA), making sure all required elements are present.
2. **[2 minutes]** Open request from physician and date stamp receipt date.
3. **[5 minutes]** Log audit request into master tracking sheet, including dollars for each item, location, service, etc.
4. **[5 minutes]** If the audited claim is a rental item, place the equipment on hold until the audit is resolved and notate in record that audit was received.
5. **[30 minutes]** Gather documents that support service.
 - a. Pull electronic signature protocol for any claims with ESOF signatures (electronic signature on file).
 - b. Pull proof that sleep physician is properly certified for interpretation of study (supplier already knows they are certified at time of delivery, but Medicare requires proof in an audit response).
 - c. Download copy of compliance.
 - d. Depending upon service rendered, proof of make, manufacturer and model via MSRP sheets from manufacturer.
 - e. Organize documents and prepare submission.
6. **[10 minutes]** Upload and send audit electronically or via fax.
7. **[10 minutes]** Audit response....research each audit to determine if paid or denied.
 - a. **[10 minutes]** If paid...release remaining claims and update notes

- b. **[45 minutes]** If denied...evaluate denial and respond appropriately
 - i. Contact carrier for error issues
 - ii. Submit redetermination appeal if necessary

Account remains on hold and no subsequent rentals/sales bills will be transmitted **Total time range 120-152 minutes depending upon /resolution of audit for ONE CLAIM**

In addition, our members reported to us their concerns about CMS' proposal to add new contractors to conduct prepay audits. AAHomecare believes this portion of the PRA submission contractors is unclear. Will these new contractors perform prepayment reviews for prior authorization? If so, CMS should refer to the guiding principles for a successful prior authorization program that we outlined below. If performing prior authorization will not be the role of these new contractors, how will CMS train and deploy them so that AAHomecare members are assured that the contractors will be able to accurately review DMEPOS medical necessity documentation as documentation varies widely between companies and is not standardized in any way?

C. CMS must factor in the cost of audited claims pending appeals under the current appeals backlog.

Suppliers do not get paid if a claim is denied in a prepayment review even though the beneficiary received and is using the equipment and receiving ongoing supplies or medications. In these circumstances, typically suppliers' only recourse is to appeal the denial. Since 2010, the number of Medicare appeals has grown exponentially that it takes a minimum of 28 months for an appeal at the administrative law judge (ALJ) level of appeal to be docketed and assigned to an ALJ. AAHomecare estimates that it could take as long as four years for an appeal of an improperly denied claim to be decided. In addition to the long waiting periods, suppliers must continue to service the patient while appeals are pending without a certainty that they will be reimbursed.

II. CMS documentation and medical review policies require suppliers to respond to repetitive, duplicative additional documentation requests and to create unnecessary information with little to no utility in a prepay medical review.

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 whether or not the information/documentation that suppliers are required to obtain is truly necessary to collect. The following examples highlight this point:

The DME MACs audit the same patient's claims for the same piece of equipment which relies on the same medical documentation repeatedly over the course of the rental period, supply or medication medical necessity period even though the

claim has been audited and paid in full in a preceding month. Because DMEPOS is paid on a monthly fee schedule, suppliers submit consecutive monthly claims for the item, supply or medication during the period of medical need. Although a beneficiary's claim was audited and paid early in a period, contractors will often continue to audit that same beneficiary's claims for the remainder of the medical need period. In addition, sometimes, the supplier receives the audit when another provider is the target of an investigation or audit by a contractor. Suppliers have their records audited in situations where the ZPIC may be investigating a physician. The supplier has to submit voluminous, repetitive documentation for the same beneficiary for the same claim multiple times given that Medicare reimburses DMEPOS either as monthly rentals or recurring purchases. There must be some effort to rationalize the paperwork burden for these types of audits as suppliers are forced to submit documentation that is already in the contractors' files.

Suppliers are required to print out electronic records they receive from referral sources, manually date stamp the record, and scan them back into their electronic systems in order to demonstrate he or she received the record within the time frame required in a policy – even though the document contains its own electronic date stamp or dated fax header. For DME items that require a written order prior to delivery (WOPD), DME contractors require suppliers to manually date stamp the written order on the day the supplier received the order notwithstanding the electronic date stamp the order bears.

There is no consensus on the documentation required to support medical necessity among the contractors. Contractors frequently change the standards suppliers and 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 suppliers and providers based on the contractor's assertion that the change is a "clarification" and not a "modification" of existing standards effectively changing the rules with no notice or comment period and no "future implementation" date.

Suppliers are required to submit extensive medical necessity documentation when the prepayment 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 supplier submits conforms to the technical requirements of an LCD, not whether it supports medical necessity. However, suppliers are required to submit voluminous records to show medical necessity for the claim under review. In an over-simplified example, if an LCD requires the supplier 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 suppliers do not know this beforehand, they must submit the level and quality of records that would otherwise support prepayment complex medical review.

Suppliers 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 bears the physician's printed name and the signature matches the signature on the order. Clearly, if all the other documentation submitted by a supplier identifies the physician, they should not have to jump through hoops to obtain physician signature attestations

Electronic submission of medical documentation (esMD) is not an efficient alternative to paper submission. CMS acknowledges that electronic medical records do not have the necessary information to substantiate a claim to the Medicare program. In these cases, the burden may be higher as a result of having to obtain additional supporting documentation from a third party that also requires education about why the electronic order does not meet Medicare requirements. It is important to note that there is a cost associated with esMD which varies across HIH providers. For example, LOISS Ltd., a company that provides esMD services, explains on their website that there is a \$3.00 fee for the first 100/pages and \$0.01 per page thereafter with possible volume discount.² Another company, Rycan, has an unlimited filing option at a flat monthly fee.³ As these two companies show, esMD is not a free service and costs vary depending on size and frequency of claim submissions.

If CMS adopts a general prior authorization program for DMEPOS, it must promote the timely delivery of equipment and services to beneficiaries by incorporating the following guidelines:

- prior authorization decisions must be completed and communicated to the provider and beneficiary within 24 hours or sooner;
- a prior authorization request for equipment needed on an emergency basis is “fast tracked” and decided within 2 or fewer hours;
- communication between the supplier and the contractor must be electronic from end-to-end, easily accessible by all suppliers and free of charge to use;
- an affirmative prior authorization for a DMEPOS item must be conclusive with respect to the medical necessity of that item for that beneficiary, although claims could be audited subsequently for technical issues such as proof of delivery;
- an affirmative prior authorization for a DMEPOS item must be conclusive with respect to the medical necessity for all of the options, supplies, and accessories that may be used with the item;
- an affirmative prior authorization for a DMEPOS item must be conclusive with respect to the medical necessity for repairs to the DMEPOS item approved;
- when an item that is submitted for prior authorization is the same or similar to an item the beneficiary is already using, the need for the new item should be considered as part of the prior authorization; and

² http://www.loiss.com/esmd/TRIMSNet_esMD.pdf

³ <https://www.rycan.com/esMD.aspx>

- an affirmative prior authorization is specific to the beneficiary with respect to the DMEPOS item approved. If the beneficiary moves or changes suppliers he does not need a new prior approval for the item.

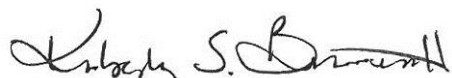
III. Conclusion

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 proposal. To this end, we recommend:

- Requiring 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 about our comments above or if I can be of any assistance to you.

Sincerely,



Kimberley S. Brummett, MBA
Vice President, Regulatory Affairs