The Centers for Medicare and Medicaid Services (CMS) received 5 complete comments from stakeholders related to CMS-10417. This is a summary of the comments.

1. Comment:

It is unclear how prepayment review of over two million claims at a cost of nearly $34 million is deemed as an efficient use of resources for both the Medicare Program as well as providers/suppliers, or how this burden is viewed as fair to providers/suppliers.

Response:

CMS sees prepayment review as an effective means to prevent improper payments. The 2011 Medicare fee-for-service error rate was 8.6%. This equates to over $28 billion in improper payments each year. CMS' goal is to reduce the error rate to 5.4% by next year. To accomplish this, CMS intends to increase resources dedicated to reducing the error rate and improper payments. Medicare receives more than 4.8 million claims per day. Medicare contractors currently process 4.8 million claims a day, and this burden estimate is for approximately 2.2 million claims a year—a very small percentage of review. While this allows for an increase in the number of claims subjected to prepayment review, CMS believes the percentage of claims will still be relatively small compared to the total claims processed.

2. Comment

The standards used by MACs for prepayment review must be transparent to providers/suppliers and open to comment. CMS must put in place measures that provide consistency among the reviews performed by their MACs. Providers /suppliers experience a wide variance in the denial rates for the same services reviewed by different MACs.

Response:

We believe CMS uses constant standards that are transparent to providers/suppliers. Contractors are required to follow policies, procedures and guidelines in the CMS manuals when reviewing claims. For example, medical review processes are outlined in Chapter 3 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c03.pdf, which are available to the public.

3. Comment:

The Agency's aggressive strategy of widespread prepayment review calls into question the necessity and utility of the information providers/suppliers are required to collect. For example:

- There is no consensus on the documentation required to support medical necessity among the contractors.

- Providers/suppliers 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.

- Providers/suppliers are required to submit extensive medical necessity documentation when the prepayment complex medical review in fact audits only compliance with technical documentation requirement.

- 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.

- Providers/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 in fact bears the physician's printed name and the signature matches the signature on the order.

Response:

CMS believes that widespread prepayment review is necessary in order to adequately discharge their obligations under Section 1893 of the Act. Which states that contractors will perform manual medical review of claims where program vulnerabilities are present. Section 1862(a)(1)(A) of the Act provides that Medicare may only make payment for services which are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Sections 1815(a) and 1833(e) of the Act provide that no payment may be made to any provider or supplier unless there has been furnished such information as may be necessary to determine the amounts due. Contractors follow policies, procedures and guidelines in the CMS manuals when reviewing claims. For example, medical review processes are outlined in Chapter 3 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c03.pdf and fraud issues are outlined in Chapter 4 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c04.pdf

4. Comment:

The broad and vague description of medical review places a significant burden on responding providers, suppliers and beneficiaries. Prepayment 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. CMS should delay submission of a control number for OMB review until a well-defined medical review process is established with proper input from the provider, supplier, and beneficiary community.

Response:

Prepayment claim review protects the Medicare Trust Funds and reduces claim payment error rates. This notice does not require providers/suppliers to create new documentation. It allows Medicare contractors to continue conducting prepayment reviews to protect the Medicare Trust Funds from improper and fraudulent payments. Contractors follow policies, procedures and guidelines in the CMS manuals when reviewing claims; such policies, procedures and guidelines are available for public inspection. For example, MR processes are in Chapter 3 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c03.pdf

5. Comment:

CMS should require contractors to request only the level and quality of information necessary to perform a review. The additional documentation review inherent in medical review continues to be ambiguous and undefined.

Response:

This information collection is not introducing any new Medicare documentation requirements; reviews are based on existing policies. Contractors follow policies, procedures and guidelines in the CMS manuals when reviewing claims. For example, MR processes are outlined in Chapter 3 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c03.pdf . Chapter 3 instructs the contractors to request only the documentation needed to make a determination on the claim.

6. Comment:

Under the PRA, an agency must certify, and provide a record supporting that certification, that each collection of information submitted to the OMB “reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency” and “is written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond.” Contrary to this clear statement from Congress, the additional supporting documentation proposed by CMS 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.

Response:

This information collection is not introducing any new Medicare documentation requirements; prepayment reviews and the documentation required to show medical necessity are based on existing policies. Medicare contractors currently process 4.8 million claims a day, and this burden estimate is for approximately 2.2 million claims a year—a very small percentage of review. While this allows for an increase in the number of claims subjected to prepayment review, CMS believes the percentage of claims will still be relatively small compared to the total claims processed.

7. Comment:

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.

Response:

Medicare contractors currently process 4.8 million claims a day, and this burden estimate is for approximately 2.2 million claims a year—a very small percentage of review. While this allows for an increase in the number of claims subjected to prepayment review, CMS believes the percentage of claims will still be relatively small compared to the total claims processed.

Contractors follow policies, procedures and guidelines in the CMS manuals when reviewing claims. For example, MR processes are outlined in Chapter 3 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c03.pdf

8. Comment:

CMS manual guidance is not sufficient authority to impose this significant burden on Medicare providers, suppliers and beneficiaries.

Response:

Under authorities contained in Title XVIII of the Social Security Act (the Act), the Centers for Medicare & Medicaid Services, through MACs, fiscal intermediaries and carriers ("affiliated" or "legacy" contractors), process claims for health services. Furthermore these contractors and some of our Recovery Audit Contractors and ZPIC/PSC contractors are tasked, under Section 1893 of the Act, with performing medical utilization review and/or fraud review activities. In order to adequately discharge their obligations under Section 1893 of the Act, the contractors perform manual review of claims where program vulnerabilities are present. Section 1862(a)(1)(A) of the

Act provides that Medicare may only make payment for services which are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Sections 1815(a) and 1833(e) of the Act provide that no payment may be made to any provider or supplier unless there has been furnished such information as may be necessary to determine the amounts due. CMS is therefore required to only pay claims that are for medically necessary items or services, and authorized by statute to take the necessary steps to ensure that medical equipment furnished to a Medicare beneficiary is medically necessary.

9. Comment:

The Agency's aggressive strategy of widespread prepayment review calls into question the necessity and utility of the information providers/suppliers are required to collect. 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.

Response:

Under authorities contained in Title XVIII of the Social Security Act (the Act), the Centers for Medicare & Medicaid Services, through MACs, fiscal intermediaries and carriers ("affiliated" or "legacy" contractors), process claims for health services. Furthermore these contractors and some of our Recovery Audit Contractors and ZPIC/PSC contractors are tasked, under Section 1893 of the Act, with performing medical utilization review and/or fraud review activities. In order to adequately discharge their obligations under Section 1893 of the Act, the contractors perform manual review of claims where program vulnerabilities are present. Section 1862(a)(1)(A) of the Act provides that Medicare may only make payment for services which are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Sections 1815(a) and 1833(e) of the Act provide that no payment may be made to any provider or supplier unless there has been furnished such information as may be necessary to determine the amounts due. CMS is therefore required to only pay claims that are for medically necessary items or services, and authorized by statute to take the necessary steps to ensure that medical equipment furnished to a Medicare beneficiary is medically necessary in each rental month.

10. Comment:

Continuing to perform prepayment review on services that are routinely reversed on appeal is not an efficient use of resources for the Medicare Program or providers/suppliers.

Response:

CMS agrees that it must use resources efficiently and consider appeals information when in the medical review process. Contractors follow policies, procedures and guidelines in

the CMS manuals when reviewing claims to ensure efficiency. For example, MR processes are in Chapter 3 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c03.pdf

11. Comment:

CMS has increased its estimates of time to review claims from 20 to 30 minutes. The range of time to review claims identified by commenters in the emergency PRA package is 30 to 185 minutes. One commenter believes that CMS should select some weighted median rather than the very lowest time estimate submitted by commenters. The commenter also does not believe that CMS takes into account a supplier's processing time to review the Medicare contractor's request or some of the steps associated with a typical review, including the additional documentation collection The estimate grossly underestimates the time and money burden on CMS' current strategy for conducting widespread service-specific or provider-specific prepayment complex medical reviews. The cost of the outstanding receivables must be included in the Agency's burden estimates. CMS should address PMD burdens separately from the prepayment review experienced by other providers and suppliers. This is because the current practice by the 4 DME MACs has been to require substantially more medical record documentation that the supplier is required to maintain under the four LCDs for PMDs. In addition to this timeframe, denied claims result in a lengthy and costly appeals process.

Response:

The CMS believes the burden estimate is appropriate. CMS recognizes and accounts for the new burden created by the increased review included in this information collection. 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. This notice is not introducing any new policies or procedures. Contractors follow policies, procedures and guidelines in the CMS manuals when reviewing claims. For example, MR processes are outlined in Chapter 3 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c03.pdf

12. Comment:

Contrary to the assertion in the Agency's submission, DMEPOS providers are not required to and do not typically collect the type of detailed medical documentation at the time they initiate service. 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.

Response:

CMS requires that suppliers have this detailed information available upon request. CMS believes that this is accounted for in the estimates. CMS contractors have historically conducted prepayment review of claims and this notice is not introducing any new policies or procedures.

Medicare contractors currently process 4.8 million claims a day, and this burden estimate is for approximately 2.2 million claims a year—a very small percentage of review. While this allows for an increase in the number of claims subjected to prepayment review, CMS believes the percentage of claims will still be relatively small compared to the total claims processed. Contractors follow policies, procedures and guidelines in the CMS manuals when reviewing claims. For example, MR processes are outlined in Chapter 3 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c03.pdf

13. Comment:

CMS must ensure that the scope of MAC prepayment review of hospital claims is limited and carefully targeted to circumstances and providers/suppliers where "aberrant billing patterns or other information that may present a vulnerability to the Medicare program" has been identified.

Response:

CMS tries to target claims reviews to those areas where the largest vulnerabilities are present. 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. CMS believes that targeting review to problem areas is the appropriate way to protect the Medicare Trust Fund.

14. Comment:

MACs must be transparent regarding the methods and standards applied to determine where aberrant billing patterns have been discovered.

Response:

CMS agrees. Contractors follow policies, procedures and guidelines in the CMS manuals when reviewing claims and doing data analysis. For example, MR processes are outlined

in Chapter 3 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c03.pdf and data analysis instructions are found in chapter 2 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c02.pdf

15. Comment:

The MACs should not perform across-the-board prepayment reviews of certain MS-DRGs, as they do not distinguish providers who have put in place significant safeguards and processes to comply with overage, coding and documentation guidelines. Permitting MACs to apply prepayment review only to those providers/suppliers 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/suppliers and penalizing those who have strong compliance programs in place.

Response:

CMS disagrees. 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 including on a wide-spread prepayment service specific review. 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. Across-the-board prepayment reviews of certain MS-DRGs or any service-specific review are undertaken when the same or similar problematic process is noted to be widespread and affecting one type of service and contractor data analysis confirms that an improper payment can be prevented through the service specific complex reviews.

16. Comment:

CMS should consider reimbursing providers/suppliers for medical records selected as part of MAC pre-pay reviews. 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. 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 to reduce burden.

Response:

CMS is currently looking into whether or not to reimburse for medical records and if we should restrict the number of records that can be requested from a single provider. CMS aims to protect the Medicare Trust Funds while limiting provider/supplier burden. At this

time CMS is not introducing any new policies or procedures regarding specific medical review prepay record limits or payment for medical records.

17. Comment:

Hospitals reported that the time devoted to managing the demanding RAC process is increasing, a burden that the addition of prepayment review will certainly exacerbate.

Response:

This notice is not introducing any new policies or procedures. CMS contractors have historically conducted prepayment review of claims.

18. Comment:

CMS must ensure that the credentials of those individuals performing reviews at the MACs are sufficient to conduct credible medical necessity determinations. 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.

Response:

CMS contractors ensure that complex reviews are performed by licensed nurses or physicians, unless the task is delegated to other licensed health care professionals. CMS contractors also ensure that the services reviewed by other licensed health care professionals are within their scope of practice and that there is a need for the specialized expertise in the adjudication of a particular claim type (e.g., speech therapy, physical therapy).

19. Comment:

Information regarding prepayment reviews should be made public by all MACs. This information should include the services under review as well as the percentage of claims reviewed, selection criteria and review outcomes.

Response:

CMS posts information on service specific reviews. Other information is not provided due to privacy and program integrity concerns. The notification policies are outlined in Chapter 3 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c03.pdf.

20. Comment:

To assist providers/suppliers in properly responding and tracking 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.

Response:

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

21. Comment:

Prepayment reviews substantially stretch out the payment period and negatively affect hospital cash flow. 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.

Response:

Medicare contractors currently process 4.8 million claims a day, and this burden estimate is for approximately 2.2 million claims a year—a very small percentage of review. While this allows for an increase in the number of claims subjected to prepayment review, CMS believes the percentage of claims will still be relatively small compared to the total claims processed. Contractors have timeframes they follow in reviewing a claim. Contractors follow policies, procedures and guidelines in the CMS manuals when reviewing claims. For example, MR processes are outlined in Chapter 3 of the Program Integrity Manual, see http://www.cms.gov/manuals/downloads/pim83c03.pdf

22. Comment:

Propose regular meetings with representatives of CMS, OMB, Medicare contractors, and representatives of physicians, treating practitioners, beneficiaries and Medicare Part B supplier to iron out the specific information that must be retained to document the claims subject to this collection of information in order to improve the utility of the proposed collection.

Response:

CMS continues to welcome the exchange of ideas to protect the Medicare Trust Funds while limiting provider/supplier burden.

23. Comment:

In the supporting statement to the final rule Medicare Program: Termination of non-random prepayment review, CMS describes far-reaching and broad medical review activities that are set forth in agency guidance documents rather than formal regulation.

Response:

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

24. Comment:

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

Response:

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

25. Comment:

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 physicians.

Response:

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

26. Comment:

Recommendations:

- Require contractors to develop, officially publish, and adhere to consistent documentation standards that apply prospectively in the four DME MAC jurisdictions. 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 physician's signatures or proof of delivery.

Response:

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

27. Comment:

For any program to improve itself, it must constantly be monitoring its 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. True 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.

Response:

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

28. Comment:

The medical review process must undergo proper notice and comment as required by federal law. 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.

Response:

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