The Centers for Medicare & Medicaid Services (CMS) received 1 complete comment from stakeholders related to CMS-10417. This is a summary of the comments.

1. **Comment:**

   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. 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.

   Response:

   In order to adequately discharge CMS's obligations under §1893 of the Social Security Act, the contractors perform manual review of claims where program vulnerabilities are present. When data analysis indicates aberrant or unusual billing patterns, which may present a vulnerability or potential fraud, the contractor requests clinical and other documents to support the need for the items or services provided by providers or suppliers who submitted claims for payment under the Medicare program. We agree that reviews targeting HCPCS codes does not, by itself, indicate wrong doing by individual suppliers or providers. CMS believes that targeting review to problem areas is the appropriate way to conduct reviews and to protect the Medicare Trust Fund.

2. **Comment:**

   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.

   Response:

   There may be multiple reasons for a claim to be selected for prepayment review. CMS believes that prepayment reviews are not a cost containment strategy, rather it is an appropriate way to safeguard the Medicare Trust Fund from inappropriate payments as required by law (e.g., Social Security Act section 1833(e), section 1842(a)(2)(B) and section 1862(a)(1)).

3. **Comment:**

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.

Response:

Medicare contractors currently subject a very small percentage of claims to prepayment review. With any increase in the amount of prepayment reviews, CMS believes the percentage of claims subjected to review will still be relatively small compared to the total claims submitted. CMS recognizes and accounts for the new burden created by the increased review included in this information collection.

4. **Comment:**

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. 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.

Response:

The CMS believes the burden estimate is appropriate. While CMS agrees that some claims will take longer to prepare while others will take less time thus creating an average of 30 minutes to prepare and submit a claim.

5. **Comment:**

There are 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?

Response:
Currently, new contractors are not performing prepayment review or prior authorization reviews. However, CMS could use new contractors to do prepayment or other reviews in the future.

6. **Comment:**

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?

Response:

While we thank you for your comment, this is outside the scope of this PRA notice.

7. **Comment:**

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. 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.

Response:

While we thank you for your comment, this is outside the scope of this PRA notice.

8. **Comment:**

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 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. 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.

Response:

CMS appreciates your comment and will take it under consideration as we review policies and procedures to reduce provider burden.

9. **Comment:**

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. 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.

Response:

The primary goal of the ZPIC is to identify cases of suspected fraud, develop them thoroughly and in a timely manner, and take immediate action to ensure that Medicare Trust Fund monies are not inappropriately paid out and that any mistaken payments are recouped. The ZPICs are required to use a variety of techniques, both proactive and reactive, to address any potentially fraudulent billing practices. The Program Integrity Manual Chapter 4 outlines fraud issues.

10. Comment:

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. Suppliers are required to submit extensive medical necessity documentation when the prepayment medical review in fact audits only compliance with "technical" documentation requirements.

Response:

There may be multiple reasons for a claim to be selected for prepayment review. The documentation required to support the medical necessity may depend upon the reason for the review. Contractors follow policies, procedures and guidelines in the CMS manuals and elsewhere when reviewing claims. The medical review processes are outlined in the Program Integrity Manual.

11. Comment:

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.

Response:

While CMS is aware of your concern, this is outside the scope of this PRA notice.

12. Comment:

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.

Response:

We are aware of the concerns regarding esMD. However, CMS believes esMD is an efficient alternative to paper. It minimizes provider burden by using their Electronic

Health Record (EHR) systems to submit documentation through a Health Information Handler (HIH). This process has resulted in reduced costs associated with shipping and handling expenses and in some cases faster notification of review decisions to providers. CMS agrees that some claims will take longer to prepare while others will take less time thus creating an average of 30 minutes to prepare and submit a claim.

13. Comment:

If CMS adopts a general prior authorization program for DMEPOS, it must promote the timely delivery of equipment and services to beneficiaries. OMB should require CMS to implement a process to accomplish this before it approves the proposal.

Response:

While we thank you for your comment, this is outside the scope of this PRA notice.