

The Centers for Medicare and Medicaid Services (CMS) received 8 complete comments and 1 incomplete comment from stakeholders related to CMS-10421. This is a summary of the comments.

1. Comment:

The agency's estimated collection profoundly understates the time and expense physicians and supplier submitters would spend responding to the proposed collection for the PMD demonstration.

Response:

We believe that the estimates for physicians and suppliers time and expense are accurate. CMS recognizes and accounts for the new burden created by the increased number of reviews that will be conducted under this demonstration in this information collection. However, it is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements. The demonstration's documentation requirements for this demonstration follow longstanding coverage requirements from the Local Coverage Determination, which can be found at <http://www.cms.gov/MCD>.

This demonstration simply allows for the collection of this existing documentation earlier-before instead of after the item is delivered to the beneficiary. Currently CMS collects records and reviews records for less than 1% of all claims submitted to Medicare before payment is made. While PMDs have historically been reviewed at a higher rate than other items/ services, due to the high levels of fraud and improper payment, many PMD claims are paid without human intervention. Therefore this demonstration will allow for nearly all applicable PMD in the 7 demonstration states to develop and demonstrate new methods for the investigation and prosecution of fraud while protecting the Trust Fund. The information collection associated with the PMD demonstration is associated with collecting this existing information early in the process on more cases.

In regards to the estimate, one commentator agreed with the CMS assumption that the prior authorization piece accounted for 30 minutes of time. CMS agrees with this estimate for the collection of existing documentation.

2. Comment:

A 30-minute burden estimate is unrealistic in light of the massive amount of paperwork sought by CMS to conduct the reviews for these demonstrations. CMS should develop its burden estimate and respondent cost to take a more global prospective including appeals.

Response:

We believe that the estimate is accurate. CMS recognizes and accounts for the new burden, created by the increased number of reviews that will be conducted under this demonstration, in this information collection. However, it is important to keep in mind that this information

collection is not introducing any new Medicare documentation requirements. These demonstrations are reviewing existing documentation based on current polices. Under these demonstrations CMS will be collecting existing documentation to develop improved methods for the investigation and prosecution of fraud and to protect the Medicare Trust Funds.

The information collection associated with these demonstrations is for the collection of existing information. Therefore, CMS believes the burden estimate is appropriate for the burden associated with only collecting existing information. The tasks involved in this information collection is relate only to assembling and sending this existing information.

CMS believes that using a “global approach” as suggested by one of the commentators would vastly over estimate the burden, since much of the burden associated with these demonstrations result from existing requirements. These requirements have the associated burden addressed in other packages. Therefore the purpose of this burden estimate is to account for only the new burden associated with the increased number of records that will be reviewed. Appeals are completed after payment has been made, so appeals burden is outside the scope of this PRA notice.

3. Comment:

The estimate of .5 hour of provider time for the burden is low. CMS should increase the estimated the burden of this information collection from 30 to 60 minutes for each pre-payment request under the Recovery Audit Pre-Payment Review Demonstration, attributing 45 minutes to administrative time, 5 minutes to physician time and 10 minutes to management oversight. CMS should provide its methodology for determining that it was only .5 hours.

Response:

The CMS believes the burden estimate is appropriate for the burden of collecting existing information since the tasks relate only to assembling and sending this existing information. The CMS used an estimate across all claim types. While CMS agrees that some claims will take longer than the average time, some will take less. This package is for collecting existing information only. There is no new documentation required. Rather, it is simply collecting the documentation on more cases.

4. Comment:

CMS has failed to provide an objectively supported estimate of the burden of the PMD demonstration in the PRA package.

Response:

We believe that the estimates are accurate and objectively supported. CMS recognizes and accounts for the new burden created by the increased number of reviews that will be conducted under this demonstration in this information collection. However, it is important

to keep in mind that this information collection is not introducing any new Medicare documentation requirements. The demonstration's documentation requirements for this demonstration follow longstanding coverage requirements from the Local Coverage Determination, which can be found at <http://www.cms.gov/MCD>.

This demonstration simply allows for the collection of this existing documentation earlier-before instead of after the item is delivered to the beneficiary. Currently CMS collects records and reviews records for less than 1% of all claims submitted to Medicare before payment is made. While PMDs have historically been reviewed at a higher rate than other items/ services, due to the high levels of fraud and improper payment, many PMD claims are paid without human intervention. Therefore this demonstration will allow for nearly all applicable PMD in the 7 demonstration states to develop and demonstrate new methods for the investigation and prosecution of fraud while protecting the Trust Fund. The information collection associated with the PMD demonstration is associated with collecting this existing information early in the process on more cases.

In regards to the estimated, one commentator agreed with the CMS assumption that the prior authorization piece accounted for 30 minutes of time. CMS agrees with this estimate for the collection of existing documentation.

5. Comment:

These demonstrations would create an enormous and inefficient paperwork burden on physicians, treating practitioners, suppliers, beneficiaries and Medicare contractor.

Response:

CMS recognizes and accounts for the new burden created by the increased review included in this information collection resulting from these demonstrations. However, it is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements instead it is reviewing based on existing polices as outlined in the existing Medicare policies and procedures. Under these demonstrations CMS will be collecting existing documentation for an increased number of reviews to protect the Trust Funds.

The CMS believes the burden estimate is appropriate for the burden of collecting existing information since the tasks relate only to assembling and sending this existing information. The CMS used an estimate across all claim types. While CMS agrees that some claims will take longer than the average time, some will take less. This package is for collecting existing information only.

6. Comment:

It is impossible to determine the paperwork burden of the PMD demonstration until all tools and documents accompanying the process are developed. Therefore the 30 minute burden estimate cannot be assessed.

Response:

CMS believes that this process is defined. CMS believes that the estimates are accurate. CMS recognizes and accounts for the new burden created by the increased number of reviews that will be conducted under this demonstration in this information collection. However, it is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements. The demonstration's documentation requirements for this demonstration follow longstanding coverage requirements from the Local Coverage Determination, which can be found at <http://www.cms.gov/MCD>.

This demonstration simply allows for the collection of this existing documentation earlier instead of after the item is delivered to the beneficiary. Currently CMS collects records and reviews records for less than 1% of all claims submitted to Medicare before payment is made. While PMDs have historically been reviewed at a higher rate than other items/services, due to the high levels of fraud and improper payment, many PMDs claims are paid without human intervention. Therefore this demonstration will allow for nearly all applicable PMDs in the 7 demonstration states to develop and demonstrate new methods for the investigation and prosecution of fraud while protecting the Trust Fund. The information collection associated with the PMD demonstration is associated with collecting this existing information early in the process on more cases.

In regards to the estimated, one commentator agreed with the CMS assumption that the prior authorization piece accounted for 30 minutes of time. CMS agrees with this estimate for the collection of existing documentation.

7. Comment:

The respondent cost is often in excess of the estimated \$5 per request for the mailing of medical records. It is questioned whether Electronic Submission of Medical Documentation (esMD) is actually a "less expensive alternative." CMS should provide the methodology used to calculate the respondent cost.

Response:

It is important to keep in mind that the \$5 submission estimate is an average across the universe of cases, including all methods of delivery. CMS believes that for many cases, providers and suppliers will choose to fax the documentation to the review contractors. Faxing entails less cost to the provider and suppliers.

CMS continues to believe that esMD may be a less expensive alternative for some providers and suppliers, particularly for those who submit a large number of records. CMS would encourage these providers and suppliers to find the Health Information Handler (HIH) that best meets the needs of their business. A list of CMS-certified HIHs can be found at www.cms.gov/esMD.

8. Comment:

The supporting statement estimates the average time for a provider to respond to medical records requests to be 30 minutes, at an average hourly rate of \$16.83, and a loaded rate of \$33.66. To the extent this expanded prepayment review is not focused on potentially problematic providers, some of these costs may be borne unfairly by compliance-minded providers who otherwise would not be subjected to prepayment review and its related costs.

Response: In some cases even compliance-minded physicians may be subject to these demonstrations. For the Prior Authorization demonstration a very small number of suppliers comprise approximately 80 percent of the PMD reimbursement; thus, PMD supplier billing practices are not unique to specific zip codes or counties. CMS believes targeting a smaller area will only lead to the improper practices moving elsewhere; therefore CMS felt it was necessary to implement this demonstration at the state level in several locations. Under the Recovery audit demonstration through data analysis and historical knowledge of paid claim errors, Recovery Auditors review only those claims most likely to contain improper payments, as they are paid only for recoveries and confirmed underpayments. There is no incentive for a Recovery Auditor to continue auditing a provider who historically has not had errors.

However, CMS used an estimate across all claim types and providers to determine the burden estimate. This package is for the collecting of the existing information only. There is no new documentation required. This documentation should be readily available when providers submit claims to Medicare in accordance with current documentation requirements. Therefore, we believe the burden estimate is appropriate as an average across all providers. It is also important to note that both demonstrations will be targeted to items and services where incidence of fraud has been found.

9. Comment:

Many of the records reviewed by the Recovery Auditor are found to be without error. The cost of employee time and production of records places undue burden on facilities.

Response:

CMS allows Recovery Auditors to only request a small percentage of claims from each facility. Through data analysis and historical knowledge of paid claim errors, Recovery Auditors review only those claims most likely to contain improper payments, as they are paid

only for recoveries and confirmed underpayments. There is no incentive for a Recovery Auditor to continue auditing a provider who historically has not had errors.

10. Comment:

These proposed demonstrations and the associated information collection are unwarranted and unnecessary in light of the duplicative effort of CMS and other governmental agencies. The plan to add a significant regulatory burden on Medicare physicians and suppliers runs counter to the President's mandates detailed in Executive Order 13563 and is duplicative of anti-fraud efforts violating PRA. The duplicative nature of the information precludes OMB approval of the proposed collection. The information subject to the proposed collection and the manner in which it is collected are entirely duplicative of current anti-fraud efforts.

Response:

CMS concurs that it must utilize its anti-fraud methods in a way that is not duplicative of other CMS or government agency activities. CMS does not believe that increasing the number of reviews conducted is duplicative in nature. Currently CMS collects records and reviews records for less than 1% of all claims submitted to Medicare before payment is made. The collection of existing documentation for the purposes of these demonstrations does not duplicate any current anti-fraud efforts; in fact these demonstrations are designed to augment and enhance those anti-fraud efforts. It is not CMS's policy to routinely review a claim more than once

11. Comment:

The prior authorization demonstration must have reasonable timeframe (i.e. 48 hours for all cases) for review and use automated collection techniques or other forms of information collection to minimize the information collection burden while ensuring proper access to care.

Response:

CMS agrees with the need to minimize the information collection burden while ensuring proper access to care. To this end CMS will allow suppliers to submit prior authorization requests through electronic collection techniques that will follow existing submission methods. Beginning in the fall of 2012, CMS plans to allow suppliers to submit prior authorization requests through CMS' electronic collection system called Electronic Submission of Medical Documentation (esMD). CMS believes in ensuring access to quality care. CMS will have a mechanism in place for an efficient response time (within 48 hours) under emergency circumstances.

CMS believes that our timeframes are reasonable and in line with other prior authorization programs used by State Medicaid agencies and private payers. This information collection is not introducing any new Medicare documentation requirements. Rather, it is simply collecting existing documentation earlier in the process for more PMDs.

12. Comment:

Allow hospitals to submit and receive all correspondence, records, and payments for records electronically to support the paperwork reduction effort.

Response:

CMS already has in place a mechanism that allows providers to electronically submit records for claims to CMS contractors in response to a documentation request. Any hospital, physician, practitioner, or supplier who is interested in submitting documentation electronically is encouraged to use CMS' new Electronic Submission of Medical Documentation (esMD) system which went live on September 15, 2011. The esMD system is based on Nationwide Health Information Network (NwHIN) standards, developed by the Office of the National Coordinator for Health Information Technology. More information about esMD can be found at www.cms.gov/esMD.

CMS and its partners are working to facilitate standards that will allow providers to electronically receive correspondence (such as a documentation request or a summary of review results) from CMS contractors. CMS expects the first of these standards to be released in 2013. More information about NwHIN standards can be found at www.connectopensource.org.

13. Comment:

The Paperwork requested in the prior authorization demonstration project is not necessary and provides minimal utility for the proper performance of the agency's function. The prior authorization demonstration fails to enhance the quality, utility and clarity of the information collection. CMS's review of the collection prior to submission to OMB must demonstrate the need for the collection. The inability of the agency to establish the utility of the proposed information collection combined with the existing efforts underscore that the PMD demonstration and the information collection is not needed to perform the function of the agency. CMS has not clearly defined what documentation is required for prior authorization. The proposed PMD demonstration should be revised to enhance the information collection's quality, utility and clarity.

Response:

CMS disagrees and believes it has established the utility of the proposed information collection to developed improved methods for the investigation and prosecution of fraud. This information is needed to perform the agency's function of paying only correct claims.

The information collection is needed to conduct the demonstration and to protect the Medicare Trust Fund from fraudulent and improper payments. CMS believes that the information collection related to these demonstrations will have utility to allow for detection of improved methods for the investigation and prosecution of fraud, while preventing fraud and abuse.

It is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements. Rather, it is simply collecting the existing documentation on an increased number of cases which increases the quality of the information. By collecting this information earlier in the process and for an increased number of PMDs, suppliers should know before the PMD is delivered whether Medicare will pay for the device, assuming all other requirements are met. This will allow for more clarity and quality in the information.

14. Comment:

During the Open Door Forum held by CMS the agency debuted a draft fax cover sheet to be used by providers and suppliers when submitting a prior authorization request.

Response:

CMS will not issue nor require submitters to use a “suggested fax coversheet.” The information collection associated with this demonstration does not introduce any new Medicare documentation requirements. By collecting this information earlier in the process and for an increased number of PMDs, suppliers will know before the PMD is delivered whether Medicare will pay for the device.

15. Comment:

The package states that “all relevant documentation” must be submitted and that such documentation “must meet all applicable rules, policies and NCD/LCD requirements.” This is too broad. The continued use of “*other relevant medical documentation*” to justify medical necessity raises significant concerns within the power mobility community due to its subjective nature. How can a burden estimate be calculated when the power mobility provider does not know exactly the documentation requirements necessary for a prior authorization approval?

Response:

CMS recognizes and accounts for the new burden created by the increased number of reviews that will be conducted under this demonstration in this information collection. However, it is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements. The demonstration’s documentation

requirements for this demonstration follow longstanding coverage requirements from the Local Coverage Determination, which can be found at <http://www.cms.gov/MCD>.

This demonstration simply allows for the collection of this existing documentation earlier-before instead of after the item is delivered to the beneficiary. Currently CMS collects records and reviews records for less than 1% of all claims submitted to Medicare before payment is made. While PMDs have historically been reviewed at a higher rate than other items/ services, due to the high levels of fraud and improper payment, many PMD claims are paid without human intervention. Therefore this demonstration will allow for review of nearly all applicable PMDs in the 7 demonstration states to develop and demonstrate new methods for the investigation and prosecution of fraud while protecting the Trust Fund. The information collection associated with the PMD demonstration is associated with collecting this existing information early in the process on more cases.

In regards to the estimate, one commentator agreed with the CMS assumption that the prior authorization piece accounted for 30 minutes of time. CMS agrees with this estimate for the collection of existing documentation.

The term “other relevant medical documentation” refers to any other documentation that a submitter chooses to supply to support the need for the PMD. CMS has issued a series of educational materials to provide further clarification of the types of documentation that can be submitted to justify the need for a PMD.

16. Comment:

Medicare must be proactive in providing guidance, in the form of guides or templates, to assist physicians and treating practitioners in filing claims and documenting medical necessity and functional limitations from the outset. CMS must be committed to providing possible “submitters” with adequate guidance on how best to ensure the accuracy of the submission and avert denials for incomplete information.

Response:

CMS has been providing guidance on its website, go.cms.gov/PAdemo about the demonstration, which is only collecting existing documentation. However, it is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements. By collecting this information earlier in the process and on an increased number of PMDs, suppliers should know before the item is delivered whether they will receive payment assuming all other requirements are met. The documentation requirements are outlined in the longstanding local coverage determination (LCD). CMS has issued a series of educational material to provide further clarification of the type of documentation that can be submitted to justify the need for a PMD. These education materials provided guidelines for the appropriate ordering and billing of PMDs.

17. Comment:

Home medical equipment providers are subject to additional burden placed on them by having to ensure that the ordering physician's medical documentation meets medical necessity requirements.

Response:

Medical necessity has always been established by a practitioner and CMS has always required the supplier to ensure that the items/services it supplies are in fact medically necessary. It is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements. By collecting this information earlier in the process and for an increased number of PMDs, suppliers should know before the PMD is delivered whether Medicare will pay for the device, assuming all other requirements are met.

18. Comment:

While the demonstration project purports to make physicians/ treating practitioner submission of prior authorization request optional, such submission represents a substantive change in Medicare law since 42 C.F.R 410.38(c)(5) states that suppliers are responsible for obtaining appropriate documentation and maintaining in their records.

Response:

The CMS disagrees that this is a substantive change in Medicare law under 42 C.F.R 410.38(c)(5). Further, CMS does not believe that a new standard for documentation is being created under this demonstration. Suppliers are still responsible for obtaining appropriate documentation and maintaining it in their records. Medical necessity has always been established by a practitioner and CMS has always required the supplier to ensure that the items/services it supplies are in fact medically necessary.

In accordance with current policy and procedures, physicians are the individuals who perform the face-to-face evaluation of the beneficiary and write the order. The physician and supplier work together to ensure the beneficiary receives the appropriate mobility device for his/her condition. In this demonstration CMS continues to expect that joint responsibility is shared whether the supplier submits the prior authorization request or if the physician submits it.

19. Comment:

Due to the timeframe for delivery, if several prior authorization requests must be submitted to gain approval, it is possible that the process will need to be restarted thus creating additional burden.

Response:

CMS has accounted for the burden associated with multiple requests in its estimates. It is important to keep in mind that this information collection is not introducing any new

Medicare documentation requirements. By collecting this information earlier in the process and for an increased number of PMDs, suppliers should know before the PMD is delivered whether Medicare will pay for the device, assuming all other requirements are met. CMS believes that our timeframes are reasonable and in line with other prior authorization programs used by State Medicaid and private payers. The CMS will work to ensure that timeframes are reasonable.

20. Comment:

CMS should continue to work with power mobility stakeholders, physicians, treating practitioners and suppliers to implement, evaluate and refine the demonstration information collection to maximize the potential to meet all parties' needs without sacrificing timely access to necessary quality care.

Response:

CMS agrees and looks forward to continued productive interactions with stakeholders. However in regards to the information collection, this demonstration does not require any new documentation requirements. The demonstration allows for upfront collection of medical documentation for applicable PMDs ordered in the seven demonstration states.

Regarding access to care, CMS is not aware of instances where beneficiaries did not have access to necessary quality care because of increased reviews. CMS has a 1-800 call center that beneficiaries can utilize to report issues including those related to access to necessary quality care because of increased reviews. CMS will monitor calls to ensure that this demonstration does not impact timely access to care for Medicare beneficiaries.

21. Comment:

The use of an electronic prior authorization template would reduce the burden on respondents and enhance the utility and clarity of the collection for the Prior Authorization Demonstration. To ensure the effectiveness and limit the burden of the collection of information, CMS should develop a practical prior authorization form or template that is approved by OMB to aggregate all data necessary for prior authorization approval in one document. CMS should finalize an automated submission system before proceeding with the demonstration.

Response:

CMS does not believe that a prior authorization request form is necessary for this demonstration. As the information collection associated with this demonstration is not introducing any new Medicare documentation requirements, a form is not necessary. By collecting this information earlier in the process and for an increased number of PMDs, suppliers should know before the PMD is delivered whether Medicare will pay for the device, assuming all other requirements are met.

To this end, CMS will allow suppliers to submit prior authorization requests through electronic collection techniques that will follow existing submission methods. Beginning in the fall of 2012, CMS plans to allow submitters to submit prior authorization requests through CMS' electronic collection system called Electronic Submission of Medical Documentation (esMD). More information is available at www.cms.gov/esmd.

22. Comment:

CMS must develop a comprehensive standard face-to-face examination medical necessity evaluation template/form for the physician and treating practitioners. CMS should develop this DME information form that captures and transmits essential objective data required for PMD coverage. A transition is needed between the start of the prior authorization demonstration and the use of a clinical medical necessity template to limit burden.

Response:

CMS does not believe that a face-to-face evaluation form is necessary for this demonstration. As the information collection associated with this demonstration is existing documentation requirements available at www.cms.gov/MCD. By collecting this information earlier in the process and for an increase number of PMDs, suppliers should know before the PMD is delivered whether Medicare will pay for the device assuming all other requirements are met.

CMS does not intend to create a required form due to the vast range of conditions that can create the need for a PMD. CMS does not believe that a template for documenting the existing face-to-face encounter is necessary to conduct this demonstration. CMS believes that the demonstration can begin after PRA approval is received.

23. Comment:

CMS should work with stakeholders on the development of a prior authorization template that allows CMS to target actual fraud.

Response:

CMS welcomes input from stakeholders. However, CMS does not believe that a template will allow CMS to improve its efforts to target fraud. As the information collection associated with this demonstration is not introducing any new Medicare documentation requirements and therefore a form is not necessary. By collecting this information earlier in the process and for an increased number of PMDs, suppliers should know before the PMD is delivered whether Medicare will pay for the device, assuming all other requirements are met. CMS believes that this information collection is necessary in order to protect the Medicare Trust Funds from fraudulent and abusive payment by developing new ways to investigate and prosecute fraud.

24. Comment:

CMS must ensure proper staffing and training for MACs responsible for processing of prior authorization requests. The PRA requires CMS to plan and allocate resources for the efficient and effective management and use of the information to be collected.

Response:

CMS agrees that for a successful demonstration that limits unnecessary burden, there must be proper staffing and training for DME MACs responsible for processing of prior authorization requests. Therefore the DME MACs will be fully staffed to review the cases received in an efficient and effective manner. CMS will ensure that the DME MACs are properly staffed to meet all timeframes and that staff is trained to ensure consistent determinations. CMS will actively monitor the demonstration in order to manage workloads and ensure consistency.

25. Comment:

The proposed demonstration presents issues with regard to unknown effectiveness, potential to limit beneficiary access, necessary provider education and actual implementation mechanism. This effort has the potential to create such a high level of burden that it will curtail utilization of certain items/services and prevent qualified Medicare beneficiaries from receiving medically necessary devices. Patients will be affected if physicians avoid performing reasonable and necessary procedures in an effort to avoid scrutiny. Prepayment review on the particular MS-DRGs that CMS intends to review initially as part of this demonstration will cause patients who present with these conditions to be inappropriately turned away.

Response:

It is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements. Rather, it is simply collecting an increased number of records.

CMS is unaware of instances where providers avoided providing medically necessary care to their patients due to Medicare audit procedures. CMS does not believe that providers will stop providing necessary care to patients because of increased reviews. CMS encourages provider participation in the Medicare program and that they continue to provide access to medically necessary access to care.

CMS has a 1-800 call center that beneficiaries can utilize if they do not have access to necessary quality care because of increased reviews. CMS will monitor calls and other feedback to ensure that this demonstration does not impact timely access to care for Medicare beneficiaries.

26. Comment:

Any new standard for documentation would need to be fully defined and undergo formal rulemaking pursuant to the Administrative Procedures Act.

Response:

CMS does not believe that a new standard for documentation is being created under this demonstration. It is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements. Rather, it is simply reviewing more medical records than previously reviewed and earlier in the process.

27. Comment:

Any new standard for documentation would need to be fully defined and undergo formal rulemaking pursuant to the Administrative Procedures Act.

Response:

CMS does not believe that a new standard for documentation is being created under this demonstration. It is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements. Rather, it is simply reviewing more medical records than previously reviewed and earlier in the process.

28. Comment:

The legal basis relied upon by CMS for the Prior Authorization demonstration is fraud authority. The Agency's examples of fraud do not justify imposing a significant burden on Physician and PMD suppliers.

Response:

CMS has targeted this demonstration to a claim type that has often been a subject of fraud. Based on previous CMS experience, OIG reports, Government Accountability Office (GAO) reports, and indictments there is extensive evidence of DME fraud committed in these states. These states have been identified as high risk fraud states in the 2012 Presidential budget as part of the Stop Gap program. Further, PMDs have been the subject of multiple fraud alerts since at least June 1998.

Health Care Fraud Prevention and Enforcement Action Team (HEAT) Task Force was launched in May 2009 and is co-chaired by the Deputy Secretary of HHS and the Deputy Attorney General of DOJ. Medicare Fraud Strike Force teams are a key component of HEAT. Medicare Fraud Strike Forces have expanded from the launch sites of South Florida (2007) to teams of investigators and prosecutors in a total of nine areas: Miami, Los Angeles, Detroit, Houston, Brooklyn, Baton Rouge, Tampa, Chicago, and Dallas. Since the inception of the Medicare Strike Force teams, based on data driven investigations, prosecutors have filed more than 600 cases charging more than 1,150 defendants who collectively billed the Medicare program more than \$2.9 billion in fraudulent claims. DME is a primary focus of

investigation for these strike forces. In addition, California, Florida, Illinois, New York and Texas have been identified by the Zone Program Integrity Contractors (ZPICs) as states with numerous incidents of health care fraud, including the submission of fraudulent Medicare claims for DME items. PMDs are DME items with a high reimbursement rate and have been susceptible to fraud

It is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements. Rather, it is simply reviewing more medical records than previously reviewed and earlier in the process. CMS believes that the information collection associated with this demonstration is necessary in order to (1) protect the Medicare Trust Funds from fraudulent payments or abusive practices that result in improper payments and (2) develop new ways to investigate and prosecute fraud.

29. Comment:

CMS should use a phase-in program to test and evaluate the utility and efficiency of the prior authorization demonstration and related information collection. The scope of the demonstration is massive and should be smaller or at a minimum “phased in.” CMS should evaluate the utility and effectiveness of the program in a smaller “pilot market.” OMB’s regulations require the Agency’s pre-OMB review to include “a test of the collection of information through a pilot program, if appropriate.”

Response:

CMS agrees there is a benefit to testing a program prior to a larger implementation to test the utility and efficiency which is why CMS choose to implement this effort in only 7 high fraud states.

Further, a very small number of suppliers comprise approximately 80 percent of the PMD reimbursement; thus, PMD supplier billing practices are not unique to specific zip codes or counties. CMS believes targeting a smaller area will only lead to the improper practices moving elsewhere; therefore CMS felt it was necessary to implement this demonstration at the state level in several locations.

30. Comment:

CMS should use a phase-in program to test and evaluate the utility and efficiency of the prior authorization demonstration and related information collection. The scope of the demonstration is massive and should be smaller or at a minimum “phased in.” CMS should evaluate the utility and effectiveness of the program in a smaller “pilot market.” OMB’s regulations require the Agency’s pre-OMB review to include “a test of the collection of information through a pilot program, if appropriate.”

Response:

CMS agrees there is a benefit to testing a program prior to a larger implementation to test the utility and efficiency which is why CMS choose to implement this effort in only 7 high fraud states.

Further, a very small number of suppliers comprise approximately 80 percent of the PMD reimbursement; thus, PMD supplier billing practices are not unique to specific zip codes or counties. CMS believes targeting a smaller area will only lead to the improper practices moving elsewhere; therefore CMS felt it was necessary to implement this demonstration at the state level in several locations.

31. Comment:

CMS should revise the Prior Authorization Demonstration to focus only on outliers and exclude physicians who do not present as extreme statistical outliers.

Response:

CMS has targeted this demonstration to a claim type that has often been a subject of fraud. Since suppliers are the entity receiving payment, suppliers are more likely to participate in possible fraudulent activities such as using a physician's NPI number as the ordering physician on a claim when that physician did not order the item. Therefore, it is impractical to focus the demonstration solely on "outlier physicians." In addition, the prior authorization concept provides suppliers, as well as beneficiaries with some assurance that the PMD is appropriate and will be covered.

Further, a very small number of suppliers comprise approximately 80 percent of the PMD reimbursement; thus, PMD supplier billing practices are not unique to specific zip codes or counties. CMS believes targeting a smaller area will only lead to the improper practices moving elsewhere; therefore CMS felt it was necessary to implement this demonstration at the state level in several locations.

32. Comment:

CMS may not implement the PMD demonstration prior to receiving the OMB approval for the collection. The PRA regulation states that payment reduction may not proceed until the OMB control number is received.

Response:

CMS concurs and has stated publicly that these demonstrations will only begin after receiving the OMB control number.

33. Comment:

The RACs could target the same power mobility providers and the same beneficiary's claims but review a different month of rental—thus, creating additional burdens on power mobility providers.

Response:

General speaking PMD claims that have a prior authorization decision will not be subject to additional review, in order to maximize resources and minimize burden. CMS does not intend to review claims more than once. If the prior authorization request for the PMD base is approved all monthly rental claims for the base will be deemed appropriate and not subject for RAC review for documentation that was submitted as part of the prior authorization process.

34. Comment:

Despite the requirement described for documenting medical necessity of a PMD, CMS's Supporting Statement for this PRA request creates a new unapproved standard for documentation. Demonstration contractors should operate under existing guidelines. CMS outlined the steps that are conducted under clinical review of documentation. The clinical review process would allow a Medicare contractor to employ "clinical review judgment" and thus supersede the professional judgment of the medical physician.

Response:

CMS disagrees with the notion that a new unapproved standard for documentation is being created. It is important to keep in mind that this information collection is not introducing any new Medicare documentation requirements. Rather, it is simply reviewing more medical records than previously reviewed and earlier in the process. By collecting this information earlier in the process and for an increase number of PMDs, suppliers will know before the PMD is delivered whether Medicare will pay for the device.

All reviews will be conducted by the DME MACs following existing policies review standards and procedures. Contractors follow policies, procedures and guidelines in the CMS manuals when reviewing claims. See

<http://www.cms.gov/manuals/downloads/pim83c03.pdf>

CMS has provided extensive education materials about our policies and requirements.

CMS disagrees that "clinical review judgment" creates a new standard. The Program Integrity Manual Section 3.3.1.3 describes the clinical review standards and procedures that all review conductors including the DME MACs will follow when conducting reviews.

35. Comment:

The "longitudinal" documentation standard proposed in this collection of information is not defined in the CMS' Supporting Statement.

Response:

CMS disagrees and believes that this information has been defined in existing CMS policy in the Program Integrity Manual, Chapter 3.3.1.3. This review is for all claim types including those that could be reviewed under the Recovery Audit prepayment demonstration.

36. Comment:

We have longstanding concerns with the manner in which Medicare contractors review medical records and the manner in which the contractors target companies and industries participating in the Medicare program. As set forth above, high error rates determined by Medicare contractors are inaccurate since a majority of Medicare claims denials are overturned during the appeals process. Companies cannot survive the routine withholding of a payment that would take place during prepayment review.

Response:

This information collection does not impose any new requirements on providers. Medicare contractors have historically conducted prepayment review of claims and this demonstration will follow the same procedures to protect the Medicare Trust Fund from improper payments. Appeals estimates are outside of the scope of this PRA information collection.

37. Comment:

This demonstration shortens the initial record submission to 30 days, compared to 45 days under the permanent RAC program, to submit medical records. The CMS should have consistent timeframe applied on all Medicare claim requests to enable hospitals to standardize tracking tools and operations associated with complying with these requests to limit burden.

Response:

This demonstration follows the same 30 day guidelines that currently exist for Medicare Administrative Contractor (MAC) prepayment review.

38. Comment:

CMS should provide response to pre-payment reviews be extended from 30 days to 45 calendar days to limit burden.

Response:

The requirements for this demonstration are consistent with those in place for Medicare Administrative Contractors (MACs) prepayment reviews. The CMS believes that this timeframe is appropriate for these reviews.

Outside of Scope

39. Comment:

CMS lacks the authority to proceed with the proposed demonstration.

Response:

While CMS is mindful of this concern, the determination on whether CMS has the authority for this demonstration is outside the scope of the PRA package. This demonstration has been approved by OMB.

40. Comment:

The scope of this demonstration is too large to be called a demonstration. The scope of the demonstration is massive and should be smaller or at a minimum “phased in.”

Response:

While CMS is mindful of this concern, the demonstration design is outside the scope of this PRA notice. This demonstration has been approved by OMB.

41. Comment:

CMS has typically cited high error rate with regards to Medicare claims including PMD claims as a part of the authority for the demonstration. The proposed demonstration is not a new method to fight fraud. Since Medicare Administrative contractors already have the ability to conduct prepayment review of claims in order to protect the Medicare trust fund from vulnerabilities. What change in policy/practice is this request implementing.

Response:

While CMS is mindful of this concern, the demonstration design is outside the scope of this PRA notice. This demonstration has been approved by OMB

42. Comment:

CMS is simply paying lip-service to the demonstration authority in an attempt to justify a drastic expansion of its already-existing claims review authority. If the agency believes that the DME benefit as a whole is particularly susceptible to fraud, then CMS should address the overall problem.

Response:

While CMS is mindful of this concern, the demonstration design is outside the scope of this PRA notice. This demonstration has been approved by OMB.

43. Comment:

Under Section 402 authority, CMS is required to obtain the advice and recommendations from specialists on how to conduct the experiment or project and the sufficiency of resources.

Response:

While CMS is mindful of this concern, this is outside the scope of this PRA notice. This demonstration has been approved by OMB.

44. Comment:

CMS should proceed with the PMD demonstration only after a formal notice and comment period. Any prior authorization system must be developed with the participation by all stakeholders in accordance with the Federal Advisory Committee Act, Administrative Procedures Act and Paperwork Reduction Act.

Response:

While CMS is mindful of this concern, this is outside the scope of this PRA notice. This demonstration has been approved by OMB.

45. Comment:

Open Door Forums are insufficient to engage all stakeholders.

Response:

While CMS is mindful of this concern, this is outside the scope of this PRA notice. This demonstration has been approved by OMB.

46. Comment:

Stakeholder would further welcome an opportunity to work with CMS on an electronic data analytic program designed to identify and capture the fraudulent actors in the Medicare Program.

Response:

While CMS appreciates this offer, creation of an analytic program is outside the scope of this PRA package.

47. Comment:

There does not appear to be any procedure for emergency consideration based on a beneficiary's immediate medical condition. CMS must establish a standard with public input governing emergency timeframe for necessary immediate delivery of a PMD.

Response:

While CMS is mindful of this concern, this is an operational detail outside the scope of this PRA package. This demonstration has been approved by OMB.

48. Comment:

Beneficiaries must be afforded appeal rights.

Response:

While CMS is mindful of this concern, this is an operational detail outside the scope of this PRA package. This demonstration has been approved by OMB.

49. Comment:

CMS should validate that the face-to-face examination requirement established by Congress was designed to strengthen the role of the treating physician in making medical necessity determinations regarding his/her patient. The prescribing physicians should be given presumption that his clinical judgment determination on the face-to-face exam is valid. A finding of medical necessity during the face-to-face examination, based on professional medical judgment shall constitute substantial evidence that the item or service is reasonable and necessary.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA package. This demonstration has been approved by OMB.

50. Comment:

CMS must ensure efficient beneficiary access through a response, automated or verbal, within 48 hours of initial (and resubmitted) prior authorization request.

Response:

While CMS is mindful of this concern, this is an operational detail outside the scope of the PRA package. This demonstration has been approved by OMB.

51. Comment:

Under the authority given to the Agency to create RACs in the Tax Relief and Health Care Act of 2006, RACs perform medical review activities on a post-payment basis. Since the Statute directs CMS to pay RACs on a contingency basis with payments derived as a percentage of funds collected from providers, we not only challenge the authority the CMS has to operate this program as it goes beyond the scope of congressional intent, but also question how the RACs would be paid under the demonstration. The prepayment authority proposed for the RACs is beyond the authority granted by Congress. Demonstration authority does not allow CMS to waive the RAC standards established by Congress.

Response:

While CMS is mindful of this concern, this is an operational detail outside the scope of the PRA package. This demonstration has been approved by OMB.

52. Comment:

There is significant ambiguity in the medical policy and medical reviews are subjective.

Response: While CMS is mindful of this concern, this is outside the scope of this PRA notice.

53. Comment:

CMS should explicitly state why a prior authorization request was denied.

Response:

While CMS is mindful of this concern, this is an operational detail outside the scope of this PRA notice. This demonstration has been approved by OMB.

54. Comment:

The medical review staff must review the entire claim. If any deficiencies are found, the medical review staff should then inform the power mobility provider of all issues so that the provider can make the necessary corrections and resubmit the authorization request. If a prior authorization request is not approved by the contractor, the physician should be able to address the specific deficiencies and/or omissions with a supplemental statement.

Response:

While CMS is mindful of this concern, this is an operational detail outside the scope of this PRA notice. This demonstration has been approved by OMB.

55. Comment:

OFM should engage with the Center for Program Integrity.

Response:

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

56. Comment:

OFM should hire a full time Medical Director.

Response:

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

57. Comment:

CMS should publish contact information for the MAC Medical directors.

Response:

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

58. Comment:

CMS should publish CERT reports in their entirety.

Response:

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

59. Comment:

CMS should utilize the OIG's evaluation of the CERT program.

Response:

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

60. Comment:

Administrative problems in the Recovery Audit program have been problematic in the context of retrospective review and will be even more burdensome in the context of prepayment review. Recovery Auditors have a poor record on appeal.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

61. Comment:

Even though a primary purpose of the Recovery Audit program is to educate providers regarding vulnerabilities, providers are unable to engage with the Recovery Auditors directly.

Response:

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

62. Comment:

Prepayment review should not be undertaken by providers who are compensated on a contingency fee basis.

Response:

The payment methodology of the review contractors is outside of the scope of this PRA information collection.

63. Comment:

Electronic prescribing and electronic health record incentive programs will also help to reduce paperwork burdens and result in accurate claim submissions.

Response:

While CMS is mindful of this comment, electronic prescribing and electronic health record incentive programs are outside the scope of this PRA package.

64. Comment:

A comment highlighted Medicare's in-the-home regulation on wheelchairs and the points to the restrictions this has on the daily lives of individuals with disabilities.

Response:

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

65. Comment:

Early communication between our RAC and the facility proved to be inconsistent and non-helpful. Fiscal Intermediary staff should receive intensive training to recognize and reconcile RAC encounters. Demand letters were not received timely and the remittance advice does not show recoupments cleanly, which requires manual work from providers to reconcile.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

66. Comment:

Allow hospitals to establish a 'RAC Post Office Box' where all correspondence can be delivered without changing the 'hospital contact' which is typically the CEO.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

67. Comment:

Allow the RAC portal to show ALL types of requests -- both complex review, automated and now pre-payment. Currently, only complex review type requests show in the portal. It is virtually impossible to know if you are missing a letter from RAC as there is no method for reconciliation. If a letter is not responded to timely due to mis-delivery, a provider will lose the cases.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

68. Comment:

Hire experienced HIM professionals possessing coding credentials that are experienced with audit programs and is knowledgeable of coding and billing in acute care provider and physician offices.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

69. Comment:

CMS should publish the final Attachments Rule, work to finalize an operational data set for chart abstraction, and adopt SNOMED for clinical terminology.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

70. Comment:

Is CMS considering relaxing the prompt payment provisions currently in place, under which MACs have 60 days to make a determination (per the Claims Processing Manual)?

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

71. Comment:

How exactly will the expanded prepayment review be coordinated with other existing prepayment and postpayment reviews (e.g. RAC, ZPIC, MAC sending demand letters for the RAC) to eliminate confusion, avoid unnecessary and duplicative reviews and ensure that consistent standards of review are applied? At a minimum, once an admission is reviewed by one CMS contractor, it should be excluded from review by other contractors. This exclusion from duplicative review also should apply to admissions that have been reviewed by a QIO and determined to be medically necessary.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

72. Comment:

The RACs and MACs should not duplicate efforts by reviewing the same DRGs. In addition, a claim subject to prepayment review by a RAC or a MAC and subsequently paid, either during the normal course of review or following a provider appeal, should be exempt from a later retrospective review. An ADR reason code that clearly identifies a RAC prepayment review is needed to ensure consistent management of these reviews by hospitals.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice

73. Comment:

There has been tremendous confusion in the postpayment RAC program since CMS moved the demand letters to the MACs. Every effort should be made to differentiate between these programs. Hospitals may have different structures that address RAC and MAC requests. Therefore, it is important to distinguish from whom the request letters are coming. This should apply to all correspondence, not just the demand letters. To further decrease the

burden on hospitals that are part of a chain provider, CMS should restore the ability of chains to designate a single contact person to handle all RAC requests, an ability that was lost when MACs began processing letters for the RACs.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

74. Comment:

CMS should clarify that any request for a hospital's records under this prepayment review demonstration must be combined with any postpayment RAC reviews and count towards the CMS cumulative record limit.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

75. Comment:

The discussion period provides hospitals with an important opportunity to review regulations and documentation with the RACs that they may have overlooked initially. Therefore, this prepayment review demonstration should include a discussion period similar to the one that is currently used under the permanent RAC program.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

76. Comment:

How will the RACs communicate new DRGs under review during the demonstration, and will approved prepayment issues be posted to the RACs' websites similar to current RAC practice under the permanent program?

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

77. Comment:

RACs should be required to reimburse hospitals for medical records selected for prepayment review at the same rates as the permanent RAC program.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

78. Comment:

Regarding the universe of hospitals subject to this RAC prepayment demonstration, the confirmation is sought that only hospitals physically located in the demo state and whose

claims are processed by the MAC serving that state would be subject to the Recovery Audit Prepayment Review demonstration.

Response:

While CMS is mindful of this comment, this is outside the scope of this PRA notice.

79. Comment:

Concerns about timeliness of payment to providers when this additional prepayment review occurs; under the current RAC program, reviews of records were not always timely. Hospitals rely heavily on payments to support daily operations.

Response:

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

80. Comment:

The program's contingency fee structure inappropriately incentivizes the Recovery Auditors to conduct "fishing expeditions" that are exceedingly burdensome for physician practices. The Recovery Audit Prepayment Review Demonstration expands the reach of the Recovery Auditors by incentivizing them to perform prepayment review, a task for which they have neither experience nor expertise.

Response:

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

81. Comment:

The RAC Demonstration Project would eliminate the necessary protections granted by Congress to healthcare providers/suppliers, such as the limitation on recoupment; instead allowing the RAC's to prevent initial payment and curtailing cash flow for providers and suppliers.

Response:

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

82. Comment:

Limit the number of RAC entities that providers must deal with.

Response:

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

83. Comment:

Concerns about timeliness of payment to providers when this additional prepayment review occurs; under the current RAC program, reviews of records were not always timely. Hospitals rely heavily on payments to support daily operations.

Response:

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

84. Comment:

CMS should collect and publish the pre-payment review overturn rate and data evaluating the question as to the demonstration project's effectiveness on reducing claims errors and fraud.

Response:

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